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 immediately post-procedure. 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 18.7±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. Three of the 4 patients discontinued anti-platelet therapy after hospital discharge and in one patient the sirolimus-eluting stent was implanted in the setting of an acute myocardial infarction.

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.

862-5
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 intimal 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: Thirty 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 echo-lucent zones suggesting plaque instability. Another pt with a bifurcation lesion presented at mid circumflex coronary artery as a result of plaque rupture at stent implantation. The third patient presented with lesion progression at the proximal edge of a Cypher™ stent implanted at a proximal RCA two years after the index procedure. This pt was treated with another Cypher™ (TLR). Therefore, for the entire patient cohort, the freedom from major cardiac events is 90%.

Conclusion: Thusfar, in the FIM experience, the sirolimus-eluting Cypher™ stent has demonstrated safety and efficacy up to 45-month follow-up, with low rates of major cardiac events. The complete 4-year follow-up results (available for presentation) should definitively establish long-term safety and efficacy of SES.