TCT-607
Atherosclerotic Swine Model Reveals Favorable Impact of Abliminal Biodegradable Polymer on the Time Course of Para-Strut Inflammation in Comparison to BMS and Durable Polymer DES
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Background: Biodegradable polymer coatings are hoped to minimize persistent inflammation associated with durable polymer usage as a drug carrier in drug-eluting stents (DES). We examined the time course of para-strut inflammation (PI) of 3 contemporary DES featuring abluminally biodegradable polymer coating (SYNERGYTM =SY) and durable polymer coating (XIENCE PRIME= EES and RESOLUTE INTEGRITY=ZES) in the familial hypercholesterolemia swine (FHS) model.

Methods: Stents (SE=29, EES=29, ZES=29 and OMEGA BMS=29) were implanted in 87 coronary arteries in 29 FHS. Para-strut inflammation (PI) was defined as contiguous regions of inflammation in contact with, or surrounding struts, and extending into the neointima, media or adventitia and examined histologically at 30, 90 and 180 days.

Results: At 30 days, PI was higher in BMS compared to the 3 DES. By 90 days, PI had markedly subsided in the BMS, but peaked in all 3 DES groups. At 180 days, PI in the SY resolved to a minimal level comparable to BMS (p=0.95), while the other 2 DES continued to show higher average PI scores than SY and BMS (EES vs. SY p<0.0001 and ZES vs. SY p=0.03).

Conclusions: In the setting of early atherosclerosis present in the FHS model at the age used (12-25 months at implant), the peak PI in DES is delayed in comparison to BMS and its resolution is slower. Polymer resorption and lower total mass of the abluminally applied polymer coating in SY appear to accelerate the resolution of PI as projected, adding to the evidence that FHS is capable of modeling clinically relevant responses to endovascular interventions.

TCT-608
A New Thin-Strut, Low-Dose, Sirolimus-Eluting Stent With Abluminally-Deposited Biodegradable Polymer Coating: Safety and Efficacy Clinical Performance of the Inspiron™ Stent in High-Risk Patients
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Background: The Inspiron™ stent incorporates a biodegradable, polymeric coating that is hoped to initially decrease strut thickness and subsequently decrease strut thickness in high-risk patients with diabetes. The Inspiron™ stent is the first drug-eluting stent (DES) with a biodegradable polymer coating, which is designed to provide a near-zero strut thickness for the first time during the implantation. The stent has a biocompatible polymer polymer layer that provides initial strut thickness reduction and a biodegradable coating that is designed to slowly disappear over time.

Methods: A total of 1,095 subjects were enrolled in the INSPIRON-US I & II studies, which included 960 patients with diabetes and 135 patients without diabetes. The study enrolled patients with ACS or stable angina and treated them with Inspiron™ stents.

Results: Compared to the Xience PRIME stent, the Inspiron™ stent demonstrated similar clinical outcomes at 1 year, including a lower rate of target lesion revascularization (TLR) in patients with diabetes (2.6% vs. 3.6%, p=0.49). Furthermore, the Inspiron™ stent demonstrated a lower rate of stent thrombosis (0.9% vs. 2.1%, p=0.13) and a similar rate of all-cause mortality (0.5% vs. 0.6%, p=0.53).

Conclusions: The Inspiron™ stent demonstrated similar clinical outcomes to the Xience PRIME stent in high-risk patients, including patients with diabetes. The biodegradable polymer coating may help to reduce strut thickness and improve clinical outcomes in high-risk patients.