DOI: https://doi.org/10.3329/cardio.v15i1.61904

Original Article

Comparison of Long-term Outcome between Diabetic and Non-Diabetic Patients with Ischemic Heart Disease following Percutaneous Coronary Intervention: A Prospective Study

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Key Words : *Diabetes mellitus, Percutaneous coronary intervention, Ischemic heart disease*

Abstract:

Background: *Diabetes Mellitus (DM) is an established independent predictor of adverse prognosis in patients undergoing percutaneous coronary intervention (PCI) even with improvements in diabetes treatment and interventional techniques. The aim of this study was to compare long term post PCI outcome between diabetic and non-diabetic patients with ischemic heart disease (IHD).*

Method: *The data was derived from a prospective observational study to evaluate the outcome after PCI in DM patients for 2 years. A total of 305 patients with IHD & DM were randomly selected and enrolled who underwent PCI from 2010 to 2013 in an urban cardiac hospital of Bangladesh. The study population were divided into two groups with group 1 consisting of patients with DM (n=108) and group 2 of patients without DM (n=197). After the PCI, all patients were followed up for 2 years. The incidences of bleeding, stent thrombosis, myocardial infarction (MI), stroke and repeat revascularization were compared.*

Results: *Diabetic patients had significant adverse outcomes having MI, stroke & MACCE respectively following 1 year (p= 0.018, 0.036 & 0.017) and MI following 2 years (p= 0.013) compared to non-diabetic patients. However, in multivariate analysis, diabetes mellitus was not found to be an independent predictor for 1-year & 2-year adverse events following PCI [OR 1.016 (0.317-3.259) & p 0.979, after 1 year and 1.554 (0.087 – 27.902) & p 0.765, after 2 years].*

Conclusions: *The outcome of PCI after 1 year and 2 years among diabetic and non-diabetic subjects with IHD differed significantly in respect of MI, stroke & MACCE. But this study failed to identify diabetes mellitus as an independent risk factor for 1-year and 2-year adverse outcomes.*

(Cardiovasc j 2022; 15(1): 5-12)

Introduction:

Diabetic patients have a higher prevalence of coronary artery disease (CAD) compared to the general population. Diabetes mellitus (DM) manifests as diffuse lesions and severe atherosclerosis,[1] severe symptoms often developing earlier in life combined with a poorer prognosis than those without diabetes.[2,3] About 25% of all PCI comprises of diabetic population.[4,5] Studies have shown DM to be associated with an increased risk of adverse clinical outcomes after PCI e.g. increased risk of de-novo lesion and increased re-stenosis rate.[6-8] Even with advancements in medical treatment and revascularization strategies, studies consistently show worse outcomes in terms of cardiovascular events and death, along with poor angiographic results post PCI in the diabetic group.[9-16] The prevalence of diabetes in Bangladesh is 8.1% and over 8 million adults have documented DM.[17] Data regarding the effect of DM on PCI in Bangladeshi population is limited. This study is aimed to compare the long-term outcome of PCI between diabetic and non-diabetic population.

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Methods:

Study Population:

The data was derived from a prospective observational study to evaluate the outcome after PCI in DM patients for 2 years. A total of 305 patients with IHD and DM were randomly selected and enrolled who underwent PCI from 2010 to 2013 in an urban cardiac hospital of Bangladesh. Type-2 DM was diagnosed on the basis of fasting plasma glucose ≥126 mg/dl (7.0 mmol/L), and or two-hour plasma glucose ≥200 mg/dl (11.1 mmol/L) during an oral glucose tolerance test (OGTT) and or HbA1c ≥6.5%.[18] Patients receiving treatment with oral hypoglycemic agents and or insulin, and those with a documented history of diabetes were also considered diabetic. Patients with type-1 diabetes, primary PCI for acute myocardial infarction, severe renal failure (eGFR <30 ml/L), & those having contraindication for dual antiplatelet therapy were excluded from the study.

Data collection

Data were collected on patient's demography (age, sex), risk factors for cardiovascular diseases (CVD) such as hypertension, dyslipidemia, family history of IHD & smoking. Clinical diagnosis was recorded. All baseline investigations were done including Electrocardiogram (ECG) & echocardiography following hospital admission. For each study subject, angiographic severity was assessed by number of vessel involvement & Gensini score. Following PCI, target vessel, stent types, number of stent per lesion, any failure to stent deployment were noted. After PCI, patients were discharged on the 3rd day depending on their clinical stability. Following discharge, they were followed up for 2 years by telephone or out-patient basis. Long term outcome such as major & minor bleeding, stent thrombosis, MI, stroke, repeat revascularization (e.g. PCI/ CABG), cardiac death and MACCEs (Major adverse cardiac and cerebrovascular event) were noted.

Patient groups

The study population were divided into two groups with group 1 consisting of patients with DM (n=108) and group 2 of patients without DM (n=197). Long term outcomes were compared between these two groups.

Study ethics

The study protocol was reviewed and approved by ethical review committee. Informed written consent was obtained from each patient.

Statistical analysis

All data were analyzed with SPSS statistical software version 16.0 (Chicago, Illinois, USA). Continuous variables (age, blood pressure data, and heart rate) were expressed as mean ± standard deviation. The comparison of continuous variables between two groups was performed using the t-test. Categorical variables were expressed as number (n) with regard to percentage (%). The comparison of categorical variables between group 1 & 2 was performed using the chi-square test. $p < 0.05$ was considered statistically significant. Multivariate logistic regression analysis was done to find out independent effect of diabetes for long term outcome.

Results:

Baseline profile:

In Table I, clinical characteristics of patients with and without DM are shown. Patients with DM were older than the non-diabetic group. Female were higher in frequency in diabetic group. Diabetic group had lower HDL level which is statistically significant from those without DM. Other parameters of lipid profile were also higher along with lower ejection fraction in DM than the non-diabetic population.

Angiographic & Procedural Findings:

Table II shows angiographic and procedural findings. Diabetic group had more extensive coronary artery disease as evidenced by higher Gensini score. The target vessels LCX & RCA were significantly more in frequency in DM patients. The DES were used more in diabetic group than the non-diabetic group.

Outcome:

Diabetic patients had significant adverse outcomes having MI, stroke & MACCE respectively following 1 year (p 0.018, 0.036 & 0.017) and MI following 2 years (p 0.013) compared to non-diabetic patients (Table 3, 4). However, in multivariate analysis, diabetes mellitus was not found to be an independent predictor for 1-year & 2-year adverse events following PCI [OR 1.016 (0.317-3.259) & p 0.979, after 1 year and 1.554 (0.087 – 27.902) & p 0.765, after 2 years] (Table V, VI).

The comparison of continuous variables between two groups was performed using the t-test. Categorical variables were expressed as number (n) with regard to percentage (%).The comparison of categorical variables between two groups was performed using the chi-square test. $p < 0.05$ was considered statistically significant.

Table-I

Demographic & Baseline characteristics of study population.

Number (%)	Group I (n=108)	Group II (n=197)	p value
Age	52.3± 8.6	51.1 ± 9.9	0.290
Male	86 (79.6%)	175 (88.8%)	0.135
Female	22 (20.4%)	22 (11.2%)	0.079
HTN	71 (65.7%)	112 (56.9%)	0.130
Smoking	55 (50.9%)	111 (56.3%)	0.363
Hyperlipidemia	62 (57.4%)	113 (57.4%)	0.994
Family History of CVD	25 (23.1%)	44.0 (22.3%)	0.871
Chronic Stable Angina	32 (29.6%)	49 (24.9%)	0.368
Unstable Angina	13 (12%)	31 (15.7%)	0.379
Acute MI	16 (14.8%)	36 (18.3%)	0.442
Old MI	47 (43.5%)	81 (41.1%)	0.684
Ejection fraction	53.5±9.2%	55.2±9.2%	0.124
Hb	12.4±1.7 gm/dl	11.5±3.5 gm/dl	0.013[s]
RBS	10.1±3.6 mmol/L	6±1.4 mmol/L	<0.001[1]
Serum creatinine	1.1±0.2 mg/dl	1.1±0.5 mg/dl	1.00
SGPT	37.1±36.2	37.6±22.4	0.882
Total cholesterol	161.8±60.1 mg/dl	152.2±60.3 mg/dl	0.184
HDL	35.8±8.3 mg/dl	38±9.2 mg/dl	0.019[s]
LDL	93.7±41.9 mg/dl	91.8±31.5 mg/dl	0.655
TG	181.2±86.8 mg/dl	163.3±82.5 mg/dl	0.076

Table-II

Angiographic & Procedural findings of study population.

Number (%)	Group I (n=108)	Group II (n=197)	p value
Severity of CAD			
Single vessel	93 (86.1%)	167 (84.8%)	0.752
Double vessel	14 (13%)	30 (15.2%)	0.590
Triple vessel	1 (0.9%)	0 (0%)	0.665
Gensini Score	21.1 ± 17.4	18.6 ± 15.3	0.195
Moderate to severe(e”36 points)	89 (82.4%)	175 (88.8%)	0.116
Normal to mild(<36 points)	19 (17.6%)	22.0 (11.2%)	
Types of Stents			
BMS	45 (41.7%)	110 (55.8%)	0.018[s]
DES	60 (55.6%)	71 (36%)	0.001[s]
BMS+DES	03 (43.5%)	16 (8.1%)	0.065
Target Vessel			
LAD	29 (26.9%)	98 (49.74%)	<0.001[1]
LCX	56 (51.9%)	79 (40.1%)	0.048[1]
RCA	34 (31.5%)	40 (20.3%)	0.029[1]
LM	1 (0.9%)	2 (1%)	0.939
OM	1 (0.9%)	1 (0.5%)	0.665
RI	1 (0.9%)	1 (0.5%)	0.665
Number of Stent per Vessel			
Single	85 (78.7%)	144 (73.1%)	0.601
Double	18 (16.67%)	43 (21.8%)	
Triple or more	04 (3.7%)	03 (1.5%)	

Table-III

Outcome after 1 year.

Number (%)	Group I (n=108)	Group II (n=197)	p value
Major Bleedings	2 (1.9%)	4 (2%)	0.914
Minor Bleedings	2 (1.9%)	1 (0.5%)	0.255
Stent Thrombosis	2 (1.9%)	2 (1%)	0.539
MI	6 (5.6%)	2 (1%)	0.018[s]
Stroke	4 (3.7%)	1 (0.5%)	0.036[s]
Repeat Revascularization	1 (0.9%)	4 (2%)	0.468
MACCE	12 (11.1%)	8 (4.1%)	0.017[1]
Death	1 (0.9%)	2 (1%)	0.939

Table IV

Outcome after 2 years.

Number (%)	Group I (n=108)	Group II (n=197)	p value
Major Bleedings	1 (0.9%)	3 (1.5%)	0.661
Minor Bleedings	1 (0.9%)	1 (0.5%)	0.665
Stent Thrombosis	1 (0.9%)	1 (0.5%)	0.665
MI	5 (4.6%)	1 (0.5%)	0.013[s]
Stroke	1 (0.9%)	2 (1%)	0.940
Repeat Revascularization	3 (2.78%)	6 (2%)	0.895
MACCE	9 (8.3%)	9 (4.6%)	0.182
Death	0 (0%)	0 (0%)	-

Table-V

Multivariate binary logistic regression analysis for determinants of adverse in-outcome after 1 year . hb, dm,hdl, types of stent, vessels involved.

Variables of interest	Multivariate	
	OR (95% CI)	P value
Age>50 years	0.413 (0.122-1.399)	0.155 [ns]
Sex	2.469 (0.662-9.21)	0.179 [ns]
Smoking	0.001 (0.0001-0.21)	1.00 [ns]
Hypertension	0.691(0.176-2.709)	0.596 [ns]
Dyslipidemia	0.733 (0.207-2.587)	0.629 [ns]
Diabetes mellitus	1.016 (0.317-3.259)	0.979 [ns]
Decreased EF	2.626 (0.561-12.285)	0.220 [ns]
Gensini Score	1.769 (0.211-14.858)	0.6 [ns]
Triple vessel involvement	1.194 (0.244-5.849)	0.827 [ns]

Table-VI

Multivariate binary logistic regression analysis for determinants of adverse outcome after 2 years.

Variables of interest	Multivariate	
	OR (95% CI)	P value
Age>50 years	0.421 (0.020-9.01)	0.580 ns
Sex	0.001 (0.0001-0.31)	0.997 ns
Smoking	0.001 (0.0001– 0.11)	0.778 ns
Hypertension	11.066(0.343–3.57)	0.175 ns
Dyslipidemia	0.733 (0.207 – 2.587)	0.629 ns
Diabetes mellitus	1.554 (0.087 – 27.902)	0.765 ns
Decreased EF	3.79 (0.0001-35.21)	0.996 ns
Gensini Score	1.23 (0.0001-25.858)	0.997 ns
Triple vessel involvement	0.316 (0.028-3.565)	0.351 ns

Discussion:

In this study, we compared clinical & angiographic characteristics, procedural aspects of PCI along with one year & two years outcome of diabetic and non-diabetic patients.

The mean age was 52.3± 8.6 vs. 51.1 ± 9.9 years in diabetic and non-diabetic population in our study with most patients (83.3% vs. 75.1%) were 45 years or more. A study performed in Bangladesh showed mean ages between the diabetic and non-diabetic groups, being 58.6±7.5 vs. 59.9±6.7 years.[19] The mean age of patients in another recent study showed to be 55.8 ± 9 years with 72.12% of patients between the ages of 40 to 60 years.[20] In contrast to some other studies the mean age of our study population was lower.[21,22]

Majority of the patients were male (79.6% vs. 88.8%) respectively indicating a male to female preponderance. This is consistent with other studies done in Bangladesh and south-east regions.[19, 23, 24.]

The most prevalent risk factor among the study population was HTN (65.7% vs. 56.9%) indicating HTN as an important risk factor in both the groups for development of CAD. Similar data has been found in several studies among diabetic and non-diabetic population.[19, 25, 26] Hyperlipidemia was the second most prevalent risk factor with significantly low HDL in DM group, followed by smoking and family history of CAD. These findings are consistent with a meta-analysis done in 2016.[27]

Most of the study population belonged to old MI (43.5% vs. 41.1%) and chronic stable angina (29.6% vs. 24.9%) followed by ACS (Acute coronary syndrome) group (26.8% vs. 33.3%). Left ventricular ejection fraction was 53.5±9.2 vs. 55.2±9.2 between diabetic and non-diabetic group. In a study in Bangladesh showed the baseline LVEF of diabetic patients was 53.9±3.8% whereas in non-diabetics was 55.5±4.7%, which is consistent with the present study.[28]

Regarding the angiographic profile, most of the cases had single vessel disease (86.15% vs. 84.8%). Gensini score was higher in diabetic group (21.1 ± 17.4 vs. 18.6 ± 15.3), although no significant difference between the two groups. In a study with diabetic patients, the mean Gensini score was 22.51 ± 10.37, which is consistent with our findings.[20] In most cases it was single stent in the target vessel (78.7% vs. 73.1%). Diabetic group had more stent deployment in LCX (51.1%) & RCA (31.5%) than the non-diabetic group (40.1% & 20.3%). Diabetic patients with CAD are reported to have dysfunctional endothelial cells, increased atherosclerotic burden and fragile lipid-rich plaques,[29,30] microcirculation disorder involving smaller vessels, and prothrombotic and proinflammatory states,[31, 32] which are related to progression of CAD. It is also confirmed that CAD in diabetic patients appears as diffuse atherosclerosis.[33]

Diabetic patients received DES more than the non-diabetic patients (55.6% vs. 36%). A study reported

that in diabetic patients treated with BMS, the target vessel failure rate was almost double that in non-diabetic patients (64.3% vs. 35.3%). In contrast, there was no influence of diabetes mellitus on target vessel failure rate in the DES group (6.3% vs. 9.4%).[34] In our case, in a developing country like Bangladesh it is often the financial restraints that limit the use of DES even if it is indicated.

After PCI, both the group were followed up for 2 years. Outcome after 1 year showed that MI (5.6% vs. 1%), stroke (3.7% vs. 0.5%) and MACCE (11.1% vs. 4.1%) was significantly increased in diabetic population (p 0.18, 0.036 & 0.017 respectively. After 2 years of PCI, MI (4.6% vs. 0.5%) was significantly increased in diabetic group (p 0.013). In a nationwide study in South Korea among 81,115 study subjects (mean follow-up 2 years) revealed that the incidence of all-cause death was significantly higher in patients with DM ($p<0.001$) than in those without.[35] In addition, the occurrence of in-hospital mortality ($p<0.001$) and composite of death and recurrent coronary revascularization ($p<0.001$) was higher in patients with DM. Even in the PCI era, studies show that patients with DM had a higher incidence of long-term adverse clinical outcomes.[36, 37]

In Multivariate analysis, diabetes mellitus was not found to be an independent predictor for 1-year & 2-year adverse events following PCI. Kedhi et al. showed that long term adverse outcome within one year following PCI with DES were more frequent in diabetic versus nondiabetic patients only in the presence of complex lesions, without differences when simple lesions were treated. In another study, diabetic patients were at high risk for MACE and repeat target-lesion revascularization but not for cardiac death or MI irrespective of disease complexity.[39] Differences in sample size, follow-up period, criteria of patient selection, regional variations and glycemic control may result in the differences among studies.

Study limitations:

The major limitation of the study is that this is a single center study with a relatively small number of patients; a multicenter study with larger study cohort may be required to give a better estimate of study parameters. HbA_1C was not done due to unavailability.

Conclusions:

The outcome of PCI among diabetic and non-diabetic subjects after 1 year and 2 year differed significantly in respect of MI, stroke & MACCE. But this study demonstrated that diabetes mellitus is not an independent risk factor for 1-year and 2-year adverse outcomes.

Conflict of Interest - None.

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