TCT-657
Multi Center, Prospective, Randomized, Single Blind, Consecutive Enrolment Evaluation Of Elixir DESyneTM Novolimus-Eluting Coronary Stent System With Durable Polymer To Endeavor Zotarolimus-Eluting Coronary Stent System: 3-Year Clinical and 9-Month Angiographic And IVUS Results: EXCELLA II Study
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Background: Aims: To evaluate safety and effectiveness of the Elixir DESyneTM Novolimus-Eluting Coronary Stent System (CSS) compared to the Endeavor Zotarolimus-Eluting CSS through assessment of clinical, angiographic, and IVUS endpoints.

Methods: 210 patients were randomized 2:1 either to the DESyne CSS loaded with 5mcg per mm of stent length of Novolimus, a sirolimus metabolite, eluted via a durable methacrylate polymer, or to the Endeavor CSS loaded with 10mcg per mm of stent length of Zotarolimus eluted via a durable phosphoryl choline polymer. All patients were analyzed for the primary endpoint of late lumen loss (LLL) assessed by QCA at 9 months. All patients also underwent evaluation for secondary endpoints which included a Device-orientated Composite Endpoint (DoCE) defined as: cardiac death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularization (TLR); and stent thrombosis all assessed at 1, 6, 9, and 12 months and annually through 5 years. Stents were also assessed for angiographic endpoints at 9 months including: in-stent and in-segment LLL. A subset of patients underwent IVUS evaluation including percent neointimal obstruction at 9 months. The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control.

Results: Table 1 summarizes 9-month angiographic and IVUS results and clinical results through 2 years which trend lower for the DESyne stent.

Table 1: 9-month Angiographic, IVUS and Clinical Results

<table>
<thead>
<tr>
<th>DESyne</th>
<th>Endeavor</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline RVD (post-procedure)</td>
<td>2.84 ± 0.43</td>
<td>2.91 ± 0.38</td>
</tr>
<tr>
<td>9-month angiographic/IVUS</td>
<td></td>
<td></td>
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<tr>
<td>In-stent LLL</td>
<td>0.11 ± 0.32</td>
<td>0.63 ± 0.42</td>
</tr>
<tr>
<td>% neointimal volume</td>
<td>4.5 ± 5.1</td>
<td>20.9 ± 11.3</td>
</tr>
<tr>
<td>Clinical Results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-month DoCE (%)</td>
<td>4.3</td>
<td>7.0</td>
</tr>
<tr>
<td>Clinically-indicated TLR</td>
<td>1.4</td>
<td>5.6</td>
</tr>
<tr>
<td>24-month DoCE (%)</td>
<td>4.3</td>
<td>9.0</td>
</tr>
<tr>
<td>Clinically-indicated TLR</td>
<td>1.4</td>
<td>7.0</td>
</tr>
</tbody>
</table>

Conclusions: The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control. Clinical results through 3 years and a review of angiographic and IVUS results will be presented.

TCT-658
Do Drug Eluting Stents Improve Survival in All Comers?
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Background: Drug eluting stents (DES) have been shown to significantly decrease restenosis with subsequent need for lesion and/or vessel revascularization when compared with bare metal stents (BMS) in selected patient groups in both randomized controlled trials and in observational registries. If their use in all-comers is also associated with a survival benefit over a longer follow-up is controversial.

Methods: Retrospective analysis of the MADIS registry for patients who underwent PCI with BMS between 1 January 1997-December 31 1998 (pre DES era, group 1; N-
190435), and patients who underwent PCI with BMS (group 2; N=12559) and DES (group 3; N=19346) between January 2003- December 31 2004 (DES era). All cause and cardiovascular mortality was followed for all groups for 5 years. Results: At 5 year follow up the unadjusted all-cause mortality was significantly higher in group 2 (18.41%; p<0.003) when compared with group 1 (14.01%) and group 3 (13.27%). The unadjusted cardiovascular mortality was significantly lower in group 3 (8.60% in gr 1 and 9.01% in gr 2; p<0.0001). After adjustment for baseline characteristics such as age, sex, race, diabetes, hypertension, renal disease, anemia, cancer, cerebrovascular disease and left ventricular dysfunction there was a survival benefit associated with DES; the hazard ratios for total mortality and cardiovascular mortality were 0.74 (95% CI 0.70 to 0.78; p<0.0001) and 0.58 (95% CI 0.53 to 0.63; p<0.0001) respectively. For the patients from group 3 there was a significant survival benefit for cardiovascular mortality (HR 0.83; CI 0.77-0.90; p<0.0001) but not for total mortality (HR 0.96; CI 0.91-1.02; p=0.16) after adjustment for baseline characteristics. Conclusions: In contemporary practice there appears to be a baseline selection bias in the choice of stent type used during a PCI with BMS being preferentially used in sicker patients. This translates in a survival benefit in patients receiving DES, which may explain the discrepancies in survival between stent registries and RCT.

TCT-659
Trends in Revascularization and Mortality for BMS and DES Coronary Stenting Procedures: A Medicare Study of 156,300 patients
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Background: It is now common practice to use coronary stents following PTCA to restore blood flow in patients with CAD. The purpose of this study is to evaluate the utilization of bare-metal stents (BMS) and drug-eluting stents (DES) and their revascularization and mortality rates in the U.S. from 1997-2009. Methods: The Medicare 5% LDS analytical files were queried to identify patients with BMS and DES between 1997-2009 using ICD-9-CM. The subsequent rates of revascularization and mortality were evaluated. Results: A total of 88,000 BMS procedures were identified between 1997-2009 with a revascularization rate of 31%. In addition, 68,300 DES procedures were identified from 2002-2009 with an overall revascularization rate of 19%. Within 2 years of FDA approval for the first generation DES, utilization of bare-metal stents was 88.4% of all coronary stent procedures in 2005. Due to DES safety concerns of late stent thrombosis, BMS utilization increased steadily to 37% in 2007 with a simultaneous decrease in DES usage; revascularization burden increased considerably from 8.2% in 1997 to 44.2% for BMS in 2009. The revascularization burden for DES increased at the same rate from 2006-2009. The majority of patients undergoing stenting procedures were also diagnosed with hypertension (75-85%) with revascularization rates higher among this population than primary procedures. Over 60% of patients undergoing a DES stenting procedure (primary or revascularization) are implanted with one stent while 27% are implanted with two stents and less than 10% receive 3 or more stents. The same trend was observed for patients undergoing primary revascularization BMS procedures. Ten-year Kaplan Meir mortality rates were also assessed among the DES and BMS patient populations. The average hospitalization charges for primary DES procedures was $64,000, whereas the average charges for BMS procedures were $10,000-23,000 lower than DES procedures. Conclusions: Temporal trends showed that concerns about late-stent thrombosis with use of DES led to a sharp decline in utilization. Analysis of mortality and revascularization following BMS and DES procedures provided information about the comparative safety and effectiveness of these procedures.

TCT-660
Incidence and Predictors of Stroke Following Percutaneous Coronary Intervention in United States
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Background: Acute cerebrovascular episode (CVA) following percutaneous coronary intervention (PCI) is a rare but devastating complication. We sought to determine the incidence and predictors of stroke following PCI in United States. Methods: The Nationwide Inpatient Sample (NIS) database was used to identify all patients who developed acute CVA following PCI between January and December 2009. Risk adjusted logistic regression was performed to identify independent predictors of acute stroke following PCI. Results: Of the 444,326 patients who underwent PCI, 437 (0.1%) acute strokes were identified. The in-hospital mortality rate in patients who developed stroke was significantly higher than in control group (2.3% vs. 0.6%, p < 0.01). Independent predictors of stroke following PCI were history of drug abuse (OR 7.2, 95% CI [4.5 - 11.4], p<0.01), valvular heart disease (OR 3.2, 95% CI [1.6 - 6.7], p < 0.01), age >65 (OR 2.9, 95% CI [1.4 - 3.7], p<0.01), diabetes with complications (OR 2.0, 95% CI [1.4 - 2.7], p < 0.01), female sex (OR 1.6, 95% CI [1.3 - 2.0], p < 0.01), history of coronary artery bypass grafting (OR 1.6, 95% CI [1.2 - 2.1], p < 0.01) and history of myocardial infarction (OR 1.5, 95% CI [1.2 - 1.9], p < 0.01). Conclusions: In this observational study we found that risk of stroke following PCI is low, whereas the in-hospital mortality associated with this complication is high. The independent predictors of stroke complication include history of drug abuse, valvular heart disease, advanced age, diabetes with complications, prior CABG or MI.

TCT-661
Clinical Relevance of Endothelial Dysfunction after Everolimus-Eluting Stent Implantation Compared to First Generation Drug-Eluting Stent.
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Background: Endothelial dysfunction of coronary artery has been reported in patients following the first generation drug eluting stent (DES) implantation. However, the incidence and clinical relevance of the second generation DES-induced endothelial dysfunction have not been fully investigated. The aim of this study was to estimate the incidence and clinical relevance of endothelial dysfunction after implantation of everolimus-eluting stent (EES). Methods: From June 2006 until August 2011, the present study enrolled 757 patients who were treated solely with DES for de novo lesions, from our prospective institutional database. The patients (279 patients with sirolimus-eluting stent (SES), 210 patients with paclitaxel-eluting stent (PES), and 268 patients with EES) were requested to undergo 8-month follow-up angiography. Endothelial function was evaluated, in case the patients had angina symptom and/or positive exercise electrocardiogram test without in-stent restenosis at the time of follow-up angiography by infusion of incremental acetylcholine and isosorbide dinitrate into the coronary artery. Vascular responses were quantitatively measured in segments proximal, distal, proximal reference and distal reference to DES location. Endothelial dysfunction was defined as abnormal vasoreactivity of ≥ 3% mean vessel diameter changes. Results: Follow-up angiography was performed in 624 patients (82.4%) of the 757 patients. There were 59 patients (7.8%) who met the inclusion criteria for endothelial function test, 25 patients (8.9%) with SES, 15 patients (7.1%) with PES, 19 patients (7.1%) with EES. In all the 3 groups significant vasodilation after acetylcholine infusion was observed in segments distal to stents compared to baseline(<p<0.05). Vasodilation in response to isosorbide dinitrate infusion was also observed. Endothelial dysfunction was quantitatively assessed in all the 59 patients at distal segments to DES. No significant differences were observed in percent diameter changes from baseline among the groups. Conclusions: Clinically relevant endothelial dysfunction following EES implantation seems to be present in approximately 7%, which is similar to the first generation DES implantation.

TCT-662
One Year Outcomes Following PCI in Patients with Asymptomatic CAD: A Report from the NHLBI Dynamic Registry
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Background: The level of appropriateness of PCI in the appropriate use criteria (AUC) are based on degree of symptoms and abnormalities on stress testing. Using these criteria, PCI in patients with asymptomatic CAD (ACAD) is often labeled as inappropriate. However, whether this is due to increased harm or perceived decreased benefit, is not clear. Furthermore, many PCI’s performed for other instances not related to angina (i.e. CHF, arrhythmias) and are not included as reasons for PCI in the AUC. Therefore, we sought to investigate the outcomes of patients undergoing PCI for asymptomatic CAD compared to those with stable angina (SA).