Comparison of Mid-term Outcome of Multivessel Percutaneous Coronary Intervention with Drug Eluting Stents in Patient with Chronic Coronary Syndrome between Diabetic and Non-diabetic Groups

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Abstract

Background: In Bangladesh, the prevalence of chronic coronary syndrome is rising which results in more revascularization with percutaneous coronary intervention (PCI), especially multi-vessel PCI. Although post-procedure patient outcomes are improving, co-morbidities and risk factors, such as diabetes, raise questions about the procedure's efficacy and longevity.

Objective: To compare the mid-term (6-month) results of drug-eluting stent multi-vessel percutaneous coronary intervention in patients with Chronic Coronary Syndrome in groups with and without diabetes.

Methods: This study was conducted at the cardiology department of Bangladesh Medical University (BMU) from September 2021 to August 2022 on 100 patients who underwent multivessel PCI six months earlier. In both diabetes and non-diabetic individuals, the study evaluated major adverse cardiac events (MACE), clinical state and functional ability. A data collecting sheet was used to gather information and patient privacy was protected. Comparing outcome variables between patients with and without diabetes before and after six months was the goal of the study.

Results: The average age (with standard deviation) of diabetic patients (53.3±8.81) diagnosed with Chronic Coronary Syndrome was less than that of non-diabetic patients (54.9±8.06). All initial characteristics were comparable between the two groups, except for functional class (NYHA) and the extent of vessel involvement. The occurrence of triple vessel disease was higher in diabetic patients than in non-diabetic patients with SIHD, although the difference was not statistically significant. The average number of stents placed per patient (2.4±0.48 vs 2.3±0.55) was greater in non-diabetic patients compared to diabetic patients with SIHD, but this difference was also statistically insignificant. The rates of in-hospital adverse outcomes, which included death from cardiovascular reasons, periprocedural myocardial infarction, hyperacute stent thrombosis, CIN and bleeding complications, showed no significant differences between the two groups. Even though MACCE were frequently observed in the diabetic group at the 6-months, these results were not statistically significant. A statistically significant positive impact on clinical status (as measured by CCS class and NYHA class) and functional status (indicated by METS) was evident at 6 months following multivessel PCI in both the diabetic and non-diabetic groups. An assessment of LV systolic function and renal function demonstrated similar stable cardiorenal conditions in both groups. However, diabetic patients exhibited a significantly higher serum creatinine level compared to their baseline measurement.

Conclusion: In both the diabetic and non-diabetic patient groups, multivessel PCI with drug-eluting stents for chronic coronary syndrome has comparable favorable in-hospital and mid-term outcomes with respect to MACE, clinical status (CCS class, NYHA class), functional status (METS), LV systolic function (LVEF), and renal function (serum creatinine). When comparing diabetes groups to non-diabetic groups, there was a noticeable increase in serum creatinine and medically treated angina.

Keywords: Diabetes, Stable ischemic heart disease, 6-month outcomes, Multivessel PCI, Stent thrombosis.

Introduction

Coronary artery disease (CAD) is a growing medical and public health concern in Bangladesh.[1] Current treatment options include Optimum Medical management, PCI, Balloon angioplasty and CABG.[2] However, there is disagreement on the best technique for multivessel coronary vessel disease. PCI is the most widely used method, but its use in patients with chronic coronary syndrome is limited. Drug-eluting stents (DES) have replaced bare metal stents in PCI procedures, offering a safer, minimally invasive option for CAD patients.[3] PCI with DES is the preferred treatment option for most patients due to its lower risk of restenosis and stent thrombosis.[4]

Multivessel PCI is a less invasive technique compared to coronary artery bypass grafting (CABG).[5] The SYNTAX score is a reliable indicator of which patients benefit most from PCI.[6] The decision-making process should involve a cardiothoracic surgeon, interventional cardiologist and patient. Technical viability, surgical risk, renal failure, expected dye load and patient compliance also influence the choice.[7] After a revascularization, active medical care, quitting smoking, exercise and weight loss/maintenance are required.[8] Factors such as ischemia burden, complete revascularization, FFR and imaging guided PCI, high pressure prolonged balloon inflation, high intensity statin therapy, appropriate duration of dual antiplatelet therapy (DAPT), and post-PCI care can optimize outcomes.[9] Diabetes mellitus (DM) influences morbidity and mortality related to cardiovascular illnesses and procedures.[10] Multivessel PCI with DES is commonly used in Bangladesh to treat patients with chronic coronary syndrome.

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Materials and Methods

This cross-sectional observational study was conducted in the department of Cardiology at BMU, Shahbag, Dhaka from September 2021 to August 2022. This study examined adult patients diagnosed with chronic coronary syndrome who underwent multi-vessel PCI with DES six months prior. Patients with congenital heart disease, significant valvular heart disease, cardiomyopathy, atrial fibrillation, systemic diseases like cancer, collagen vascular diseases or amyloidosis were excluded from the study. All patients underwent OMT with appropriate pre-procedural data.

Purposive sampling was used to recruit participants. The sample size was calculated using statistical formulae for hypothesis testing. Based on previous studies reporting proportions of asymptomatic patients after PCI in diabetic and non-diabetic group groups (60% vs. 70%, respectively, and considering a 5% margin of error and potential dropouts, the final sample included 48 patients in the non-diabetic group and 52 in the diabetic group, with all of the respondents having multi-Vessel PCI having background CCS.

The study involved patients with chronic coronary syndrome who underwent multivessel PCI with DES before 6 months, adhering to Helsinki Declaration guidelines. Post-PCI assessment included symptoms, MACEs history, clinical examinations, ECG, cardiac biomarkers (Troponin I) and 2D echocardiography (Ejection Fraction). Functional status (METs) was assessed by ETT or subjective assessment of daily activity. Pre and post-PCI variables were compared in diabetic and non-diabetic patient groups.

After coding and editing the collected data were analyzed with the appropriate statistical procedure. Quantitative data will be calculated as mean as the mean±SD. On the other hand, qualitative variables like MACE were expressed as percentage and frequency. Comparison of variables before and after procedure in both diabetic and non-diabetic were calculated with Chi-square test, independent t test and Wilcoxon Signed Ranks. A p-value <0.05 was considered to be statistically significant. All of the statistical calculations were performed using SPSS/PASW (Predictive Analytics Software) Statistics Version 25 (SPSS Inc., Chicago, IL, USA).

Before beginning, the study was approved by the institutional review board (IRB) of BSMMU and followed the Declaration of Helsinki's guidelines. All participants or their legal guardians were informed of the study's goals and their right to discontinue participation at any time without compromising their regular care and they were then asked for their informed written consent. All data were anonymized in order to carefully safeguard patient anonymity.

Results

Table-I provides the mean differences and cross-tabulation of the baseline and clinical values. There were more patients in the baseline non-diabetic group who had dyspnea (NYHA class II) (P value 0.033). All other baseline characteristics were similar and comparable between the two groups. The mean age for diabetic group was 53.3±8.81 years and non-diabetic group was 54.9±8.06 years. There was no significant difference in age between the two groups (p=0.835).

Table-I: Baseline patients Characteristics

	Non-DM (n=48)	DM (n=52)	P Value
Male	42 (87.5%)	42 (80.77%)	0.359[a]
Female	6 (13.5%)	10 (19.23%)	
Family history of CAD	15 (31.25%)	26 (50%)	0.057[a]
Smoking	10 (20.8%)	12 (23.07%)	0.787[a]
Previous History of CABG	0	2 (3.84%)	0.170[a]
Hypertension	21 (43.75%)	32 (61.5%)	0.075[a]
DAPT	47 (97.9%)	50 (96.1%)	0.606[a]
Beta blocker	45 (93.75%)	48 (92.3%)	0.778[a]
CCB	10 (20.8%)	11 (21.15%)	0.969[a]
Nitrates	24 (50%)	29 (55.76%)	0.564[a]
Statin	47 (97.9%)	51 (98.07%)	0.954[a]
NYHA II	11 (22.9%)	4 (7.7%)	0.033[a]
Age	54.9±8.06	53.3±8.81	0.835[b]
LVEF (%)	53.7±7.12	54.2±6.1	0.705[b]
Serum Creatinine	1.2±0.23	1.1±0.13	0.107[b]

[a]P Value from chi square test,[b]P Value from independent t test, CAD: Coronary Artery Disease, CABG: Coronary Artery Bypass Surgery; CCB: Calcium Channel Blocker, NYHA II: New York Heart Association Class II, LVEF: Left Ventricular Ejection Fraction

Double vessel disease as well as double vessel PCI was predominant in both groups of patients. Target vessel was also similar to both groups of patients. Statistically number of stent deployment was also similar and comparable to both diabetic and non-diabetic patient groups.

Table-II: Immediate Angiographic characteristics and procedural results

Characteristics		Non-DM (n=48)	DM (n=52)	P value
	DVD	43 (89.58%)	42 (80.77%)	0.217 [a]
	TVD	5 (10.4%)	10 (19.23%)	
PCI type	Double vessel	43 (89.58%)	46 (88.46%)	0.858 [a]
	Triple vessel	5 (10.4%)	6 (11.54%)	
Target vessel	LAD	40 (83.33%)	43(88.46%)	0.772 [a]
	LCX	27 (56.25%)	26 (50%)	
	RCA	33 (68.75%)	41(78.85%)	
	Number of stents implanted per patients	2.4±0.48	2.3±0.55	0.794 [b]

[a]P Value from chi square test [b]P Value from independent t test; LAD: Left anterior descending; LCX: Left circumflex; RCA: right coronary artery; DM: Diabetes mellitus; Non-DM: Non-Diabetes Mellitus

Overall occurrence of in-hospital adverse events was few in numbers. Death due to cardiovascular cause was more in diabetic group (3.8% vs 2.08%; p = 0.606) but statistically insignificant. Access site hematoma >5cm (3.84%), CIN (1.92%) and hemoglobin drop 5gm/dl (1.92%) were found in the diabetic group, though difference was not statistically significant. Single event of periprocedural MI (2.08%) was noted in non-diabetic patient. No patient developed hyperacute stent thrombosis, access site hematoma, significant hemoglobin drops or contrast induced nephropathy in non-diabetic group.

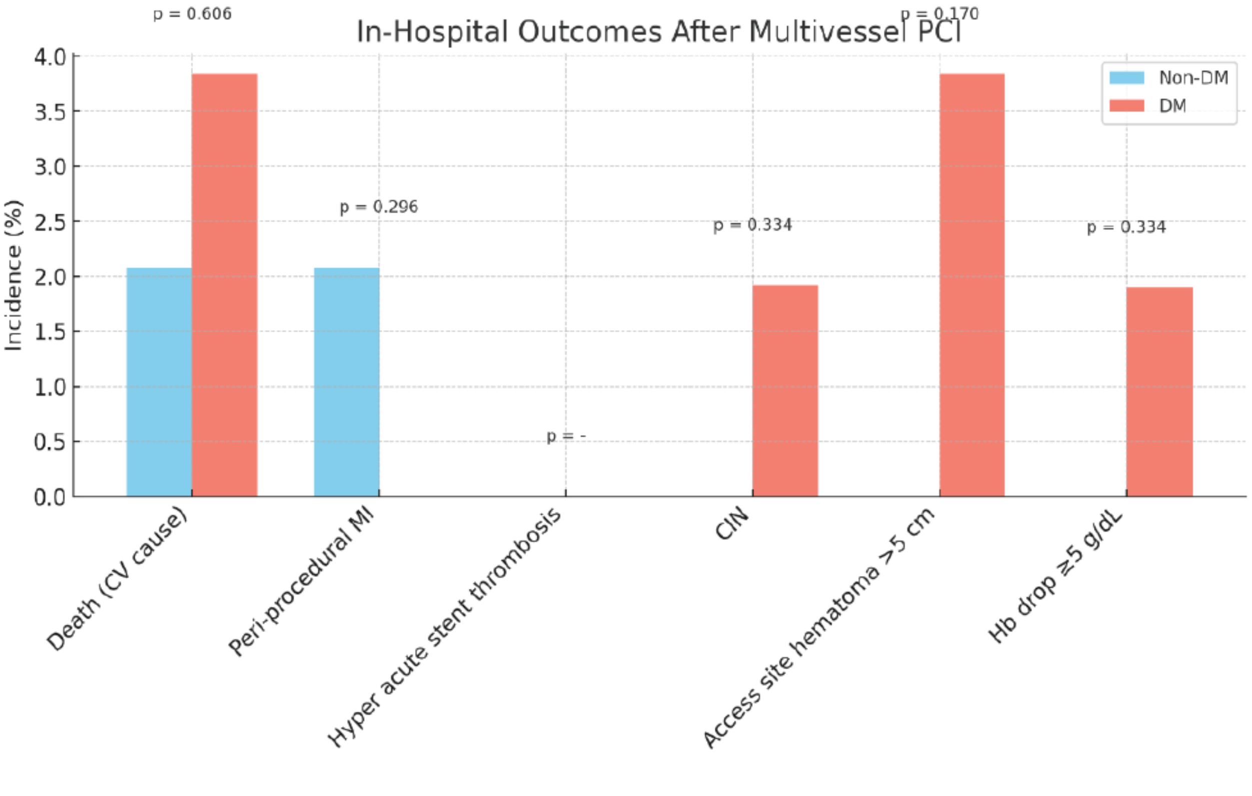


Figure-1: In-hospital outcomes after multivessel PCI

Here's the bar chart visualizing the in-hospital outcomes after multivessel PCI for Non-DM and DM groups. Each bar shows the percentage of patients experiencing specific complications.

At the end of 6-months, in terms of MACE, death was 2.08% in non-diabetic group and 1.92% in diabetic group. NSTEMI and STEMI were found in 2 (3.84%) and 1 (1.92%) diabetic patient respectively. Non diabetic patients are more asymptomatic than diabetic group (85% versus 71.15%; P value 0.36) although it was statistically insignificant. Ischemia-driven revascularization was more common in the diabetic group and but it was also statistically insignificant. Symptomatic improvement in terms of chest pain (CCS class), functional capacity (METS) and shortness of breath (NYHA class) were noticed in both diabetic and nondiabetic groups of patients. But difference in outcome in both groups was statistically insignificant. After 6months of multivessel PCI, occurrence of dyspnea was more in diabetic group compared to non-diabetic. These findings are also statistically insignificant. The details are given in Table-III.

Table-III: Outcomes after 6-months of multivessel PCI

	Non-DM (n=48)	**DM** (n=52)	P value
Death due to cardiovascular cause	1 (2.08%)	1(1.92%)	0.953
NSTEMI	0	2 (3.84%)	0.170
STEMI	0	1 (1.92%)	0.335
Asymptomatic	41 (85.41%)	37 (71.1%)	0.360
Medically treated angina	7 (14.58%)	15 (28.8%)	0.041
Other vessel revascularization	0	2 (3.84%)	0.170
Dyspnea (NYHA)			
NYHA 0	40 (83.3%)	36 (69.2%)	0.160
NYHA I	5 (10.4%)	13 (25%)	
NYHA II	2 (4.16%)	2 (3.84%)	
Functional capacity (METS)			
4—7	6 (12.5%)	10 (19.2%)	0.360
>7	41 (85.4%)	41 (78.8%)	
Stroke	0	1 (1.92%)	0.335
Stent thrombosis	0	0	-
In stent restenosis	0	0	-
CABG after Re-angiography	0	0	-

P Value from chi square test; Non-DM: Non-Diabetes; DM: Diabetes; NSTEMI: Non-ST Elevated Myocardial Infarction; STEMI: ST segment Elevated Myocardial Infarction; NYHA: New York Heart Association; METS: Metabolicequivalents

Figure-Comparative MACCE in both groups after 6 months of PCI in CCS

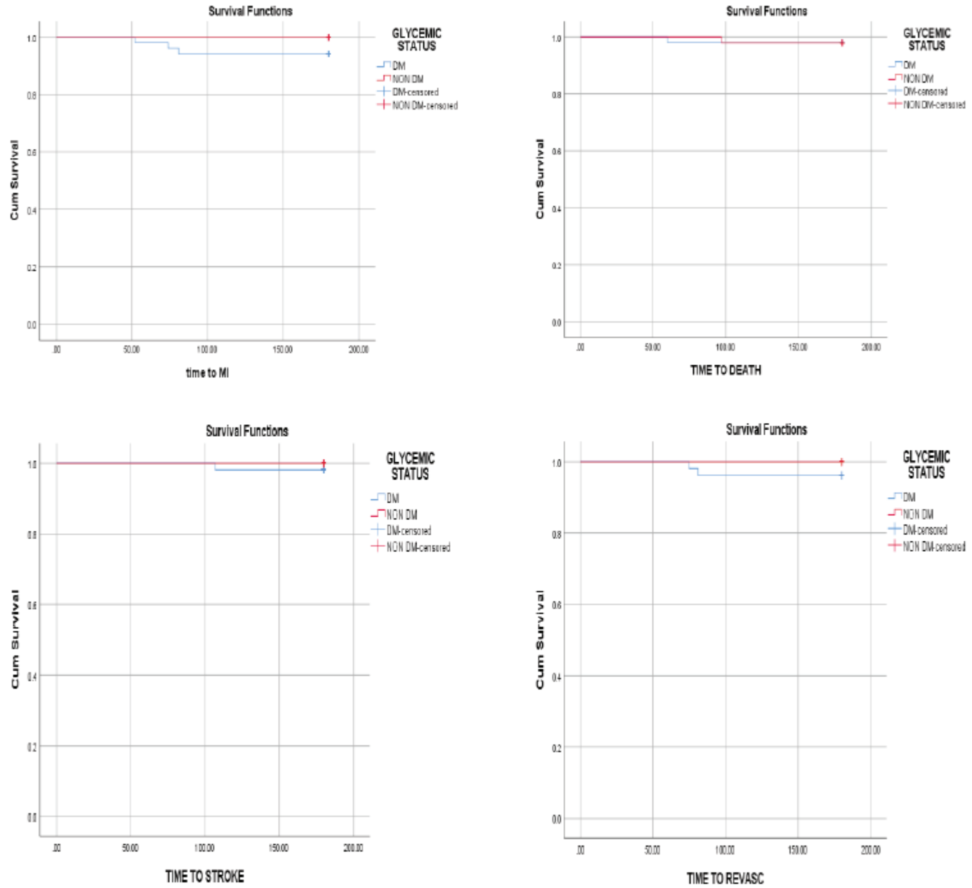


Figure-2: Kaplan Meier survival curves showing no significant difference noted in between DM and Non-DM patients having CCS.

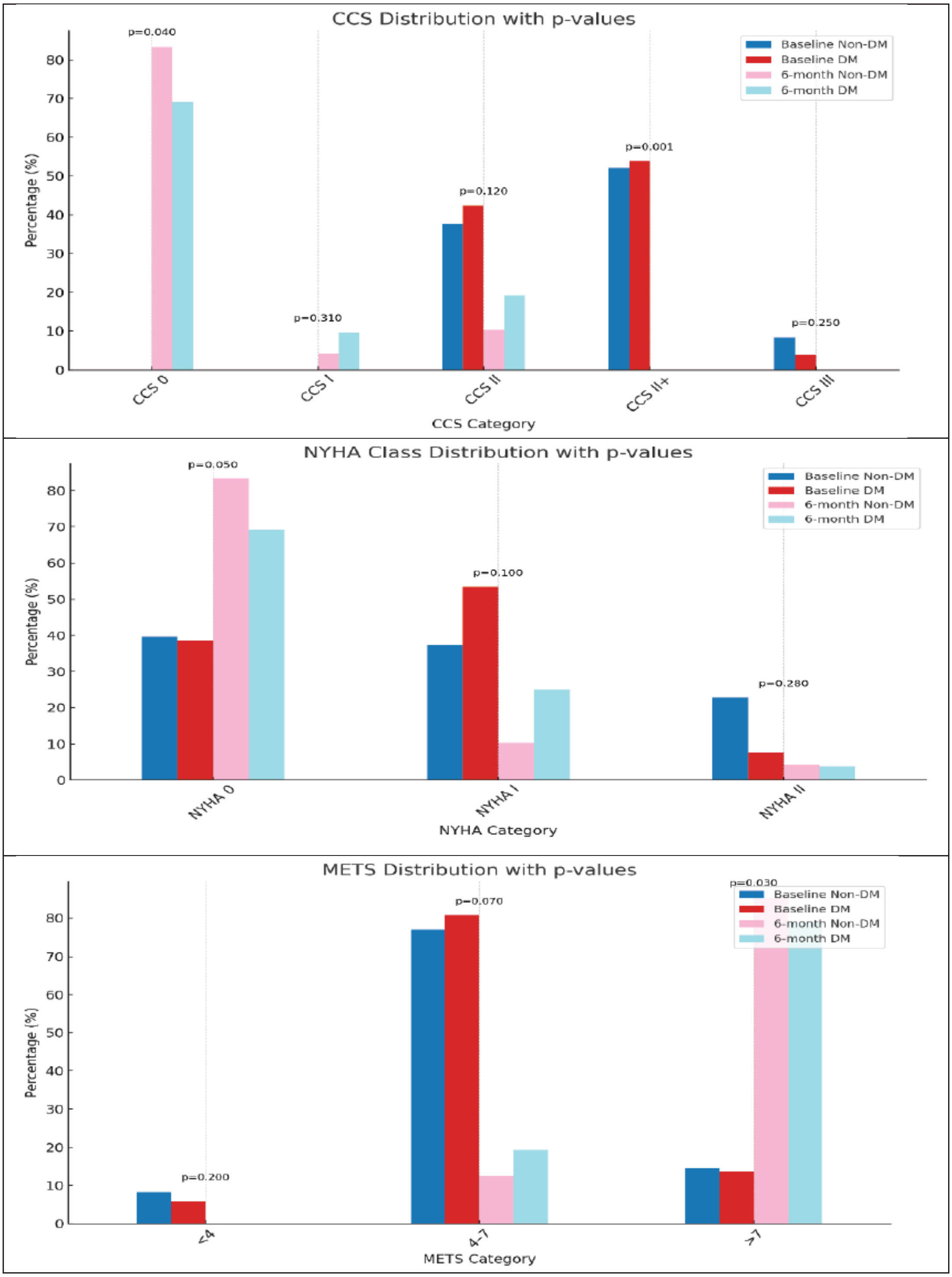


Figure-3: Distribution of CCS, NYHA and METS at baseline and 6 months post PCI based on DM status

Clinical outcome of multivessel PCI was assessed by CCS class, NYHA class and functional capacity by METS. PCI significantly improved angina symptoms, functional class, and exercise capacity in both DM and Non-DM patients. On-DM patients consistently show slightly better outcomes in all metrics at 6 months post-PCI. DM appears to be associated with somewhat reduced improvement, though benefits are still substantial.

Statistically significant Symptomatic and functional improvement were observed in both intra and inter group (diabetic and non-diabetic) comparison which signify the beneficial role of multivessel PCI on functional outcome, angina and dyspnea in both diabetic and non-diabetic patient group (Table-IV).

Table-IV: Change of clinical and functional of status from baseline to 6month post PCI

Variable	Improvement from baseline to 6-month post PCI	Non-DM		DM	
		Case	P Value	Case	P Value
CCS	Improved (from higher CLASS at baseline to lower CLASS at 6 months follow u	45	**<0.01**	48	**<0.01**
	Unchanged	1		3	
	Decline	0		0	
NYHA	Improved (from higher class at baseline to lower class at 6 months follow up)	24	**<0.01**	22	**0.01**
	Unchanged	21		24	
	Decline	2		5	
METS	Improved (from lower level at baseline to higher level at 6 months follow up)	36	**<0.01**	37	**<0.01**
	Unchanged	11		12	
	Decline	0		2	

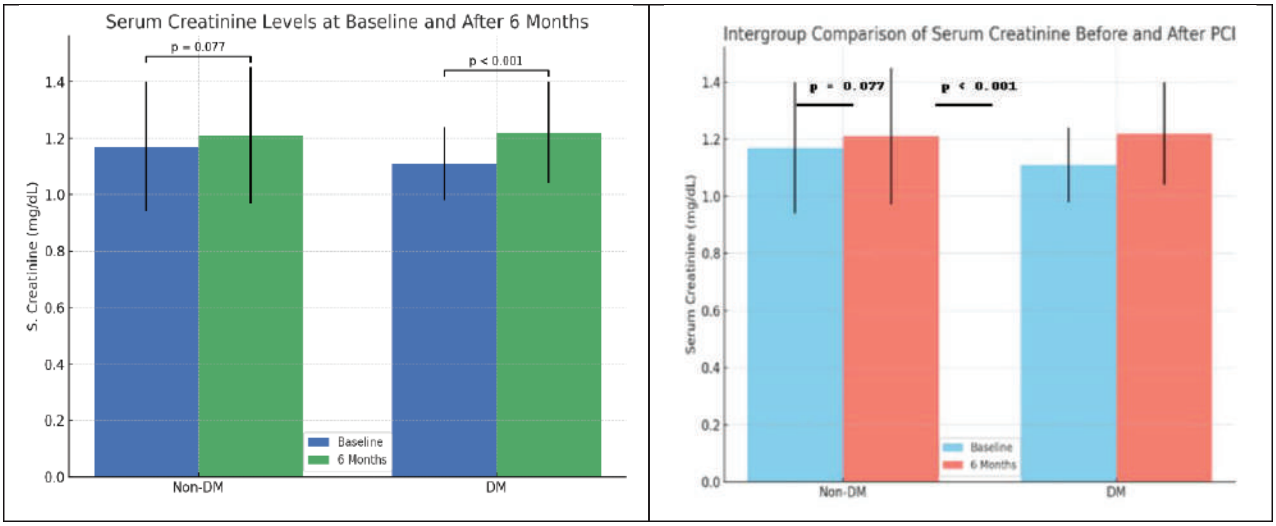
P value from Wilcoxon Signed Ranks Test based on improvement of status from baseline to follow up; CCS: Canadian cardiovascular Society; NYHA: New York Heart Association; METS: Metabolic equivalents; DM: Diabetes mellitus; Non-DM: Non-Diabetes mellitus

Table-V: Echocardiographic intragroup comparison of LV systolic function

Intragroup comparison	**Non-DM**			**DM**		
	At baseline	At 6 months	p values	At baseline	At 6months	p values
LVEF (%)	53.7 ± 7.1	54.4 ± 9.7	0.568[a]	54.2 ± 6.1	54.9 ± 9.1	0.494[a]
Intergroup Comparison	**Non-DM**	**DM**	**p**			
LVEF (%) at baseline	53.7±7.1	54.2±6.1	0.705			
LVEF (%) at 6months	54.4±9.7	54.9±9.1	0.789			

a-p calculated by paired t test; LVEF: Left ventricular Ejection fraction; DM: Diabetes mellitus; b-*p calculated by independent t test*

Table-V showing, intragroup comparison of left ventricular systolic function in term of LVEF in diabetic and non-diabetic group, before and 6-months after multivessel PCI showed insignificant changes. Both group patient showed stable left ventricular systolic function. Intergroup comparison showing stable LV systolic function in both diabetic and nondiabetic group. Statistically that was insignificant.



P value from paired t test; LVEF: Left ventricular Ejection fraction; S: serum

Figure-4: Intragroup and intergroup comparison of serum creatinine before and after PCI

Renal function was assessed with serum creatinine before and after PCI. Intragroup comparison showed there was significant rise of serum creatinine in diabetic group after 6months of PCI (Figure-4).

Discussion

A worldwide pandemic, diabetes is becoming more common in both developed and developing nations.[11] Over 95% of instances of diabetes globally are type II. Poorer clinical outcomes after percutaneous coronary intervention (PCI) are known to be predicted by diabetes.[12,13] According to estimates, the prevalence of diabetes was 9.3% worldwide in 2019 and 14.2% in Bangladesh in 2021.[1] The study's objectives were to compare the outcomes of diabetes and non-diabetic groups, assess the incidence of MACE and assess the clinical and functional outcomes of multivessel PCI in chronic coronary syndrome. Compared to early-generation DESs and bare metal stents, modern DESs provided superior clinical safety.[14] The primary cause of the early start of coronary artery disease in diabetic individuals is dyslipidemia and increased atherosclerosis, which are caused by diabetes mellitus's detrimental effects on endothelial function.[15-17] Diabetes increases the risk of coronary disease by two to four times, especially in women. It is a powerful independent risk factor for coronary disease.[16]

In this study, patients underwent multivessel percutaneous coronary intervention in the background of chronic coronary were predominantly male (84% male; 16% female) with double vessel disease being the common angiographic pattern. DM patients are more at risk of adverse clinical outcomes after percutaneous coronary intervention (PCI), either during the hospital stay or after 6-months. In hospital outcomes, diabetic patients were found to have more death due to cardiovascular cause (3.84%; non-DM 2.08%; P=0.6), access site hematoma >5cm (3.84%), Hb drop 5gm/dl (1.9%) and CIN (1.92%). However, periprocedural MI (2.08%) was found in non-diabetic groups during hospital stay. Usually patients with DM undergoing percutaneous coronary intervention (PCI) are more likely to develop stent restenosis and major adverse cardiac and cerebrovascular events (MACCE), and have worse clinical outcomes in both the short and long term than non-DM patients undergoing PCI.[18] These differences have been reported to be due to chronic hyperglycemia, which induces vascular endothelial injury, inflammatory reactions, reactive oxygen species, or advanced glycation end products, leading to accelerated cell proliferation or other pathological conditions.[19] After 6-months of PCI, both diabetic and non-diabetic patients showed similar lower incidence of major adverse cardiac events. Good glycemic control, less comorbidities, proper adherence, good compliance, earlier, 6-months outcome, small sample size, 3rd generation drug eluting stents, efficient experienced operators, stents and optimal medical therapy may explain the favorable outcomes of both groups of patients.

The advantages of percutaneous coronary intervention (PCI) in chronic coronary syndrome depend on how it impacts angina, physical activity, mental well-being and quality of life. PCI reduces angina and the requirement for anti-anginal medicines, boosts exercise capacity and improves quality of life.[20] When stable angina has significantly reduced quality of liefe (QOL) prior to the procedure, these advantages are stronger. This study found similar functional outcomes both in diabetic and non-diabetic groups.[21] Both groups achieved statistically significant good functional recovery in terms of METs, less occurrence of dyspnea in NYHA class and angina free life in CCS class.[22]

Properly selected and prepared patients for elective PCI with experienced operators may result in low incidence of LV systolic dysfunction and renal impairment.[23] The outcome of multivessel PCI also depends on the type of chronic coronary syndrome.[24-27] Patients of stable ischemic heart disease with previous history of myocardial infarction showed low LV systolic function at baseline.[28-30] After multivessel PCI, comparatively less favorable outcomes in terms of LV systolic function compared to patients without previous MI irrespective of DM status. In conclusion, the study found that both diabetic and non-diabetic groups showed stable renal function before and after 6-months of multivessel PCI in chronic coronary syndrome.

Conclusion

This study shown that the current generation of DES is linked with similar favourable in-hospital and mid-term (6-months) results following multivessel PCI in patient with chronic coronary syndrome both with and without diabetes. After 6-months of multivessel PCI, Patients with chronic coronary syndrome exhibited no statistically significant differences in MACE between DM and non-DM patients. But in DM with chronic coronary syndrome, medically treated angina was more frequent. Both group of patients showed significant clinical (angina, dyspnea) and functional improvement (METs) following multivessel PCI in chronic coronary syndrome settings. However, the clinical, angiographic, functional significance of coronary lesion, complete revascularization, adequate coronary lesion preparation and unique patient profile must be considered when deciding whether to proceed with a coronary intervention. The development of DES has significantly improved the outcomes of both diabetic and non-diabetic patients undergoing multivessel PCI in the background of chronic coronary syndrome.

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