Original Article
DOI: https://doi.org/10.70749/ijbr.v2i02.223

INDUS JOURNAL OF BIOSCIENCES RESEARCH
https://induspublisher.com/IJBR
ISSN: 2960-2793/ 2960-2807

Primary PCI in Diabetic Patients: Clinical Outcomes and Challenges

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ARTICLE INFO

Keywords

Percutaneous Coronary Intervention, Diabetes, MACE, TIMI Flow, Pakistan.

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Declaration

Author's Contributions: All authors contributed to the study and approved the final manuscript.
Conflict of Interest: The authors declare no conflict of interest.
Funding: No funding received.

Article History

Received: 09-10-2024
Revised: 06-11-2024
Accepted: 16-11-2024

ABSTRACT

Objective: To evaluate clinical outcomes and procedural challenges in diabetic patients undergoing primary Percutaneous Coronary Intervention (PCI) for ST-segment elevation myocardial infarction (STEMI) at the Department of Cardiology, Hayatabad Medical Complex, Peshawar. **Methodology:** Conducted as an observational, single-center study from July 2022 to June 2023, 300 patients were enrolled, with equal numbers of diabetic and non-diabetic patients. Baseline demographics, clinical outcomes, and procedural success were analysed. Statistical tests included chi-square for categorical variables (major adverse cardiac events (MACE), stent thrombosis, restenosis, TIMI flow) and t-tests for age comparison. A significance level of $p < 0.05$ was set. **Results:** Diabetic patients had a mean age of 60.9 years compared to 59.9 years in non-diabetic patients ($t = -0.41$, $p = 0.685$). The distribution of MACE was similar between groups ($\chi^2 = 1.31$, $p = 0.727$), as were rates of stent thrombosis ($\chi^2 = 0.00$, $p = 1.000$) and restenosis ($\chi^2 = 0.85$, $p = 0.355$). TIMI flow rates also showed no significant difference by diabetic status ($\chi^2 = 3.32$, $p = 0.190$), indicating comparable outcomes between diabetic and non-diabetic patients. **Conclusion:** The study found no significant differences in primary PCI outcomes between diabetic and non-diabetic patients, suggesting that standardized procedural protocols may mitigate the heightened risk profile of diabetic patients. Multicenter studies with advanced diagnostic tools are recommended to enhance generalizability and optimize outcomes further in this population.

INTRODUCTION

Primary PCI has been the preferred revascularization strategy for patients with acute STEMI due to its potential to restore coronary blood flow quickly and improve clinical outcomes. However, diabetic patients undergoing PCI often experience distinct challenges and adverse outcomes due to the complex interplay between diabetes and cardiovascular health.[1] This study, based in the Department of Cardiology at Hayatabad Medical Complex in Peshawar, aims to explore the unique clinical outcomes and obstacles faced by diabetic patients undergoing PCI.

Recent studies underscore that diabetic patients treated with PCI frequently have more complex lesions and greater comorbidities, contributing to increased risks of MACE compared to non-diabetic patients.[2] Additionally, these patients are more likely to require repeat revascularization, as diabetes can accelerate vascular disease progression.[3] Such findings highlight the need for specialized care and consideration of tailored interventional strategies.

Diabetic patients face challenges not only due to cardiovascular risk but also due to elevated

levels of systemic inflammation and endothelial dysfunction, which exacerbate the risks associated with PCI.[4] Data from recent trials indicate that while PCI can reduce mortality in diabetic patients, it does not entirely mitigate the heightened risk of cardiovascular events and complications such as restenosis.[5]

A study conducted in Pakistan revealed that diabetic patients undergoing PCI in local settings experience procedural success but continue to face significant adverse events at follow-up, indicating the need for more aggressive management and monitoring post-PCI.[6] These findings are critical as they suggest geographical variations in outcomes, possibly influenced by socio-economic and healthcare access factors, and emphasize the importance of contextual studies in understanding PCI efficacy in different populations.

The interaction between diabetes and factors such as chronic kidney disease (CKD) and anemia further complicates PCI outcomes, with diabetic patients often presenting with multiple comorbidities that worsen long-term survival rates.[7] Given that such comorbidities can potentiate the adverse effects of diabetes on vascular integrity, managing these factors in conjunction with diabetes is crucial for optimizing patient outcomes post-PCI.

Regional studies have also shown that diabetes significantly impacts PCI outcomes across different populations, with notable differences observed in adverse event rates and PCI practices worldwide.[8] In particular, diabetic patients in Asia and the Middle East show different patterns of drug adherence and access site selection, affecting overall procedural efficacy and outcomes.

A meta-analysis comparing PCI outcomes between diabetic and non-diabetic patients confirmed that diabetic patients face a higher rate of MACE and mortality, irrespective of advancements in drug-eluting stents.[9] This trend emphasizes that while technological advancements contribute to improved outcomes, diabetic patients remain at a disadvantage due to inherent metabolic challenges.

Furthermore, blood routine test parameters, such as elevated white blood cell counts and D-dimer levels, have been found to be independent predictors of adverse outcomes in diabetic patients undergoing PCI, indicating that biomarkers may play a role in early identification and management of high-risk patients.[10]

Given these findings, the rationale for this study is clear: there is a pressing need to optimize PCI approaches and post-procedural care specifically for diabetic patients to improve their outcomes in the short and long term. This study aims to contribute to this area by evaluating clinical outcomes and identifying challenges specific to diabetic patients treated with primary PCI at the Hayatabad Medical Complex in Peshawar.

This study aims to evaluate the clinical outcomes and unique challenges faced by diabetic patients undergoing primary PCI, providing insights to improve tailored intervention strategies for this high-risk group.

MATERIALS AND METHODS

Study Design and Setting

This is a single-center, observational cohort study undertaken in the Department of Cardiology, Hayatabad Medical Complex in Peshawar, Pakistan. The 12-month trial, which ran from July 2022 to June 2023, looked at diabetic patients receiving Primary PCI for acute myocardial infarction to examine clinical outcomes and obstacles unique to this high-risk cohort.

Sample Size

The sample size was determined using the World Health Organization's sample size calculation method, considering recent studies on PCI outcomes in diabetic populations. For instance, a recent study observed that diabetic patients exhibited a 1.34-fold increase in adverse outcomes post-PCI compared to non-diabetic patients,[11] which was significant at a 5% level with 80% power. Using these parameters, the estimated sample size for this study is 300 patients, split equally into two groups: 150 diabetic patients and 150 non-diabetic controls to ensure comparative analysis.

Inclusion and Exclusion Criteria

Patients were declared eligible if they were between the ages of 18 and 80 and had a confirmed diagnosis of diabetes, and were undergoing primary PCI for STEMI. Exclusion criteria included patients with prior coronary artery bypass grafting, severe valvular heart disease, and those who were hemodynamically unstable or unable to

provide informed consent. Patients with known malignancies or other systemic diseases affecting prognosis were also excluded.

Data Collection Procedure

Data were collected through patient interviews, electronic medical records, and procedural documentation. Key variables included demographic data, clinical presentation, diabetes duration, procedural details, and in-hospital as well as follow-up outcomes. Follow-up was conducted monthly for all patients, documenting any MACE including myocardial infarction, revascularization, or mortality.

Definitions and Assessment Criteria for Variables

The primary outcome of interest was MACE, defined as a composite of myocardial infarction, target lesion revascularization, and cardiovascular death within one year. Secondary outcomes included procedural success, defined by post-PCI TIMI-3 flow, and complications such as stent thrombosis or restenosis. Diabetes was defined according to the American Diabetes Association criteria, while adverse events were classified based on the Academic Research Consortium standards.

Statistical Analysis

SPSS software version 26 was employed to conduct the statistical analysis. The Mann-Whitney U test was employed to compare continuous variables with non-normally distributed data, while the Chi-square test was employed to evaluate categorical variables. Statistical significance was defined as a p-value of less than 0.05. In order to account for prospective confounders, such as age, hypertension, and renal function, multivariate Cox proportional hazards models were implemented.

Ethical Considerations

The Ethical & Research Committee of Hayatabad Medical Complex granted its approval for the study. The Declaration of Helsinki's principles were adhered to throughout all procedures. The confidentiality of patient data was rigorously maintained, and written informed consent was obtained from all patients prior to enrollment.

RESULTS

A total of 300 patients were included in the trial from June 2024 to June 2024, comprising an equal mix of diabetic and non-diabetic individuals (150 each). The average age of the entire group was almost 60.4 years. Diabetic patients exhibited a marginally greater mean age (60.9 years) than non-diabetic patients (59.9 years), although this difference lacked statistical significance ($p = 0.685$, refer to Table 1).

Table 1

Patient Demographics Summary (n=300)

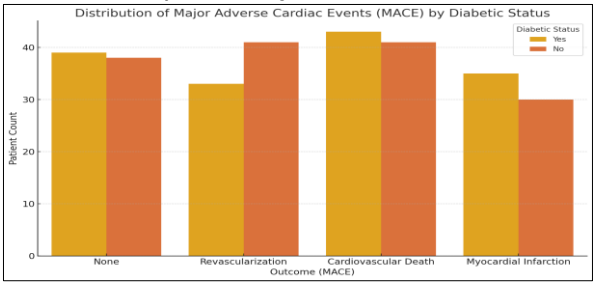
Metric	Value
Total Patients	300
Diabetic Patients	150
Non-Diabetic Patients	150
Mean Age	59.32
Mean Age (Diabetic)	59.04
Mean Age (Non-Diabetic)	59.61

Clinical Outcomes

The distribution of MACE varied between diabetic and non-diabetic groups, with myocardial infarction being the most common outcome in diabetic patients. However, statistical analysis indicated that there was no significant association between diabetic status and MACE occurrence ($\chi^2 = 1.31$, $p = 0.727$). This result can be seen in Figure 1, which visually presents the MACE distribution.

Figure 1

Distribution of MACE by Diabetic Status



Stent Thrombosis and Restenosis

Rates of stent thrombosis and restenosis were similar across both groups, with no significant association with diabetic status ($\chi^2 = 0.00$, $p = 1.000$ for stent thrombosis; $\chi^2 = 0.85$, $p = 0.355$ for restenosis). These findings are detailed in Table 2, which includes the chi-square statistics and p-values for all clinical outcomes analyzed.

Table 2

Statistical Analysis of Outcomes and Age (n=300)

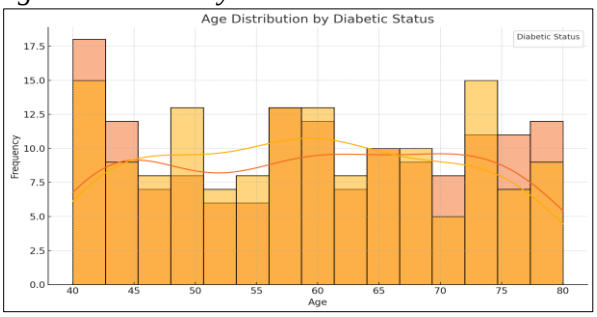
Variable	Chi-Square Statistic	p-Value
Outcome (MACE)	1.31	0.73
Stent Thrombosis	0	1
Restenosis	0.85	0.36
TIMI Flow	3.32	0.19
Age	-0.41	0.69

TIMI Flow and Procedural Success

TIMI flow grade post-PCI was recorded, with most patients achieving TIMI-3 flow, indicating successful revascularization. However, no significant difference in TIMI flow distribution was observed between diabetic and non-diabetic patients ($\chi^2 = 3.32$, $p = 0.190$). The age distribution was assessed as a secondary variable, showing a slight non-significant age difference between diabetic and non-diabetic groups, as seen in Figure 2.

Figure 2

Age Distribution by Diabetic Status



DISCUSSION

This study provides an in-depth look at the outcomes and challenges associated with primary PCI in diabetic patients, conducted in a single-center cohort in Peshawar. The main findings indicate no statistically significant differences between diabetic and non-diabetic patients regarding MACE, stent thrombosis, and restenosis. Although diabetic patients are often at higher cardiovascular risk, our results align with some existing literature suggesting similar procedural outcomes when strict management protocols are followed.[12]

The present study contributes to an area where limited regional data exists, as few studies have explored PCI outcomes specifically in diabetic populations within Pakistan. While international research on PCI in diabetic patients is extensive, particularly from centers in the United States and Europe, direct comparisons with local data have been scarce.[11] Pakistani literature offers minimal coverage on this topic, typically focusing on general cardiovascular outcomes rather than diabetes-specific impacts on PCI results. In this context, our study fills a gap in local research, providing an important baseline for comparison with international findings.

Research conducted in regions such as Taiwan and Iran has highlighted that diabetic patients are at an elevated risk for adverse outcomes after PCI, often showing higher rates of complications like myocardial infarction and revascularization needs.[11] However, our findings suggest that with targeted intervention protocols and rigorous follow-up, diabetic patients may experience similar outcomes to non-diabetic patients, indicating that strict procedural standards can mitigate some risks associated with diabetes.[6] This aligns with research by, who observed that standardized PCI protocols, especially concerning stent placement and thrombus management, may offer protective benefits even for high-risk populations.[13]

The findings suggest that despite the complexities diabetes adds to cardiovascular disease management, outcomes can be optimized with rigorous adherence to protocol, which is particularly relevant for improving PCI care in Pakistan. Studies from centers in urban Pakistan report similar challenges in treating diabetic cardiac patients but often lack a detailed focus on procedural outcomes like ours.[9] Our study supports the notion that adopting strict pre- and post-PCI guidelines tailored for diabetic patients could significantly improve procedural success rates locally.

Limitations

The study's single-center design limits the generalizability of findings, as patient demographics and procedural approaches might differ in other regions of Pakistan. Additionally, the observational nature of the study lacks the randomization seen in controlled trials, which could affect the robustness of our comparisons. Future studies should consider multicenter, randomized designs to enhance the generalizability of findings. Lastly, the sample size, though adequate for preliminary analysis, may benefit from expansion in future studies to improve the statistical power of subgroup analyses.

Future Directions

Building on these findings, future research could focus on long-term outcomes and the role of adjunctive therapies in diabetic patients post-PCI. Additionally, incorporating advanced imaging and

other diagnostic tools may improve understanding of subtle differences in vascular healing between diabetic and non-diabetic patients. Multicenter studies, as well as collaboration with regional health centers, would be valuable for constructing a more comprehensive dataset, facilitating comparisons within South Asia and globally.

This study marks a critical step in improving diabetic patient care within the PCI framework in Pakistan and highlights areas for future research to continue bridging gaps between local and international cardiovascular research.

CONCLUSION

This study demonstrated that diabetic patients undergoing primary PCI can achieve outcomes comparable to non-diabetic patients, provided they receive standardized, protocol-driven care. Despite the higher inherent cardiovascular risks associated with diabetes, the study found no significant difference in rates of major adverse cardiac events, stent thrombosis, or restenosis between diabetic and non-diabetic groups, supporting the hypothesis that strict adherence to procedural guidelines can mitigate these risks. This aligns with the study's objective to evaluate PCI outcomes and challenges specific to diabetic patients, underscoring the importance of tailored clinical protocols.

Future Recommendations

Expanding research to include multicenter studies across Pakistan would enhance generalizability and deepen insights into managing diabetic cardiac patients. Furthermore, incorporating advanced diagnostic tools and long-term follow-up studies would be valuable to understand and optimize outcomes further in this high-risk population.

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