DOI: https://doi.org/10.53350/pjmhs22161530

ORIGINAL ARTICLE

The Frequency of Early Subacute Stent Thrombosis after Primary Percutaneous Coronary Intervention in Patients with St-Segment Elevation Myocardial Infarction

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ABSTRACT

Introduction: Acute coronary syndrome(ACS) is associated with activation ofplateletsand thecoagulationsystem which could influence the incidence of early stentthrombosis(EST).Stent thrombosis is a relatively uncommon phenomenon, yet it is a serious complication which often presents as an ST-segment elevation myocardial infarction (STEMI) and/or sudden cardiac death[1,2].Stent thrombosis (ST) is an uncommon but life-threatening complication after percutaneous coronary intervention (PCI), frequently manifesting as acute coronary syndrome (ACS) or even cardiac death.Platelet activation and the heightening of the coagulation system play a major role in the pathogenesis of acute coronary syndrome (ACS) and might impact the occurrence of stent thrombosis in those patients who undergo stenting during ACS. Unfortunately, stent thrombosis (ST) is more frequent after stenting for STEMI than after elective stenting with both drug-eluting stents (DES) and baremetal stents (BMS).

Objective: To determine the frequency of early subacute stent thrombosis after primary percutaneous coronary intervention in patients with STsegment elevation myocardial infarction

Methodology:

Study Design: Descriptive Case Series

Setting: This study was conducted in NICVD Hospital, Karachi

Subjects and Methods: Study was approved by hospital ethical review committee. All patients who fulfilled the inclusion criteria were included in the study. Pre-operatively a written consent was taken from each patient by the primary investigator of this study. All these patients were undergone primary PCI and stent either drug-eluting stents (coated with medication) or bare-metal stent was placed. These patients were observed for 24 hours for early subacute stent thrombosis. All the collected data were entered into the proforma attached at the end.

Results: Mean ± SD of age was 55.56±12.24 with C.I (53.52------57.59) years. Mean ± SD duration of surgery was 33.48±9.26 with C.I (31.90------35.05) minutes. Out of 142 patients 103 (72.53%) were male and 39 (27.4%) were female. Frequency of early subacute stent thrombosis was found to be 4(2.82%).

Conclusion: It is to be concluded that frequency of early acute stent thrombosis after primary PCI was found to be 2.82%.Patients presenting with STEMI who are hemodynamically unstable and have multivessel coronary disease undergoing coronary stenting during ACS, are at increased risk of EST.

Keywords: Acute myocardial Infarction, Primary PCI, Early Subacute Stent, Thrombosis, STEMI

INTRODUCTION

Stent thrombosis (ST) is the most feared complication of coronary stent treatment because of its morbidity and mortality. Subacute thrombosis (SAT) is a major concern in patients undergoing percutaneous coronary intervention (PCI). One of the major concerns remaining in the treatment with stenting of patients with acute myocardial infarction (AMI) is the occurrence of stent thrombosis (ST). Early subacute ST is reported to occur with an incidence ranging from 0.5–2.0 % [1-3]. These early events may be related to lesion-related and procedural factors such as edge dissection, residual thrombus or tissue protrusion, compromised flow, stent under expansion or a combination of these. [4-5]

Stent thrombosis (ST) is an uncommon but life-threatening complication after percutaneous coronary intervention (PCI), frequently manifesting as acute coronary syndrome (ACS) or even cardiac death. The use of coronary stents has become the preferred therapy with primary percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI). This is based on data showing that stents have been able to reduce ischemicdriven target vessel revascularization and angiographically documented restenosis and re-occlusion. [6] Unfortunately, stent thrombosis (ST) is more frequent after stenting for STEMI than after elective stenting with both drug-eluting stents (DES) and bare-metal stents (BMS). [7-8]

In other different studies, early subacute stent thrombosis after primary percutaneous coronary intervention for ST-segment elevation myocardial infarction was reported as 5.3% [9], 62%[10.] Primary percutaneous coronary intervention (PCI) for treatment of ST-segment elevation myocardial infarction (STEMI) has significantly improved clinical outcome as compared with thrombolytic therapy.[11] Stent thrombosis (ST) is a recognized complication occurring in 0.5% to 2.2% of patients with coronary artery disease treated by percutaneous coronary intervention (PCI) with stent implantation.[12,13]Its occurrence is expected to increase with the number of stents in particular drug-eluting stent (DES) implantation procedures

done worldwide. Clinical consequences of ST are generally catastrophic, including short-term mortality rates of up to 20% to 25% and major myocardial infarction (MI) in 60% to 70% of cases and 6-month mortality rates, among survivors of ST, of up to 20% to 25% [14]. The presentation of ST is very often an STsegment elevation myocardial infarction (STEMI).[15]

Rationale: The rationale of the study is to measure the frequency of early subacute stent thrombosis after primary percutaneous coronary intervention for ST-segment elevation myocardial infarction. Several studies have shown early subacute stent thrombosis after primary PCI in patients with STEMT.[9-15] However, the evidence is still lacking in a Pakistani population. Developing early subacute stent thrombosis in patients already suffering from PCI (STEMI) will not only increase the morbidity but also their hospital stays and disease burden. As there is a significant No. of patients who develops early subacute stent thrombosis during 24 hours of their hospital stay after PCI in our setups. This study will help the clinicians to identify the group of patients with high risk of stent thrombosis. In addition, by my study emphasis may be given on early detection and its appropriate management plan to save the patients from irreversible cardiac damage and to reduce morbidity, disease burden and hospital stay in this already compromised group of patients.

METHODOLOGY

SAMPLE SELECTION

Inclusion Criteria

- Age between 25-75 years
- Either gender
- Patients presenting with ST-segment elevation myocardial infarction (as mention in operational definition).

Exclusion Criteria

- Prior history ST-segment elevation myocardial infarction.
- Prior history of cardiac surgery and PCI, heart failure.
- Patients who do not give consent.

Data Collection: Study was start after taken permission from the Institutional Ethics Review Committee and approval of synopsis from college of Physician and Surgeons Pakistan before the commencement of the study. All those patients admitted with STEMI NICVD Karachi, meeting the inclusion criteria was asking to give consent by themselves to be the part of study. Those who would give the consent by themselves were included in the study. All these patients were undergoing primary PCI by researcher himself under the supervision of senior registrar or consultant cardiology having > 5 years of experience and stent either drug-eluting stents (coated with medication) or bare-metal stent was be placed. These patients were observed for 24 hours for early subacute stent thrombosis. Patients who was develop sudden onset of typical chest pain, indicating acute ischemia in the distribution of the target vessel (in which stent is placed), in these patient's angiography was be done (relook) if it shows complete occlusion within the stented segment with evidence of thrombus, patient was be labeled as having acute stent thrombosis. Exclusion criteria was be followed strictly to avoid confounding variables.

Data Analysis: All the collected data was be entered and analyzed by using SPSS (version 20.0). Mean ± standard was be calculated for age, duration of surgery, weight, height and BMI. Frequency and percentage were calculated for gender, hypertension, smoking status, diabetes mellitus and outcome variable i.e. early subacute stent thrombosis (yes/no). Effect modifiers were controlled through stratification of age, gender, hypertension, diabetes mellitus, BMI, height, weight smoking status and duration of surgery to see its effect on outcome followed by chi-square test by using $P \leq 0.05$ as significant.

RESULTS

In this study 142 patients were included to assess the frequency of early sub-acute stent thrombosis after primary PCI in patients with STEMI and the results were analyzed as Mean ± SD of age was 55.56±12.24 with C.I (53.52------57.59) years. Mean ± SD duration of surgery was 33.48±9.26 with C.I (31.90--------35.05) minutes. Mean ± SD of BMI was 27.56±6.28 with C.I (26.51------28.60) kg/m^2. Mean ± SD of height was 1.76±0.48 with C.I (1.68-------1.83) meters. Mean ± SD of weight was 58.25±8.48 with C.I (56.84------59.65) kg. Out of 142 patients 103 (72.53%) were male and 39 (27.4%) were female. Out of 142 patients 68 (47.88%) were hypertensive while 74 (52.12%) were found to be normaL. Out of 142 patients 65 (45.77%) were diabetic while 77 (54.23%) were found to be normal. Out of 142 patients 100 (70.42%) were smokers while 42 (29.58%) were non-smoker. Frequency of early subacute stent thrombosis was found to be 4 (2.82%).

In stratification of age group 25—55 and > 55 years early sub-acute stent thrombosis was found to be 0% and 2.8% respectively which shows highly significant association between age and early subacute stent thrombosis i.e. (P=0.047) as shown in TABLE 1. Early sub-acute stent thrombosis was found 2.1% in male and 0.7% in female which shows non-significant difference between gender and early sub-acute stent thrombosis i.e. (P=0.303) as shown in TABLE 2. In stratification for duration of surgery (30----45) minutes 0.7% had early sub-acute stent thrombosis and in >45 minutes 2.1% had early sub-acute stent thrombosis and highly significant association was found i.e. (P=0.04) as shown in TABLE 3. In stratification of weight group 45—60 and > 60 kg early sub-acute stent thrombosis was found to be 0.7% and 2.1% respectively which shows highly significant association between age and early sub-acute stent thrombosis i.e. (P=0.03) as shown in TABLE 4. In stratification of height group 1.5—1.8 and > 1.8 meter early sub-acute stent thrombosis was found to be 2.1% and 0.7% respectively which shows non-significant association between height and early sub-acute stent thrombosis i.e. (P=0.527) as shown in TABLE 5. In stratification of BMI 18.5—27 and > 27 kg/m^2 early sub-acute stent thrombosis was found to be 1.4% each which shows nonsignificant association between BMI and early sub-acute stent thrombosis i.e. (P=0.291) as shown in TABLE 6. Early sub-acute stent thrombosis was found 2.8% in hypertensive and 0% in non-hypertensive patients which shows significant association between hypertension and early sub-acute stent thrombosis i.e. (P=0.05) as

shown in TABLE 7. Early sub-acute stent thrombosis was found to be 2.8% in diabetes patients which shows significant association between diabetes mellitus and early sub-acute stent thrombosis i.e. (P=0.04) as shown in TABLE 8. Early sub-acute stent thrombosis was found 0% in smoker and 2.8% in non-smoker which shows highly significant association between smoking and early sub-acute stent thrombosis i.e. (P=0.007) as shown in TABLE 9.

Table 1: Stratification Of Age Group With Respect To Early Subacute Stent Thrombosis N= 142

AGE GROUP (In years)		EARLY SUBACUTE STENT THROMBOSIS		P-VALUE
		Yes	No	
25---55	Count	0	75	0.047
	% of Total	0.0%	52.8%	
>55	Count	4	63	
	% of Total	2.8%	44.4%	

Applied Fisher's Exact test

Table 2: Stratification Of Gender With Respect To Early Subacute Stent Thrombosis N= 142

GENDER		EARLY SUBACUTE STENT THROMBOSIS		P-VALUE
		Yes	No	
MALE	Count	3	100	1.00
	% of Total	2.1%	70.4%	
FEMALE	Count	1	38	
	% of Total	0.7%	26.8%	

Applied Fisher's Exact test

Table 3: Stratification For Duration Of Surgery With Respect To Early Subacute Stent Thrombosis N= 142

DURATION (In Minutes)		EARLY SUBACUTE STENT THROMBOSIS		P-VALUE
		Yes	No	
30----45	Count	1	106	0.046
	% of Total	0.7%	74.7%	
>45	Count	3	32	
	% of Total	2.1%	22.5%	

Applied Fisher's Exact test

Table 4: Stratification Of Weight With Respect To Early Subacute Stent Thrombosis N= 142

WEIGHT (In kg)		EARLY SUBACUTE STENT THROMBOSIS		P-VALUE
		Yes	No	
45---60	Count	1	111	0.03
	% of Total	0.7%	78.2%	
>60	Count	3	27	
	% of Total	2.1%	19.0%	

Applied Fisher's Exact test

Table 5: Stratification Of Height With Respect To Early Subacute Stent Thrombosis N= 142

HEIGHT (In m)		EARLY SUBACUTE STENT THROMBOSIS		P-VALUE
		Yes	No	
1.5---1.8	Count	3	115	0.527
	% of Total	2.1%	81%	
>1.8	Count	1	23	
	% of Total	0.7%	16.2%	

Applied Fisher's Exact test

Table 6: Stratification Of Bmi With Respect To Early Subacute Stent Thrombosis N= 142

BODY MASS INDEX (In kg/m^2)		EARLY SUBACUTE STENT THROMBOSIS		P-VALUE
		Yes	No	
18.5---27	Count	2	102	0.291
	% of Total	1.4%	71.8%	
>27	Count	2	36	
	% of Total	1.4%	25.4%	

Applied Fisher's Exact test

Table 7: Stratification Of Hypertension With Respect To Early Subacute Stent Thrombosis N= 142

HYPERTENSION		EARLY SUBACUTE STENT THROMBOSIS		P-VALUE
		Yes	No	
YES	Count	4	64	0.05
	% of Total	2.8%	45.1%	
NO	Count	0	74	
	% of Total	0%	52.1%	

Applied Fisher's Exact test

Table 8: Stratification Of Diabetes Mellitus With Respect To Early Subacute Stent Thrombosis N= 142

DIABETES MELLITUS		EARLY SUBACUTE STENT THROMBOSIS		P-VALUE
		Yes	No	
YES	Count	4	61	0.04
	% of Total	2.8%	43.0%	
NO	Count	0	77	
	% of Total	0%	54.2%	

Applied Fisher's Exact test

Table 9: Stratification Of Smoking Status With Respect To Early Subacute Stent Thrombosis N= 142

SMOKING STATUS		EARLY SUBACUTE STENT THROMBOSIS		P-VALUE
		Yes	No	
YES	Count	0	100	0.007
	% of Total	0%	70.4%	
NO	Count	4	42	
	% of Total	2.8%	26.8%	

Applied Fisher's Exact test

DISCUSSION

Coronary stenting has opened new dimensions in interventional cardiology.[3] The main findings of the present study show no differences in outcome for patients with large coronary vessels treated by BMS or DES. BMS implantation in large coronary vessels appears equally effective as DES implantation even after adjustment for stent diameter and stent length.

Patients with vessels >3.5 mm in diameter represent a low-risk population in whom BMSs confer a similarly low event rate as DESs. Clinically driven target lesion revascularization rates of 3% for BMS versus 7% for DES at six months, were almost equally low in the 2 populations. Stent thrombosis did not occur in either group, despite thienopyridine discontinuation after 1 month in the BMS group and after ≥ 6 months in the DES group.

Our findings are similar to the previous research. Vessel diameter influences restenosis rates with BMSs,[16] and in the SIRolImUScoated stent in treatment of patients with de novo coronary artery lesions (SIRIUS) trial, multivariate analysis demonstrated an increased risk of

restenosis with smaller vessel diameters.[4] Further, subgroup analysis in TAXUS-IV demonstrated that the significant benefit of DESs over BMSs was limited to vessels <3.0 mm.[6] Our study supports the hypothesis that DESs do not have an edge over BMSs for larger vessels. It stands to reason that, given a similar degree of neointimal proliferation around a stent of any diameter, neointimal growth occurring in large vessels would be less likely to cause clinically or angiographically significant restenosis. With regard to BMSs, even a late loss of 1 mm (rarely seen with the new generations of BMSs) in a ≥3.5 mm vessel would render a 2.5 mm diameter vessel at long-term follow up. This translates into binary restenosis of <50% and sufficient patency that neither compromises hemodynamics nor requires further intervention.

In our study the Mean ± SD of age was 55.56±12.24 years with male to female ratio was (1:2.6). Mean ± SD for duration of surgery was 33.48±9.26 minutes with 27.56±6.28 kg/m^2 BMI and frequency of early acute stent thrombosis was found to 2.8%. Baber U, et al.[17] conducted a retrospective cohort study at a tertiary care university hospital in Karachi, Pakistan. A total of 277 consecutive patients undergoing primary PCI between January 2001 and December 2005 were reviewed. Cox proportional hazards models were constructed. Another study conducted by Kastrati A et al[18]; reported the frequency of acute stent thrombosis 0.8%. This study also validates the outcome of our study.

In a report form National Cardiovascular Data Registry, clinical characteristics and in-hospital outcomes were assessed in consecutive PCI cases from January 1, 2004, to March 30, 2006. The analysis cohort consisted of 308,161 patients from 465 PCIcapable facilities. The procedural success in this report was documented for primary PCI was 92% which was based on TIMI score > 2[75]. The results of our study can be compared to David J Clark[19] and colleagues who concluded that deployment of ≥3.5 mm diameter stents in large coronary arteries is associated with low rate of mortality and major adverse cardiac events (MACE) at 30 days and 1 year with DES or BMS use.

The results of our study can be compared to Bryan P.Yana[20] and colleagues who concluded that BMS implantation in large native coronary vessels ≥3.5 mm was associated with a low risk of MACE and repeat revascularization at 12 months that was comparable to DES. it showed that there were no significant differences in 12month mortality (0.5 vs. 2.9%, p=0.07), TVR (3.6 vs. 4.8%, p= 0.54), MI (6.3 vs. 3.4%, p=0.15), stent thrombosis (0.9 vs. 1.0%, p=0.88), or MACE (9.4 vs. 9.4%, p=0.90) in patients who received DES vs. BMS.In addition, Marzocchi et al[21] evaluated the effectiveness of sirolimus-eluting stents in a real-world scenario. At 9 months, they found similar rates of death and myocardial infarction, and the unadjusted major adverse cardiac event rate also showed no significant difference between the 2 groups (12.1% vs 12.3%, p=NS). Only in a pre-specified high-risk population was there a significant difference in major adverse cardiac events. The difference was entirely driven by target vessel revascularization.[22] Low-risk populations (i.e., those with large vessels) would not receive benefit from DESs. Although a wealth of data currently exist for patients with various clinical risk factors and coronary lesion subsets demonstrating relative superiority of DESs over BMSs for long-term restenosis, no study has demonstrated a mortality benefit of one approach over the other.[9,10]

Further, widespread DES implantation is not without concerns. First, DES implantation, due to inhibition of wound healing by sirolimus or paclitaxel, mandates long-term dual platelet inhibition.[11] Although it aids in decreasing in-stent restenosis and minimizing stent thrombosis, long-term thienopyridine administration exposes patients to risks of bleeding. Second, after thienopyridine discontinuation, patients are then exposed to risks of late restenosis and late stent thombosis.[9,11,12] Third, the cost of DESs is significantly higher than that of BMSs, even after 6-month follow-up and inclusion of the cost borne by subsequent events.[13] Based on these issues, it is desirable to identify populations in whom BMSs have equivalent efficacy tDESs. With target lesion revascularization rates of 3% vs. 7% at 6 months (p=NS), patients with large coronary vessels represent such a population. In our study age, gender, duration of surgery, BMI, height, weight hypertension, diabetes mellitus, and smoking status are played as a role of effect modifier of the study and we control it through stratification.

In stratification of age group 25—55 and > 55 years early sub-acute stent thrombosis was found to be 0% and 2.8% respectively which shows highly significant association between age and early subacute stent thrombosis i.e. (P=0.047).Early sub-acute stent thrombosis was found 2.1% in male and 0.7% in female which shows non-significant difference between gender and early subacute stent thrombosis i.e. (P=0.303).In stratification for duration of surgery (30----45) minutes 0.7% had early sub-acute stent thrombosis and in >45 minutes 2.1% had early sub-acute stent thrombosis and highly significant association was found i.e. (P=0.04.In comparison of weight group 45—60 and > 60 kg early sub-acute stent thrombosis was found to be 0.7% and 2.1% respectively which shows highly significant association between age and early sub-acute stent thrombosis i.e. (P=0.03).In comparison of height group 1.5—1.8 and > 1.8 meter early sub-acute stent thrombosis was found to be 2.1% and 0.7% respectively which shows non-significant association between height and early subacute stent thrombosis i.e. (P=0.527).In stratification of BMI 18.5— 27 and > 27 kg/m^2 early sub-acute stent thrombosis was found to be 1.4% each which shows non-significant association between BMI and early sub-acute stent thrombosis i.e. (P=0.291).Early sub-acute stent thrombosis was found 2.8% in hypertensive and 0% in nonhypertensive patients which shows significant association between hypertension and early sub-acute stent thrombosis i.e. (P=0.05).Early sub-acute stent thrombosis was found to be 2.8% in diabetes patients which shows significant association between diabetes mellitus and early sub-acute stent thrombosis i.e. (P=0.04).Early sub-acute stent thrombosis was found 0% in smoker and 2.8% in non-smoker which shows highly significant association between smoking and early sub-acute stent thrombosis i.e. (P=0.007). Our results correlate with all national and international studies.

Strength of our study was use of consecutive sampling best suited for our study design and sample

selection, as our inclusion and exclusion criteria were stringent. The use of objective definitions for predictor and outcome variable also minimizes the source of bias in our study. The main limitations of our study were use of a weak study design case series the analysis and strength of evidence of which is limited and therefore the study design does not require any prior sample size calculation. Also limited outcomes selected in our study affects the worth of our study. There were many variables and factors that have association with our predictor and outcome variables that could have been included in our study. The use of non-probability sampling also limits generalizability. This study was hospital-based study; hence the figure does not reflect true frequency and severity of the disease. Moreover, the study was conducted in one unit in single hospital which further confine its generalization.

CONCLUSION

It is to be concluded that frequency of early acute stent thrombosis after primary PCI was found to be 2.82%.Patients presenting with STEMI who are hemodynamically unstable and have multivesselcoronary disease undergoing coronary stenting during ACS, are at increased risk of EST.

Future prospective, there is a need to conduct randomized studies using large sample size over a longer period of time will be more representative, particularly in case of rarer disease with multiple study centers in Pakistan are needed to confirm the findings of present study. It will also nullify any regional bias due to fewer centers of treatment. Our research findings are useful for prioritizing future acute stent thrombosis research needs.

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