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Original Article

Internal Medicine Section

Incidence and Outcomes of Early Stent Thrombosis in Patients Receiving Drug-eluting Stents: A Retrospective Study from a Tertiary Care Centre in India

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ABSTRACT

Introduction: Early stent thrombosis is a relatively rare but deleterious complication of Percutaneous Coronary Intervention (PCI). Data on early stent thrombosis from an Indian setting are rare and indistinct.

Aim: To determine the incidence and clinical outcomes of early stent thrombosis in patients receiving drug-eluting stents.

Materials and Methods: In this retrospective study, data of all consecutive patients who underwent PCI with stenting and reported an incidence of early stent thrombosis between March 2014 and November 2016 at our Tertiary Care Centre (King George's Medical University, Lucknow, India) were considered. Incidence of early stent thrombosis was determined based on total number of patients who underwent PCI with drug-eluting stents during the study period. Subsequently, the patient-related, lesion-related, procedure-related, and stent-related characteristics were examined for patients with early stent thrombosis. Clinical outcomes of stent thrombosis were also analysed for these patients. Additionally, a comparative analysis for various characteristics was performed between patients who died and patients who survived.

Results: Early thrombosis was noted in 41 (1%) patients out of 3,869 PCI that were performed during the study period. Among this cohort, substantial presence of established risk factors of stent thrombosis was observed including for diabetes (n=12, 29.3%), smoking (n=19, 46.3%), STEMI (n=30, 73.2%), chronic total occlusion (n=8, 16.3%), thrombus-containing lesion (n=24, 49%), Type C lesions (n=36, 73.5%). Although, all patients were aimed to manage appropriately, mortality in patients with early stent thrombosis was reported in 18 (43.9%) patients and re-infarct was reported in 26.8% (n=11) patients.

Conclusion: Although, the incidence of stent thrombosis in patients receiving drug-eluting stents was around 1%, it was found to be associated with a higher 30-day mortality rate. Further studies examining a larger cohort of patients, incidence of late and very late stent thrombosis, and a comparative analysis of characteristics between patients with and without stent thrombosis are warranted.

Keywords: Coronary artery, Mortality, Percutaneous coronary intervention

INTRODUCTION

Stent thrombosis is an uncommon but catastrophic event of PCI, despite advances in stent technology. It is associated with sudden occlusion of a stented coronary artery due to thrombus formation [1,2]. It is a complication with a wide chronological spectrum that can occur anywhere from intraprocedurally to years after implantation [3]. Traditionally, it is categorised into early (including acute and sub acute, within 24 hours and from 24 hours to 30 days, respectively), late (from 30 days to 1 year), and very late (after 1 year) [3]. However, majority of these events occur within the first month of PCI [3,4]. In general clinical practice, the expected rate of early stent thrombosis is ~1%, and beyond 30 days is 0.2%-0.6% per year [2,3]. Earlier, a study by Aoki J et al., reported that the events of stent thrombosis post-PCI occurs in about 1.4% of patients with acute coronary syndrome, and about 0.3-0.5% of patients in stable condition [5]. The aetiology of early stent thrombosis (within 30 days) is multifactorial and the treatment requires emergent repeat PCI, although, optimal reperfusion is only achieved in two-thirds of patients [6,7]. Hence, the clinical consequences of stent thrombosis are frequently deleterious and include death in 20-48% or major myocardial infarction in 60-70% of the cases [8]. Thus, stent thrombosis has been a nightmare for interventional cardiologist. Although, the incidence and prevalence of stent thrombosis has been followed very closely [3], data on its incidence from India is not robust due to either lack of studies or not being reported. Hence, there was a need to perform a study in this context. With this background, we conducted the present study to determine the incidence and clinical outcomes of stent thrombosis at our centre.

MATERIALS AND METHODS

The study population for this retrospective study comprised all patients who underwent PCI between March 2014 and November 2016 at King George's Medical University, Lucknow, India. The major inclusion criteria included a reported incidence of acute and early stent thrombosis post-PCI. In order to analyse the outcomes in real-world population, no additional clinical descriptors or angiographic exclusion criteria were defined. The protocol of the study was approved by Institutional Ethics Committee and the study conformed to the principles of good clinical practice and the Declaration of Helsinki.

The data used for the analysis in this study were retrieved from the patient records maintained at the institute. In these reports, the data on demographic features, presence of coronary risk factors, and past medical history had been documented at the time of admission, while the details of affected lesions and implanted stents had been noted during the index procedure. Incidence of stent thrombosis and outcomes for these patients were specifically analysed.

Study Definitions and Outcome Measures

Events of stent thrombosis were determined based on the criteria laid by the Academic Research Consortium (ARC) and were classified

in to definite (angiographic or pathologic evidence), probable (unexplained death within 30 days of the procedure or MI at any time in the territory of previous PCI), and possible (unexplained death occurring 30 days post procedure) stent thrombosis [9]. Additionally, the events of stent thrombosis were categorised as acute (<24 hours post procedure), early (24 hours to 30 days post procedure), late (31 days to one year post procedure) and very late (>one year post procedure). Early stent thrombosis were further grouped into intra-procedural (during the procedure) and sub acute, from the end of the procedure to 30 days thereafter [1,4]. Here, the term stent thrombosis was collectively used for acute as well as early stent thrombosis. Incidence of stent thrombosis was calculated as the number of patients with stent thrombosis divided by total number patients who underwent PCI with stenting during the study period.

STATISTICAL ANALYSIS

All data were analysed using the Statistical Package for Social Sciences (SPSS; Chicago, IL, USA) program, version 15.0. Continuous variables are presented as mean±standard deviation, while categorical variables are presented as frequency and percentages. For the statistical comparison between the two groups, the non parametric Student's t-test (i.e., the Mann-Whitney U test) was used for continuous variables (i.e., age, onset of symptoms, ejection fraction, and number of stents) and the chi-square test or the Fisher's-exact test was used for categorical variables (i.e., males, smoking, diabetes mellitus, STEMI, primary PCI, multi-vessel disease, intra-procedural GpIIb/IIIa use, and clopidogrel prescription). A two-sided alpha level of 0.05 was used to identify statistically significant difference between two groups.

RESULTS

Demographic Characteristics

A total of 3,869 PCI were performed at our institute. Of them, the incidence of early and acute stent thrombosis was noted in 41 (1%) patients. Data of these 41 patients (mean age: 54.0±10.5 years) were examined extensively in the present study. Of this study population, 36 (87.8%) were males, 12 (29.3%) were diabetic, 8 (19.5%) were hypertensive, 6 (14.6%) were dyslipidaemic, and 19 (46.3%) were smokers and multiple risk factors were present in seven patients. For these patients, angina status prior to PCI revealed STEMI in 30 (73.2%) patients (anterior-wall STEMI, inferior-wall STEMI, posterior-wall STEMI in 21 (51.2%), 8 (19.5%), and 1 (2.4%) patients respectively), NSTEMI in 7 (17.1%) patients, unstable angina in 1 (2.4%) patient, and stable angina in 3 (7.3%) patients. Other demographic characteristics of the study population are described in [Table/Fig-1].

Angiographic and Angioplasty Procedure Characteristics

For the study population, single-vessel disease was present in 22 (53.7%) patients while multi-vessel disease was noted in the 19 (46.3%) patients. PCI was performed in 49 lesions with target coronary vessel being left anterior descending artery in 31 (63.3%) cases, left circumflex artery in 7 (14.3%) cases, and right coronary artery in 11 (22.4%) cases. Site of culprit lesion were ostial, proximal, mid, and distal in 8 (16.3%), 29 (59.2%), 11 (22.5%), and 1 (2.0%) cases. Of these, thrombus was present in 24 (49.0%) lesions and 8 (16.3%) were calcified lesions, while total occlusion was observed in 8 (16.3%) lesions. [Table/Fig-2,3] describe the lesion and procedural characteristics of the patients respectively. A total of 51 stents were implanted with mean size of 27.3±6.6 mm length and 2.9±0.3 mm diameter. Of STEMI patients, 6 had their primary angioplasty done in window period, 16 patients received thrombolytic therapy prior PCI within the window period, while 8 patients were admitted late and did not qualify the criteria of window period for receiving thrombolytic therapy. Pre-dilation and post-dilation was performed for 34 (69.3%) and 38 (77.5%) lesions respectively. Intra-procedural GPIIb/IIIa was used in 10 (24.4%) patients. Procedure was uneventful in 26 (63.4%) patients, while intra-procedural complications of slow flow, no flow, dissection, hypotension, and hypotension with cardiogenic shock was noted in 5 (12.2%), 2 (4.9%), 2 (4.9%), 4 (9.8%), and 2 (4.9%) patients respectively. End result was TIMI Grade III flow in 38 (92.7%) patients and TIMI Grade II flow in 3 (7.3%) patients. Details of various stents used in the PCI procedures for these patients that experienced are given in [Table/Fig-4].

Characteristic	41 patients
Demographic details	
Age (years), mean±SD	54.0±10.5
Males, n (%)	36 (87.8%)
Ejection fraction (%), mean±SD	49.9±7.3
Hb levels (g/dL), mean±SD	12.4±1.3
RBS levels (mg/dL), mean±SD	157.2±49.9
Onset of symptoms (hours), mean±SD	47.1±81.6
Coronary risk factors	
Diabetes mellitus, n (%)	12 (29.3%)
Hypertension, n (%)	8 (19.5%)
Hypercholesterolemia, n (%)	6 (14.6%)
Smoking, n (%)	19 (46.3%)
Angina status at presentation prior PCI	
STEMI, n (%)	30 (73.2%)
AWMI, n (%)	21 (51.2%)
IWMI, n (%)	8 (19.5%)
PWMI, n (%)	1 (2.4%)
NSTEMI, n (%)	7 (17.1%)
Unstable angina, n (%)	1 (2.4%)
Stable angina, n (%)	3 (7.3%)
Severity of CAD	
Single-vessel disease, n (%)	22 (53.7%)
Multi-vessel disease, n (%)	19 (46.3%)

[Table/Fig-1]: Demographic characteristics.

Characteristic	41 patients; 49 lesions
Total number of lesions, n	49
Target coronary artery	
Left anterior descending artery, n (%)	31 (63.3%)
Left circumflex artery, n (%)	7 (14.3%)
Right coronary artery, n (%)	11 (22.4%)
Lesion location	
Ostial segment, n (%)	8 (16.3%)
Proximal segment, n (%)	29 (59.2%)
Mid segment, n (%)	11 (22.5%)
Distal segment, n (%)	1 (2.0%)
Lesion characteristics	
Percentage occlusion, mean±SD	89.5±8.5
Thrombotic lesion, n (%)	24 (49.0%)
Calcified lesion, n (%)	8 (16.3%)
Total occlusion, n (%)	8 (16.3%)
Type A*, n (%)	1 (2.0%)
Type B*, n (%)	12 (24.5%)
Type C*, n (%)	36 (73.5%)

[Table/Fig-2]: Lesion characteristics.
*According to the American College of Cardiology (ACC)/American Heart Association (AHA) criteria

Outcomes of Stent Thrombosis

Of 41 cases of early stent thrombosis, 29 (70.7%) were definite and 12 (29.3%) were probable stent thrombosis. These patients were managed appropriately with thrombosuction in 23 (56.1%) cases, thrombolysis therapy in 4 (9.8%) cases, POBA in 24 (58.5%) cases, and conservative therapy using infusion of GPIIb/IIIa inhibitors in 12 (29.3%) cases. However, mortality was reported in 18 (43.9%) patients, while 23 (56.1%) patients were discharged successfully in a stable state. Of those died, 8 (44.4%) patients died before they could be taken up for emergency PCI before they had died. Overall, 17 (41.5%) died due to cardiac death, 1 (2.4%) patient died due to non cardiac death, 11 (26.8%) patients had experienced re-infarct, and 1 (2.4%) patient had experienced stroke. The outcomes of stent thrombosis are described in [Table/Fig-5].

Characteristic	41 patients; 49 lesions; 51 stents
Patients undergoing primary PCI, n (%)	6 (14.6%)
Patients with thrombolysis prior PCI, n (%)	16 (39.0%)
Window period (hours), mean±SD	8.1±6.4
No. of stents per patient, mean±SD	1.2±0.6
Average stent length (mm), mean±SD	27.3±6.6
Average stent diameter (mm), mean±SD	2.9±0.3
Lesions pre-dilated, n (%)	34 (69.4%)
Lesions post-dilated, n (%)	38 (77.5%)
Patients given intra-procedural GPIIb/IIIa inhibitors, n (%)	10 (24.4%)
Resultant TIMI flow	
TIMI Grade II, n (%)	3 (7.3%)
TIMI Grade III, n (%)	38 (92.7%)
Intra-procedural complications	
Slow flow, n (%)	5 (12.2%)
No flow, n (%)	2 (4.9%)
Dissection, n (%)	2 (4.9%)
Hypotension, n (%)	4 (9.8%)
Hypotension+DV shock, n (%)	2 (4.9%)
Antiplatelet prescribed (post-procedure)	
Clopidogrel	40 (97.6%)
Prasugrel	1 (2.4%)

[Table/Fig-3]: Procedural characteristics.

Stent name	Drug	Polymer	Platform	Number of stents implanted	Deaths post-ST
Tetriflex	Sirolimus	Biodegradable	Cobalt chromium	1	0
Nobori	Biolimus A9	Biodegradable	Stainless steel	1	0
Xience Prime	Everolimus	Durable	Cobalt chromium	2	0
Endeavour Sprint	Zotarolimus	Durable	Cobalt chromium	4	0
Emagic Plus	Sirolimus	Biodegradable	Cobalt chromium	6	1
Orsiro	Sirolimus	Biodegradable	Cobalt chromium	10	2
Promus Element Plus	Everolimus	Durable	Platinum Chromium	5	1
Yukon Choice Flex	GmBH sirolimus	Biodegradable	Cobalt chromium	2	1
Yukon Choice PC	GmBH sirolimus	Biodegradable	Cobalt chromium	2	1
Metafor	Sirolimus	Biodegradable	Cobalt chromium	4	2
Promus Element	Everolimus	Durable	Platinum Chromium	6	3
Xience V	Everolimus	Durable	Cobalt chromium	4	3
Supraflex	Sirolimus	Biodegradable	Cobalt chromium	4	4

[Table/Fig-4]: Details of implanted stents and events of death.

Characteristic	41 patients
Type of stent thrombosis*	
Definite	29 (70.7%)
Probable	12 (29.3%)
Management	
Thrombosuction	23 (56.1%)
Thrombolysis therapy	4 (9.8%)
POBA	24 (58.5%)
Conservative treatment	12 (29.3%)
Outcomes	
Death	18 (43.9%)
Cardiac death	17 (41.5%)
Non-cardiac death	1 (2.4%)
Re-infarct/myocardial infarction	11 (26.8%)
Stroke	1 (2.4%)

[Table/Fig-5]: Details of stent thrombosis and outcomes.
*According to the Academic Research Consortium (ARC) criteria

Analysis of Predictors of Survival

A comparative analysis of various demographic, clinical and procedural characteristics between patients who died after the onset of stent thrombosis and patients who survived after the onset of stent thrombosis was performed. The outcomes for this analysis are given in [Table/Fig-6]. Interestingly, the onset of symptoms (days) to initial presentation to hospital was significantly shorter in

Characteristic	Died (n=18)	Survived (n=23)	Statistical significance
Age (years), mean±SD	56.7±10.5	52.0±12.4	0.173
Onset of symptoms (hours), mean±SD	27.11±44.9	62.8±99.8	0.013*
Males, n (%)	15 (83.3%)	21 (91.3%)	0.439
Ejection fraction (%), mean±SD	50.6±7.3	49.3±7.3	0.644
Smoking, n (%)	11 (61.1%)	8 (34.8%)	0.093
Diabetes mellitus, n (%)	5 (27.8%)	7 (30.4%)	0.853
STEMI, n (%)	12 (66.7%)	18 (78.2%)	0.607
Primary PCI, n (%)	4 (22.2%)	2 (8.7%)	0.377
Thrombotic lesion, n (%)	11 (61.1%)	13 (56.5%)	0.767
Multi-vessel disease, n (%)	9 (50%)	10 (43.5%)	0.678
Number of stents, mean±SD	1.3±0.8	1.2±0.4	0.647
Intra-procedural GpIIb/IIIa, n (%)	3 (16.7%)	7 (30.4%)	0.308
Clopidogrel prescription, n (%)	17 (94.4%)	23 (100%)	0.439

[Table/Fig-6]: Comparative analysis of clinical and procedural characteristics based on survival.
* Mann-Whitney U test; p-value <0.05 is considered statistically significant

patients who died than that in patients who survived (27.11±44.9 vs. 62.8±99.8; p=0.013). Other factors including age, gender, ejection fraction at presentation, smoking, diabetes mellitus, STEMI, primary PCI, thrombotic lesion, multi-vessel disease, intra-procedural use of GPIIb/IIIa inhibitors, or prescription of clopidogrel were statistically comparable between two groups.

DISCUSSION

Early stent thrombosis (≤30 days after stent implantation) is a relatively rare however most feared complication related to coronary stent placement PCI [10]. In present study, early stent thrombosis was identified in 41 (1%) of the 3,869 patients implanted with drug-eluting stent during the study period. This finding is encouraging as the incidence reported in present study is comparatively lower than the available literature [3,5,11-14].

In general, the underlying mechanism of stent thrombosis is multifactorial and includes various patient-related, lesion-related, stent-related, procedure-related, and post-procedure related factors. The patient-based factors comprise presence of acute myocardial infarction, acute coronary syndrome, diabetes mellitus, renal failure, low ejection fraction, younger age, and smoking. The lesion-based factors comprise diffuse disease, small-vessel disease, bifurcation lesion, chronic total occlusion, and thrombus-containing lesions. Stent-related factors comprise role of antiproliferative agent, coating technologies, polymer biocompatibility, stent material, strut/polymer thickness, stent structure, and drug dosage. The procedure-related factors comprises stent underexpansion, stent malapposition, stent length, multiple stents, persistent slow flow, residual stenosis, edge dissections, and development of neoatherosclerosis within stents with new plaque rupture. The post procedure related factors include type and duration of antiplatelet therapy and adherence to prescribed regimen [7,15]. Based on these, it is recommended to have strict attention on patients' risk factor profile and their ability to adhere to prescribed medical regimens before proceeding with stent implantation. In addition, all interventional cardiologists should take utmost care to technical details in order to optimise stent implantation and deployment, particularly in complex disease [7]. In the present study, substantial presence of these risk factors was observed among patients with early stent thrombosis, including diabetes (29.3%), smoking (46.3%), STEMI (73.2%), chronic total occlusion (16.3%), thrombus-containing lesion (49%), Type C lesions (73.5%), and intra-procedural complications (36.7%). We believe that the occurrence of stent thrombosis can be minimised with careful patient section and stent selection and deployment.

In the present study, we also analysed the clinical consequences of stent thrombosis in the study cohort. Of patients with early stent thrombosis, we found that 70.7% cases were definite and 29.3% cases were probable stent thrombosis. Although all patients were aimed to manage appropriately, morality was reported in 43.9% patients and re-infarct was reported in 26.8% patients. Although, the mortality rates in the present study are comparable with that reported in literature [8]. it should be noted that eight patients had died before they could be taken up for emergency. Furthermore, we observed no statistically significant difference for majority of demographic, clinical and procedural characteristics between patients who died after the onset of stent thrombosis and patients who survived after the onset of stent thrombosis. This finding signifies that appropriate and timely treatment is the most important predictor of survival after stent thrombosis, while the demographic, clinical, and procedural characteristics play no role. We opine that the present study fittingly turns the attention to the deleterious issue of early stent thrombosis and its clinical consequences in Indian setting.

LIMITATION

This study has several important limitations; it was a retrospective observational study and study population was confined to patients who presented with early (acute or subacute) stent thrombosis. The sample cohort included only 41 consecutive patients with reports of early stent thrombosis from a single-centre; subclinical stent thrombosis may have occurred in some patients but remained undetected. Also, the incidence of late or very late stent thrombosis was not analysed. The outcomes were not compared between various material of stents used in the study. Despite these limitations, the present study is valuable as it describes the incidences and patient/lesion/procedural characteristics of patients experiencing early stent thrombosis in an Indian setting. Further studies examining a larger cohort of patients, incidence of late and very late stent thrombosis, and a comparative analysis of characteristics between patients with and without stent thrombosis are warranted.

CONCLUSION

In the present study, various established risk factors of early stent thrombosis including diabetes, smoking, STEMI, chronic total occlusion, thrombotic lesion, complex lesion, and intra-procedural complications were substantially present among the patients with early stent thrombosis. We believe that the occurrence of stent thrombosis can be minimised with careful patient section and stent selection and deployment. In the present study cohort, we observed a high incidence of myocardial infarction and death among patients with early stent thrombosis. We are of opinion that appropriate and timely management is most critical for the survival of the patients after early stent thrombosis.

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