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Original Article

Internal Medicine Section

Impact of Duration of Disease and Glycosylated Haemoglobin Level in Determining the Severity of Coronary Artery Disease in Patients with Type-2 Diabetes Mellitus: A Prospective, Cross-sectional, Observational Study

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ABSTRACT

Introduction: Duration of Type 2 Diabetes Mellitus (T2DM) and degree of glycaemic control play a pivotal role in the development of macrovascular complications of T2DM, including Coronary Artery Disease (CAD). However, association of the duration of T2DM and Glycosylated Haemoglobin (HbA1c) level with the severity of CAD is still an ongoing matter of debate in the diabetic patient subset.

Aim: To investigate the association of duration of T2DM and HbA1c level with severity of CAD in patients presenting with T2DM suspected of CAD.

Materials and Methods: This prospective, cross-sectional, observational study was conducted on 500 T2DM patients at GNRC Medical, Guwahati, Assam, India from June 2017 to June 2019. The T2DM patients with suspected CAD were studied and stratified according to the duration of T2DM (<10 and ≥10 years) and HbA1c level (<7% or ≥7%). All patients underwent coronary angiography to assess number of diseased vessels i.e., insignificant CAD (defined as <50% diameter stenosis in left main and <70% diameter stenosis in other branches), Single Vessel Disease (SVD), Double Vessel Disease (DVD), Triple Vessel Disease (TVD), and Left Main Coronary Artery (LMCA) disease. Chi-square test was used to assess the association of the duration of T2DM and HbA1c level with angiographic severity of CAD. The data were analysed using the Statistical Package for Social Sciences (SPSS) version 16.0, (Chicago, IL, USA).

Results: A total of 500 patients were studied, of which, 295 (59%) and 205 (41%) patients had <10 and ≥10 year duration of T2DM, respectively. Overall, 264 (52.8%) patients had HbA1c <7%, and 236 (47.2%) had ≥7%. Normal coronary artery (42.4% vs. 5.9%; p=0.00001), insignificant CAD (9.8% vs. 2.4%; p=0.00124), SVD (21% vs. 6.8%; p=0.00001), and LMCA disease (2.4% vs. 13.2%; p=0.00001) were significantly higher in patients with <10 year duration of T2DM than ≥10 year. On the other hand, DVD (12.9% vs. 28.8%; p=0.00001), and TVD (11.5% vs. 42.9%; p=0.00001) were significantly higher in patients with ≥10 year duration of T2DM as compared to <10 year. Normal coronary artery (34.8% vs. 19.1%; p=0.0001), and insignificant CAD (10.2% vs. 2.9%; p=0.0013) was higher in patients with HbA1c level <7% than ≥7%. The prevalence of TVD (18.6% vs. 30.9%; p=0.0013), and LMCA disease (3.8% vs. 10.2%; p=0.0047) were significantly lower in patients with HbA1c level <7 than ≥7%.

Conclusion: The T2DM patients with suspected CAD, longer duration of T2DM and poor glycaemic control were associated with more severe CAD.

Keywords: Coronary angiography, Double vessel disease, Insignificant coronary artery disease, Left main coronary artery disease, Single vessel disease, Triple vessel disease

INTRODUCTION

Approximately 69.2 million individuals are estimated to have diabetes in India [1], which is expected to rise to 79.4 million by 2030 [2]. The T2DM is becoming an increasingly significant metabolic threat worldwide, however more so in India. T2DM is often accompanied by a broad spectrum of complications, including microvascular complications such as renal, retinal, and neuropathic diseases and macrovascular complications such as vascular disease and CAD [3]. The cardiovascular system is the most affected, which may even consequence death. The leading cause of death among people with diabetes is atherosclerotic disease. The association between T2DM and higher prevalence of CAD along with higher morbidity, more fatal coronary events owing to the higher frequency of plaque rupture, and superimposed thrombosis in diffusely diseased coronary arteries have been demonstrated earlier [4].

The duration of T2DM and degree of glycaemic control play essential roles in the development of macrovascular complications of T2DM [5]. Nevertheless, substantial literature about the relationship between the duration of T2DM and HbA1c level with the severity of CAD in patients with T2DM reveals controversial findings. Some studies have revealed an association between the duration of T2DM and the progression of cardiovascular disease [6-8], while others have not [9,10]. HbA1c level is a surrogate marker for long term glycaemic control in patients with T2DM. Many studies have revealed that elevated HbA1c levels correlate with the severity of CAD and indicate HbA1c as a biomarker of extensive CAD [11,12]. Controversially, Shahim B et al., did not observe a positive correlation between HbA1c and cardiovascular related outcomes such as death, non fatal myocardial infarction, stroke, or hospitalisation due to heart failure [13]. According to new clinical practice recommendations from the American Diabetes Association (ADA), reduced HbA1c levels are associated with decreased risk of neuropathic, microvascular and macrovascular complications. However, these guidelines advocate that more research is warranted to establish a relationship between HbA1c level and macrovascular complications of T2DM [14].

Much research has been done to demonstrate the duration of T2DM and HbA1c as a predictor of the severity of coronary artery disease in people with T2DM in the past [6,7,15-17]. Nevertheless, data

regarding the relationship between duration of T2DM and HbA1c level with the severity of CAD among Indian patients with T2DM is still not well established. Hence, the present study aimed to assess the association of duration of T2DM and HbA1c level with the severity of CAD in patients presenting with T2DM with suspected CAD.

MATERIALS AND METHODS

This prospective, cross-sectional, observational study comprised 500 consecutive T2DM patients at GNRC Medical, Guwahati, Assam, India, who underwent coronary angiography at a tertiary care Hospital, from June 2017 to June 2019. This study was conducted with the permission of the Head of Cardiology Department, GNRC Medical, Assam, India. This study conforms to the principles outlined in the Declaration of Helsinki, and patients were enrolled in the study after providing informed written consent.

Inclusion criteria: Irrespective of age and gender, T2DM patients with suspected CAD based on the clinical history and positive stress tests were included in the study.

Exclusion criteria: Patients with the acute coronary syndrome were excluded from the study.

Patients were subdivided into two groups according to the duration of T2DM: (a) <10 year duration of T2DM; or (b) ≥10 year duration of T2DM. Patients were also stratified into two groups according to HbA1c level: (a) HbA1c <7%; or (b) HbA1c level ≥7%.

Study Procedure

The CAD was diagnosed based on the following angiographic criteria: (a) ≥70% diameter stenosis; and (b) ≥50% diameter stenosis in LMCA disease. Patients were considered type 2 diabetics if they fulfilled any one of the following criteria put forth by the American Diabetes Association (ADA) for the diagnosis of T2DM; a) Fasting Plasma Glucose (FPG) ≥126 mg/dL (7.0 mmol/L), fasting was defined as no caloric intake for atleast 8 hours; b) two hour plasma glucose concentration of ≥200 mg/dL (11.1 mmol/L) during an Oral Glucose Tolerance Test (OGTT); c) classic symptoms of hyperglycaemia or hyperglycaemic crisis or random plasma glucose ≥200 mg/dL (11.1 mmol/L) [18].

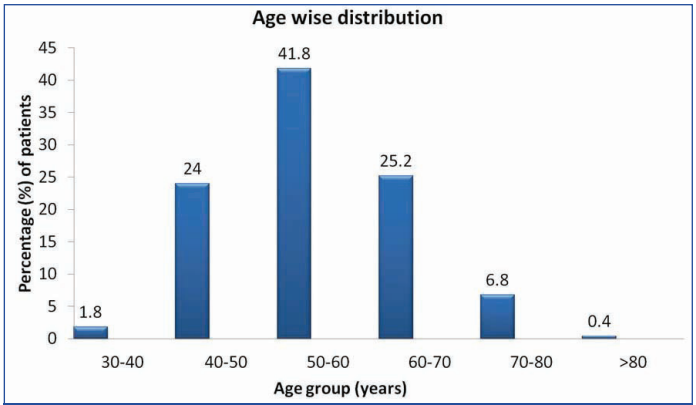
Severity of Coronary Artery Disease (CAD) and Type 2 Diabetes Mellitus (T2DM): The severity of CAD was measured according to the number of diseased vessels categorised as: normal coronary arteries, insignificant Coronary Artery Disease (CAD), Single Vessel Disease (SVD), Double Vessel Disease (DVD), Triple Vessel Disease (TVD), and Left Main Coronary Artery (LMCA) disease. Insignificant CAD was defined as <50% diameter stenosis in the left main and <70% diameter stenosis in other branches. The severity of T2DM was assessed by glycaemic control, which was determined by estimating of HbA1c using high performance liquid chromatography. HbA1c was measured before starting the angiography procedure. HbA1c level <7% was considered good glycaemic control, whereas HbA1c level ≥7% was considered poor glycaemic control.

STATISTICAL ANALYSIS

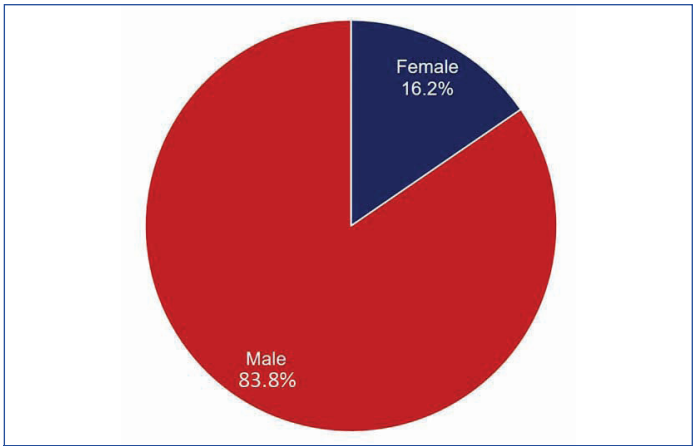
The data were analysed using the Statistical Package for Social Sciences (SPSS) version 16.0, (Chicago, IL, USA). The data are presented as numbers and percentages. The association of duration of T2DM and HbA1c level with angiographic severity of CAD was analysed using the Chi-square test. Throughout the analysis, p≤0.05 was the criteria for statistical significance.

RESULTS

Demographic characteristics: A total of 500 patients were included in this prospective analysis. The majority (41.8%) of the patients were between 50 and 60 years of age, followed by 60-70 years (25.2%) [Table/Fig-1]. Males outnumbered females constituting 83.8% of the study population [Table/Fig-2]. Out of the total, 152 (30.4%) patients had hypertension, 162 (32.4%) had dyslipidaemia, 52 (10.4%) had a family history of CAD, 76 (15.2%) were smokers, and 66 (13.2%) were obese.



[Table/Fig-1]: Age-wise distribution of study participants.



[Table/Fig-2]: Gender-wise distribution of study participants.

Angiography findings: Coronary angiographies detected normal coronary arteries in 137 (27.4%) patients, insignificant CAD in 34 (6.8%) patients, and abnormal angiography findings in 329 (65.8%) patients [Table/Fig-3]. Of the 329 patients with abnormal angiography findings, there were 76 (15.2%) patients with SVD, 97 (19.4%) with DVD, 122 (24.4%) with TVD, and 34 (6.8%) with LMCA disease.

Angiography findings	Patients, n (%)
Normal coronary arteries	137 (27.4)
Insignificant CAD	34 (6.8)
Single vessel disease	76 (15.2)
Double vessel disease	97 (19.4)
Triple vessel disease	122 (24.4)
Left main coronary artery disease	34 (6.8)

[Table/Fig-3]: Angiography findings of 500 study participants (N=500).
Data are presented as numbers and percentages; CAD: Coronary artery disease

Association between angiography findings and duration of type 2 diabetes mellitus: There were 295 (59.0%) patients with <10 year duration of T2DM and 205 (41.0%) patients with ≥10 year duration of T2DM. Angiography findings revealed that the proportion of patients with DVD (12.9% vs. 28.8%; p=0.00001) and TVD (11.5% vs. 42.9%; p=0.00001) were significantly differed between <10 and ≥10 year duration of T2DM [Table/Fig-4].

Association between angiography findings and Glycosylated Haemoglobin level (HbA1c): There were 264 (52.8%) patients with HbA1c <7% and 236 (47.2%) patients with HbA1c level ≥7%. The prevalence of TVD (18.6% vs. 30.9%; p=0.0013) and LMCA disease (3.8% vs. 10.2%; p=0.0047) were significantly higher in patients with HbA1c level ≥7% as compared to <7% [Table/Fig-5].

Angiography findings	Duration of diabetes mellitus, n (%)		p-value
	<10 year (n=295)	≥10 year (n=205)	
Normal coronary arteries	125 (42.4)	12 (5.9)	0.00001*
Insignificant CAD	29 (9.8)	5 (2.4)	0.00124*
Single vessel disease	62 (21.0)	14 (6.8)	0.00001*
Double vessel disease	38 (12.9)	59 (28.8)	0.00001*
Triple vessel disease	34 (11.5)	88 (42.9)	0.00001*
Left main coronary artery disease	7 (2.4)	27 (13.2)	0.00001*

[Table/Fig-4]: Association between angiography findings and duration of type 2 diabetes mellitus.
Data are presented as numbers and percentages; CAD: Coronary artery disease; *Statistically significant associations (p<0.05)

Angiography findings	Glycosylated haemoglobin level (HbA1c), n (%)		p-value
	<7% (n=264)	≥7% (n=236)	
Normal coronary artery	92 (34.8)	45 (19.1)	0.0001*
Insignificant CAD	27 (10.2)	7 (3.0)	0.0013*
Single vessel disease	42 (15.9)	34 (14.4)	0.6404
Double vessel disease	44 (16.7)	53 (22.5)	0.1021
Triple vessel disease	49 (18.6)	73 (30.9)	0.0013*
Left main coronary artery disease	10 (3.8)	24 (10.2)	0.0047*

[Table/Fig-5]: Association between angiography findings and glycosylated haemoglobin level (HbA1c).
Data are presented as numbers and percentages; CAD: Coronary artery disease; *Statistically significant associations (p<0.05)

DISCUSSION

Due to the availability of more advanced treatment and technology to treat cardiovascular diseases, a significant decline in morbidity and mortality rates has been noted. T2DM, remains the leading risk factor for the development of cardiovascular disease including CAD. Accordingly, there is considerable interest in identifying the relationship between the duration of T2DM and HbA1c level with the severity of CAD in patients with T2DM. With elevated HbA1c levels and increased duration of T2DM, a more severe, extensive, and distal type of CAD was observed in the study population.

As mentioned earlier, the risk of chronic vascular complications of T2DM elevates as a function of the duration of T2DM and the degree of hyperglycaemia. The Framingham Heart Study, reported a 1.38 fold increased risk for CAD and a 1.86 fold higher risk for cardiovascular death for each 10 year increase in the duration of T2DM [19]. Similarly, a recent analysis by Wannamethee SG et al., proposed that early onset diabetes with >10 year duration was associated with an increased risk of major coronary heart diseases and mortality [20]. Benjamin BK et al., noted that in the group of ≤10 year duration of T2DM, the combined incidences of DVD and TVD were reported in 80% of cases, while it was 89.2% in the group of >10 year duration of T2DM [21]. Collectively, all previous studies indicate that the duration of T2DM influences the coronary arteries of Indian patients more adversely. Consistent with earlier findings, the current study also found that the presence of the most severe forms of coronary atherosclerosis, i.e., DVD and TVD, as well as stenosis in LMCA artery, were observed in patients with ≥10 year duration of T2DM. On the contrary, Uddin SN et al., presented results suggestive of no significant correlation of the severity of CAD with severity (r=0.089602; p>0.1) and duration (r=0.07865; p>0.1) of T2DM on univariate analysis [22]. In line with the study as mentioned earlier, one prospective study showed no statistical association between the duration of T2DM and the severity of CAD in patients with T2DM [23]. The reason for these contradictory findings remains unknown. However, authors opine that differences in intensive glycaemic control, presence of other co-morbidities/ cardiovascular risk factors, and duration of diabetes could have played a significant role.

Hyperglycaemia is the most common feature of T2DM and is key factor in the development of vascular complication in the people with diabetes [24,25]. The mechanism behind this may be attributed to hyperglycaemia related sequential mechanisms involving the polyol pathway, formation of advanced glycation end products, activation of Protein Kinase C (PKC) isoforms, 12/15 lipoxygenase pathway, and hexosamine pathway that result in increased formation of reactive oxygen species, promotes diabetic atherosclerosis, and ultimately cause cardiovascular diseases [26]. Stamler J et al., hypothesised that optimal glycaemic control (defined as HbA1c ≤7%) results in reduced incidence of macrovascular complications in patients with T2DM [27]. There is consistent evidence of a significant positive correlation between HbA1c level and the number of vessels involved [28-30]. Khaw KT et al., demonstrated that a 1% rise in HbA1c concentration was associated with an approximately 30% increase in all cause mortality and 40% increase in cardiovascular or ischaemic heart disease mortality in diabetics [31]. A recent study proved that HbA1c is an independent predictor for the severity of CAD [11]. Findings from the United Kingdom Prospective Diabetes Study (UKPDS) revealed that a 1% reduction in baseline HbA1c levels decreased the event of myocardial infarction by 5% [32]. In contrast to earlier findings, Lazzeri C et al., asserted that HbA1c level was not associated with the mortality in ST elevation myocardial infarction patients with known diabetes submitted to mechanical revascularisation [33]. In support of this finding, from his systemic review, Liu Y et al., also stated that an elevated HbA1c level is an independent risk factor for mortality in CAD without diabetes [34]. Current study could be explained by the fact that the same cut-off value that defined elevated HbA1c may have been significantly too low to identify those with chronic hyperglycaemia in diabetic patients than non diabetic patients. In the present study, authors found that extensive CAD in terms of number of vessels involved and stenosis in the LMCA artery was more prevalent in patients with poor glycaemic control i.e., ≥7% HbA1c levels.

Limitation(s)

The study's major limitation is that it was a single centre study with limited patient population; a multicentre study with a larger study cohort may provide a more accurate estimation of study parameters. Secondly, the study participants are exclusively limited to Indian patients; therefore, generalisations to other ethnic groups should be made with caution. Lastly, the duration of diabetes was either self-reported or acquired from clinical records review. Hence, it is probable that the reported duration of T2DM may have been either overestimated or underestimated.

CONCLUSION(S)

Increased duration of T2DM and poor glycaemic control can lead to more severe CAD concerning the involvement of more vessels and stenosis in LMCA artery in T2DM patients with suspected CAD. This study emphasises the identification of CAD changes in a specific time frame due to T2DM, which would benefit better management and prevention of CAD among the T2DM population.

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