Subacute Stent Thrombosis After Successful Placement of Sirolimus-Eluting Coronary Stents: Real-World Experience

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Background: Subacute stent thrombosis (SAT) is a rare but devastating complication of intracoronary stent implantation. The incidence with potent anti-platelet therapy has been reported to be between 0.5-1.9%. Recently, the sirolimus-eluting Cypher™ stent was introduced in the US. The randomized SIRIUS trial reported a 0.4% rate of SAT. However, the Food and Drug Administration has received 47 reports of SAT that occurred in clinical practice and the manufacturer has subsequently issued a warning letter. The aim of this study was to evaluate the incidence and potential risk factors of SAT in patients receiving the sirolimus-eluting stent outside of clinical trials.

Methods: Since the commercial introduction of Cypher™ stents to the US in April 2003, all patients that received sirolimus-eluting stents at our institution were followed in a registry. Percutaneous coronary intervention was performed using standard techniques. All patients were treated with aspirin pre- and clopidogrel or ticlopidine if ticlopidine was contraindicated. The primary endpoint of the study was the incidence of SAT at 30 days. Results: A total of 456 patients underwent implantation of 608 sirolimus-eluting stents. The mean stent diameter was 2.8±0.3 mm and the mean stent length was 19.7±5.7 mm. There were no cases of SAT during the index hospitalization, with 4 cases reported after discharge during the first 30 days post-stenting (mean onset 9±4 days). There was no apparent difference in stent diameter (2.6±0.2 mm) or stent length (19.7±6.1 mm) between patients with SAT and the rest of the population.

Conclusion: Even in ‘real world’ patients, the incidence of SAT after sirolimus-eluting stent implantation is less than 1%, and within the expected range for bare metal stents. The discontinuation of anti-platelet therapy appears to be the most important risk factor for the development of SAT.

Comparative Incidence of Angiographically Proven Early Stent Thrombosis in Unselected Sirolimus- and Paclitaxel-Eluting Stent Populations

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Background: The true incidence of early stent thrombosis after sirolimus or paclitaxel-eluting stent (PES) implantation in an unselected group is at present controversial. So far, the randomized SIRIUS trial showed a rate of early stent thrombosis in the sirolimus-eluting Cypher™ stent group of 0.4%. However, the Food and Drug Administration has received 47 reports of early stent thrombosis to date.

Methods: We report the incidence of early stent thrombosis in both PES stents. The study included all patients that received sirolimus-eluting stents at our institution. The population included 1000 consecutive patients undergoing percutaneous coronary intervention at our institution.

Results: The incidences of early stent thrombosis are as follows:

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Incidence</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bare stent</td>
<td>5/500</td>
<td></td>
</tr>
<tr>
<td>SES</td>
<td>9/1000</td>
<td>5/500</td>
</tr>
<tr>
<td>PES</td>
<td>1.0%</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

Conclusion: The incidence of early stent thrombosis after sirolimus-eluting and paclitaxel-eluting stent implantation in unselected patients in a real world setting is comparable to historical bare stent controls in the real world population of unselected patients. The study indicates that the incidence of early stent thrombosis after sirolimus-eluting stent is 0.9%.

Late Four-Year Follow-Up From the First-In-Man Experience After Implantation of Sirolimus-Eluting Stents

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Background: Short-term (4-months) and intermediate-term (2-year) results after implantation of sirolimus-eluting (Cypher™) stent in human coronary arteries have been reported. Between 4 to 24 months intramural hyperplasia was consistently suppressed as assessed by follow-up MLD that showed minimal changes, and IVUS percent obstruction volume that increased minimally from 0.3±0.8% to 3.3±8.4%. The aim of this study is to determine if deleterious pathobiologic responses are present after a long (4-year) follow-up.

Methods: Sixty-three patients treated with Cypher™ stents for single de novo coronary lesions (15 fast-release and 15 slow-release formulation) will complete 4-year follow-up in February, 2004. Clinical follow-up and stress test will be performed in all patients.

Results: At present (45±2 months) there has been 3 cardiac events: one pt presented with acute MI at 14 months due to non-target site coronary occlusion proximal to the Cypher™ stent. Serial IVUS interrogation of this Mi culprit lesion demonstrated plaque progression with eccentric lumen narrowing. This pt was treated with another Cypher™ (TRL). Therefore, for the entire patient cohort, the mean±SD follow-up time is 40±2 months. Three of the 4 patients discontinued anti-platelet therapy after discharge in one patient the sirolimus-eluting stent was implanted in the setting of an acute myocardial infarction. A total of 456 patients underwent implantation of 608 sirolimus-eluting stents. The mean stent diameter was 2.8±0.3 mm and the mean stent length was 19.7±5.7 mm. There were no cases of SAT during the index hospitalization, with 4 cases reported after discharge during the first 30 days post-stenting (mean onset 9±4 days). There was no apparent difference in stent diameter (2.6±0.2 mm) or stent length (19.7±6.1 mm) between patients with SAT and the rest of the population.

Conclusion: This is the first study to demonstrate that both SES and PES are safe and likely to remain more expensive than CABG during long term follow up.