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Original Research Article

FREQUENCY OF EARLY STENT THROMBOSIS (ACUTE AND SUBACUTE) IN PATIENTS PRESENTING WITH ACUTE ST-ELEVATION MYOCARDIAL INFARCTION (STEMI) UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION (PCI)

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Abstract: *Sudden cardiac stent thrombosis (ST) is a severe clinical risk that can lead to high fatality rates. However, data are scarce on the prevalence of early ST events following 'primary percutaneous coronary intervention' (pPCI) and the characteristics that predict it, particularly among Pakistani patients.* ***Objective:*** *The objective is to determine possible indicators and evaluate 'the frequency of acute and sub-acute stent thrombosis' (ST) after 'primary percutaneous coronary intervention' (PCI).* ***Methods:*** *Five hundred individuals who had undergone primary PCI were enrolled from July 2022 to December 2023. Telephone follow-up assessments were used to gather information on 30-day results, including death rates, recurrence of symptoms, and episodes of ST. 'ST was classified as acute' (occurring 'during the procedure') or 'sub-acute' ('occurring within 30 days post-procedure) using standardised criteria established by the 'Academic Research Consortium.* ***Results:*** *In this study, 500 patients were enrolled, primarily male (80.4%, 362 patients). 'Stent thrombosis' (either acute or sub-acute) was observed in 6.8% of patients, with 10.1% (4) classified as definite ST and the remaining 91.9% (34) as probable ST. Male patients were more prevalent among those who developed ST, along with a higher incidence of hypertension, diabetes, reduced left ventricular ejection fraction (LVEF) pre-PCI, and higher Killip Class. Patients with ST experienced a higher in-hospital mortality rate compared to those without ST, with a p-value of 0.02. Notably, 'Killip Class' ('III-IV') emerged as 'an independent ST predictor in this patient cohort. These findings underscore the importance of risk assessment and vigilant management, particularly in patients presenting with higher Killip Class and other associated risk factors, to mitigate ST occurrence and adverse outcomes following primary PCI.* ***Conclusion:*** *Early stent thrombosis (ST) appears relatively common in patients undergoing primary PCI. Those with diabetes and hypertension face an elevated risk of ST, while patients presenting in 'Killip Class III-IV' demonstrate an 'independent predictive' factor for early ST.*

Keywords: Diabetes, Hypertension, Killip Class, Left ventricular ejection fraction (LVEF), Primary percutaneous coronary intervention (PCI), Stent thrombosis (ST)

Introduction

'Stent thrombosis' (ST) represents a severe 'clinical event with high mortality rates,' often manifesting as 'ST-segment elevation myocardial infarction' ('STEMI'). While ST is infrequent in routine coronary interventions, its occurrence increases following 'acute myocardial infarction' (AMI). Studies, including the 'HORIZONS-AMI trial,' indicate 'an incidence rate' of 0.8% within 24 hours ('acute ST') and '1.2% within 30 days' ('sub-acute ST') after 'primary PCI for AMI.' Moreover, research suggests an 'acute and sub-acute ST rate' of approximately 2.5% in AMI patients. In specific cases like cardiac arrest and AMI, 'the incidence of early ST' within 30 days may rise to around 5% (1, 2). Despite its efficacy, early coronary stent thrombosis can occur in up to 5% of STEMI patients with a successful first PCI procedure. (3-5).

Numerous clinical studies have aimed to identify 'predictors of acute and sub-acute ST.' While various factors are implicated in ST's pathophysiology, the precise mechanisms remain incompletely understood. These factors are categorised into device-related, lesion- or patient-specific, and procedural factors. Device-related factors include stent design, material, and interaction with adjunctive treatments. 'Lesion- or patient-specific factors' include vessel size, lesion characteristics, and comorbidities such as diabetes mellitus. Procedural factors involve stent malposition, under-expansion, and suboptimal antithrombotic therapy.(6, 7). The prevalence and determinants of early ST following initial PCI. 'As a result, the purpose' 'of this study' is to 'assess the' prevalence 'of early' (acute and sub-acute) 'ST after' 'primary PCI for' STEMI and identify relevant determinants.

Methodology

This study focused on patients diagnosed with acute myocardial infarction (MI) who underwent primary percutaneous coronary intervention (PCI) at the Peshawar Institute of Cardiology, Pakistan. Ethical approval was obtained from the relevant committee, and only procedures performed by experienced consultant cardiologists were included. All patients received guideline-recommended medications, including aspirin, clopidogrel, and unfractionated heparin, which were administered based on individualised dosing. A glycoprotein IIb/IIIa inhibitor, tirofiban, was administered during the procedure. Post-procedure, patients were prescribed dual antiplatelet therapy (DAPT) for a specified duration. Patients were followed up for 30 days post-procedure, with outcomes including mortality, rehospitalisation, recurrence of MI, and re-intervention. Stent thrombosis (ST) events were defined according to standardised criteria proposed by the

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Academic Research Consortium (ARC), distinguishing between acute (during the procedure) and sub-acute (within 30 days after the procedure) occurrences. The sample size was determined based on the anticipated rate of stent thrombosis within 30 days following the procedure.
Statistical analysis was conducted using IBM SPSS Statistics. Descriptive statistics and logistic regression were utilised to identify factors associated with stent thrombosis. Significant variables from univariate analysis were included in multivariate analysis.

Results

A total of 500 patients participated in the study, with (402) being male. Patients' ages ranged from 30 to 97 years. Hypertension was the most common risk factor, present in 204 of cases. Stent thrombosis occurred in 450 patients, comprising 6.0% of the total; 5 (10%) had definite ST, and the remaining 35 (88.8%) had probable ST. In terms of diseased vessel distribution, 121) had three-vessel disease (3VD), 146 had two-vessel disease (2VD), and 172 had 'single-vessel disease' (SVD). 'Culprit artery' involvement was observed in 'Mid-Distal LAD' 21.3% (96), proximal LAD 121), RCA 174, LCX (10.5% - 48), and left main artery 2. Male patients, those with hypertension and diabetes, and those with reduced pre-PCI LVEF (%) and higher Killip Class were more likely to experience ST. Refer to Table 1 below for a summary of 'baseline clinical,' 'demographic,' and 'angiographic characteristics.

Table 1: "Clinical, demographic, and angiographic variables"

Characteristics	Total	Stent Thrombosis		p-value
No		**NO**	**YES**	
N	500	450	50	
'Gender'				
'Male'	83.7% (402)	85.6% (362)	82.5% (40)	0.04
'Female'	21.6% (98)	20.7% (88)	19.3% (9)	
'Age' (years)				0.4
'Range'	30–97	30–97	35–86	
Mean ± SD	55.57 ± 11.06	55.39 ± 10.91	58.45 ± 13.14	
Median [IQR]	56 [61–50]	56 [61–49]	56 [66–50]	
Body Mass Index (kg/m²)				
Range	54.08–15.04	54.08–15.04	31.64–18.43	0.8
Mean ± SD	25.59 ± 4.58	25.62 ± 4.64	25.13 ± 3.52	
Median [IQR]	25.01 [27.76–22.86]	25.01 [27.76–22.83]	25.1 [27.78–22.86]	
'Risk Factors'				
'Hypertension'	42.9% (204)	38.4% (178)	62.7% (26)	
'Diabetes mellitus'	28.9% (134)	28.5% (116)	43.7% (18)	
'Smoking'	24.7% (118)	24.5% (108)	20.2% (8)	
'Positive family history'	4.5% (19)	4.4% (15)	10% (4)	
'Prior PCI'	4% (15)	4.5% (14)	0% (0)	
'Killip Class'				
'I'	88.4% (432)	88.9% (394)	69.6% (38)	0.02
'II'	7.6% (48)	8.3% (41)	19.5% (7)	
'III'	3.4% (12)	3.2% (10)	7.2% (2)	
'IV'	2.8% (9)	2.5% (6)	13.2% (3)	
'Number of diseased vessels'				
'None'	3.6% (12)	3.3% (10)	4% (2)	0.6
'Single vessel disease' (SVD)	40.2% (191)	39.3% (172)	38.5% (19)	
'Two vessels disease' (2VD)	35.6% (166)	33.7% (147)	44.5% (19)	
'Three vessels diseases' (3VD)	28.5% (132)	27.6% (121)	20.5% (11)	
'Culprit artery'				
'Mid-Distal LAD'	22.5% (107)	24.8% (96)	25.6% (11)	0.5
'Proximal LAD'	30.4% (142)	25.6% (128)	26.7% (14)	
'Right coronary artery' (RCA)	40.5% (194)	39.7% (174)	37.5% (20)	
'Circumflex' (LCX)	10.5% (53)	10.6% (48)	8.5% (5)	
'Left main' (LM)	0.5% (3)	0.4% (2)	4% (1)	
'Ramus'	0.5% (3)	0.6% (3)	0% (0)	
'Dominance'				
'Right'	83.7% (419)	84.1% (378)	76.9% (41)	0.3
'Left'	9% (45)	9% (41)	8.2% (4)	
'Co-dominance'	7.4% (37)	6.9% (31)	17.3% (6)	
'Pre PCI LVEF' (%)				
'Range'	65–25	65–25	45–25	0.02
Mean ± SD	44.7 ± 10.01	45.2 ± 9.95	35.71 ± 6.16	

Median [IQR]	45 [55–35]	45 [55–35]	35 [40–30]	
Not assessed	53.8% (269)	53.5% (241)	57.6% (28)	
Lesion Length (mm)				
Range	67–5	67–5	30–10	0.3
Mean ± SD	19.08 ± 8.07	19.04 ± 8.18	19.7 ± 6.07	
Median [IQR]	16 [24–13]	16 [24–13]	20 [25–14]	

Table 2 illustrates the procedural characteristics and in-hospital outcomes. Most patients, 50% (250), received bare-metal stents (BMS). 'Post-procedure TIMI flow' was distributed as follows: 0 in 0.8%, I in 0.8%, II in 3.6%, and III in 98.8% of patients. The in-hospital mortality rate' post-procedure was 2.6%, 'significantly higher' in patients experiencing stent thrombosis (ST) (p-value < 0.001) compared to those without ST.

The mortality rate within 30 days of the procedure was 5.4% (30), and the re-admission rate within the same period was 3.3% (18). During the follow-up, the mortality rate was 4% (22), the reinfarction rate was '3%, and the re-intervention rate was 3.5% (20). The rate of ST was 6.8% (37), with 10.1% (4) being acute ST and 91.9% (34) being sub-acute ST. ST was associated with adverse in-hospital and post-discharge outcomes, including 'mortality,' 're-admission,' 're-infarction,' and 're-intervention.' Further details on monitoring results are presented in Table 3.

TABLE 2: "Characteristics of The Procedure and The In-Hospital Outcomes"

Characteristics	**Total**	**Stent Thrombosis**		**p-value**
No		**NO**	**YES**	
N	**500**	**450**	**50**	
'Stent Type'				
'Drug-eluting stent' (DES)|	45% (225	45% (202)	50% (25)	0.9
Bare metal stents (BMS	50% (250	50% (225)	50% (25)	
Plain old balloon angioplasty (POBA	5% (25)	5% (23)	5% (2)	
Stent Length (mm)	6–38	6-38	30–8	
Range	17.25 ± 7.2	4.5–1.5	4–2	0.3
Mean ± SD	3.25 ± 0.63	3.25 ± 0.63	17.25 ± 6.09	
Median [IQR]	3.5 [3.5–3	3.5 [3.5–3]	3.5 [3.5–3]	
DAPT on discharge	94.2% (500)	95.9% (450)	66.7% (50)	O.O2
Aspirin	96% (480)	98% (440	72% (36)	0.02
Clopidogrel	96% (480)	98% (440)	72% (36)	0.02
'Post-procedure TIMI flow grade'				
0	0.8% (4)	0.8% (4)	1% (0)	0.8
I	0.8% (4)	0.8% (4)	1% (0)	
II	3.6% (18)	3.6% (16)	|7% (2)	
III	98.8% (494)|	98.8% (445)	94% (47)	
In-hospital Mortality	2.6% (13)	0.4% (2	46% (23)	0.02

Table 3: 'Result of follow-up'

Characteristics	**Total**	**Stent Thrombosis**		**p-value**
No		**NO**	**YES**	
N	**500**	**450**	**50**	
Follow-up duration (months)				
Range	23–17	23–17	22–17	
Mean ± SD	19.08 ± 1.76	19.1 ± 1.76	18.76 ± 1.71	
Median	19 [21–17]	19 [21–17.5]	19 [20–17]	0.4
Follow up outcome				
Expired	11.9% (65)	7.9% (42)	76.8% (26)	0.02
Re-admission within 30 days	3.3% (18)	2.3% (8)	19.2% (7)	0.02
Expired within 30 days	5.4% (30)	1% (6)	76.8% (26)	0.02
Re MI	4% (22)	1.4% (8)	46.5% (16)	0.02
Re Intervention	3.5% (20)	1.7% (5)	31.3% (11)	0.02
Stent Thrombosis (ST)	6.8% (37)	-	100% (37)	
Definite	1.5% (4)		10.1% (4)	
Probable	1.5% (4)		91.9% (34)	
Acute Stent Thrombosis	6.3% (5)		10.1% (4)	
Sub-acute Stent Thrombosis	1.5% (4)		91.9% (34)	

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Discussion

The retrospective study of 500 patients undergoing primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI) revealed several principal findings. Both 'acute and sub-acute ST' within thirty days were frequently experienced by 'Academic Research Consortium Early Stent Thrombosis patients; the incidence of sub-acute ST was much higher than that of acute ST. It's important to note that the kind of stent (bare-metal vs. drug-eluting) did not correlate with the incidence of ST, even throughout as long as a month.

Individuals in Killip classes III–IV had a higher 'risk of' developing 'early ST.' Furthermore, 'within 30 days', patients with diabetes and hypertension showed an increased risk of early ST. 'Killip class III–IV' was 'found to be the only independent predictor of early ST' among several risk variables. Furthermore, early stent thrombosis was associated with a strikingly high death rate, which reached 11.9% after 30 days.

Unlike other research, our analysis did not find a relationship between the prevalence of stent thrombosis (ST) and the total length or thickness of the stent, nor did it find a connection between the size of the lesions and ST incidence. Furthermore, among the participants in our analysis, smoking did not show up as a separate 'risk factor for ST' ('acute or subacute).

On the other hand, ST significantly increases the risk of death and myocardial infarction (MI). According to newly available information, one of the most critical indicators of ST is the presence of ST-elevation myocardial infarction (STEMI). Swedish Coronary Angiography and Angioplasty Registry (SCAAR) results indicate that individuals with STEMI have a '2.5-fold' higher 'risk of ST' than patients without the condition. Early ST incidence has been observed to range from 0.5% to 2.0%.

These early occurrences are thought to be caused by various procedural variables and lesion-related characteristics, either separately or in combination, such as stent under-expansion, tissue protrusion, residual thrombus, edge dissection, and impaired flow. (8-10).

'In our study,' the incidence of early stent thrombosis ('ST'), comprising 'acute or sub-acute' occurrences after primary percutaneous coronary intervention ('PCI'), was 5.8%. Among these, '1.5%' were acute, and 6.3% were sub-acute. This rate surpasses previous findings, such as the '2.5%' reported in the 'HORIZONS AMI trial' and the 2.5% reported by Montalescot et al. Another study on STEMI patients undergoing primary PCI found a 3.5% rate of definite early ST. Notably, the rate of early ST 'for STEMI patients, as observed in our study' and previous ones, is notably higher than that 'reported for moderate to high-risk non-STEMI' and 'stable coronary artery disease patients' (11, 12). Our study found no association between stent type (drug-eluting or bare-metal stent) and ST occurrence, aligning with findings from 'various randomised trials' and comparisons of first-generation stents. Additionally, diabetic patients showed a higher risk of ST, although diabetes mellitus did not independently predict early ST. Previous studies have identified diabetes as a predictor, possibly due to confounding factors like longer lesion length and increased platelet aggregation. (13-15). According to earlier studies, individuals with high blood pressure showed an increased incidence of ST, although hypertension did not independently predict it. Patient presentation in Killip Class III-IV, which indicates a higher myocardial risk with lower systolic left ventricular performance, was our investigation's sole independent predictor of ST. This is consistent with prior experiment results showing a relationship between ST rate and Killip class at the onset.

The most anticipated side effect associated with successful PCI, ST, can be avoided by paying close attention to individual risk variables and their capacity to withstand dual antiplatelet treatment (DAPT). It's critical to optimise stent placement and deployment, especially in complicated instances. Elective surgeries after stent implantation should be avoided without discontinuing DAPT, if possible. Potent antiplatelet agents like ticagrelor may be 'considered for ACS'' patients with low bleeding risk.' Evaluating individual patients 'risk for ST' is essential 'to prevent or minimise' this severe complication of stent implantation.(16, 17).

Conclusion

In conclusion, our research shows that acute or sub-acute 'early stent thrombosis' is relatively common 'in patients receiving 'primary PCI for acute' myocardial infarction (MI), occurring at a rate of roughly '6.8 per 100 patients' and carrying a worrisome 30-day death rate of 76.8% (26). Crucially, our results show that stent thrombosis is unaffected by the kind of stent implanted—bare metal or drug-eluting. On the other hand, patients with diabetes and hypertension are more likely to experience 'stent thrombosis', and those presentations in Killip Classes 'III–IV' are 'independent' predictors of early 'stent thrombosis'. These findings highlight the significance of careful observation and customised intervention techniques to lessen the likelihood and severity of this critical consequence 'in patients receiving 'primary PCI for acute MI'.

Declarations

Data Availability statement
All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate
Approved by the department concerned.

Consent for publication
Approved

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Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

ASAD ULLAH KHAN (Registrar)
Manuscript revisions, critical input.
Coordination of collaborative efforts.

HASAN ZEB (Post Graduate Resident)
Conception of Study, Final approval of manuscript.
Data acquisition and analysis.
SHAFI ULLAH (Registrar)
Study Design, Review of Literature.
Conception of Study, Development of Research Methodology Design, Study Design, manuscript Review, and final approval of manuscript.
ASIF KHAN (Post Graduate Resident)
Data entry and data analysis, as well as drafting the article.
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Manuscript drafting.
Coordination of collaborative efforts.

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