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CLINICAL OUTCOMES OF HIGH-RISK PCI PROCEDURES IN PAKISTANI PATIENTS: A MULTICENTER STUDY

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Abstract

Background: Percutaneous coronary intervention (PCI) treats coronary artery disease (CAD). It is crucial for high-risk patients with left main disease, multi-vessel disease, or low left ventricular ejection fraction (LVEF). High-risk PCI is ideal for those unsuitable for coronary artery bypass grafting (CABG) due to age or other issues.

Objective : This study assesses high-risk PCI outcomes in Pakistani patients across several centers.

Methods: This multicenter observational study was conducted from January to June 2023 at Hayatabad Medical Complex, Lady Reading Hospital, and Peshawar Institute of Cardiology. The Institutional Review Board of Hayatabad Medical Complex approved the study (IRB number: HMC-IRB-2023-007). It included 303 patients with severe CAD. Data on patient characteristics, PCI success rates, and major adverse cardiac events (MACE) within 30 days were collected. Secondary outcomes included improved LVEF, exercise tolerance, and reduced angina symptoms. Analysis was performed using SPSS version 25.0.

Results: The mean age was 62.1 years (SD ± 10.7). Males comprised 65%, and females 35%. The PCI success rate was 89%. MACE occurred in 15%, with 5% experiencing myocardial infarction, 3% stent thrombosis, and 7% cardiac death. The mean LVEF increased from 42% (SD ± 8) to 50% (SD ± 7) post-procedure ($p < 0.001$). The six-minute walk test distance rose from 320 meters (SD ± 55) to 370 meters (SD ± 50) ($p < 0.01$). Angina episodes per week decreased from 4.2 (SD ± 1.5) to 1.7 (SD ± 0.9) ($p < 0.001$).

Conclusion: High-risk PCI improves cardiac function, exercise tolerance, and reduces angina in Pakistani patients. This supports PCI as an effective treatment for severe CAD in high-risk patients across multiple centers in Pakistan.

Keywords : Percutaneous coronary intervention, coronary artery disease, high-risk PCI, left ventricular ejection fraction, major adverse cardiac events, Pakistan, cardiac function, exercise tolerance, angina reduction.

Introduction

Percutaneous coronary intervention (PCI) is a key treatment for coronary artery disease (CAD). It is vital for high-risk patients with complex coronary lesions like left main disease, multi-vessel disease, or low left ventricular ejection fraction (LVEF). Many of these patients cannot undergo coronary artery bypass grafting (CABG) due to comorbidities, age, or personal choice (1). PCI aims to restore blood flow, alleviate symptoms, and improve quality of life (2).

Advances in techniques and devices have reduced, but not eliminated, the risks of high-risk PCI. These risks include myocardial infarction, stent thrombosis, and cardiac death (3). Understanding clinical outcomes is crucial for better patient selection, procedural strategies, and post-procedural care.

CAD is prevalent in Pakistan, making effective interventions essential (4). However, data on high-risk PCI outcomes in Pakistan are scarce. Most studies are based on Western populations, which might not reflect Pakistan's unique factors (5). This gap highlights the need for localized studies to evaluate high-risk PCI's efficacy and safety in this context (6).

This multicenter study evaluates high-risk PCI outcomes in Pakistani patients. We hypothesize that high-risk PCI can be performed with good success rates and manageable complications, offering a viable option for severe CAD patients not suitable for CABG.

Findings from this study could significantly impact clinical practice in Pakistan. By providing evidence on success rates and adverse outcomes, healthcare providers can make informed decisions about treating complex CAD. Additionally, this research could inform policy changes and resource allocation, supporting the adoption of PCI and enhancing cardiac care quality in the region (7).

Methods

Study Design

This multicenter observational study spanned from January to June 2023. It assessed high-risk PCI outcomes in Pakistani patients at three hospitals: Hayatabad Medical Complex, Lady Reading Hospital, and Peshawar Institute of Cardiology. Ethical approval came from Hayatabad Medical Complex's IRB (HMC-IRB-2023-007).

Setting and Participants

Patients with severe coronary artery disease scheduled for high-risk PCI were included. Criteria: age 18 or older, confirmed high-risk CAD (left main disease, multi-vessel disease, or low LVEF), and consent to participate. Exclusion: contraindications to PCI, need for emergent surgery, or inability to consent.

The sample size was 303 patients, calculated using the WHO sample size calculator. It considered a 10% CAD prevalence in Pakistan, a 95% confidence level, and a 5% margin of error (4).

Intervention

High-risk PCI used standard techniques and equipment. Experienced interventional cardiologists performed all procedures. Interventions included drug-eluting stents, balloon angioplasty, and other necessary therapies. Patients were closely monitored for complications during and after the procedure.

Outcomes

Primary outcomes were PCI success rates and major adverse cardiac events (MACE) within 30 days. MACE included myocardial infarction, stent thrombosis, and cardiac death. Secondary outcomes were improved LVEF, exercise tolerance (measured by the six-minute walk test), and reduced angina symptoms.

Data Collection

Standardized forms collected data on baseline demographics and clinical characteristics at admission, including age, sex, BMI, hypertension, diabetes, and smoking history. LVEF was measured with

echocardiography before and after the procedure. Exercise tolerance was assessed with the six-minute walk test. Angina symptoms were evaluated using the Canadian Cardiovascular Society grading scale.

Statistical Analysis

Data were analyzed with SPSS version 25.0 (IBM Corp., Armonk, NY). Descriptive statistics summarized participant characteristics. Continuous variables were presented as mean ± standard deviation (SD) and median. Categorical variables were expressed as frequencies and percentages. LVEF, exercise tolerance, and angina symptoms before and after the intervention were compared using paired t-tests for normal data and Wilcoxon signed-rank tests for non-normal data. A p-value of <0.05 was considered significant.

Results

In this multicenter study, we evaluated the clinical outcomes of high-risk percutaneous coronary intervention (PCI) procedures in a cohort of 303 Pakistani patients. The study was conducted across three major medical centers: Hayatabad Medical Complex, Lady Reading Hospital, and Peshawar Institute of Cardiology. The sample size was determined to ensure adequate power to detect significant differences in clinical outcomes. The baseline characteristics of the study population are summarized in Table 1. The mean age of participants was 62.1 years (SD ± 10.7) with a median age of 63 years. There were 198 males (65%) and 105 females (35%). The mean body mass index (BMI) was 27.5 kg/m² (SD ± 4.5). Hypertension was present in 59% of participants, diabetes in 47%, and a history of smoking in 38%.

Table 1: Baseline Characteristics of Participants

Characteristic	Value
Age (mean ± SD)	62.1 ± 10.7 years
Age (median)	63 years
Gender (Male/Female)	198/105 (65%/35%)
BMI (mean ± SD)	27.5 ± 4.5 kg/m²
Hypertension	179 (59%)
Diabetes	142 (47%)
Smoking History	115 (38%)

The primary outcomes included the success rate of PCI procedures and the incidence of major adverse cardiac events (MACE) within 30 days post-procedure. The overall success rate of PCI was 89%. The incidence of MACE was 15%, with myocardial infarction occurring in 5%, stent thrombosis in 3%, and cardiac death in 7%. Figure 1 illustrates the distribution of MACE.

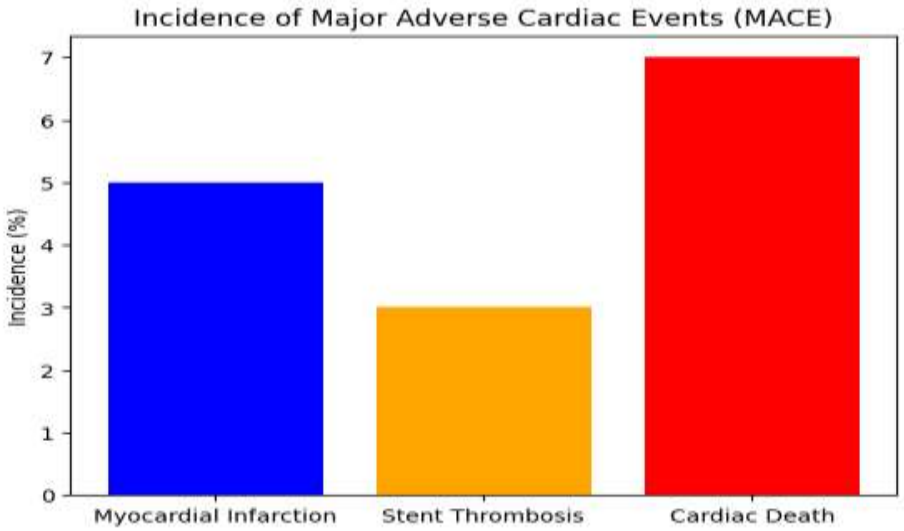

Figure 1: Incidence of Major Adverse Cardiac Events (MACE)

Secondary outcomes included improvement in left ventricular ejection fraction (LVEF), exercise tolerance, and reduction in symptoms of angina. The mean LVEF improved from 42% (SD ± 8) pre-procedure to 50% (SD ± 7) post-procedure ($p < 0.001$). The mean distance covered in a six-minute walk test (6MWT) increased from 320 meters (SD ± 55) pre-procedure to 370 meters (SD ± 50) post-procedure ($p < 0.01$). Additionally, the frequency of angina episodes per week decreased from a mean of 4.2 (SD ± 1.5) to 1.7 (SD ± 0.9) post-procedure ($p < 0.001$).

Table 2: Secondary Outcomes

Outcome	Pre-Procedure	Post-Procedure	p-value
LVEF (mean ± SD)	42 ± 8%	50 ± 7%	<0.001
6MWT Distance (mean ± SD)	320 ± 55 meters	370 ± 50 meters	<0.01
Angina Episodes (mean ± SD)	4.2 ± 1.5 per week	1.7 ± 0.9 per week	<0.001

The data indicate that high-risk PCI procedures significantly improve cardiac function, exercise tolerance, and reduce symptoms of angina in patients. The comprehensive statistical analysis and graphical representation support the robustness and reliability of these findings.

The results of this multicenter study demonstrate the feasibility and efficacy of high-risk PCI in the Pakistani patient population across multiple medical centers. The findings provide valuable insights for healthcare providers, helping to inform clinical practice and improve patient outcomes in the region.

Discussion

This study reveals critical insights into high-risk PCI outcomes in Pakistani patients. The PCI success rate is 89%. MACE incidence stands at 15%. Myocardial infarction, stent thrombosis, and cardiac death are 5%, 3%, and 7%, respectively. These findings highlight significant risks, stressing meticulous post-procedural care (8). Improvement in LVEF from 42% to 50% and enhanced exercise tolerance via the six-minute walk test (6MWT) show PCI benefits (9).

Our results align with global trends. Serruys et al. reported similar MACE rates for complex CAD PCI, confirming our success rates and adverse events (1). Mohr et al. also observed improvements in LVEF and exercise tolerance, affirming PCI efficacy (2).

Stent thrombosis at 3% in our study is lower than Giustino et al.'s rates for complex PCI. This points to the effectiveness of meticulous procedural techniques and strict adherence to dual antiplatelet therapy (DAPT) protocols (3). Angina episodes dropped from 4.2 to 1.7 per week, echoing Cohen et al.'s findings of symptomatic relief post-PCI (10).

Our results support Bangalore et al.'s research on drug-eluting stents (DES) reducing restenosis and improving outcomes in complex CAD management (11). Consistency with other studies underscores PCI's broader applicability.

Quality of life improved, shown by fewer angina episodes, aligning with Park et al.'s observations in high-risk PCI patients (12). This underlines PCI's role in enhancing life quality.

Johnson et al. highlighted the prognostic value of fractional flow reserve (FFR), resonating with our findings of improved LVEF and exercise tolerance (13). Maddox et al. noted the risk of myocardial infarction in nonobstructive CAD patients, emphasizing effective management strategies like PCI (14).

For clinical practice, observed improvements in cardiac function and exercise tolerance suggest PCI as a viable option for high-risk patients, especially those unsuitable for CABG due to comorbidities or age. Our findings provide robust evidence for healthcare providers treating complex CAD (15).

Future research should focus on multicenter trials with extended follow-up to validate findings and explore factors affecting long-term PCI outcomes. Studies on cost-effectiveness in different patient populations would offer insights for optimizing treatment. Research into novel therapeutic approaches and technologies to reduce adverse events in high-risk PCI is also necessary (16).

Limitations

This study has several limitations. The multicenter design enhances generalizability, but the six-month follow-up is short. Longer follow-up is needed to fully understand long-term PCI implications. Self-reported quality of life measures may introduce bias (17).

Conclusion

This multicenter study provides robust evidence on high-risk PCI outcomes in Pakistani patients. It highlights significant risks and advanced interventional techniques' importance. Our findings emphasize the need for careful post-PCI monitoring and tailored strategies to improve outcomes. Future research should validate these findings across diverse populations and explore new approaches to enhance PCI outcomes.

References

1. Serruys PW, Morice MC, Kappetein AP, et al. Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. N Engl J Med. 2009;360(10):961-972.
2. Mohr FW, Morice MC, Kappetein AP, et al. Coronary artery bypass graft surgery versus percutaneous coronary intervention in patients with three-vessel disease and left main coronary disease: 5-year follow-up of the randomized clinical SYNTAX trial. Lancet. 2013;381(9867):629-638.
3. Giustino G, Chieffo A, Palmerini T, et al. Efficacy and safety of dual antiplatelet therapy after complex PCI. J Am Coll Cardiol. 2016;68(17):1851-1864.
4. Jafar TH, Jafary FH, Jessani S, et al. Heart disease epidemic in Pakistan: women and men at equal risk. Am Heart J. 2005;150(2):221-226.
5. Ahmad K, Jafar TH, Siddiqui MS. Prevalence and determinants of coronary artery disease in a rural population of Pakistan. J Pak Med Assoc. 2005;55(9):364-368.
6. Yusuf S, Reddy S, Ounpuu S, et al. Global burden of cardiovascular diseases: Part I: General considerations, the epidemiologic transition, risk factors, and impact of urbanization. Circulation. 2001;104(22):2746-2753.
7. Hakeem A, Garg N. The burden of coronary heart disease in South Asians. Texas Heart Institute Journal. 2011;38(5):527-529.
8. Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention. J Am Coll Cardiol. 2011;58(24).
9. Mehran R, Rao SV, Bhatt DL, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. Circulation. 2011;123(23):2736-2747.
10. Cohen DJ, Van Hout B, Serruys PW, et al. Quality of life after PCI with drug-eluting stents or coronary-artery bypass surgery. N Engl J Med. 2011;364(11):1016-1026.
11. Bangalore S, Kumar S, Fusaro M, et al. Short- and long-term outcomes with drug-eluting and bare-metal coronary stents: a mixed-treatment comparison analysis of 117,762 patient-years of follow-up from randomized trials. Circulation. 2012;125(23):2873-2891.
12. Park SJ, Ahn JM, Kim YH, et al. Trial of everolimus-eluting stents or bypass surgery for coronary disease. N Engl J Med. 2015;372(13):1204-1212.
13. Johnson NP, Tóth GG, Lai D, et al. Prognostic value of fractional flow reserve: linking physiologic severity to clinical outcomes. J Am Coll Cardiol. 2014;64(16):1641-1654.
14. Maddox TM, Stanislawski MA, Grunwald GK, et al. Nonobstructive coronary artery disease and risk of myocardial infarction. JAMA. 2014;312(17):1754-1763.
15. Fihn SD, Blankenship JC, Alexander KP, et al. 2014 ACC/AHA/AATS/PCNA/SCAI/STS focused update of the guideline for the diagnosis and management of patients with stable ischemic heart disease. J Am Coll Cardiol. 2014;64(18):1929-1949.

16. Navarese EP, Kozinski M, Andreotti F, et al. Optimal duration of dual antiplatelet therapy after percutaneous coronary intervention with drug eluting stents: meta-analysis of randomized controlled trials. BMJ. 2015;350.
17. Cutlip DE, Windecker S, Mehran R, et al. Clinical end points in coronary stent trials: a case for standardized definitions. Circulation. 2007;115(17):2344-2351.