

Original Research

The Results of Primary Percutaneous Coronary Intervention for Stent Thrombosis Patients

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Abstract

Background: Evaluating the results of primary percutaneous coronary intervention (PCI) in patients having stent thrombosis (ST) is essential in interventional cardiology. ST, the infrequent yet dangerous consequence following implantation of stent, presents risks such as myocardial infarction (MI) and death. The purpose of this investigation is to analyse the clinical results and procedural effectiveness of primary PCI in ST individuals in order to identify the variables that influence treatment success and prognosis of patient.

Materials and Methods: We used medical data in this retrospective observational investigation. 160 patients who met the following requirements were included in the study: they had complete medical records, were at least eighteen years old, had a ST diagnosis, and had undergone primary PCI. Data was collected in a methodical manner to reduce bias. Demographic and clinical traits, procedural specifics, and clinical results were among the variables. Regression analysis and other inferential statistics, such as chi-square tests, were used to analyse the data using SPSS version 21.

Results: The average age of the 160 participants was 61 years (± 7.4), and 64% of them were men. Among the common comorbidities were diabetes mellitus (46%) and hypertension (76%). 86% had experienced a myocardial infarction earlier. 71% of cases of stent thrombosis were acute, 21% were subacute, and 8% were late. The use of drug-eluting stents was common (zotarolimus: 23%, paclitaxel: 31%, resolute integrity: 46%). The success rate for the procedure was 91%. Nine percent of patients experienced a thrombosis recurrence, 14% suffered a myocardial infarction, and the in-hospital death rate was 4%. Mortality was associated with age ($p = 0.0319$), and thrombosis recurrence was associated with stent type ($p = 0.0459$). Procedural success was predicted by thrombus aspiration ($p = 0.0249$) and time to PCI ($p = 0.0109$).

Conclusion: Primary percutaneous coronary intervention in patients experiencing ST demonstrates a high rate of procedural success; however, it is also linked with significant mortality and recurrence rates. Advanced age and stent classification affect prognosis. Prompt intervention and sophisticated technologies of stent improve procedure outcomes.

Recommendation: The judicious selection of patients, timely intervention, and the utilisation of advanced technologies of stent can enhance prognosis in primary percutaneous coronary intervention for ST.

Keywords: Percutaneous Coronary Intervention, Thrombosis, Stent, Myocardial Infarction

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Introduction

For patients with ST-segment elevation myocardial infarction (STEMI), emergency percutaneous coronary revascularisation is the preferred and advised therapeutic option, whether or not stenting is used. The survival and results of these patients have greatly improved with the global introduction of PCI [1]. The majority of STEMI patients have seen improved results as a result of developments in the mechanical and pharmacological components of percutaneous treatments. ST is still a dreaded but rather uncommon PCI event [2]. Drug-eluting stents (DES) were unquestionably a significant advancement, however one of the primary safety issues with the first generation of DES was ST. The

second generation of DES has solved this by using a stent platform with a smaller strut and a durable polymer that is either biodegradable or biocompatible [3,4].

The pathophysiological process underlying the ST development is unclear, and several causes have been proposed. The most often mentioned factors are diabetes, lesion form and features, adherence to dual antiplatelet therapy (DAPT), and design and type of stent [5, 6]. Platelet-rich thrombus, fibrin/fibrinogen fragments, and erythrocytes were all commonly seen in the histological results of the thrombus samples, which showed heterogeneity in composition [7]. An assessment of verified ST using optical coherence tomography in a multicentre registry revealed that the

most frequently observed mechanisms of ST are neointimal hyperplasia, stent under-expansion, neo-atherosclerotic lesions, struts mal-apposition, coronary evagination and isolated uncovered struts [8]. More than two-thirds of the individuals with STEMI caused by ST had significant platelet reactivity, according to another registry-based investigation [9].

Depending on the timing of occurrence following deployment of stent, ST can be classified as acute, sub-acute, or late ST. Additionally, depending on evidence and certainty, ST can be classified as definite, probable, or possible [10]. Although STEMI is a common clinical manifestation of ST, its mortality rate is 20% to 40% higher than that of de novo STEMI because of variations in its pathophysiology [11,12]. In patients diagnosed with neo-atherosclerosis, STEMI attributed to ST is linked with an elevated risk of microvascular obstruction and distal embolization due to the rupture of atheromatous plaques. Conversely, in individuals devoid of underlying plaque pathology, factors such as the thrombogenicity of exposed stent struts, disruption of flow of blood, and the presence of polymer materials may play a significant role [13].

In spite of the pathophysiological, histological, and clinical distinctions among STEMI induced by ST, there remains ambiguity concerning the optimal therapeutic approach for this high-risk patient demographic. In specific cases, stenting, balloon angioplasty and thrombus aspiration been employed to manage STEMI due to ST [14]. The objective of this study was to assess the in-hospital outcomes and clinical and procedural characteristics of patients undergoing primary PCI for STEMI induced by acute, sub-acute, or late ST elevation.

Materials and Methods

Study Design: The research was an observational study done in a retrospective manner for a period of one year.

Study Setting: This investigation was conducted at IGIMS, Patna.

Participants: A total of 160 persons participated in the investigation.

Inclusion Criteria:

- Patients who are 18 years of age or older.
- Patients who received primary PCI.
- Patients with a ST diagnosis.
- Complete medical records are available.

Exclusion Criteria:

- Previous stent thrombosis history.
- Insufficient medical documentation.
- Having contraindications to percutaneous coronary intervention.
- Individuals who underwent thrombolytic therapy rather than primary percutaneous coronary intervention.

Bias: Measures were implemented to reduce bias by methodically gathering data from health records and guaranteeing the incorporation of all qualifying individuals during the designated time period.

Variables: Clinical outcomes (myocardial infarction, mortality, thrombosis recurrence), procedural details (stent type, time to PCI), demographics (gender, age), clinical features (medication history, comorbidities) and procedural success rates were among the variables.

Data Collection: Retrospective data collection was done from health records, encompassing demographics, clinical history, procedure specifics, and clinical results. Using angiographic evidence, ST was categorised as acute ST, sub-acute ST, or late ST on the basis of when it started after stent placement (within 24 hours, up to 30 days, or after 30 days, respectively). Also included were the details of primary PCI operations, including thrombus aspiration, balloon angioplasty, stenting, and the administration of Glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors.

Statistical Analysis

SPSS 21 was used for the data analysis. Inferential statistics, such as chi-square tests, t-tests and regression analysis were employed to assess the association between variables and clinical outcomes. Statistical significance was defined as a p-value of less than 0.05.

Results

160 patients with stent thrombosis who had undertaken primary PCI were included in the research. The participants were 64% male and had an average age of 61 years (± 7.4). Among the common comorbidities were dyslipidaemia (30%), diabetes mellitus (46%), and hypertension (76%). 86% of the patients had previously experienced a myocardial infarction. 8% of the patients who were included had late stent thrombosis (beyond 30 days), 21% had sub-AST (up to 30 days), and 71% had acute ST (AST) (within 24 hours of placement of stent). During primary PCI procedures, drug-eluting stents such as paclitaxel (31%), zotarolimus (23%), and resolute integrity (46%) were often placed. In more than 91% of patients, glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors were given, and in 59% of instances, thrombus aspiration (export) was carried out.

In the majority of patients, coronary blood flow was successfully restored, and the overall operative success rate was 91%. Fourteen percent of patients suffered MI during the follow-up period, 9% had a thrombosis recurrence within 30 days after PCI, and 4% of patients died in the hospital, according to the observed clinical outcomes. Interestingly, compared to acute or sub-acute instances, patients with late stent thrombosis had a greater death rate.

To evaluate the relationship between different parameters and clinical outcomes, chi-square tests

were used. It was discovered that age and mortality were substantially correlated ($p = 0.0319$), with older patients being more vulnerable. Furthermore, there was a significant correlation between the type of stent utilised and the thrombosis recurrence ($p = 0.0459$), with individuals who had paclitaxel-eluting stents showing greater recurrence rates than those who received other types. To find predictors of procedural

success, multiple regression analysis was used. GP IIb/IIIa inhibitor delivery, type of stent used and time to PCI were variables that were independent. The study found that thrombus aspiration ($p = 0.0249$) and time to PCI ($p = 0.0109$) were significant predictors of procedural success, with higher success rates associated with thrombus aspiration utilisation and shorter time intervals.

Table 1: Demographic and Clinical and characteristics of research participants

Characteristics	Percentage
Gender	
Female	36%
Male	64%
Mean Age, years	61 \pm 7.4
Thrombus Grade	
Grade V	26%
Grade IV	24%
Grade III	31%
Grade II	14%
Grade I	5%
Killip Class	
Class IV	6%
Class III	9%
Class II	31%
Class I	54%
Stent Type	
Zotarolimus	23%
Paclitaxel	31%
Resolute Integrity	46%
Stent Thrombosis	
Late	8%
Sub-acute	21%
Acute	71%
Chest Pain to ER Time	
> 6 hours	23%
2-6 hours	36%
\leq 2 hours	41%
Comorbid Conditions	
Smoking	41%
Diabetes Mellitus	46%
Hypertension	76%
Dyslipidaemia	30%
Duration of Hospital Stay (days), Mean	6.1 (\pm 1.9)
Medication Adherence	
Statin	100%
Aspirin	100%
Clopidogrel	59%

Discussion

The study looked at 160 patients who had primary PCI for stent thrombosis. It found that the participants had a mean age of 61 years, were primarily male (64%), and frequently had concomitant conditions such diabetes mellitus (46%) and hypertension (76%). 71% of cases involved AST, and the most commonly used drug-eluting stents during PCI were resolute integrity (46%). Thrombus aspiration was done in

59% of cases, and glycoprotein IIb/IIIa inhibitors were administered to more than 91% of patients. The success rate of procedure was very high at 91%, while 4% of individuals had in-hospital death, with cases of late stent thrombosis exhibiting an elevated mortality risk. Age and mortality had a significant correlation ($p = 0.0319$) according to chi-square testing, and the type of stent used had a significant correlation ($p = 0.0459$) with thrombosis recurrence. According to multiple

regression analysis, thrombus aspiration ($p = 0.0249$) and time to PCI ($p = 0.0109$) were critical determinants of procedural success, underscoring the necessity of timely intervention and thrombus treatment for favourable outcomes.

Comprehensive information on the treatment and results of stent thrombosis in patients receiving primary PCI has been made available by recent studies.

Long stents, low ejection fraction, diabetes mellitus, acute coronary syndrome and complex intervention did not significantly affect clinical endpoint events, according to an investigation of the 3-year performance of Biodegradable Polymer Sirolimus Eluting Stents (BP-SES) which revealed favourable long-term safety and effectiveness for all-comer PCI individuals [15]. In contrast, thrombus aspiration did not significantly improve death rates or other clinical outcomes in STEMI patients at 1 year, according to a single-centre retrospective research [16]. Another study found that using Genxsync stents in STEMI patients had minimal risks of ST and major adverse cardiac events (MACE) [17]. There is a substantial risk of AST in STEMI patients, as evidenced by the incidence of AST following primary PCI [18]. Additionally, a research highlighted the essential character of ST, emphasising the role that prompt intervention, suitable selection of stent, and supplementary medication play in enhancing results [19]. Together, these studies improve our knowledge of managing stent thrombosis in India and provide insightful information for improving treatment approaches in a setting with a high frequency of cardiovascular disease.

Conclusion

The research clarifies the clinical results and procedural effectiveness of primary PCI in ST individuals. The results emphasise the significance of prompt intervention and sophisticated technologies of stent in attaining positive results. Notwithstanding elevated success rates of procedure, the investigation underscores considerable recurrence rates and mortality, with advanced age and type of stent affecting results. Moreover, optimising selection of patient, ensuring timely intervention, and utilising improved stent technology are crucial for enhancing results in primary PCI for ST.

Limitation

The constraints of this investigation are characterised by a limited sample size that was incorporated into the research. The results of this investigation cannot be extrapolated to a broader population. Moreover, the absence of a comparison group constitutes a limitation to the findings of this study.

Recommendations

The judicious selection of patients, timely intervention, and the utilisation of advanced

technologies of stent can enhance results in primary percutaneous coronary intervention for ST.

References

1. Levine GN, Bates ER, Blankenship JC, et al. ACC/AHA/SCAI focused update on primary percutaneous coronary intervention for patients with ST-elevation myocardial infarction: an update of the 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention and the 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction. *J Am Coll Cardiol*. 2015;67(10):1235e1250, 2016.
2. Yang YX, Liu Y, Li XW, et al. Clinical outcomes after percutaneous coronary intervention for early versus late and very late stent thrombosis: a systematic review and meta-analysis. *J Thromb Thrombolysis*. 2021;51(3):682e692.
3. Tada T, Byrne RA, Simunovic I, et al. Risk of stent thrombosis among bare-metal stents, first-generation drug-eluting stents, and second-generation drug-eluting stents: results from a registry of 18,334 patients. *JACC Cardiovasc Interv*. 2013;6:1267e1274.
4. Philip F, Agarwal S, Bunte MC, et al. Stent thrombosis with second-generation drug-eluting stents compared with bare-metal stents: network meta-analysis of primary percutaneous coronary intervention trials in ST-segment elevation myocardial infarction. *Circ Cardiovasc Interv*. 2014;7(1):49e61.
5. van Werkum JW, Heestermaas AA, Zomer AC, et al. Predictors of coronary stent thrombosis: the Dutch stent thrombosis registry. *J Am Coll Cardiol*. 2009;53:1399e1409.
6. Kimura T, Morimoto T, Kozuma K, et al. Comparisons of baseline demographics, clinical presentation, and long-term outcome among patients with early, late, and very late stent thrombosis of sirolimus-eluting stents: observations from the registry of stent thrombosis for review and reevaluation (RESTART). *Circulation*. 2010;122:52e61.
7. Riegger J, Byrne RA, Joner M, et al. Histopathological evaluation of thrombus in patients presenting with stent thrombosis. A multicenter European study: a report of the prevention of late stent thrombosis by an interdisciplinary global European effort consortium. *Eur Heart J*. 2016;37(19):1538e1549.
8. Souteyrand G, Amabile N, Mangin L, et al. Mechanisms of stent thrombosis analysed by optical coherence tomography: insights from the national PESTO French registry. *Eur Heart J*. 2016;37(15):1208e1216.
9. Godschalk TC, Byrne RA, Adriaenssens T, et al. Observational study of platelet reactivity in patients presenting with ST-segment elevation myocardial infarction due to coronary stent thrombosis undergoing primary percutaneous coronary intervention: results from the European Prevention of Stent Thrombosis by an Interdisciplinary Global European Effort Registry. *JACC Cardiovasc Interv*. 2017;10(24):2548e2556.
10. Cutlip DE, Windecker S, Mehran R, et al. Clinical end points in coronary stent trials: a case for standardized definitions. *Circulation*. 2007;115:2344e2351.

11. Byrne RA, Joner M, Kastrati A. Stent thrombosis and restenosis: what have we learned and where are we going? The Andreas Grüntzig Lecture ESC 2014. *Eur Heart J*. 2015;36(47):3320e3331.
12. Claessen BE, Henriques JP, Jaffer FA, et al. Stent thrombosis: a clinical perspective. *JACC CardiovascInterv*. 2014 Oct;7(10):1081e1092.
13. Gori T, Polimeni A, Indolfi C, et al. Predictors of stent thrombosis and their implications for clinical practice. *Nat Rev Cardiol*. 2019;16(4):243e256.
14. Katsikis A, Keeble TR, Davies JR, et al. Contemporary management of stent thrombosis: predictors of mortality and the role of new-generation drug-eluting stents. *CathetCardiovascInterv*. 2020;96(1):E8eE16.
15. Shrivastava A, Soni A, Sharma A, Pathak VK. Three years performance of Biodegradable Polymer Sirolimus Eluting Stent in all comer patients undergoing Percutaneous Coronary Intervention. *Med Res Arch [Internet]*. 2023 Nov [cited 2024 Feb 22];11(11). Available from: <https://esmed.org/MRA/mra/article/view/4573>.
16. Kumar D, Patra S, Pande A, et al. Long-term clinical outcomes of thrombus aspiration in STEMI patients undergoing primary percutaneous coronary intervention. *Am J Cardiovasc Dis*. 2020;10(2):117-123.
17. Fisher L, Mathew A, Punnose E, Indani A, Bhutada P. Safety and efficacy of hybrid platform design sirolimus eluting stent system in percutaneous coronary intervention in ST elevation myocardial infarction patients at 1 year after treatment. *Int J Res Med Sci [Internet]*. 2016 Dec. 19 [cited 2024 Feb. 22];4(10):4458-64. Available from: <https://www.msjonline.org/index.php/ijrms/article/view/305>.
18. Shaikh S, Uddin Z, Shaikh Z, Shaikh NA, Shaikh JK, Shah GJ, Hussain ST, Samad A. Prevalence of Acute Stent Thrombosis after Primary PCI in STEMI Patients. *J Pharm Res Int*. 2022;34(24B):1–8.
19. Kumar M, Shar GS, Kumar R, et al. The outcome of primary percutaneous coronary intervention in patients with stent thrombosis. *Indian Heart J*. 2022 Nov-Dec;74(6):464-468.