Cardiovascular disease risk assessment and treatment among person with type 2 diabetes mellitus at the primary care level in rural central India

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Abstract

Introduction: Despite evidence in support of assessment and treatment of risk factors to prevent cardiovascular disease (CVD) among people with type 2 diabetes mellitus (T2DM), studies have shown gaps in practises at the primary care level. The study was undertaken to find out the prevalence and management of risk factors for CVD in patients with T2DM from rural area India. **Methodology:** A crosssectional study was conducted in a tertiary care hospital in rural India. Around 192 persons with T2DM over 35 years of age were interviewed and examined using a structured questionnaire to determine the presence of CVD risk factors, previous assessment and management of these risk factors. **Results:** The mean age was 58.91 (SD 11.30) years. Tobacco use and harmful consumption of alcohol were reported by 67.7% and 27%, respectively. Nearly 43.8% were doing moderateintensity physical activity, 2.1% were consuming more than 6 servings of green leafy vegetables/fruits per week, 22.9% were overweight and 5.2% were obese. A family history of CVD was present in 12.5%. About 75% of participants were having one or more risk factors for CVD, and a comprehensive CVD risk assessment was done by 15%. The most commonly assessed risk factor was blood pressure (84.3%) and blood sugar (40%). Around 30% were advised for weight reduction and 23.4% were advised to quit tobacco. Dietary counseling and diet plan were prepared for 17 (8.9%) participants. **Conclusion:** Nearly threefourths were receiving treatment for hypertension. The majority of people with T2DM in rural areas had one or more CVD risk factors; however, very few were assessed and treated for CVD risk factors at the primary care level. Patient education and training of the diabetes care providers at the primary care level may be useful for comprehensive CVD risk assessment and treatment to prevent CVD complications in patients of T2DM.

Keywords: Cardiovascular disease, prevention, risk assessment, risk factors, type 2 diabetes mellitus

Introduction

India has one of the highest prevalence of type II diabetes (T2DM) in the world.[1] Individuals with diabetes have an increased risk of developing coronary artery disease; a two to four-fold increase which is approximately the same as an individual with non-diabetes who has suffered a prior myocardial infarct. Consequently, cardiovascular disease (CVD) is the largest cause of death in those with diabetes.[2-4] CVD is one of the leading causes of death amongst Indians. Studies have shown that in India, cardiovascular events occur on an average of 6 years earlier as compared to other countries.[5]

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It has been estimated that India may lose 43.5 million disability-adjusted life years by 2020, thereby making the prevention and control of CVD amongst populations at an increased risk such as individuals with T2DM, a health priority.[6] Insulin resistance has now been linked with and is also thought to set the stage for other risk factors for coronary artery disease.[7,8] While diabetes was conventionally thought to raise coronary risk through processes such as the increased atherogenicity of cholesterol particles, renal dysfunction and oxidative stress,[9] the emerging link between insulin resistance itself and coronary atherosclerosis has massive implications for the Indian diabetic population which already has an increased tendency towards coronary disease.[8] A comprehensive targeting of all cardiovascular risk factors in persons with T2DM has been shown to reduce macrovascular events and other complications.[10-16] Hence, a complete risk assessment and comprehensive risk reduction therapy may be the most appropriate strategy to prevent cardiovascular complications for an individual with T2DM.

Despite evidence in support of comprehensive interventions and relatively low cost of treatment to prevent CVD among people with diabetes, studies have shown that at a primary care practise in rural India there are critical gaps in the implementation of assessment protocol and treatment for control of risk factors of CVD amongst people with T2DM.[17-20] This study was undertaken to study CVD risk assessment and management in persons with T2DM from a rural area of central India at the primary care level.

Methodology

This cross-sectional study was conducted in a tertiary care teaching hospital situated in a rural area of Wardha District. Study participants were persons with T2DM (ADA criteria). Patients with apparent CVD such as AMI, stroke or angina, peripheral vascular disease and pregnant women with gestational diabetes were excluded from the study.

Considering the 50% prevalence of CVD in persons with T2DM, 95% level of significance and absolute precision of 50%, the desired minimum sample size was 192. Since there are no population-based studies on the prevalence of CVD risk factors in person with T2DM from rural India, we considered a 50% prevalence of CVD as it yields the maximum sample size at the specified absolute precision of 10% and 95% confidence levels.

Study participants were interviewed and examined using the structured questionnaire to determine the presence of CVD risk factors, the extent to which these factors have been previously identified and the proportion of those with risk factors received preventive therapy. The questionnaire was pilot tested before data collection. The protocol was approved by the institutional ethics committee. Ethics approval was obtained from the Ethics Committee of Datta Meghe Institute of Medical Sciences,

Sawangi (M) Wardha. Informed written consent was taken and participants were assured of the confidentiality.

Participants were interviewed in the local language (*Marathi*). Information on sociodemography; time since diagnosis of diabetes; current medication; family history of diabetes or CVD; presence of cardiovascular risk factors such as age, gender, family history, dyslipidemia, hypertension, physical inactivity, inappropriate diet, harmful use of alcohol and tobacco in all forms; average number of times or frequency of visits to health facility for follow-up and physical activity were collected. Participants were assessed for previous assessment and management of CVD risk factors.

Information about the diet was obtained from a 24-h food recall. Blood pressure was measured using a mercury sphygmomanometer, a minimum of two times in every participant in a sitting position and the mean of the readings was used for analysis. The lipid profile and fasting blood sugar were determined by analysing a sample of venous blood after asking the participants to fast overnight.

Weight (kg), height (m) and waist and hip circumference (cm) were measured using standardised equipment and procedures.[21] Body weight was measured (to the nearest 0.5 kg) with the subject standing motionless on the weighing scale with feet apart, and weight equally distributed on both legs. Height was measured (to the nearest 0.5 cm) with the subject standing in erect position against a vertical scale positioned so that the top of the external auditory meatus is in level with the inferior margin of the bony orbit. BMI was calculated as weight divided by height (kg/m²).

Definitions

Study participants were classified based on their body mass index as per WHO guidelines as underweight <18.5 kg/m², normal 18.5–24.9 kg/m², overweight 25.0–29.9 kg/m² and high risk >30.0 kg/m².[22] Abdominal adiposity was defined as a waist circumference >102 cm in men and >88 cm in women and a waist-to-hip circumference of ≥0.8 for women and ≥1.0 for men.[23]

Hypertension was defined as having an elevated blood pressure of ≥140/90 mmHg (as per the Eighth Report of the joint national committee on prevention, detection, evaluation and treatment of high blood pressure JNC8 criteria)[24] or being on blood pressure-lowering medication.

The National Cholesterol Education Programme Adult Treatment Panel III (NCEP ATP III) guidelines was used to determine ideal levels for LDL-C (<100 mg/dL); borderline (150–199 mg/dL), high (200–499 mg/dL) and very high (≥500 mg/dL) serum triglycerides and low HDL-C (<40 mg/dL).[25]

Smoking or tobacco intake was considered a risk factor if the patient currently smokes or has in the past smoked or taken non-smoked forms of tobacco for 6 months.

Nutrition risk factors were the consumption of inadequate fruit and vegetable intake (<4 servings/week).[26]

Harmful use of alcohol was defined as intake of more than one drink or >10 g alcohol a day for women and two drinks or >20 g alcohol per day for men.[27]

The participant was considered as physically active if he/she does at least 150 min/week of moderate-intensity, spread over at least 3 days/week no more than 2 consecutive days without exercise.[27]

A comprehensive CVD risk assessment

Comprehensive risk assessment was defined as a person with T2DM was assessed for all risk factors hypertension, dyslipidemia, tobacco use, obesity, dietary risk factor, physical inactivity and family history of CVD and was counselled regarding the presence of CVD risk factor/factors by health care providers.

Preventive therapy for CVD

Preventive therapy for CVD was considered if he/she consuming medication such as antiplatelet drugs - aspirin or clopidogrel; lipid-lowering drugs - statins; blood pressure-lowering drugs - angiotensin-converting enzyme inhibitors; angiotensin-II receptor blockers and/or beta-blockers.

Data analysis

The main outcome variables were CVD risk factors like hypertension, dyslipidemia, tobacco use, obesity, dietary risk factor, physical inactivity and family history of CVD. Chi-square (for categorical variables) and Student's *t*-test (for continuous variables) were used to test the association between risk factors and various predictors. The proportion of participants who underwent the comprehensive CVD risk assessment and currently taking preventive therapy were estimated.

Result

The mean age of study participants was 58.91 (SD 11.30) years and the age ranges from 35 years to 85 years. Nearly 74% were over 50 years of age. Males were more than women and most (70%) were from rural areas [Table 1].

Tobacco use and harmful consumption of alcohol were reported by 67.7% and 27% of participants, respectively. About 43.8% were doing moderate-intensity physical activity as recommended and merely 2.1% were consuming more than 6 servings of green leafy vegetables and/or fruit in a week. The mean BMI of the study participants was 22.82 (4.39) kg/m² and 22.9% were overweight, and 5.2% were obese. Mean Waist Hip Ration (WHR) of the study population was 0.95 (SD 0.05) and 82% have WHR less than 1.10 [Table 1].

Out of 192 participants with T2DM, in 12.5% diabetes was recently diagnosed (within a month) and 18 (18.8%) participants were having T2DM for more than 10 years. With regards to

Table 1: Characteristics of the study population

Characteristics		No (*n*=192)	Percent
Age group (years)	31 to 40	12	6.3
	41 to 50	38	19.8
	51 to 60	54	28.1
	More than 60	88	45.8
Sex	Male	120	62.5
	Female	72	37.5
Residence	Rural	134	69.8
	Urban	58	30.2
Current tobacco use (smoking + Other forms), No (%)		130	67.7
Currently use alcohol, No (%)		52	27.1
Physical activity		84	43.8
Green leafy vegetables or/and fruits	< 3 servings per week	148	77.1
	3 to 6 servings per week	40	20.8
	> 6 servings per week	4	2.1
Body Mass Index (BMI)	Underweight	38	19.8
	Normal	100	52.1
	Overweight (25-29.9)	44	22.9
	Obesity (>=30)	10	5.2
WHR	Less than 1	158	82.3
	More than or equal to 1	34	17.7

Table 2: Diabetes history, biochemical parameters and blood pressure among study participants

		No	Percent
Duration of DM	Recently diagnosed (> 1 months)	24	12.5
	1 month to 5 years	102	53.1
	5 years to 10 years	30	15.6
	More than 10 years	36	18.8
Current antidiabetes medication	Biguinades	68	35.4
	Insulin	14	7.3
	Sulphonylurea	10	5.2
	Biguinades + Sulphonylurea	50	26
	Biguinades + Insulin	20	10.4
	Biguinades + Insulin + Sulphonylurea	12	6.2
	Biguinades + Acarbose inhibitor	4	2.1
	Other combinations of above-mentioned drugs	14	7.3
Biochemical parameters	RBS (mg/dL); mean (SD)	279.16 (126.70)	
	FBS (mg/dL); mean (SD)	160.66 (76.38)	
	PMBS (mg/dL); mean (SD)	243.73 (96.32)	
	T-Cholesterol (mg/dL); mean (SD)	174.55 (48.63)	
	HDL, (mg/dL); mean (SD)	38.88 (4.94)	
	LDL, (mg/dL); mean (SD)	102.15 (35.04)	
	TG, (mg/dL); mean (SD)	163.65 (87.96)	
Blood pressure (mmHg) JNC 8 criteria	Normal	52	27.1
	Prehypertension	88	45.8
	Hypertension, stage 1	42	21.9
	Hypertension, stage 2	10	5.2

medication for diabetes, 100 (52%) were on multiple anti-diabetic drugs and 92 (47.9%) were on monotherapy. The most commonly

used drugs as monotherapy were metformin (35.4%), followed by sulfonylurea or insulin [Table 2].

The mean random blood sugar of participants was 279.16 (SD 126.70) mg/dL. Mean fasting blood sugar was 160.66 (SD 76.38) mg/dL and mean postprandial blood sugar was 243.73 (SD 96.32) mg/dL. The average level of total cholesterol, HDL, LDL and triglyceride was 174.55 (SD 48.63) mg/dL, 38.88 (SD 4.94) mg/dL, 102.15 (SD 35.04) mg/dL and 163.65 (SD 87.96) mg/dL, respectively. As per the JNC 8 criteria, 27% had normal blood pressure, 45% were pre-hypertensive and 27.1% hypertensive [Table 2].

A family history of CVD, hypertension or stroke was present in 12.5% of the total population. BMI more than or equal to 25 kg/m² was observed in 28% of participants and among this 26% were males and 30% female. 68% of males have waist circumference >90 cm and 27% of females had waist circumference >80 cm and the difference was found to be statistically significant ($P = 0.001$). Out of 53% of participants with a waist-hip ratio of more than one, males more compared to females ($P = 0.02$) [Table 3].

A statistically significant difference was observed between male and female participants with regards to the harmful use of alcohol ($P < 0.01$) and tobacco use (smoker and smokeless form) ($P < 0.01$). Almost 98% were consuming less than one serving of green leafy vegetables and/or fruit in a day and 56.2% were physically inactive [Table 3].

Out of 192 participants with T2DM, 74 had systolic blood pressure more than or equal to 140 mmHg. Out of 19.8% with diastolic blood pressure more than or equal to 90 mmHg males were more compared to female ($P = 0.02$).

Out of 106 participants with a fasting blood glucose level of more than 100 mg/dL; 51% were males and 61% females. A post-prandial blood glucose level of more than 140 mg/dL was observed in 120 participants and among this 68% were males and 52% females. LDL above 100 mg/dL and triglyceride levels of more than 150 mg/dL were seen in 40% and 48%, respectively whereas 96% had HDL level less than 50 mg/dL [Table 3].

Table 4 presents details regarding the assessment of the various CVD risk factors and risk reduction interventions received in the recent 6 months. Out of 192 participants with T2DM, 165 (85.9%) were assessed for some of the cardiovascular risk factors; however, the comprehensive risk assessment for CVD was done in 15% participants. The most commonly assessed risk factor was blood pressure (84.3) followed by blood sugar assessment (40%). Only 17.7% were assessed systematically for dietary risk factor and lipid profile was done in 21.9%. Overall 148 (77.1%) participants were on some risk reduction intervention and most were on anti-hypertensive medication (74%). The most commonly prescribed antihypertensive drug was the angiotensin-converting enzyme inhibitor. With regards to advice for behavioral modification, around 30% were advised for physical activity and weight reduction and 23.4% were advised to quit tobacco and cut down alcohol consumption. Dietary counseling and diet plan were prepared for 17 (8.9%) participants.

Discussion

This study showed a high prevalence of cardiovascular risk factors in people with T2DM, a comprehensive assessment of the CVD risk was done in very few patients despite its role in the prevention of the CVD complications in persons of T2DM. The most common risk factors were a diet high in carbohydrates and fats, low in fruit and vegetable, physical inactivity, tobacco consumption, hypertension, poor glycemic control, low HDL

Table 3: Distribution of risk factors for CVD with the sex of the study participants				
Risk factors for CVD	Total *n*=192	Male *n*=120	Female *n*=72	*P*
Age; mean (SD)	58.90 (11.30)	58.10 (12.19)	60.22 (9.65)	T=0.89; *P*=0.37
F/H of CVD/HT/stroke; no (%)	24 (12.5)	12 (10)	12 (16.7)	Chi=3.77; *P*=0.08
BMI > = 25 kg/m²; no (%)	54 (28.1)	32 (26.7)	22 (30.6)	Chi=168; *P*=0.682
Waist circumference >90 cm for males and >80 cm in female; no (%)	102 (53.1)	82 (68.3)	20 (27.8)	**Chi=14.86; *P*=0.01**
WHR >1; no (%)	34 (17.7)	32 (26.7)	2 (2.8)	**Chi=8.81; *P*=0.02**
Current tobacco use; no (%)	130 (67.7)	92 (76.7)	38 (52.8)	**Chi=5.87**; *P*=0.01
Current alcohol; no (%)	52 (27.1)	48 (40)	4 (5.6)	**Chi=13.5; *P*=0.00**
Dietary risk factors; no (%)	188 (97.9)	116 (96.6)	72 (100)	FET, *P*=0.526
Physical inactivity; no (%)	108 (56.2)	64 (53.3)	44 (61.1)	Chi=0.55, *P*=0.45
SBP, > = 140 mmHg	142 (74)	96 (80)	46 (63.9)	Chi=3.03; *P*=0.82
DBP, > = 90 mmHg	38 (19.8)	32 (26.7)	6 (8.3)	**Chi=4.76; *P*=0.02**
RBS >200 mg/dL; no (%)	76 (39.5)	48 (60)	28 (38.9)	FET, *P*>0.05
FBS >100 mg/dL; no (%)	106 (55.2)	62 (51.7)	44 (61.1)	Chi=1.42; *P*=0.23
PMBS >140 mg/dL; no (%)	120 (62.5)	82 (68.3)	38 (52.8)	Chi=0.35; *P*=0.55
T-Cholesterol >200 mg/dL; no (%)	138 (72)	99 (82.6)	39 (54.1)	FET, *P*=0.205
HDL, < 50 mg/dL; no (%)	184 (96)	120 (100)	64 (88.9)	FET, *P*=0.346
LDL, > 100 mg/dL; no (%)	77 (41.7)	37 (30.8)	40 (62.5)	FET, *P*=0.234
TG, > 150 mg/dL; no (%)	92 (48)	45 (37.5)	47 (65.3)	FET, *P*=0.218

Table 4: CVD risk assessment and risk reduction interventions by participants in recent 6 months		
CVD risk assessment in recent 6 months and risk reduction interventions	No	Percentage
Assessment of CVD risk factors		
Assessed for tobacco use	61	31.8
Assessed for Alcohol use	36	18.8
Assessed for nutrition/dietary intake	34	17.7
Assessed for physical activity	33	17.2
Estimated BMI	28	14.6
Measured Blood pressure	160	83.3
Blood sugar (FBS+PMBS) assessment	76	39.6
Lipid profile	42	21.9
Risk reduction interventions		
Asprin	19	9.9
Statins	11	5.7
Clopidogril	7	3.6
Antihypertensive medications	142	74.0
ACE inhibitor	64	45.1
AT receptor blockage	49	34.5
Calcium channel blocker	15	10.6
Beta-blocker	14	9.9
Advised for low salt diet and blood pressure	33	17.2
Advised for quitting tobacco and cut down alcohol	45	23.4
Advised for physical activity and weight reduction	56	29.2
Counselled for dietary modification and diet plan prepared	17	8.9

and high total cholesterol. Three-fourths of participants were having one or more risk factors for CVD.

Epidemiological studies reported that physical inactivity increases the risks of CVD.[16,17] In the present study over half of the participants were physically inactive. Similar observations have been made in studies from India as well.[18] A sedentary lifestyle was more prevalent in women as compared to men, which may be attributed to some social and cultural factors in rural India.[19,20,28] Around two-thirds of participants were either having normal BMI or were underweight. Abdominal obesity as a risk factor was defined as female participants with waist circumference >80 cm and males with >90 cm. More than half of the participants in our study had abdominal obesity and among these most of them were women. Tobacco use and harmful use of alcohol were seen in nearly two-thirds of the participants; more among males compared to female participants.

Nearly half of the participants were having hypertension as per the JNC 7 criteria and were currently on antihypertensive medication. The high prevalence of sedentary lifestyle, elderly population, unhealthy diet, low awareness regarding salt restriction and tobacco consumption may have contributed to increasing the risk of hypertension in study participants. Low HDL-cholesterol as a risk factor, more in females compared to males was observed in the study as well. The possible reasons for low HDL-C may be a sedentary lifestyle, obesity and ethnicity as shown in previous studies[22] and in-migrant Asian Indians.[24,25]

Fasting and postprandial blood sugar were done to assess glycemic control. Around two-thirds of the subjects were having FBS >100 and PMBS >140. Patients with T2DM have an excess risk of CVD and linear relationship between glycaemia and CVD. Uncontrolled diabetes, as evident by high glycaemia, is not the sole consideration in CVD risk in people with T2DM, rather it plays a role in the confluence of multifactorial influences.[20]

Recent guidelines for CVD management in diabetes are based on the premise that most patients with diabetes are at high risk for future CVD events. Even in the absence of CVD, both the ADA and the AHA identify diabetes as a high-risk condition for complications in patients with T2DM.[7,8] It is widely recognized that absolute risk for CVD varies among individuals with diabetes, and an accurate assessment of risk depends on the individuals' characteristics.[13] Therefore, the assessment of risk factors for CVD in patients with diabetes is most important for primary and secondary prevention of CVD in the future. In addition to these patients with diabetes should be educated regarding the status of risk factors and measures to reduce the risk of CVD. In this study, we looked for CVD risk assessment of study participants in the most recent 6 months. The study revealed that except blood sugar and blood pressure assessment, only around one-third of participants were assessed for other risk factors such as tobacco use, harmful use of alcohol, physical activity, BMI and lipid profile. Surprisingly, dietary risk factors were not assessed in any of the study participants in the last 6 months.

Patients were aware of blood sugar monitoring and blood pressure management in the last 6 months. However, they were unaware of their assessment of other CVD risk factors. Around one-third were currently on antihypertensive drugs but surprisingly less than one-fifth knew their current blood pressure levels. Similarly, only less than half of the patients knew their current blood sugar level. Almost all participants mentioned that they received advice from their care provider regarding the importance of adherence to medication and regular follow-up. Almost all participants were counselled to cut down sweets and undertake regular follow-up for blood pressure assessment but only one-third of them received advice to reduce salt intake. Only around one-fifth of the participants mentioned that they received advice regarding calories and lipid restriction in diet, cutting down harmful use of alcohol and physical activity.

Primary care practise in rural India faces multiple challenges to deliver diabetes diagnosis and care services due to the lack of trained diabetes care providers.[29,30] Despite the increased risk of CVD in persons of T2DM and benefits of management of this risk factor, our study revealed only a few received comprehensive risk assessment and treatment for these risk factors. People with T2DM from the rural area were having one or more risk factors for CVD, yet awareness regarding CVD risk factors in these populations was unsatisfactory. Therefore, considering the current evidence and high prevalence of CVD risk factors among the Indian population with T2DM, all persons with diabetes

mellitus should undergo periodic comprehensive risk assessment for CVD and measures to reduce the risk for prevention of CVD events in future. Capacity building of healthcare providers, especially in the primary care level, needs to train and certified regarding guidelines for assessment and management of CVD risk factors in person with T2DM. However, we have not assessed the physicians or care providers' views on this issue.

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Conflicts of interest

There are no conflicts of interest.

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