RESEARCH ARTICLE

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Study of Coronary Artery Disease Severity with HbA1c in Patients with Diabetes Mellitus with SYNTAX Score II - A Prospective Observational Study

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Abstract

Background and Aim: Coronary artery disease (CAD) is a major contributor to mortality in those with diabetes. Chronic hyperglycaemia exacerbates endothelial dysfunction, vascular inflammation, and atherosclerosis, hence worsening the severity of CAD. The SYNTAX score II (SSII) is a common tool for assessing the complexity of CAD and guiding treatment decisions. This study seeks to evaluate the severity of CAD in diabetic patients using the SSII and examining the association between glycated hemoglobin (HbA1c) and additional risk factors.

Materials and Methods: An observational study was conducted at SRM Medical College Hospital and Research Centre, enrolling 121 diabetic patients with angiographically confirmed CAD. SSII was applied to classify patients into low (<22), intermediate (23-32), and high (≥33) risk categories. Logistic regression and chi-square tests were employed to assess the associations between HbA1c levels, duration of diabetes, and severity of CAD.

Results: The average HbA1c was 8.53%±1.68, and the diabetes duration was 7.17±4.64 years. Higher HbA1c levels were significantly associated with severe CAD (P = 0.040), with each 1% increase in HbA1c raising the odds of high-risk SSII by 62.9% [odds ratio (OR) =1.62, P = 0.014]. Prolonged diabetes duration (OR =1.13, P = 0.049) and reduced left ventricular ejection fraction (OR =0.0004, P = 0.019) were also independent predictors.

Conclusion: Elevated HbA1c levels and prolonged diabetes duration are strongly associated with CAD severity in diabetic patients. SSII functions as a valuable instrument for risk stratification and the formulation of treatment plans.

Keywords: Coronary artery disease, diabetes mellitus, SYNTAX score II, HbA1c, cardiovascular risk, glycemic control

INTRODUCTION

The prevalence of coronary artery disease (CAD), particularly in the diabetic population, is an important public health issue worldwide. Diabetes accelerates atherosclerosis by increasing endothelial dysfunction, chronic inflammation, and oxidative stress, resulting in more severe CAD. Diabetes mellitus (DM) substantially elevates cardiovascular risk profiles, while cardiovascular pathologies continue to be the primary cause of global mortality.[1] About 77 million people in India had diabetes in 2019. That number is expected to increase to 134 million by 2045, which would make it one of the countries with the highest diabetes burdens in the world.[2] The prevalence varies regionally, with urban populations and states like Kerala, Tamil Nadu, and Punjab exhibiting higher rates.[3] Given this increasing burden, identifying predictors of CAD severity is essential for improving clinical outcomes.

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Glycated hemoglobin (HbA1c) is a crucial indicator of sustained glycemic regulation and is associated with cardiovascular risk. Increased HbA1c levels facilitate atherosclerosis advancement, plaque instability, and elevated coronary complexity.[4] Uncontrolled diabetes contributes to endothelial dysfunction, systemic inflammation, and a prothrombotic condition, all of which intensify the severity of CAD. Research indicates that a 1% elevation in HbA1c is associated with an approximate 18% increase in cardiovascular risk with people sustaining HbA1c levels over 5.6% exhibit a higher risk for coronary stenosis.[5,6]

The SYNTAX score II (SSII) is an established angiographic tool used to quantify CAD severity by assessing the complexity of coronary lesions. Studies have shown a strong relationship between SYNTAX scores and HbA1c levels, suggesting that more severe coronary lesions are linked to poorer glycemic control.[7] Nonetheless, few studies have investigated the direct correlation between HbA1c levels and the severity of CAD utilizing SSII, particularly in Indian populations, where genetic and lifestyle factors contribute to early-onset and aggressive disease progression. This study aims to assess the severity of CAD in diabetic populations utilizing SSII and examines the association of HbA1c in predicting the complexity of disease.

METHODS

Patients and Study Design

This prospective observational longitudinal study was conducted at SRM Medical College Hospital and Research Centre, Kattankulathur, Chengalpattu, a tertiary healthcare facility. The study aimed to evaluate the association between HbA1c levels and the severity of CAD in diabetic patients. Following approval from the Ethics Committee of the SRM Medical Faculty Hospital and Research Center, (protocol no: SRMIEC-ST0723-790, date: 14.09.2023), the study was conducted over 13 months, from September 2023 to October 2024. The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines of the International Council for Harmonisation. All participants provided written consent before enrolment.

The sample size was estimated based on the expected effect size in a multivariable logistic regression model, the primary analytic method in this study. Using Cohen's f^2 framework for regression, a medium effect size (f^2=0.15) with up to 10 predictors, an alpha of 0.05, and 80% power requires a minimum of 118 subjects to detect significant associations.[8] Our final sample size of 121, therefore, exceeds this requirement, ensuring adequate power to detect moderate associations between HbA1c, clinical covariates, and CAD severity.

Patients were enrolled consecutively according to predefined inclusion and exclusion criteria. Consecutive sampling was used to minimize selection bias and ensure representativeness of the eligible population. The study included patients with a confirmed diagnosis of DM, HbA1c levels above 6.5%, and angiographically confirmed CAD. Patients with a history of prior coronary revascularization [percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG)], hemoglobinopathies, anemia, recent blood transfusion, or HbA1c below 6.5% were excluded. Inclusion of only angiographically confirmed CAD limits external validity to the diabetic patients with established disease. Informed consent was obtained from all participants before enrolment.

Coronary Angiography and SYNTAX Score II Assessment

All patients underwent coronary angiography to assess CAD severity. The SSII was calculated using dedicated software (version 2.11, www.syntaxscore.com), incorporating clinical and angiographic parameters such as age, renal function, left ventricular ejection fraction (LVEF), and lesion complexity. Patients were stratified into low, intermediate, and high SSII categories using thresholds derived from existing literature. Specifically, tertile-based groupings ($\leq$22, 23-32, $\geq$33) as used by Serruys et al.[9] were adopted to assess associations with clinical outcomes.

Study Procedure

Patients meeting the inclusion criteria underwent HbA1c measurement before coronary angiography. Following angiographic assessment, the SSII was determined, and treatment recommendations for revascularization (PCI vs. CABG) were formulated based on the severity of CAD.

Statistical Analysis

Comprehensive statistical methodologies were employed to assess the relationship between HbA1c levels and CAD severity as quantified by the SSII. Continuous variables were presented as mean $\pm$ standard deviation or median with interquartile range, depending on the distribution characteristics. Categorical variables were represented as proportions or percentages. To find the association between CAD and other risk factors, the Chi-square test was used for categorical variables, and the Kruskal-Wallis test was used for continuous variables. Post-hoc pairwise comparisons were performed using the Bonferroni correction. Regression analyses were performed to evaluate the predictive value of HbA1c for CAD severity, adjusting for potential confounding variables including age, gender, renal function, and comorbid conditions. Statistical significance was set at $P < 0.05$.

The scoring system stratifies risk as follows:

- Low risk classification: <22
- Moderate risk classification: 23-32
- High risk classification: ≥33

RESULTS

The study included 121 diabetic patients with CAD, with 91.7% who were above 45 years of age and a male preponderance (65.5%). 28.1% of patients reported smoking, while 33.1% reported using alcohol. Triple vessel disease (TVD) was present in 32.2% of cases. Chronic obstructive pulmonary disease (COPD) was observed in 3.3% of patients, while peripheral vascular disease (PVD) was noted in 2.5% of patients. Systemic hypertension was observed in 81% of the study population (Table 1). Table 2 summarizes the descriptive statistics of the duration of diabetes, HbA1c, lipid profile, renal parameters, and echocardiography.

The SSII classification categorized 77 patients as low risk, 26 as intermediate risk, and 18 as high risk (Table 3). Gender was not significantly associated with CAD severity ($P = 0.373$), while in severe cases, TVD was more prevalent ($P = 0.002$). No significant differences were found in COPD ($P = 0.244$), PVD ($P = 0.148$), or alcohol consumption ($P = 0.237$). Patients exhibiting more severe CAD demonstrated a prolonged duration of DM ($P = 0.004$), elevated HbA1c levels ($P = 0.040$), increased low-density lipoprotein (LDL) cholesterol ($P = 0.043$), and decreased high-density lipoprotein cholesterol (HDL) cholesterol ($P = 0.026$). Creatinine clearance demonstrated a significant decline ($P < 0.001$) and LVEF decreased with the progression of CAD severity ($P = 0.05$).

Post-hoc analysis revealed a significant difference in diabetes duration between low and high-risk groups ($P = 0.008$) and intermediate and high-risk groups ($P = 0.002$); however, the difference between low and intermediate-risk groups was not significant ($P = 0.088$). HbA1c levels were significantly elevated in the high group compared to the low group ($P = 0.005$) and in the intermediate group compared to the high group ($P = 0.001$), but not between the low and intermediate groups ($P = 0.065$). Creatinine clearance was significantly lower in low-risk groups, compared to high-risk groups ($P < 0.001$); and in intermediate groups, compared to high-risk groups ($P = 0.012$); however, no significant difference was observed between low and intermediate risk groups ($P = 0.471$). LVEF was significantly lower in high-risk patients: the comparisons low vs. high ($P = 0.021$) and intermediate vs. high ($P = 0.023$) showed statistical significance. LDL levels were significantly higher in high vs. low ($P = 0.049$) and intermediate vs. high ($P = 0.023$), while HDL levels were significantly lower in high-risk patients ($P = 0.028$ and $P = 0.013$, respectively) (Table 4).

Table 1. Patient characteristics and comorbidities

Category		n (%)
Age group	Less than 45 years	10 (8.3%)
	More than 45 years	111 (91.7%)
Gender	Female	43 (35.54%)
	Male	78 (64.46%)
Smoking	Yes	34 (28.10%)
	No	87 (71.90%)
Alcohol	Yes	40 (33.10%)
	No	81 (66.90%)
TVD	Yes	39 (32.20%)
	No	82 (67.80%)
COPD	Yes	4 (3.30%)
	No	117 (96.70%)
PVD	Yes	3 (2.50%)
	No	118 (97.50%)
SHTN	Yes	98 (81.00%)
	No	23 (19.00%)

TVD: Triple vessel disease, COPD: Chronic obstructive pulmonary disease, PVD: Peripheral vascular disease, SHTN: Systemic hypertension

Table 2. Descriptive statistics of diabetes duration, glycemic control, lipid profile, ejection fraction and renal function parameters

Variable	Mean	Median	SD	Minimum	Maximum
Duration of DM	7.168	5	4.6388	0.7	20
HbA1c	8.529	8.3	1.6868	5.6	13.3
Cholesterol	181.752	172	57.8033	68	349
LDL	128.826	126	43.2446	41	261
HDL	40.421	38	11.9977	18	87
TG	175.884	131	153.7642	30	1349
CrCl (mL/min)	88.752	95	21.3472	15	123
Creatinine	0.931	0.8	0.4577	0.4	4.5
LVEF	0.528	0.52	0.09	0.3	0.67

DM: Diabetes mellitus, LVEF: Left ventricular ejection fraction, CrCl: Creatinine clearance, SD: Standard deviation, LDL: Low-density lipoprotein cholesterol, HDL: High-density lipoprotein cholesterol

Significant predictors of CAD severity, the duration of DM and HbA1c, according to multinomial logistic regression analysis with the low-risk group as the reference category. In the intermediate-risk group, each year's increase in diabetes duration increased the odds of CAD severity by 11.2% [odds ratio (OR) =1.11, $P = 0.049$], and each unit's increase in HbA1c raised the risk by 35.4% (OR =1.35, $P = 0.049$). Creatinine clearance ($P = 0.342$) and LVEF ($P = 0.992$) exhibited no significant predictive value in this group. In the high-risk group, the duration of diabetes was a significant predictor, with each additional year associated with a 1.13 times higher odds of being in the severe CAD group (OR =1.13, $P = 0.049$). Each 1% increase in HbA1c was associated with 1.62 times higher odds of being in the severe CAD group (OR = 1.62, $P = 0.014$). Lower creatinine clearance was a significant predictor of severe CAD (OR = 0.95, $P = 0.001$), while reduced LVEF showed a strong association with severe CAD (OR =0.0004, $P = 0.019$) (Table 5).

Table 3. Association between CAD and other risk factors using chi-square test for categorical variables and the Kruskal-Wallis test for continuous variables

Variable		Low (n=77)	Intermediate (n=26)	High (n=18)	*P*-value
Gender	Female	25 (32.5%)	9 (34.6%)	9 (50.0%)	0.373
	Male	52 (67.5%)	17 (65.4%)	9 (50.0%)	
TVD	Yes	18 (23.4%)	9 (34.6%)	12 (66.7%)	0.002
	No	59 (76.6%)	17 (65.4%)	6 (33.3%)	
COPD	Yes	1 (1.3%)	2 (7.7%)	1 (5.6%)	0.244
	No	76 (98.7%)	24 (92.3%)	17 (94.4%)	
PVD	Yes	1 (1.3%)	2 (7.7%)	0 (0%)	0.148
	No	76 (98.7%)	24 (92.3%)	18 (100%)	
Alcohol	Yes	20 (26.0%)	6 (23.1%)	8 (44.4%)	0.237
	No	57 (74.0%)	20 (76.9%)	10 (55.6%)	
Age		58.026±8.19	58.00±8.14	60.72±10.23	0.621
Duration of DM		6.08±3.93	8.35±4.94	10.10±5.52	0.004
HbA1c		7.32±1.48	8.38±1.74	9.19±1.94	0.040
Cholesterol		184.29±56.23	181.42±63.76	171.39±57.70	0.573
LDL		120.70±34.94	134.04±38.47	147.72±40.71	0.043
HDL		40.27±10.76	37.77±14.73	35.56±18.37	0.026
TGL		166.86±106.70	213.42±255.42	160.28±131.46	0.616
CrCl (mL/min)		93.25±18.44	88.81±21.57	69.44±22.94	<0.001
LVEF		0.54±0.09	0.53±0.09	0.48±0.09	0.05

TVD: Triple vessel disease, COPD: Chronic obstructive pulmonary disease, PVD: Peripheral vascular disease, DM: Diabetes mellitus, HbA1c: Glycated hemoglobin, LDL: Low-density lipoprotein, HDL: High-density lipoprotein, TGL: Triglycerides, LVEF: Left ventricular ejection fraction, CAD: Coronary artery disease

Table 4. Post-hoc analysis between the CAD and other risk factors

Variable	Comparison groups	W statistic	*P*-value
Duration of DM	Low vs. intermediate	2.98	0.088
	Low vs. high	4.2	0.008
	Intermediate vs. high	1.63	0.002
HbA1c	Low vs. intermediate	3.164	0.065
	Low vs. high	1.24	0.005
	Intermediate vs. high	2.34	0.001
Creatinine clearance (mL/min)	Low vs. intermediate	-1.66	0.471
	Low vs. high	-5.22	<0.001
	Intermediate vs. high	-4.06	0.012

Table 4. Continued

Variable	Comparison groups	W statistic	*P*-value
LVEF	Low vs. intermediate	1.22	0.665
	Low vs. high	3.8	0.021
	Intermediate vs. high	3.6	0.023
LDL	Low vs. intermediate	6.22	0.665
	Low vs. high	4.8	0.049
	Intermediate vs. high	4.6	0.023
HDL	Low vs. intermediate	5.22	0.665
	Low vs. high	5.5	0.028
	Intermediate vs. high	5.7	0.013

CAD: Coronary artery disease, DM: Diabetes mellitus, LVEF: Left ventricular ejection fraction, LDL: Low-density lipoprotein cholesterol, HDL: High-density lipoprotein cholesterol

Table 5. Comparison between the CAD and other risk factors using multinomial logistic regression

CAD Severity	Predictor	Estimate	SE	Z	*P*-value	OR (95% CI)
Intermediate	Duration of DM	0.1065	0.0541	1.9675	0.049	1.11(1.00-1.24)
	HbA1c	0.303	0.1538	1.9697	0.049	1.35 (1.00-1.83)
	Creatinine clearance (mL/min)	-0.0119	0.0125	-0.951	0.342	0.99 (0.96-1.01)
	Left ventricular ejection fraction	-0.0256	2.5286	-0.0101	0.992	0.97 (0.69-1.38)
High	Duration of DM	0.1256	0.0638	1.9682	0.049	1.13 (1.00-1.29)
	HbA1c	0.4878	0.1986	2.456	0.014	1.63 (1.10-2.40)
	Creatinine clearance (mL/min)	-0.0447	0.0138	-3.2402	0.001	0.96 (0.93-0.98)
	Left ventricular ejection fraction	-7.7541	3.2934	-2.3545	0.019	0.0004 (0.0000007-0.273)

CAD: Coronary artery disease, DM: Diabetes mellitus, HbA1c: Glycated hemoglobin, LVEF: Left ventricular ejection fraction, SE: Standard error, OR: Odds ratio, CI: Confidence interval

DISCUSSION

This study evaluates the distribution of biochemical, clinical, and demographic parameters across the mild, moderate, and severe levels of CAD severity. The incidence was higher for males in all categories, but there was no significant difference in the gender distribution between groups ($P = 0.373$). Nonetheless, the high-severity group experienced TVD more frequently (66.7%, $P = 0.002$), suggesting that increasing coronary involvement is associated with more severe CAD. There was no statistically significant difference in the prevalence of PVD and COPD across the groups ($P = 0.148$ and $P = 0.244$, respectively), indicating that these comorbidities were equally distributed throughout CAD severity levels. Patients with high severity consumed more alcohol (44.4%), although the disparity was not statistically significant ($P = 0.237$). This implies that while alcohol intake may influence overall health, it may not have a direct impact on CAD severity in this cohort.

Clinical and biochemical parameters demonstrated significant variations among the severity groups. The association between uncontrolled diabetes and deteriorating coronary involvement was further supported by the substantial correlations between higher HbA1c levels, longer duration of diabetes, and greater CAD severity ($P = 0.040$ and 0.004, respectively). Ma et al.[10] emphasized that poor glycemic management and long-term diabetes both significantly contribute to coronary pathology, and they found a strong correlation between higher HbA1c and the severity of CAD. There were also noticeable differences in the lipid profiles, with the high-severity group having lower HDL levels ($P = 0.026$) and higher LDL levels ($P = 0.043$). In line with our results, Achila et al.[11] comparative data from research that included 319 elderly individuals in Asmara, Eritrea, showed a mean total cholesterol of 202.2±40.63 mg/dL and LDL-C of 125.95±33.16 mg/dL. Triglyceride levels were also higher in our sample (175.8 mg/dL) than in their research (129±57.1 mg/dL), suggesting a larger burden of dyslipidaemia in our cohort.

A significant correlation between the severity of CAD and cardiac and renal function was also observed. Creatinine clearance was significantly lower in patients in the high-severity group ($P < 0.001$), suggesting that more severe CAD is associated with deteriorating renal function. In the same way, the high-severity group's LVEF was significantly lower ($P = 0.050$), suggesting that those with advanced CAD had diminished cardiac function.

Key determinants of the severity of CAD were identified using multinomial logistic regression analysis. Higher HbA1c levels (OR =1.35, $P = 0.049$) and longer diabetes duration (OR =1.11, $P = 0.049$) were significant predictors in the intermediate-severity group. Duration of DM was associated with higher odds of severe CAD (OR =1.13, 95% CI: 1.00-1.28, $P = 0.049$), though the association was borderline, and higher HbA1c (OR =1.62, $P = 0.014$) continued to be a significant predictor of high-severity CAD. The negative impact of uncontrolled diabetes on the development of CAD was highlighted by Khan et al.[12], who discovered a strong correlation between severe coronary involvement and HbA1c values over 7.5%, with a mean HbA1c of 10.23±2.58%, which is similar to our study, in which the mean HbA1c was 8.53%. Similar findings were reported by Ma et al.[10] and Jiao et al.[13], confirming the association between elevated HbA1c and severe CAD in diabetic populations.

Each 1% increase in HbA1c was associated with higher odds of belonging to the severe CAD group according to our study (OR =1.62, $P = 0.014$). These findings align with studies from Northeastern India, where HbA1c levels above 5.1% independently predicted SYNTAX scores exceeding 22 [OR =1.6, 95% confidence interval (CI): 1.04-2.46], reinforcing the strong relationship between uncontrolled diabetes and complex coronary disease.[13,14] Furthermore, data analysis revealed, that each 1% increase in HbA1c corresponded to a 15% elevated risk of severe coronary heart disease (OR =1.14).

In addition to glycemic control, reduced creatinine clearance and lower LVEF were also associated with severe CAD. In multinomial logistic regression, lower creatinine clearance was significantly associated with severe CAD (OR =0.96, 95% CI: 0.93-0.98, $P = 0.001$), indicating that each 1 mL/min decline in creatinine clearance corresponded to approximately 4% higher odds of being in the severe CAD group. This emphasizes the predictive significance of renal function in assessing the severity of CAD, as even minor declines in kidney function significantly impact cardiovascular outcomes. Pereg et al.[14] discovered that a drop of 10 mL/min in creatinine clearance was associated with a 4.77-fold increased risk of developing CAD, particularly in young, healthy males without diabetes or cardiovascular disease. Furthermore, LVEF was found to be a strong predictor of CAD severity, with lower ejection fractions correlating with more extensive coronary disease. Our findings that cardiac dysfunction is a crucial indicator of advanced coronary disease, were supported by Dorbala et al.[15], who found a clear correlation between decreasing LVEF and increasing CAD complexity.

In comparison with previous research, this study highlights strong associations between worsening CAD and reduced LVEF, uncontrolled diabetes, impaired kidney function, and longer duration of diabetes. This study clarifies the association between diabetes, glycemic control, renal function, lipid profile, and the severity of CAD. Future longitudinal multicentre research, including genetic and lifestyle factors, could provide more data on how CAD develops in diabetic populations.

Study Limitations

As a prospective observational study without long-term follow-up, this study design limits the ability to establish causality or assess temporal changes between variables. As it is a single-center study, the possibility of selection bias cannot be fully excluded. Our study excludes well-controlled diabetics, which restricts the generalizability of the findings. Furthermore, the observed relationships may be influenced by the absence of information on relevant confounders, including nutrition, exercise, and genetic susceptibility, necessitating further thorough investigation.

CONCLUSION

Prolonged duration of illness and uncontrolled diabetes contribute to increased severity of CAD, with the latter significantly influencing severity. HbA1c is strongly associated with angiographic severity of CAD. The link between metabolic, renal, and cardiac dysfunction emphasizes the necessity for a comprehensive risk management strategy. Effective glycemic control, cholesterol modulation, and renal function monitoring are critical in lowering the CAD burden in diabetic patients, as they stress the need for early and personalized therapeutic interventions.

Ethics

Ethics Committee Approval: The study was obtained from the Ethics Committee of SRM Faculty of Medicine Hospital and Research Center (protocol no: SRMIEC-ST0723-790, date: September 14, 2023).

Informed Consent: All participants provided written informed consent.

Footnotes

Authorship Contributions

Surgical and Medical Practices: K.V., P.R., V.T.A., Concept: K.V., A.S.B., P.R., V.T.A., R.J.D., Design: A.S.B., P.R., V.T.A., R.J.D., Data Collection or Processing: K.V., A.S.B., R.J.D., Analysis or Interpretation: K.V., P.R., V.T.A., R.J.D., Literature Search: P.R., V.T.A., R.J.D., Writing: K.V., A.S.B., P.R., V.T.A., R.J.D.

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