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Title: **Comparison of In-Hospital Mortality and Complications of Primary Percutaneous Coronary Intervention in Diabetics and Non-diabetic Patients at a Large Tertiary Care Hospital**

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Comparison of In-Hospital Mortality and Complications of Primary Percutaneous Coronary Intervention in Diabetics and Non-diabetic Patients at a Large Tertiary Care Hospital

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ABSTRACT

Background. Ischemic heart disease (IHD) is the leading cause of death in Pakistan. The current study aimed to compare in-hospital mortality and the complications of primary percutaneous coronary intervention (PCI) in diabetic and non-diabetic patients with a diagnosis of ST-elevation myocardial infarction (STEMI).

Methods. This cross-sectional study was conducted at a tertiary care hospital and involved 560 patients. The patients were categorized into diabetic and non-diabetic groups. Demographic characteristics, risk factors, coronary vessel details, and post-PCI complications were compared between the groups. The sample comprised 560 patients.

Results. The mean age of the patients was 52.17±11.5. Male patients comprised 88.6% of the sample. The study found that premature coronary disease and hypertension were more prominent among diabetics, while the percentage of smokers was higher in the non-diabetic group. No statistical significance was noted in the severity of stenosis or culprit vessels between groups. The incidence of post-PCI complications was insignificant among both groups. TIMI 0 and 3 were more prevalent in the non-diabetic group, while TIMI 1 and 2 were common among diabetics.

Conclusion. In this single-center study, no significant difference was noted between in-hospital mortality and other post-PCI complications between both groups. Further multicenter, prospective, and larger sample-size studies are needed for extensive results.

Keywords: complication, diabetes, mortality, percutaneous coronary intervention (PCI), ST-elevation myocardial infarction (STEMI)

Highlights

- Outcome of primary PCI is related with co-morbidities especially disease like diabetes affecting vasculature and leading to advanced level of atherosclerosis.
- Smoking, Hypertension and family history of ischemic heart disease was found significantly associated with studied groups.
- TIMI flow was not significantly different in both the groups. Multi-center studies targeting larger population of different ethnicity are recommended.

GRAPHICAL ABSTRACT

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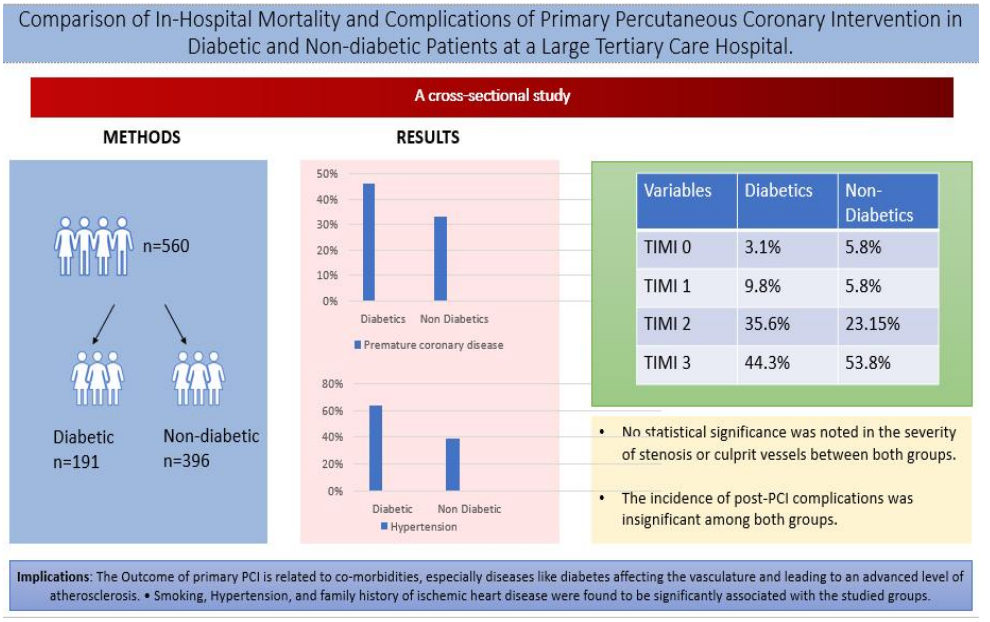

1. INTRODUCTION

There is a huge burden of cardiovascular diseases (CVDs), especially in developing countries such as Pakistan. The standardized incidence of CVDs in Pakistan is 918.18/100,000, while it is 684.33/100,000 all over the globe [1]. In Punjab (a province in Pakistan), 17.5% of people have CVDs, which is associated with gender, sedentary lifestyle, and family history [2]. As far as developed countries are concerned, approximately 40% of deaths in the population greater than 65 years of age in the United States of America are due to cardiovascular etiologies [3]. CVDs-related mortality is one of the major problems in the world. PCI has been widely used worldwide to resolve this long-standing issue.

For the percutaneous coronary intervention (PCI) to be the most beneficial for patients with an ST-segment elevation myocardial infarction (STEMI), it is recommended to perform PCI within 90 minutes of the patient's arrival in the hospital, termed door-to-balloon (D2B) time. An increase in D2B time can increase the risk of complications [4]. Time is not the only constraint while determining the risk of PCI complications. There are other risk factors that lead to greater risk of complications and death. Diabetes Mellitus (DM) is one of those important risk factors that increase the risk of death from cardiovascular events 2 to 6 times [5].

About 44% of deaths by DM type 1 and 52% of deaths by DM type 2 are due to CVDs, which implies a strong link between CVDs and DM [6]. The mortality after STEMI and PCI complications and the need for revascularization is higher in the patients of DM [7]. There is very limited literature available that provides evidence on mortality rates among diabetic and non-diabetic patients after the PCI procedures.

The current study aims to compare in-hospital mortality and complication rates in diabetic and non-diabetic patients after undergoing PCI. This would bridge the much-needed gap in the comparison of PCI complications and mortality in diabetic vs. non-diabetic patients in Southeast Asia.

2. MATERIAL AND METHOD

This study was a prospective cross-sectional survey made with patients and based on their follow up. The study was conducted at a tertiary care hospital. A total of 560 patients participated in it. All of them had a primary diagnosis of MI and a history of undergoing PCI. The patients were followed up in the hospital for 48 hours. The study was conducted with the approval of the Institutional Review Board of the Punjab Institute of Cardiology (PIC). Informed consent was obtained from the patients before the collection of their data.

The inclusion criteria of this study comprised a diagnosis of STEMI, symptoms that persist for less than 24 hours, ST-segment elevation that persists from 24 to 48 hours of the onset of symptoms, and the eligibility for PCI. Whereas, the cases of thrombolytic use after the diagnosis of STEMI, left bundle branch block for more than 48 hours after the onset of symptoms, and the patients of CKD and left ventricular failure were excluded. Moreover, all patients were divided into two groups depending on their diabetes status. A detailed history pertaining to IHD risk factors (hypertension, dyslipidemia, family history, and smoking), as well as the previous history of MI, CABG, or PCI was taken. Demographic characteristics including age and gender, coronary vessel details, and post-PCI complications such as M I, heart failure, shock, stent thrombosis, bleeding, and death were noted. The data was entered into SPSS 24 and analyzed for details.

3. RESULTS

The mean age for 560 patients was 52.17±11.5. Of these, 496 (88.6%) were male patients and 64 (11.4%) were female patients. The mean D2B time was 94.56±103.9 minutes. A total of 374 (66.8%) patients had their D2B time within 90 minutes, while 186 (33.2%) patients were out of the 90-minute window. There were 16 (2.9%) dyslipidemia patients, 292 (52.1%) smokers, and 270 (48.2%) hypertensive patients. Moreover, 213 (38%) patients had a previous history of CAD, 2 (0.4%) had drug abuse history, 25 (4.5%) had a history of prior PCI, 1 (0.2%) had underwent CABG in the past, and 21 (2.8%) had a previous episode of MI.

In subgroup analysis, Group A (consisting of diabetic patients) included 191 patients, while Group B (consisting of non-diabetic patients) included 369 patients. The demographic characteristics of both groups, A and B, are shown below in Table 1.

Table 1. Descriptive Statistics of Demographic and Risk Factors

Variables	Group A (Diabetics) $n = 191$	Group B (Non-diabetics) $n = 396$	p-value
Age	53.34±10.2	51.57 ± 12.09	0.089
Male	156 (81.7%)	340 (92.1%)	0.001
Hypertension	123 (64.4%)	147 (39.8%)	0.001

Variables	Group A (Diabetics) *n* = 191	Group B (Non-diabetics) *n* = 396	*p*-value
Dyslipidemia	8 (4.2%)	8 (2.2%)	0.174
Smokers	73 (38.2%)	219 (59.3%)	0.001
Family History of Premature Coronary Disease	88 (46.1%)	125 (33.9 %)	0.005
Prior PCI	9 (4.7%)	16 (4.3%)	0.839
Drug Use	1 (0.5%)	1 (0.3%)	0.636
Prior CABG	1 (0.5%)	0 (0%)	0.165
Prior MI	6 (3.1)	15 (4.1%)	0.586

The comparison of significant stenosis (more than 80%) in all vessels including LMS, LAD, LCX, RCA, Ramus, LMS (non-culprit), LAD (non-culprit), LCX (non-culprit), RCA (non-culprit), and Ramus (non-culprit) was insignificant. The frequency of culprit vessels in both groups is shown in Table 2.

Table 2. Comparison of Significant Stenosis (>80%) among Both Groups

Culprit Vessel	Group A (Diabetics) *n* = 191	Group B (Non-diabetics) *n* = 396
LMS	4 (2.1%)	6 (1.6%)
LAD	128 (67%)	226 (62.1%)
LCX	49 (26.1%)	74 (20.1%)
RCA	79 (41.2%)	145 (29.3%)
Ramus	3 (1.6%)	8 (2.2%)

Overall, there was no statistical significance between the two groups regarding MI, cardiogenic shock, heart failure, stroke, death, stand thrombosis, bleeding events (within 72 hours), tamponade (and other vascular complications), and hematoma formation. These adverse events were found to be more common in the non-diabetic group than in the diabetic group, although the difference remained statistically insignificant.

Table 3. Comparison of Outcomes between Both Groups

Variables	Group A (Diabetics) *n* = 191	Group B (Non-diabetics) *n* = 396	*p*-value
MI	0 (0%)	2 (0.5%)	0.309
Cardiogenic Shock	4 (2.1%)	10 (2.7%)	0.149
Heart Failure	3 (1.6%)	4 (1.1%)	0.624
CVA/Stroke	0 (0%)	4 (1.1%)	0.149
Death	0 (0%)	0 (0%)	
Stent Thrombosis	1 (0.5%)	1 (0.5%)	0.636
Bleeding Events (within 72 hours)	0 (0%)	2 (0.5%)	0.309
Tamponade	0 (0%)	0 (0%)	

Variables	Group A (Diabetics) n = 191	Group B (Non-diabetics) n = 396	p-value
Hematoma	5 (2.6%)	8 (2.2%)	0.738

TIMI 0 and TIMI 3 incidences were slightly higher in the non-diabetic group than in the diabetic group; meanwhile, TIMI 1 and TIMI 2 incidences were higher in the diabetic group but the difference was not statistically significant. The p-values of TIMI 0, TIMI 1, TIMI 2, and TIMI 3 are 0.321, 0.340, 0.070, and 0.188, respectively.

Table 4. Comparison of TIMI Flow among Both the Groups

Variables	Group A (Diabetics) n=191	Group B (Non-diabetics) n=396	p-value
TIMI 0	16 (3.1%)	3 (5.8%)	0.321
TIMI 1	50 (9.8%)	3 (5.8%)	0.340
TIMI 2	181 (35.6%)	12 (23.1%)	0.070
TIMI 3	225 (44.3%)	28 (53.8%)	0.188

4. DISCUSSION

The results of the current study shed light on the differences in outcomes and complications among diabetic and non-diabetic patients with STEMI undergoing PCI. The study included 560 patients with a mean age of 52.17±11.5 years. Among them, 496 (88.6%) were male patients and 64 (11.4%) were female patients. Notably, the mean D2B time was 94.56±10.39 minutes, with 66.8% of patients meeting the recommended 90-minute window. Subgroup analysis revealed significant differences between Group A (diabetics) and Group B (non-diabetics). While both groups had similar mean ages, men were more predominant in Group B. Hypertension was more common in Group A, whereas smokers were more prevalent in Group B. These findings align with the existing evidence that diabetes and associated risk factors contribute to cardiovascular outcomes [8, 9].

The study compared significant stenosis (>80%) in various vessels, including LMS, LAD, LCX, RCA, and Ramus. Surprisingly, there was no statistically significant difference between the two groups. The frequency of culprit vessels showed similar patterns with no significant differences. This suggests that the severity of stenosis alone may not fully explain the observed outcomes.

The incidence of complications post PCI was rare. Overall, the study found MI, cardiogenic shock, and heart failure in a number of patients following PCI. In the previous literature, diabetic patients were found to have worse cardiovascular outcomes after the revascularization for MI than non-diabetic patients [10, 11]. Jeger et al. made similar claims regarding post PCI outcomes in diabetic patients, as compared to non-diabetics. They found that DM increases the risk of repeat revascularization and other post-PCI complications, such as cardiogenic shock, MI, and death [12].

The risk of stroke following PCI was found to be higher among the non-diabetic group. The said finding contradicts the findings of Milojevic et al. They claimed that the 3-year composite primary endpoint of death, MI, or stroke was significantly higher in diabetic as

compared with non-diabetic patients (20.0% vs. 12.9%) [13].

No death occurred in any subgroup during this study. Hence, it was not possible to find any difference in all-cause mortality among diabetics and non-diabetics following PCI in this study. In the study of Norhammar et al., a contradictory claim of increased long-term mortality in diabetic patients was made as compared to those without diabetes, highlighting the need for intensive secondary preventive measures [14].

The risk of bleeding events within 72 hours following the procedure was found to be slightly higher among the non-diabetics. This is in contradiction with the previous studies. According to an analysis by Chichareon et al., the rate of post-PCI ischemic events was higher in diabetic patients, while bleeding risk was comparable between the two groups [15]. The rates of hematoma formation were slightly higher among non-diabetics in the current study.

The TIMI flow grades provide insights into coronary blood flow. Interestingly, TIMI 0 (no perfusion) and TIMI 3 (complete perfusion) were found to be more common in the non-diabetic group. Meanwhile, TIMI 1 (penetration without perfusion) and TIMI 2 (partial perfusion) were prevalent in the diabetic group. These variations warrant further investigation to understand their clinical implications.

4.1. Limitations

Several limitations of the current study should be acknowledged including its retrospective nature, which introduces potential biases. Secondly, the patient cohort represents a single tertiary care institution in Pakistan, limiting generalizability. Moreover, the analysis did not include some relevant factors (angiographic parameters, procedural details). Future research should explore genetic predispositions, evolving risk factors, healthcare accessibility, awareness levels, and medication adherence to address diabetic status-based differences in STEMI outcomes. Multicenter studies with larger sample sizes can provide more robust insights.

4.2. Conclusion

In this single-center study, no significant relationship was noted among both the diabetic and non-diabetic groups regarding post-PCI complications and mortality. However, TIMI flow 0 and 3 were found to be more common in the non-diabetic group, while TIMI 1 and 2 were found to be prevalent in the diabetic group. This highlights the need for multicenter, prospective, and larger sample-size studies to develop targeted interventions for better patient care.

CONFLICT OF INTEREST

The authors of the manuscript have no financial or non-financial conflict of interest in the subject matter or materials discussed in this manuscript.

DATA AVALIABILITY STATEMENT

The data associated with this study will be provided by the corresponding author upon request.

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No funding has been received for this research.

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