Stent Thrombosis is a major concern in clinical practice, a single Saudi center experience

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# ARC Definitions

## Level of Certainty

<table>
<thead>
<tr>
<th>Definite</th>
<th>Early</th>
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<tr>
<td>Angiographic or pathologic confirmation of partial or total thrombotic occlusion within the peri-stent region AND at least ONE of the following, additional criteria:</td>
<td>Acute (&lt;24 hrs)</td>
</tr>
<tr>
<td>Acute ischemic symptoms</td>
<td>Subacute (24 hrs – 30 d)</td>
</tr>
<tr>
<td>Ischemic ECG changes</td>
<td>Late</td>
</tr>
<tr>
<td>Elevated cardiac biomarkers</td>
<td>31 d – 1 yr</td>
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## Probable

*Any unexplained death <30 days of stent implantation*

*Any MI related to documented acute ischemia in the territory of the implanted stent w/o angiographic confirmation of stent thrombosis and in the absence of any other obvious cause*

## Possible

*Any unexplained death beyond 30 day*
• IVUS studies showed that the majority of stents were inadequately implanted and that this could be improved by adjunct high pressure balloon inflation

• Stent thrombosis was reduced by the recognition that this was a platelet mediated event which responded to Rx with thienopyridines plus aspirin – initially with ticlopidine and later clopidogrel
Predictors of Thrombosis After Successful Implantation of DES

- Diabetes: 2.5%
- Unprotected LMCA: 3.3%
- Bifurcation lesion: 3.6%
- Bifurcation with 2 stents: 3.9%
- Renal failure: 6.2%
- Prior brachytherapy: 8.7%
- Premature Antiplatelet Therapy Discontinuation: 20.4%

Incidence of Stent Thrombosis (%)
Premature Discontinuation of Thienopyridine Therapy After DES Implantation

- Multicenter, prospective PREMIER registry in patients admitted with myocardial infarction
  - 500 DES patients enrolled at 19 sites
  - 68 (14%) patients d/c thienopyridine

Factors associated with premature Thienopyridine discontinuation
- older age
- lower socioeconomic status
- preexisting cardiovascular disease
- inadequate discharge instructions
- lack of referral to cardiac rehab

Mortality Between 30 Days and 1 Year

- Death: HR=9.0, P<0.001
- Rehosp.: HR=1.5, P=0.08

Off Thienopyridine
- Death: 7.5%
- Rehosp.: 23%

On Thienopyridine
- Death: 0.7%
- Rehosp.: 14%
Antiplatelet Therapy and DES

• Adequate inhibition of platelet aggregation during and after PCI
• Compliance with dual antiplatelet therapy particularly during the first 6 months after stent implantation
• Whether dual antiplatelet therapy beyond 12 months prevents very late ST, is associated with a lower rate of ischemic cardiovascular events, and has a favorable net clinical benefit (balance of ischemic vs. bleeding events) requires confirmation in randomized, prospective trials
• Individualize decision to prolong dual antiplatelet therapy beyond 6-12 months according to risk profile
  ▪ diabetes, multivessel disease, previous MI
• Prasugrel may become an attractive alternative to clopidogrel in patients undergoing PCI
Stent Thrombosis After SES Implantation in Diabetic vs Non-Diabetic Patients

**Stent Thrombosis**

![Graph showing stent thrombosis rates in diabetic and non-diabetic patients](image)

- **Diabetic (N=844)**: 2.3%
- **Non-Diabetic (N=887)**: 0.8%

Logrank p = 0.03

<table>
<thead>
<tr>
<th>Follow-up (days)</th>
<th>Diabetic (pts)</th>
<th>Non-diabetic (pts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>859</td>
<td>847</td>
<td>823</td>
</tr>
<tr>
<td>437</td>
<td>210</td>
<td>125</td>
</tr>
<tr>
<td>755</td>
<td>202</td>
<td>135</td>
</tr>
</tbody>
</table>

Red: Single Vessel CAE
Blue: Multivessel CAE
“We have shown that in humans delayed healing is common with current DES and that in those that thrombose, other factors, such as hypersensitivity reaction, bifurcating and ostial stenting, penetration of a necrotic core, stent malapposition, and restenosis, may also be important predictors of thrombosis.”
DES Implantation Technique

- Residual dissections
  - Most important predictor of early ST
  - Do not leave residual dissections untreated
- Inadequate stent expansion
  - Risk factor for early ST
  - Correlates with stent length and calcifications
  - Ensure full stent deployment over entire stent length
  - Liberal use of high pressure post-dilatation
- Excessive stent hardware
  - Long stents, stent overlap, and bifurcation stenting
  - Risk factor for early ST
  - A precautionary attitude to refrain from excessive overall stent length ("full metal jacket") and multiple stent overlap advisable
  - Provisional side branch stenting preferred
  - Avoid crush technique
Before implanting a DES, the interventional cardiologist should discuss with the patient the need for and duration of dual antiplatelet therapy (DAT) and confirm the patient’s ability to comply with the recommended therapy for DES.

In patients who are undergoing preparation for PCI and are likely to require invasive or surgical procedures for which DAT must be interrupted during the next 12 months, consideration should be given to use a BMS or performance of balloon angioplasty with provisional stent implantation.
## Stent Thrombosis and Restenosis During Extended Follow-up of Pts Treated With BMS (n=4503)

<table>
<thead>
<tr>
<th></th>
<th>1 Year % (95% CI)</th>
<th>5 Years % (95% CI)</th>
<th>10 Years % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All stent thrombosis</td>
<td>0.8 (0.6-1.1)</td>
<td>1.3 (1.0-1.7)</td>
<td>2.0 (1.5-2.5)</td>
</tr>
<tr>
<td>On-label patients</td>
<td>0.6 (0.2-0.9)</td>
<td>1.0 (0.5-1.2)</td>
<td>1.4 (0.9-2.0)</td>
</tr>
<tr>
<td>Off-label patients</td>
<td>1.1 (0.7-1.5)</td>
<td>1.7 (1.2-2.2)</td>
<td>2.5 (1.7-3.3)</td>
</tr>
</tbody>
</table>

### %Stent Thrombosis

- **30 Days**: 0.5
- **1 Year**: 0.8
- **5 Years**: 1.3
- **10 Years**: 2.0

↑ Mortality Risk: HR=22, P<0.001

### %MI Due to Restenosis

- **1 Year**: 1.0
- **5 Years**: 1.8
- **10 Years**: 2.1

↑ Mortality Risk: HR=2.4, P<0.001
Multifactorial Nature of DES Thrombosis

**Device factors**
- Surface
- Drugs
- Polymer
- Stent overlap

**Procedural factors**
- Dissection
- Incomplete stent apposition
- Stent expansion

**Lesion factors**
- Vessel size/length
- Thrombus
- Plaque characteristics
- Bifurcation
- Calcification
- Total occlusions

**Patient factors**
- Drug response/interactions
- Gene polymorphism
- LV function
- Acute coronary syndrome
- Renal failure
- Diabetes

**Platelet and Coagulation factors**
- Coagulation activity
- Inhibition of platelet aggregation
- Inadequate response to anti-platelet therapy
- Premature anti-platelet therapy discontinuation
Early Stent Thrombosis

Meta-analysis
SES vs BMS
Bavry A et al. Am J Card 2005

RR = 0.76
95% CI = 0.30 - 1.80
P = 0.55

Meta-analysis
PES vs BMS
Stone G et al. NEJM 2007

RR = 0.80
95% CI = 0.32 - 2.03
P = 0.79
Late Definite ST (1 Month - 1 Year)
Drug-Eluting vs Bare Metal Stents

63 late ST cases (0.4%) of 18,023 patients

BMS (N=4822) 0.41
PES (N=5178) 0.39
SES (N=5673) 0.41
Pooled Analysis of Data Comparing SES With BMS
Estimated 4-year cumulative incidence of stent thrombosis, death, MI, and TLR
Pooled Analysis of Data Comparing PES With BMS

Estimated 4-year cumulative incidence of stent thrombosis, death, MI, and target lesion revasc.

- **Stent Thrombosis (%)**
  - Paclitaxel stent (1.3%)
  - Bare-metal stent (0.9%)
  - *P* = .30

- **Death (%)**
  - Bare-metal stent (6.6%)
  - Paclitaxel stent (6.1%)
  - *P* = .68

- **Myocardial Infarction (%)**
  - Paclitaxel stent (7.0%)
  - Bare-metal stent (6.3%)
  - *P* = .66

- **Target-Lesion Revascularization (%)**
  - Bare-metal stent (20.0%)
  - Paclitaxel stent (10.1%)
  - *P* < .001
Stent Thrombosis is a major concern in clinical practice, a single Saudi center experience

- Mohammed Balghith
- Ali Alghamdi
- Kamal Ayoub
- Amir Saleh
- Mohammed Aziz
- Monirah algahtany
Background

- The Drug-eluting stents (DES) are used in the majority of patients who undergo percutaneous coronary intervention (PCI).
- DES has reduced the rate of in-stent restenosis and repeated revascularization as compared with bare metal stents.
- However, Stent thrombosis is an uncommon but a serious complication of coronary artery stents that almost always presents as death or a large non-fatal myocardial infarction (MI), usually with ST elevation.
Objective

• To study the incidence of Stent thrombosis (ST) in middle eastern Saudi patients

• ST can occur acutely (within 24 hours), sub acutely (within 30 days), or as late as one year (late) or even more than 1 year (very late) in pt who underwent PCI using both DES and BMS.
Methods

- Observational, single center study in cath lab a total of 1386 patients underwent Percutaneous coronary intervention PCI between Jan 2008 and Sep 2010,
- All patients in that period were included in this study, Acute coronary syndrome and stable CAD patients
Results

- Total of 1386 patients had PCI and stents deployment,
- 19 (1.3%) patients had Stent Thrombosis
- 4 patients (21%) received BMS
- 15 patients (79%) received DES
- 9 patients (47%) have DM
- 8 patients (42%) have Hypertension
Results

• Acute ST in 4 patients
• Subacute ST in 5 patients,
• Late ST in 8 patients
• Very late in 2 patients
In the chart, the number of PCI cases is 1386, which is significantly higher than the 19 (1.3%) cases of ST.
Patients with ST

- **15 (79%)** DES
- **4 (21%)** BMS
Conclusion

- The incidence of ST in our Saudi patients who received DES is similar to international reported numbers.
- Half of ST patients are diabetics.
- There is increasing concern that the risk for late stent thrombosis is slightly higher with DES than BMS in this study.