PROCEDURAL ANALYSIS OF PATIENTS WITH STENT THROMBOSIS (ST)

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ABSTRACT

Objective: To analyze the procedural details of patients presenting as ST and undergoing PCI.

Study Design: Descriptive study.

Place and Duration of Study: Armed Forces Institute of Cardiology – National Institute of Heart Diseases (AFIC-NIHD) from Jan 2007 to Dec 2010.

Patients and Methods: A descriptive, single center study done at AFIC Rawalpindi from Jan 2007 to Dec 2010. During this period patients with prior stenting who presented to AFIC E/R with acute ischaemic symptoms with ECG changes and had angiographically confirmed ST were studied. Their procedural details (index PCI and ST procedure) were analyzed.

Results: Over this four year study period, 7694 coronary angioplasties were carried out and 12871 stents (10633 DES and 2238 BMS) were implanted. Amongst these, 32 patients (28 males and 4 females) later had angiographically confirmed ST and were treated with PCI. Mean age was 51.57 years. Dual antiplatelet therapy (DAPT) non-compliance was not a contributory factor in our study. Coronary distribution involved in ST included 20 cases of LAD, 7 of LCX and 5 of RCA territory. Thirteen (40%) patients had overlapping stents, 11 (34.4%) had direct stenting. Average diameter of stents with ST was 2.86 mm and the average length was 24.17 mm. Incidence of ST was higher in BMS as compared to DES (p0.003). Of these 32 patients, 14 (43.75%) were treated with further stenting whereas 18 (56.25%) underwent POBA only. Telephonic follow up after second PCI was possible in only 15 cases, out of which five (33.33%) deaths were reported on the day of thrombotic procedure.

Conclusion: ST has a high mortality and there was an overall higher frequency of ST in BMS compared to DES. Acute and subacute ST were mainly related to BMS whereas late ST was more common in DES. However PCI technique i.e direct stenting and overlapping stents, was a major predictor of stent thrombosis.

Keywords: Stent, Thrombosis

INTRODUCTION

Reduction in restenosis might have been obtained at the expense of a higher incidence of ST, particularly late ST. The incidence of ST has been reported in a number of studies most of which have found an incidence of 0.5-2 % with a mortality as high as 45%[1]. ST was defined by Academic Research Consortium (ARC)[2] as under;

- Definite or confirmed event (symptoms suggestive of an acute coronary syndrome and angiographic or pathologic confirmation of ST)
- Probable event (unexplained death within 30 days or target vessel myocardial infarction without angiographic confirmation of ST)
- Possible event (any unexplained death after 30 days).

The objective of our study was to analyze the procedural details of patients presenting as ST and undergoing PCI.

MATERIAL AND METHODS

It was a retrospective, single center study done at AFIC Rawalpindi from Jan 2007 to Dec 2010. During this period patients with prior stenting who presented to AFIC E/R with acute ischaemic symptoms with ECG changes and an angiographically confirmed ST were studied. Their index PCI and post ST PCI procedural details were analyzed. Based on the elapsed time since stent implantation ST was classified as:

- Acute (within 24hrs)
- Sub-acute (after 24hrs -30 days)

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- Late (>30 days)
- Very late (>12 months)

Data was collected from the cath lab record at AFIC/NIHD Rawalpindi. Statistical package for social sciences (SPSS version 13) was used to record and analyze the data.

RESULTS

Over the period of four years 12871 stents {BMS- 2238 (17%) and DES-10633 (83%)} were placed in 7694 coronary angioplasties.

During this four year period, 32/7694 (0.4%) patients (28 males and 4 females) were treated with PCI for ST. Out of these 4 (13%) had acute, 3 (9%) had subacute and 25 (78%) had late stent thrombosis. No case of very late stent thrombosis was documented.

The mean age of patients suffering from stent thrombosis was 51.1±22 years .

Out of the 32 patients who could be followed up 12 had diabetes, 6 had hypertension, 8 had past history of MI, 10 had history of smoking , 6 were obese and only one gave history of discontinuation of dual antiplatelet therapy.

20 patients (62.5%) had stent thrombosis involving the LAD. 7 (21.8%) had involvement of LCx and 5 (15.6%) had ST involving the RCA.

Three out of thirty two (9.3%) who had stent thrombosis were originally CTOs.

The frequency of stent thrombosis was higher in BMS as compared to DES (p=0.003 using the chi square test). Stent thrombosis was documented in 18/10633 (0.2%) of all the DES used and 11/2238 (0.5%) of all the BMS used. 3 cases were those who had DES-BMS combination. (Table 1and 2)

All 4 /4 acute ST, 2/3 subacute ST and 5/25 late ST occurred in BMS whereas 1/3 subacute ST and 20/25 late ST involved DES. Hence acute and subacute ST were common in BMS and late ST was more frequent in DES.

The average diameter of stents with ST was 2.86 mm and the average length was 24.17 mm. (Fig. 1 and 2)

Amongst these 32 cases, 13 patients (40.6%) had overlapping stents , 11 (34.4%) had direct stenting. (Table 3)

Out of these 32 ST cases 14 (43.75%) were treated with further stenting whereas 18 (56.25%) had POBA only. Thrombuster was

Table-1: ST frequency among individual DES

DES Type (Trade Names)	Frequency of ST	Percentage
Nobori	1/131	0.76%
Active	2/349	0.57%
Xience Prime	2/358	0.55%
Pico	1/281	0.35%
Biomatrix	3/1207	0.24%
Axxion	1/408	0.24%
Cypher	2/1235	0.16%
Coroflex Please	1/684	0.14%
Excel	3/2099	0.14%
Endeavour	1/1048	0.01%
Xience	1/2645	0.03%
Others	0/188	0.00%
DES (drug type)	**Frequency of ST**	**Percentage**
Paclitaxel	5/1686	0.30%
Rapamycin	3/2099	0.20%
Biolimus	4/1508	0.19%
Sirolimus	2/1245	0.16%
Zotarolimus	1/1069	0.09%
Everolimus	3/3023	0.06%
Tradipil	0/0003	0.00%

Table:2- ST Frequency among individual BMS

BMS	Frequency of ST	Percentage
Tsunami	3/437	0.68%
Coroflex Blue	3/456	0.65%
Vision	1/460	0.21%
Gazelle	2/90	0.02%
R Stent	2/188	0.011%
Others (Apolo, Driver, Genous, Prokinetic).	0/607	0.0%

Table-3: Yearly frequency of ST and overlapping stents

Yearly ST Dist 2007	06/1529 (0.4%)
2008	06/1827 (0.3%)
2009	07/2093 (0.3%)
2010	11/2245 (0.5%)
Overlapping Stents	13 (40.6%)
DES DES overlap	7
• Rapamycin +Rapamycin	3
• Biolimus + Biolimus	1
• Biolimus + Paclitaxel	1
• Rapamycin + Paclitaxel	2
BMS BMS overlap	3
DES BMS overlap	3

used in 7 of these cases. All 32 patients received intravenous GP IIbIIIa inhibitor infusions but 25 cases also had additional intracoronary boluses.

Out of 15 patients followed up, five deaths were recorded.

DISCUSSION

Since the first angioplasty performed in 1977 by Gruntzig[3], BMS significantly reduced the risk of acute vessel closure but only provided a limited solution to the emerging problem of restenosis[4,5]. Drug-eluting stents (DESs) dramatically reduced the rate of restenosis;[6] however, they were thought of as a trade-off with regard to the higher risks of stent thrombosis. The stent polymer and antiproliferative properties of DES impair/ delay endothelialization such that blood is exposed to thrombogenic stent struts, potentially precipitating ST.

The incidence of stent thrombosis following BMS or DES implantation is different in different studies. The introduction of thienopyridins, dramatically reduced the rate of acute and sub-acute stent thrombosis. In a meta-analysis, Cutlip[7] included a total of 6186 patients and the incidence of BMS thrombosis in this meta-analysis was 0.9%. In the initial randomized clinical trials, the incidence of DES thrombosis was less than 1% (0.4% at 1 year in the Sirolimus-Eluting Stent [SIRIUS] study[5] and 0.6% at 9 months in the TAXUS IV study[8] . In our study the overall incidence of stent thrombosis was 0.4% which does not actually reflect the true incidence at our Hospital. This value is less because of certain study limitations. Our's study being a retrospective data analysis, could not follow all the patients who actually had coronary angioplasty during the four year period. Only those patients who had angiographically proven stent thrombosis were included. The patients who may have presented to other hospital settings could not be followed up.

Camenzind *et al*. presented a pooled analysis of randomized clinical trials that found a trend toward more frequent death and Q wave MI for SESs (but not for paclitaxel-eluting

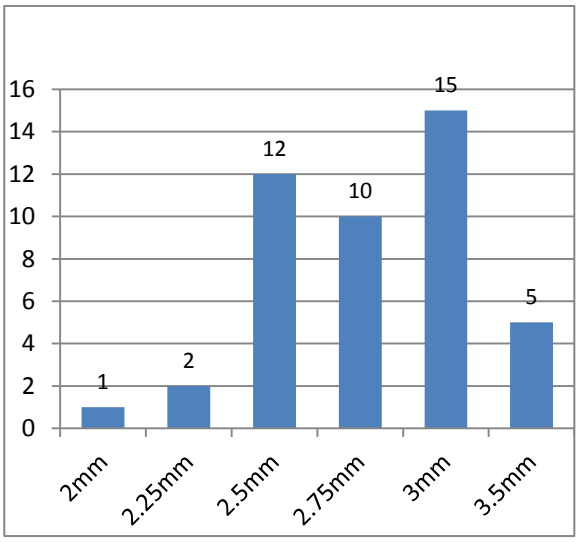

Fig. 1: Stent diameters involved in ST

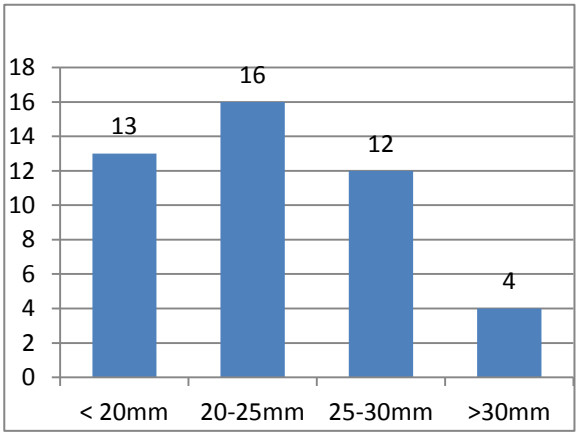

Fig. 2: Stent lengths involved in ST

stents) compared with BMSs.[9] These results were consistent with a recent meta-analysis showing a significant increase in late thrombosis with DESs compared with BMSs.[10] Our study also confirms the same finding of increased incidence of late ST with DES (20/25 cases of late ST) as compared to BMS (5/25 cases of late ST). However in our study the overall frequency of stent thrombosis was higher in BMS than DES (p=0.003) but this incresed BMS frequency actually mainly comprised acute and subacute ST.

ST is a multifactorial problem related to patient, lesion, procedural factors, coagulation system and response to antiplatelet therapy. ACT checks during PCI, proper anticoagulation and proper preloading with dual anti platelets are extremely vital to prevent acute ST. Pre

discharge counselling regarding regular use of dual antiplatelets should be emphasized. In the procedure technique, stent length and diameter are independent risk factors for ST. Suh et al.[11] document that, when stents 31.5 mm in length are used, there is an increased risk of LST, MI, and death. While in our study the average stent length in patients encountering stent thrombosis was 22.29mm with 78% presented as late ST. Among individual DES almost comparable frequencies of stent thrombosis were encountered. In our study higher incidence of ST in overlapping stents probably indicates the increase in metal length and also the fact that adequate high pressure may not have been given to the overlapped stent segments.

STUDY LIMITATIONS

Being a retrospective descriptive analysis the possible contributory comorbid conditions and platelet sensitivity could not be studied.

IVUS was not used during the procedures giving very little insight into possible contributory technical factors like stent under deployment and edge dissections but for a third world country cost constraints remain a big hurdle.

CONCLUSIONS

ST has a high mortality and there was an overall higher frequency of ST in BMS compared to DES. Acute and subacute ST were mainly related to BMS whereas late ST was more common in DES. However PCI technique i.e direct stenting and overlapping stents, was a major predictor of stent thrombosis.

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