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**Original Research Article**

# CLINICAL PROFILE AND OUTCOME OF PATIENTS WITH STENT THROMBOSIS IN A TERTIARY CARE CENTER-A PROSPECTIVE OBSERVATIONAL STUDY

**Thirulogachandar E[1], R. Ramesh[2], C Balachandar[3], R. Anto Prabhu[4], G.S. Sivakumar[5], S. Sathish Kumar[5], S. Balasubramanian[6]**

[1]Assistant Professor, Department of Cardiology, Tirunelveli Medical College, Tirunelveli, Tamilnadu, India
[2]Senior Assistant. Professor, Department of Cardiology, Madurai Medical College, Madurai, Tamilnadu, India
[3]Associate Professor, Department of Cardiology, Tirunelveli Medical College, Tirunelveli., Tamilnadu, India
[4]Senior Resident, Department of Cardiology, Tirunelveli Medical College, Tirunelveli, Tamilnadu, India
[5]Senior Assistant Professor, Department of Cardiology, Madurai Medical College, Madurai, Tamilnadu, India
[6]Professor, Department of Cardiology, Madurai Medical College, Madurai, Tamilnadu, India

## Abstract

**Background:** Stent thrombosis is of major concern as the number of coronary interventions increases due to coronary artery disease, and incidence varies from 0.5-2% in various studies. The study aimed to describe the clinical profile, procedural factors, lesion factors, and outcome of patients with stent thrombosis. **Materials and Methods:** This is a single-centre, prospective observational study conducted in the Cardiology department of Madurai Government Rajaji Hospital from August 2015 to March 2018. Patients who presented with features of stent thrombosis were enrolled, and angiography was done and confirmed. Patient, procedural, and lesion factors were analyzed, and management and outcome at one month were analyzed. **Result:** 31 patients presented with ST; the most common presentation mode was ST Elevation Myocardial Infarction (35.5%). The majority were males (77.4%). Around 14 (45.1%) patients had diabetes. Early ST occurred in 16 (51.6%), late ST in 7 (22.6%) and very late ST in 8 (25.8%) patients. Premature antiplatelet withdrawal was documented in 9 (29%) patients with ST. Early ST patients presented with thrombus-containing and Type B/C lesions compared to late/very late ST. Among procedural factors, Lesion mismatch and dissection were found in 12.5% of patients with Early ST. All-cause mortality at one month was 22.6%, and target vessel failure occurred in 19.4% of patients with ST.
**Conclusion:** The most common factors predisposing to stent thrombosis in our study were ACS presentation, poor adherence to antiplatelet therapy, thrombus containing lesion, Type B/C lesion, previous PCI lesion mismatch and dissection.

## INTRODUCTION

Cardiovascular disease has become the most important cause of mortality over the past decade globally. Rapid epidemiologic transition leading to a life of inactivity and obesity contributes to the huge increase in non-communicable diseases like coronary artery disease and diabetes. These diseases have surpassed infectious diseases to become the leading cause of mortality. [1,2] It is estimated that 28.1% of all deaths in India can be attributed to cardiovascular disease. [3] Percutaneous coronary intervention is the mainstay of reperfusion therapy, surpassing thrombolytics to decrease morbidity and mortality in ACS. Coronary stents were primarily designed to bring down the incidence of abrupt closure of coronary vessels. However, they are associated with a relatively increased stent thrombosis (ST), a dreaded and potentially lethal complication. The incidence of stent thrombosis reported in the literature varies from 0.5% in randomised trials to 4.9% in observational cohorts. [4-6] The primary concerns of BMS implantation, such as restenosis and target vessel revascularization, were overcome by first-generation drug-eluting stents. Yet, there is no significant variation in the incidence of early stent

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thrombosis for bare metal and drug-eluting variants. In contrast, late stent thrombosis is slightly higher for drug-eluting stents. [7,8] This has been further confirmed by data reported by a meta-analysis in which bare metal stents (BMS) were compared with Drug-eluting stents. [9] Also, stent thrombosis can result in 15%-50% mortality, making it a dreaded complication. [10,11] Inconsistent results are reported regarding the timing of stent thrombosis and the clinical outcomes likely to vary with population characteristics and various other patient and procedural factors. [12,13] Hence, additional data on the attributes of stent thrombosis and the outcome of patients belonging to low and middle-income countries from a semi-urban background are needed. Hence the present study was carried out to describe the clinical profile, procedural and lesion factors of patients with Early and late/very late Stent Thrombosis and to describe the management and outcome at one month for patients with stent thrombosis.

## MATERIALS AND METHODS

This was a single-centred observational study conducted in the Cardiology department of a tertiary care institute from August 2015 to March 2018 in patients who had undergone percutaneous coronary intervention with Drug Eluting Stent (Sirolimus) for coronary artery disease.
The Institutional Ethics Committee approved the study per the Declaration of Helsinki. Written informed consent was obtained from all the study participants, and confidentiality was maintained.
**Inclusion Criteria**
Both males and females aged ≥18, patients who had undergone Percutaneous Coronary Intervention with a Drug-Eluting stent for coronary artery disease and presented with suspected stent thrombosis were included.
**Exclusion Criteria**
Patients who underwent Percutaneous old Balloon Angioplasty were excluded.
Stent thrombosis was defined by per Academic Research Consortium (ARC) (14). [14] The ARC categorises stent thrombosis according to the level of documentation and timing.
Definite or confirmed event (symptoms suggestive of an acute coronary syndrome and angiographic or pathologic confirmation of stent thrombosis). Probable event (unexplained death within 30 days or target vessel myocardial infarction without angiographic confirmation of stent thrombosis) and possible event (any unexplained death after 30 days). Based on the elapsed time since stent implantation, stent thrombosis can be classified as Early (0-30 days post-stent implantation), late (>30 days), and very late (>12 months). Often, early stent thrombosis is further subdivided into acute (<24 hours) and subacute (1-30 days) events.

Complete patient profile was collected through structured study proforma. Presenting complaints of the patients admitted with suspected stent thrombosis were noted. Complete medical history of past illness such as diabetes, systemic hypertension, chronic kidney disease, coronary artery disease or acute coronary syndrome and type of stent implanted, procedural details including Lesion type, Evidence of Thrombus containing lesion, Inflation details, TIMI flow before and after the procedure was recorded for each patient enrolled in the study.
History regarding personal habits such as smoking, alcohol intake and medication history were noted down. Patients were asked about any family history of premature cardiac disease, coronary artery disease, or sudden death. A clinical examination and detailed history of each patient enrolled in the study were done. Blood investigations such as random blood sugar, CPK –MB, lipid profile, blood urea and serum creatinine were done at enrolment, and the results were recorded.
ECG and ECHO were done for all patients. Suspected stent thrombosis was confirmed with a coronary angiogram, and the patients have managed accordingly. Details regarding the procedural factors of the coronary stents were collected in structured proforma. The factors responsible for stent thrombosis were analysed based on patient, procedural, and lesion characteristics. The patients were followed up for one month in the Cardiology outpatient department and by telephone, and the outcome was assessed.
**Statistical Analysis**
The data collected were analysed with IBM SPSS version 23.0. Descriptive statistics were used to analyse the data. Mean, and standard deviations were calculated for continuous variables. Frequencies and percentages were used to analyse categorical variables. The chi-square test was used to compare the categorical variables and the unpaired t-test for continuous variables, and a p-value of 0.05 was taken as statistically significant.

## RESULTS

A total of 31 cases presented with stent thrombosis during the study period. Of the 31 patients, four presented with stent thrombosis had undergone PCI with drug-eluting stents outside this institution. Of 1364 patients placed with coronary stents in the study centre, 27 (1.97%) presented with stent thrombosis.
Stent thrombosis was confirmed angiographically in 25 (80.6%) patients. Early stent thrombosis occurred in 16 patients (51.6%), including six probable stent thromboses, whereas late stent thrombosis in 7 (22.6%) patients and very late stent thrombosis occurred in 8 (25.8%) patients. (Table 1). Of 31 patients, 5 (16.1%) patients were ≤40 years, 8 (25.8%) were 41-50 years,14 (45.1%) were 51-60 years, and 4 (11.2%) were greater than 60 years.
Of 31 patients who developed stent thrombosis, 24 (77.4%) were male, and 7(22.59%) were female. The baseline

demographic and patient factors are depicted in Table 2. The mean age of patients who developed Early vs. Late/Very late Stent Thrombosis was 49 ±10.81 years and 54.9 ± 8.1 years. Among patient factors, the comorbidity status of diabetes, hypertension, chronic kidney disease, and smoking had no significant association with the timing of stent thrombosis (Table 2). Regarding the indication of Stent Implantation, ST Elevation Myocardial Infarction constituted about 67.7% (21) patients, followed by Unstable Angina/Non-ST Elevation Myocardial Infarction in 25.8% (8) patients and 6.5% (2) patients had undergone stenting for In-stent Restenosis. Early Stent Thrombosis occurred in 57.1% (12) patients with PCI for Acute STEMI and 42.8% (9) patients with Late/Very Late Stent Thrombosis. Left Ventricular Ejection Fraction <40% was found in 32.2% (10) patients. Premature antiplatelet withdrawal was found in 9(27.9%) patients with Late/Very Late Stent Thrombosis. Among them, 6 (18.6%) developed Late Stent Thrombosis with no intake of both Aspirin and Clopidogrel, and 9.3% (3) had no history of intake of either Aspirin or Clopidogrel.

Baseline characteristics and demographics did not vary significantly between early stent thrombosis and late /very late cases, except for antiplatelet withdrawal, which had a significant association with late thrombosis. ST-elevation myocardial infarction (STEMI) was the most common mode of presentation in 11(35.5%) of patients, followed by Unstable Angina/Non-ST elevation myocardial infarction (NSTEMI) in 7(22.6%) of patients. (Table 2).

**Table 1: Patients with stent thrombosis**

|  | Definite + Probable ST (n=31) | Definite ST | Probable ST |
|---|---|---|---|
| Early (0-30 days) | 16 (51.6%) | 10 (32%) | 6 (19.4%) |
| Acute <24 hrs | 7 (22.6%) | 3 (9.6%) | 4 (12.9%) |
| Subacute >24hrs | 9 (29%) | 7 (22.5%) | 2 (6.4%) |
| Late >30 days | 7 (22.6%) | 7 (22.5%) | - |
| Very late >1 year | 8 (25.8%) | 8 (25.8%) | - |
| All ST | 31 (100%) | 25 (80.6%) | 6 (19.4%) |

(ARC- Academic Research Consortium, ST-Stent Thrombosis)

**Table 2: Clinical profile and mode of presentation of stent thrombosis patients**

|  | Total Stent thrombosis N=31 | Early Stent thrombosis N=16 | Late/Very Late Stent thrombosis N=15 | P-value |
|---|---|---|---|---|
| Age (Mean) |  | 49±10.81 | 54.93± 8.13 | 0.0967 |
| Male: Female | 24:7(77.4:22.6) | 13:3(81:19) | 11:4(73:27) | 0.685 |
| Diabetes | 14(45.1) | 6(37.5) | 8(53.3) | 0.479 |
| Hypertension | 8(25.8) | 3(18.8) | 5(33.3) | 0.433 |
| Smoker | 14(45.1) | 9(56.3) | 5(33.3) | 1 |
| Chronic Kidney Disease | 1(3.22) | 0 | 1(6.7) | 0.483 |
| Antiplatelet Withdrawal | 9(29.0) | 0 | 9(60) | 0.002 |
| Ejection Fraction<40% | 10(32.2) | 5(31.2) | 5(33.3) | 1 |
| Prior H/O MI | 21(67.7) | 12(57.1) | 9(42.8) | 1 |
| Prior H/O UA | 8(25.8) | 3(18.7) | 5(33.3) | 0.433 |
| Previous PCI | 2(6.45) | 1(6.25) | 1(6.6) | 1 |
| **Mode of presentation** |  |  |  |  |
| STEMI | 11(35.5) | 6(37.5) | 5(33.3) | 0.614 |
| Unstable Angina | 7 (22.6) | 4(25) | 3(20) |  |
| LV failure | 5 (16.1) | 2(12.5) | 3(20) |  |
| AVRT | 1 (3.2) | 0 | 1(6.7) |  |
| Recurrent VT | 4 (12.9) | 3(18.75) | 1(6.7) |  |
| Sudden death | 5(16.12) | 4(25) | 1(6.7) |  |

AVRT-Atrioventricular reentrant tachycardia, VT-Ventricular tachycardia

**Table 3: Lesion factors in patients of stent thrombosis**

| Lesion factors | Early ST N=16 (%) | Late/Very late ST N=15 (%) | P-value |
|---|---|---|---|
| Thrombus containing lesion | 7(43.8) | 0 | 0.006 |
| Lesion length(mean) | 23.2±7.5 | 26.4±9.7 | 0.310 |
| Complete occlusion | 3(18.8) | 0 | 0.225 |
| Bifurcation lesion | 1(6.3) | 0 | 1 |
| Type B / C lesion | 5(31.3) | 2(13.3) | 0.394 |
| In-stent Restenosis | 2(12.5) | 0 | 0.483 |

**Table 4: Procedural factors of stent thrombosis**

| Procedural factors | Early ST N=16 | Late/Very late ST N=15 (%) | P-value |
|---|---|---|---|
| Mean stent diameter(mm) | 2.92±0.43 | 3.09±0.32 | 0.224 |
| Mean stent length (mm) | 26.2±11.4 | 27.3±10.5 | 0.782 |
| Maximum inflation pressure(atm) | 12.2±3.5 | 15.1±5.2 | 0.239 |
| ST vessel |  |  | 0.518 |
| 1.LAD | 13 (81.3%) | 11(73.3%) |  |
| 2.LCX | 1 (6.3%) | 0 |  |
| 3.RCA | 2 (12.5%) | 4 (26.6%) |  |
| Dissection | 2(12.5%) | 0 | 0.483 |
| Lesion mismatch | 2 (12.5%) | 0 | 0.483 |
| TIMI grade flow(initial) |  |  |  |

| | | |
|---|---|---|
| TIMI 0 | 3 (18.8%) | 0 |
| TIMI 1 | 5 (31.3%) | 3 (20%) |
| TIMI 2 | 5 (31.3%) | 5 (33.3%) |
| TIMI 3 | 3 (18.8%) | 7 (46.7%) |
| TIMI grade flow(final) | | |
| TIMI 0 | 0 | 0 |
| TIMI 1 | 0 | 0 |
| TIMI 2 | 4 (6.3%) | 0 |
| TIMI 3 | 12 (75%) | 15 (100%) |
| Tirofiban use | 8 (50%) | 5 (33.3%) |

**Table 5: Modes of management and outcome**

| Management | Total N=31 | Early ST (n=16) | Late ST/very late ST (n=15) |
|---|---|---|---|
| Target vessel revascularisation | 19 | 10 | 9 |
| Target vessel failure | 6 | 2 | 4 |
| PCI | 3 | - | 3 |
| Thrombus Aspiration | 6 | 6 | 0 |
| POBA | 10 | 8 | 2 |
| Thrombolysis | 6 | 4 | 2 |
| **Outcome at one month** | | | |
| All-cause mortality | 7 (22.6%) | 5 (71.4%) | 2 (28.6%) |
| Cardiovascular Mortality | 6 (85.7%) | 5 (71.4%) | 1 (14.3%) |
| Major bleed (ICH) | 1 (14.3%) | 1 | 0 |

POBA-Plain old balloon angioplasty ICH-Intracranial haemorrhage.

Among Lesion factors, as in Table 3, a statistically significant proportion of early ST had thrombus-containing lesions (p=0.006), followed by Type B/C lesions in 5/16 (31.3%) of patients with Early Stent Thrombosis and 3/15 (13.3%) of patients with Late/Very Late stent Thrombosis. The mean Lesion length was 23.2±7.5 mm in Early vs. 26.4±9.7mm in Late/very Late Stent Thrombosis. In-stent Restenosis due to previous Drug Eluting Stent was the factor in (12.5%) of patients for which PCI with DES was done, and they developed Early Stent Thrombosis.

When analysis of procedural factors as in Table:4 was considered, mean stent diameter, mean length of the stent, and pre-dilatation pressure did not vary significantly in Late/very late stent thrombosis. The Left anterior descending artery (LAD) was the most common vessel involved in 81.3% (13/16) with Early vs. 73.3% (11/15) in Late/Very late stent thrombosis followed by the Right coronary artery (RCA). Two (12.5%) patients developed dissection of the stented vessel. Among them, one patient had Ostioproximal LAD dissection and died immediately with Acute stent thrombosis. Another patient had Ostial RCA dissection, and subsequent stenting was done from the Ostium, and he subsequently developed reinfarction. Lesion mismatch was present in 12.5% (2/16) of patients with Early Stent Thrombosis.

Management of stent thrombosis (Table.5) was done by either Thrombolysis, Balloon Angioplasty, Thrombus aspiration, repeat stenting of the vessel or by conservative management with Heparin injection and Tirofiban infusion in whom attempt to revascularisation failed. Successful Thrombus Aspiration and Balloon Angioplasty restored TIMI 3 flow in 16 (51.6%) patients. Repeat DES stenting was done in 3 (9.7%) patients. Target Vessel revascularisation was done in 19 (61.2%) patients. Target Vessel failure occurred in 6 (19.4%) patients. Among 31 patients, 7 (22.6%) died of all-cause mortality at one month.

## DISCUSSION

In the present study of patients with Stent Thrombosis (ST), early Stent Thrombosis constituted 51.6% of patients, 22.6% with late stent thrombosis, and 25.8% with very late stent thrombosis. Definite stent thrombosis comprised 80.6% of patients, and the remaining 19.6% with probable stent thrombosis. A higher proportion of stent thrombosis could be attributed to the non-compliance of patients with Antiplatelet therapy (29% or one-third of patients with Stent Thrombosis). This might be due to a lack of awareness from the patient's perspective. Nonadherence to antiplatelet therapy is associated with a statistically higher occurrence of ST, as shown in a study by Kamenik M et al. [12]. Interruption of antiplatelet therapy is the strongest predictor for stent thrombosis in literature. [13] The mortality rate of stent thrombosis was 22.6% at one month and comparable (22-27%) to various studies in the literature. [15,16] The presence of risk factors Diabetes Mellitus, Smoker, Chronic Kidney Disease, and low Ejection Fraction<40% did not vary significantly in early and late stent thrombosis. This contrasts a study based on the Victorian registry, where diabetes was found to be an independent risk factor for early stent thrombosis. [17]

Among lesion factors, thrombus-containing lesions were frequent with early stent thrombosis. Other lesion factors found were Type B/C lesion, Bifurcation lesion length of the lesion, and In-stent restenosis. When the Procedural factors were considered, the Mean stent diameter did not vary significantly in early vs Late/Very late stent thrombosis. Left Anterior Descending Artery (LAD) was the most common vessel involved, followed by the Right coronary artery (RCA). Dissection of the stented vessel predisposed to early stent thrombosis in 6.2% of patients, and lesion mismatch was found

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in 6.2% of patients with early stent thrombosis. Bifurcation lesions, coronary calcifications, in-stent restenosis with rupture of plaques, and stent size mismatch are the common procedural risk factors cited in the literature to be associated with stent thrombosis. [12] In the present study, the all-cause mortality rate at one month is 22.6%, similar to a study by Mukesh Kumar et al., where the in-hospital mortality of stent thrombosis patients was 27%. [18] In the current study, target vessel revascularisation was done through Thrombus Aspiration, Balloon Angioplasty, Heparin, and Tirofiban infusion. Successful TIMI 3 flow was achieved in 61% of the patients with stent thrombosis. Target vessel failure occurred in 19% of patients with stent thrombosis. Repeat Stenting was done in 9.6% of patients with stent thrombosis.

The angiographic assessment to prove definite ST increases the reliability of the study. Yet, it is limited by single centred observational nature of the study, limited sample size, and short follow-up period. Also, further multicentric studies with large sample sizes are required to assess the strength of the association of the factors described in the current study. Another limitation is that intracoronary imaging was not done, which could have provided more profound insights into the enigma called Stent thrombosis.

## CONCLUSION

Stent thrombosis is a challenging yet avoidable complication of coronary intervention. Clinicians and researchers are still working on ways to avoid this dreaded complication. The most common factors found to be present in stent thrombosis patients were poor adherence to antiplatelet therapy, thrombus-containing lesions, Type B/C lesions, previous PCI lesion mismatch, and dissection. All-cause mortality was high in stent thrombosis patients.

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