<u>Original Research Article</u>

Analysing the Results of Primary Percutaneous Coronary Intervention in Individuals Affected by Stent Thrombosis

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Abstract:

Background: Analyzing the outcomes of primary percutaneous coronary intervention (PCI) in individuals with stent thrombosis is crucial in interventional cardiology. Stent thrombosis, a rare yet severe complication post-stent implantation, poses risks like myocardial infarction and mortality. The study focuses to examine the clinical outcomes and procedural efficacy of primary PCI in patients presenting with stent thrombosis, aiming to elucidate factors influencing treatment success and patient prognosis.

Methods: This retrospective observational study utilized medical records. Participants included 80 patients meeting inclusion criteria: aged ≥18 years, diagnosed with stent thrombosis, underwent primary PCI, and had complete medical records. Bias was minimized by systematic data collection. Variables included demographic and clinical characteristics, procedural details, and clinical outcomes. Data were examined using SPSS version 21, employing inferential statistics like chi-square tests and regression analysis.

Results: Of the 80 participants, mean age was 62 years (± 8.5), with 65% male. Common comorbidities included hypertension (75%) and diabetes mellitus (45%). Most had prior myocardial infarction (85%). Acute stent thrombosis occurred in 70%, sub-acute in 20%, and late in 10%. Drug-eluting stents (resolute integrity: 45%, paclitaxel: 30%, zotarolimus: 25%) were frequently used. Procedural success rate was 92%. In-hospital mortality was 5%, with 10% experiencing thrombosis recurrence and 15% myocardial infarction. Age correlated with mortality ($p = 0.032$), and stent type with thrombosis recurrence ($p = 0.046$). Time to PCI ($p = 0.011$) and thrombus aspiration ($p = 0.025$) predicted procedural success.

Conclusion: Primary PCI in stent thrombosis patients demonstrates high procedural success but significant mortality and recurrence rates. Older age and stent type influence outcomes. Timely intervention and advanced stent technologies enhance procedural success.

Recommendations: Optimal patient selection, prompt intervention, and advanced stent technologies can improve outcomes in primary PCI for stent thrombosis.

Keywords: Stent Thrombosis, Primary Percutaneous Coronary Intervention, Drug-Eluting Stents, Clinical Outcomes.

Introduction

Analyzing the results of primary percutaneous coronary intervention (PCI) in patients who experience stent thrombosis is a critical area of research within interventional cardiology. Stent thrombosis, a rare but serious complication following stent implantation, poses significant risks, including myocardial infarction and death. Primary PCI, a cornerstone treatment for acute coronary syndromes (ACS), involves the mechanical opening of coronary arteries using stents. The effectiveness and safety of primary PCI in the context of stent thrombosis require thorough investigation to optimize patient outcomes and guide clinical practice.

Stent thrombosis is classified based on the timing of occurrence post-stent implantation: acute (within 24 hours), subacute (within 30 days), late (between 30 days and one year), and very late (after one year). The pathophysiology of stent thrombosis involves multiple factors, including procedural issues, patient-related factors, and stent design, highlighting the complexity of managing affected individuals [1]. The advent of drug-eluting stents (DES) has substantially reduced the frequency of stent thrombosis compared to bare-metal stents (BMS), yet the risk persists, necessitating ongoing research and innovation in stent technology and antiplatelet therapy [2].

The analysis of primary PCI results in the setting of stent thrombosis involves evaluating procedural success rates, mortality, and recurrent myocardial infarction rates. Studies have shown that timely

intervention and the use of advanced stent technologies, along with optimal antiplatelet therapy, are key to improving outcomes for these patients [3]. Moreover, the role of intravascular imaging techniques, such as optical coherence tomography (OCT) and intravascular ultrasound (IVUS), in detecting underlying causes of stent thrombosis and guiding intervention, has been increasingly recognized [4].

Therefore, the study focuses to investigate the clinical outcomes and procedural efficacy of primary percutaneous coronary intervention (PCI) in patients presenting with stent thrombosis, aiming to elucidate factors influencing treatment success and patient prognosis.

Methodology

Study Design: The study was conducted as a retrospective observational study.

Study Setting: The study utilized medical records from M.L.B. Medical College over the period of February 2022 to February 2023.

Participants: A total of 80 participants who met the inclusion criteria were involved in the study.

Inclusion Criteria:

1. aged 18 years or older.
2. diagnosed with stent thrombosis.
3. who underwent primary PCI.
4. Availability of complete medical records.

Exclusion Criteria:

1. incomplete medical records.
2. prior history of stent thrombosis.
3. who received thrombolytic therapy instead of primary PCI.
4. with contraindications to PCI.

Bias: Efforts were made to mitigate bias by systematically collecting data from medical records and ensuring the inclusion of all eligible patients within the specified time frame.

Variables: Variables included demographic characteristics (age, gender), clinical characteristics (comorbidities, medication history), procedural details (time to PCI, type of stent used), clinical outcomes (mortality, recurrence of thrombosis, myocardial infarction), and procedural success rates.

Data Collection: Data were gathered retrospectively from medical records, including demographic information, clinical history, procedural details, and clinical outcomes. Angiographic evidence was utilized to categorize stent thrombosis (ST) as acute, sub-acute, or late, based on time of onset after stent deployment (within 24 hours, up to 30 days, or beyond 30 days, respectively). Additionally, details of primary PCI procedures, including administration of Glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors, thrombus aspiration, balloon angioplasty, and stenting, were documented.

Statistical Analysis: The analysis of the data was done with SPSS 21. Regression analysis, t-tests, and chi-square tests are examples of inferential statistics that were used to evaluate relationships between factors and clinical outcomes. A p-value of less than 0.05 was deemed statistically significant.

Ethical Considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

Result

Table 1: Clinical and demographic features of study participants

Variable	Percentage
Mean Age, years	62 ± 8.5
Gender	
Male	65%
Female	35%
Chest Pain to ER Time	
$\leq$ 2 hours	40%
2-6 hours	35%
> 6 hours	25%
Killip Class	
Class I	55%
Class II	30%
Class III	10%
Class IV	5%
Comorbid Conditions	
Hypertension	75%
Diabetes Mellitus	45%
Smoking	40%

Family History of CAD	25%
Stent Thrombosis	
Acute	70%
Sub-acute	20%
Late	10%
Thrombus Grade	
Grade I	5%
Grade II	15%
Grade III	30%
Grade IV	25%
Grade V	25%
Stent Type	
Resolute Integrity	45%
Paclitaxel	30%
Zotarolimus	25%
Medication Adherence	
Aspirin	100%
Clopidogrel	60%
Statin	100%
Duration of Hospital Stay (days), Mean	5.8 (±2.3)

The study included a total of 80 participants with stent thrombosis who undertook primary PCI. The mean age of the participants was 62 years (± 8.5), with 65% being male. Common comorbidities included hypertension (75%), diabetes mellitus (45%), and dyslipidemia (30%). The majority of patients (85%) had a history of prior MI (myocardial infarction).

Among the included patients, 70% presented with acute stent thrombosis (AST) (within 24 hours of stent deployment), 20% with sub-AST (up to 30 days), and 10% with late stent thrombosis (beyond 30 days). Drug-eluting stents, including resolute integrity (45%), paclitaxel (30%), and zotarolimus (25%), were commonly implanted during primary PCI procedures. Glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors were administered in over 90% of cases, and thrombus aspiration (export) was performed in 60% of cases.

The overall procedural success rate was 92%, with successful restoration of coronary blood flow achieved in the majority of cases. Among the observed clinical outcomes, 5% of patients experienced in-hospital mortality, 10% had recurrence of thrombosis within 30 days post-PCI, and 15% developed MI during the follow-up period. Notably, the mortality rate was higher in patients presenting with late stent thrombosis compared to acute or sub-acute cases.

Chi-square tests were carried out to assess the correlation between various factors and clinical outcomes. Age was found to be significantly related with mortality (p = 0.032), with older patients being at higher risk. Additionally, the type of stent used showed a significant association with the recurrence of thrombosis (p = 0.046), with patients receiving paclitaxel-eluting stents demonstrating higher rates of recurrence compared to other types.

Multiple regression analysis was accompained to identify predictors of procedural success. Factors such as time to PCI, type of stent used, and administration of GP IIb/IIIa inhibitors were included as independent variables. The analysis revealed that time to PCI (p = 0.011) and use of thrombus aspiration (p = 0.025) were significant predictors of procedural success, with shorter time intervals and utilization of thrombus aspiration associated with higher success rates.

Discussion

The study examined 80 participants who underwent primary PCI for stent thrombosis, revealing a cohort with a mean age of 62 years, predominantly male (65%), and commonly afflicted with comorbidities such as hypertension (75%) and diabetes mellitus (45%). AST accounted for 70% of cases, with drug-eluting stents like resolute integrity (45%) being the most frequently used during PCI. Over 90% of patients received glycoprotein IIb/IIIa inhibitors, with thrombus aspiration performed in 60% of cases.

The procedural success rate was notably high at 92%, although 5% of patients experienced in-hospital mortality, with late stent thrombosis cases demonstrating a higher mortality rate. Chi-square tests indicated a significant association between age and mortality (p = 0.032), while the type of stent used correlated significantly with thrombosis recurrence (p = 0.046). Multiple regression analysis identified time to PCI (p = 0.011) and thrombus aspiration (p = 0.025) as significant predictors of procedural success, emphasizing the importance of prompt intervention and thrombus management in achieving favorable outcomes.

Recent studies have provided comprehensive insights into the management and outcomes of stent thrombosis in individuals undergoing primary PCI. A study on the three-year performance of Biodegradable Polymer Sirolimus Eluting Stents (BP-SES) demonstrated favorable long-term safety and efficacy for all-comer patients undergoing PCI, with no significant impact from diabetes mellitus, acute coronary syndrome, low ejection fraction, long stents, and complex intervention on clinical endpoint events [5]. Conversely, a single-center retrospective study found no considerable benefit of thrombus aspiration on mortality or other clinical outcomes at one-year in STEMI patients [6].

Another research reported low risks of stent thrombosis and major adverse cardiac events (MACE) with the use of Genxsync stent in STEMI patients [7]. The incidence of AST after primary PCI in STEMI patients was highlighted, indicating a high risk of AST [8]. Furthermore, a study emphasized the critical nature of stent thrombosis, underscoring the importance of timely intervention, appropriate stent selection, and adjunctive pharmacotherapy in improving outcomes [9]. These studies collectively enhance the understanding of stent thrombosis management in India, offering valuable insights for optimizing treatment strategies in a high-prevalence cardiovascular disease setting.

Conclusion

The study sheds light on the clinical outcomes and procedural efficacy of primary PCI in patients presenting with stent thrombosis. The findings underscore the importance of timely intervention and advanced stent technologies in achieving favorable outcomes. Despite high procedural success rates, the study highlights significant mortality and recurrence rates, with older age and stent type influencing outcomes. Furthermore, optimizing patient selection, ensuring prompt intervention, and leveraging advanced stent technologies are essential for improving outcomes in primary PCI for stent thrombosis.

Limitations: The limitations of this study include a small sample population who were included in this study. The findings of this study cannot be generalized for a larger sample population. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

Recommendation: Optimal patient selection, prompt intervention, and advanced stent technologies can improve outcomes in primary PCI for stent thrombosis.

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List of abbreviations:

PCI: Percutaneous Coronary Intervention

ACS: Acute Coronary Syndromes

AST: Acute Stent Thrombosis

BMS: Bare-Metal Stents

CAD: Coronary Artery Disease

DES: Drug-Eluting Stents

ER: Emergency Room

GP IIb/IIIa: Glycoprotein IIb/IIIa

IVUS: Intravascular Ultrasound

MI: Myocardial Infarction

OCT: Optical Coherence Tomography

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