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Original Article

Assessment of Cardiovascular disease risk and treatment among the patients with type 2 diabetes mellitus

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ABSTRACT:
Introduction: Over the past few decades, several risk assessment tools have been developed to estimate the total CVD risk in individuals with T2DM. This study was undertaken to study CVD risk assessment and management in persons with T2DM. **Materials and Methods:** 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. **Results:** A family history of CVD, hypertension or stroke was present in 12.2% of the total population. BMI more than or equal to 25 kg/m2 was observed in 26% 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). **Conclusion:** It is sufficient to say that the Diabetes mellitus disease is high risk for CVD, especially men but not CVD risk equivalent (meaning is looking contradictory)..Better to write clear findings, hence the individualized approach to treatment is mandatory.
Keywords: Cardiovascular disease, T2DM, Diabetes, Risk.

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INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality among people with diabetes mellitus, who have a risk of cardiovascular mortality two to four times greater than that of people without diabetes.[1] Diabetes is commonly associated with other cardiovascular risk factors, interacting with these to accelerate atherogenesis.[2-5] Multifactorial interventions, such as those targeting hyperglycaemia, hypertension and hypercholesterolaemia, significantly reduce the risk of both fatal and non-fatal CVD.[6] Furthermore there is a high prevalence ofasymptomatic coronary artery disease (CAD), and higher incidences of silent ischaemia and of atypicalsymptoms.[7]

Several primary prevention strategies are proven to be effective in reducing future cardiovascular events in patients with T2DM. In particular, lipid-lowering therapy with statin, blood pressure control with antihypertensives, and antiplatelet therapy with aspirin have been shown to be effective in patients with T2DM.[8-9] Although interventions focused on individual CVD risk factors have proven benefits in patients with T2DM, a previous study has shown that adopting total risk approach, in comparison to treatment decisions being based on the level of a single risk factor, could lead to reductions in expenditure.[10]

Over the past few decades, several risk assessmenttools have been developed to estimate the total CVD risk in individuals with T2DM. The Framingham risk score is one of the most widely used risk assessment tools globally. It is based on the findings of the Framingham study conducted predominantly among the Caucasian population.[11] The UK Prospective Diabetes Study (UKPDS) risk engine is another risk assessment tool, which was developed based on data from this study. Unlike other risk assessment tools, the UKPDS risk engine is diabetes-specific and it incorporates glycemia, systolic blood pressure (SBP), and lipid levels as risk factors, in addition to age, sex, ethnic group, smoking status, and timesince diagnosis of diabetes.[12]

The extent to which the excess risk associated with type 2 diabetes may be mitigated, or potentially eliminated,

by contemporary evidence-based treatment and multifactorial risk-factor modification is unclear. In ancillary analyses, we estimated the strength of the associations between various risk factors and the incremental risks of death and cardiovascular outcomes associated with diabetes. Moreover, we examined the association be- tween selected risk-factor variables such as levels of glycated hemoglobin, systolic blood pressure, and low-density lipoprotein (LDL) cholesterol within evidence-based target ranges and these outcomes.

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 practice 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.[13] This study was undertaken to study CVD risk assessment and management in persons with T2DM from a rural area of India at the primary care level.

METHODOLOGY

This cross-sectional study was conducted collaboratively by department of general medicine & community medicine, SVS Medical College, Mahabubnagar, Andhra Pradesh from October 2012 to March 2013. 212 individuals were anticipated in this study. 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. Informed written consent was taken and participants were assured of the confidentiality. 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.

We included studies reporting CVD risk assessment tools or scores that: (1) were derived from prospective cohort studies or randomised trials; (2) were derived in the general population and evaluated in individuals with diabetes, or developed in a diabetic population; and (3) reported a measure of performance of the risk score for predicting CVD.

STATISTICAL ANALYSIS

This was done using statistic calculator Medcalc with $P < 0.05$ taken as statistically significant. The continuous data were expressed as mean ± standard deviation (SD) and 95% confidence interval (CI) for the difference was calculated. Comparisons between means were done by two sample t-test calculator. The categorical variables are represented in percentage.

RESULTS

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. Tobacco use and harmful consumption of alcohol were reported by 63.6% 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 23.1% were overweight, and 7.0% 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].

Table 1: Characteristics of the study population

Characteristics		No (*n*=212)	Percent
Age group (years)	31 to 40	17	8.0
	41 to 50	43	20.2
	51 to 60	59	27.8
	More than 60	93	43.8
Sex	Male	130	61.3
	Female	82	38.6
Residence	Rural	144	67.9
	Urban	68	32.0
Current tobacco use (smoking + Other forms),No (%)		135	63.6
Currently use alcohol, No (%)		56	26.4
Physical activity		88	41.5
Green leafy vegetables or/and fruits	< 3 servings per week	155	73.1
	3 to 6 servings per week	47	22.1

	> 6 servings per week	10	4.7
Body Mass Index (BMI)	Underweight	43	20.2
	Normal	15	7.0
	Overweight (25-29.9)	49	23.1
	Obesity (>=30)	15	7.0
WHR	Less than 1	168	79.2
	More than or equal to 1	44	20.7

Out of 212 participants with T2DM, in 13.2% diabetes was recently diagnosed (within a month) and 40 (18.8%) participants were having T2DM for more than 10 years. With regards to used drugs as monotherapy were metformin (34.4%), followed by sulfonylurea or insulin [Table 2].

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

		No	Percent
Duration of DM	Recently diagnosed (> 1 months)	28	13.2
	1 month to 5 years	106	50
	5 years to 10 years	34	16.0
	More than 10 years	40	18.8
Current antidiabetes medication	Biguinades	73	34.4
	Insulin	19	8.9
	Sulphonylurea	15	7.0
	Biguinades + Sulphonylurea	55	25.9
	Biguinades + Insulin	25	11.7
	Biguinades + Insulin + Sulphonylurea	17	8.0
	Biguinades + Acarbose	8	3.7
Blood pressure (mmHg) JNC 8 criteria	Normal	57	26.8
Blood pressure (mmHg) JNC 8 criteria	Prehypertension	93	43.8
	Hypertension, stage 1	47	22.1
	Hypertension, stage 2	15	7.0

A family history of CVD, hypertension or stroke was present in 12.2% of the total population. BMI more than or equal to 25 kg/m2 was observed in 26% 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).

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 51.8% were physically inactive [Table 3].

Table 3: Distribution of risk factors for CVD with the sex of the study participants

Risk factors for CVD	**Total *n*=212**	**Male *n*=130**	**Female *n*=82**	***P***
Age; mean (SD)	59.91 (12.29)	59.11 (13.16)	61.21 (9.68)	T=0.90; *P*=0.38
F/H of CVD/HT/stroke; no (%)	26 (12.2)	14 (10.7)	14 (17.0)	Chi=3.78; *P*=0.09
BMI > = 25 kg/m^2; no (%)	56 (26.4)	34 (26.1)	24 (29.2)	Chi=168; *P*=0.682
Waist circumference >90 cm for males and >80 cm in female; no (%)	105 (49.5)	84 (64.6)	22 (26.8)	**Chi=14.87; *P*=0.01**
WHR >1; no (%)	36 (16.9)	34 (26.1)	4 (4.8)	**Chi=8.82; *P*=0.02**
Current tobacco use; no (%)	132 (62.2)	94 (72.3)	40 (48.7)	**Chi=5.88**; ***P*=0.01**
Current alcohol; no (%)	54 (25.4)	50 (38.4)	6 (7.3)	**Chi=13.6; *P*=0.00**
Dietary risk factors; no (%)	190 (89.6)	118 (90.7)	82 (100)	FET, *P*=0.527
Physical inactivity; no (%)	110 (51.8)	66 (50.7)	46 (56.0)	Chi=0.56, *P*=0.46
SBP, > = 140 mmHg	144 (67.9)	98 (75.3)	48 (58.5)	Chi=4.01; *P*=0.83
DBP, > = 90 mmHg	40 (18.8)	34 (26.1)	8 (9.7)	**Chi=5.71; *P*=0.02**
RBS >200 mg/dL; no (%)	78 (36.7)	50 (38.4)	30 (36.5)	FET, *P*>0.05
FBS >100 mg/dL; no (%)	108 (50.9)	64 (49.2)	46 (56.0)	Chi=1.43; *P*=0.24

PMBS >140 mg/dL; no (%)	122 (57.5)	84 (64.6)	40 (48.7)	Chi=0.36; *P*=0.56
T-Cholesterol >200 mg/dL; no (%)	140 (66)	101 (77.6)	41 (50)	FET, *P*=0.206
HDL, < 50 mg/dL; no (%)	186 (87.7)	130 (100)	66 (80.4)	FET, *P*=0.347
LDL, > 100 mg/dL; no (%)	79 (37.2)	39 (30)	42 (51.2)	FET, *P*=0.235
TG, > 150 mg/dL; no (%)	94 (44.3)	47 (36.1)	49 (59.7)	FET, *P*=0.219

DISCUSSION

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

The study indicates that having all five risk-factor variables within the target ranges could theoretically eliminate the excess risk of acute myocardial infarction. However, there was a substantial excess risk of hospitalization for heart failure among patients who had all the variables within target ranges. We identified a monotonic relationship among younger age, increasing number of variables not within target ranges, and a higher relative risk of adverse cardiovascular outcomes. The results suggest that there may be greater potential gains from more aggressive treatment in younger patients with diabetes.

The following risk factors were considered to be the strongest predictors for cardiovascular out- comes and death: low physical activity, smoking, and glycated hemoglobin, systolic blood-pressure, and LDL cholesterol levels outside the target ranges. Using real-world data, we found that levels of glycated hemoglobin, systolic blood pressure, and LDL cholesterol that were lower than target levels were associated with lower risks of acute myocardial infarction and stroke.

The past studies have reported that adults with diabetes mellitus had the same risk for future MI as adults with previous MI and without diabetes mellitus. Consequently, the National Cholesterol Education Program Adult Treatment Panel III guidelines in 2001 recommended that all individuals with DM be considered as 'coronary heart disease risk equivalent'.[14] This statement has been controversial since the publication of a systematic review and meta-analyses by Bulugahapitiya et al.,[15] in 2009. The risk stratification not only allows the intensive risk care management but also a cost-effective in a resource-limited country like India. The knowledge of anticipated risks can improve patient's behavior towards his health and compliance to interventions may improve.

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 HDLC may be a sedentary lifestyle, obesity and ethnicity as shown in previous studies[16] and in migrant Asian Indians.[17] 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.[18]

CONCLUSION

Estimates of CVD risk can be useful for both clinicians and patients: for clinicians, it gives a prognostic information that can support them in the choice of therapeutic and preventive strategies; such as use of aspirin, statins and SGLT-inhibitors and GLP-1 receptor agonists, for patients, it can be a motivation tool to adopt healthy lifestyle measures and to observe prescribed risk-modifying treatments. It is sufficient to say that the Diabetes mellitus disease is high risk for CVD, especially men but not CVD risk equivalent, hence the individualized approach to treatment is mandatory.

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