Clinical Trials
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TCT-346

First Five-Year Clinical Follow-Up from a Randomized Trial of a Polymer-Based, Paclitaxel-Eluting Stent: TAXUS I

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Background: As the first human study evaluating the polymer-based, paclitaxel-eluting, slow-release (TAXUS-SR) stent (Boston Scientific, Natick, Mass.), TAXUS I showed stable safety profiles and sustained reductions in target lesion revascularization through 4 years post-implantation. Designed to follow all patients for a total of 5 years, we now present results from the final 5-year clinical follow-up.
Methods: TAXUS I was a blinded, prospective, controlled, multicenter, randomized study enrolling 61 patients with single de novo or restenotic coronary lesions. Thirty-one patients received the TAXUS-SR stent and 30 received an identical appearing bare metal stent (Control). The composite clinical endpoint of major adverse cardiac events (MACE: cardiac death, myocardial infarction, and target vessel revascularization) and stent thrombosis were assessed at 1, 6, 12, 24, 36, and 60 months post-implantation.
Results: The cumulative 4-year MACE rate was 3.23% in the TAXUS group (1/31) versus 13.33% (4/30) for Controls (p=0.20). The single MACE in TAXUS was a target vessel revascularization occurring distal to the mid RCA target lesion at 200 days post index procedure in the distal RCA. No new MACE occurred in TAXUS or Control between 1 and 4 years post index procedure. No cases of stent thrombosis were reported in either treatment group through 4 years follow-up. The final study results including 5-year clinical follow-up data will be presented for the first time in October 2006.
Conclusions: This study describes the longest follow-up with polymer-based paclitaxel-eluting TAXUS stents. Absence of stent thrombosis through 4 years and no new MACE after 1 year post stent implantation extend the long-term safety pattern in TAXUS I. The 5-year analysis will further examine the durability of clinical safety over time and provide insight into whether restenosis reduction in this first-in-man study of the TAXUS-SR stent is sustained through extended long-term follow-up.

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Sirolimus-Eluting Stent Implantation for the Percutaneous Treatment of Unprotected Left Main Coronary Artery Disease: A Clinical Analysis Based on J-Cypher Registry

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Background: The role of stenting in the treatment of left main coronary artery (LMCA) disease using sirolimus-eluting stent (SES) remains controversial.
Methods: Design of this registry was multi-center prospective enrollment of consecutive patients from 40 centers in Japan. From Aug 2004 to Feb 2006, 293 patients received SES for the treatment of unprotected LMCA and followed for 30 days, and 179 patients achieved 6 month follow-up. Patients were divided into two groups of single-stent approach [stenting only in main branch; group S; 214 patients (68%)] and two-stents approach [stenting both in main and side branch; group T; 79 patients (32%)]. Two strategies were selected according to the operators' discretion. We compared 30 days and 6 months mortality rates of both strategies.
Results: Procedural successes were achieved in all patients. In group T, distal LMCA diseases were more commonly observed (96% vs. 66%, P<.0001). Mean LVEF was comparable between the two groups (54% vs 56%, NS). The mortality rates according to the strategies are shown in table.

Mortality rates after stenting at unprotected LMCA according to the strategies			
	30 days		6 months
	Death/Cardiac death/ Sudden death (%)		Death/Cardiac death/ Sudden death (%)
All cases		All cases	
Total (n = 293)	2.1/1.4/1.0	Total (n = 178)	7.9/3.4/1.7
Group S (n = 214)	0.5/0.0/0.0	Group S (n = 125)	7.2/2.4/0.8
Group T (n = 79)	6.3/5.1/3.8	Group T (n = 53)	9.4/5.7/3.8
Elective cases		Elective cases	
Total (n = 247)	1.2/0.8/0.8	Total (n = 145)	4.1/2.1/1.4
Group S (n = 181)	0.6/0.0/0.0	Group S (n = 103)	2.9/1.0/0.0
Group T (n = 66)	3.0/3.0/3.0	Group T (n = 42)	7.1/6.8/4.8

Conclusions: In our population, SES implantation for unprotected LMCA disease was safe with regard to immediate and mid-term mortality rate. In two-stents approach, the incidences of sudden cardiac death appeared to be relatively high. Because event numbers are too small to analize the difference of the mortality rate between the two strategies, further enrollment of patients and longer term follow-up are needed.

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Pooled Analysis of the Incidence of Stent Thrombosis With the Endeavor Zotarolimus-Eluting Stent System in 1,317 Patients

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Background: Among patients treated in clinical trials with the phosphorylcholine polymer-based, cobalt alloy Endeavor stent eluting zotarolimus, we examined the frequency and clinical implications of stent thrombosis.
Methods: Clinical and angiographic outcomes were analyzed in systematic overview of four trials: Endeavor I first-in-human study; Endeavor II randomized controlled study (comparison with bare metal stent); Endeavor II continued access (CA) registry; and Endeavor III randomized trial (comparison with sirolimus-eluting stents). In all protocols stent thrombosis was defined as (1) the occurrence of angiographically determined thrombus or subacute closure in the target vessel or (2) MI in the target vessel or (3) any death not attributed to a noncardiac cause within 30 days of the index procedure. It is also possible to apply a broader definition that adjudicates all cardiac deaths as either definite, possible or cannot exclude stent thrombosis events in the absence of angiographic or post-mortem confirmation.
Results: A total of 1,317 patients were treated with the Endeavor stent in 4 randomized clinical trials. Following revascularization, patients received aspirin and clopidogrel for a minimum of 3 months per protocol. Overall, the mean stent length was 22.7 mm; mean lesion length, 14.6 mm; mean reference diameter, 2.73 mm. Most lesions (72.6%) were classified as type B2/C, and 22.5% of patients had diabetes. Overlapping/multiple stents occurred in approximately 100 patients. The cumulative 12-month rate of stent thrombosis (per protocol) was 0.3% (N=4). No episodes of stent thrombosis occurred beyond 14 days post-procedure. Independent adjudication of all cardiac deaths