TCT-806

12-Month Angiographic and Clinical Follow up of the Fantom Sirolimus-eluting Bioresorbable Scaffold

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BACKGROUND Fully bioresorbable coronary scaffolds are designed to overcome the limitations of metallic stents. Potential benefits include restoration of endothelial function and vasomotion, complete resorption over time and no side branch jailing. The sirolimus-eluting bioresorbable FANTOM scaffold is visible under x-ray, and designed to maintain structural integrity for 3 months before degrading over time. This study is designed to demonstrate the safety and efficacy of the FANTOM scaffold in the treatment of native coronary arteries.

METHODS This prospective, multi-center study enrolled patients with clinical evidence of myocardial ischemia and de novo lesions in 2.5 to 3.5 mm vessels. Angiographic and IVUS or OCT was planned at 6 months in Cohort A and 9 months in cohort B. Independent core laboratories reviewed all imaging.

RESULTS A total of 240 patients (117 Cohort A and 123 Cohort B) were enrolled in 28 centers. Patients were 70.4% male with mean age of 62.7±10.1 years and 23.8% with diabetes. Mean vessel diameter was 2.71 ± 0.37 mm, lesion length 11.56 ± 3.89 mm, acute gain 1.68 ± 0.41 mm and late lumen loss (LLL) 0.25 ± 0.40 mm for Cohort A and 0.33 ± 0.36 mm for Cohort B, respectively. IVUS and OCT will be presented. Acute technical success (successful implantation of the scaffold without device related complications) was 95.8% and acute procedural success (acute technical success with no in-hospital major adverse cardiac events (MACE) and residual DS% <50%) was 99.1%. At 30-days clinical success, defined as acute procedural success with no MACE at 30 days was 99.6%. At 12 months MACE was 4.2% and included a single stent thrombosis (ARC defined). Clinically driven target lesion revascularization (TLR) was 2.5%

CONCLUSION Based on the results of this registry, the FANTOM scaffold appears safe, is associated with a low LLL and very low target lesion revascularization at 12 months. A randomized clinical trial is planned to confirm these results.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-807

Accuracy of the Society of Thoracic Surgeons (STS) Mortality and Stroke Risk Scores for Predicting Outcomes in Patients With Left Main Coronary Artery Disease Undergoing CABG Versus PCI: Insights From the EXCEL Trial

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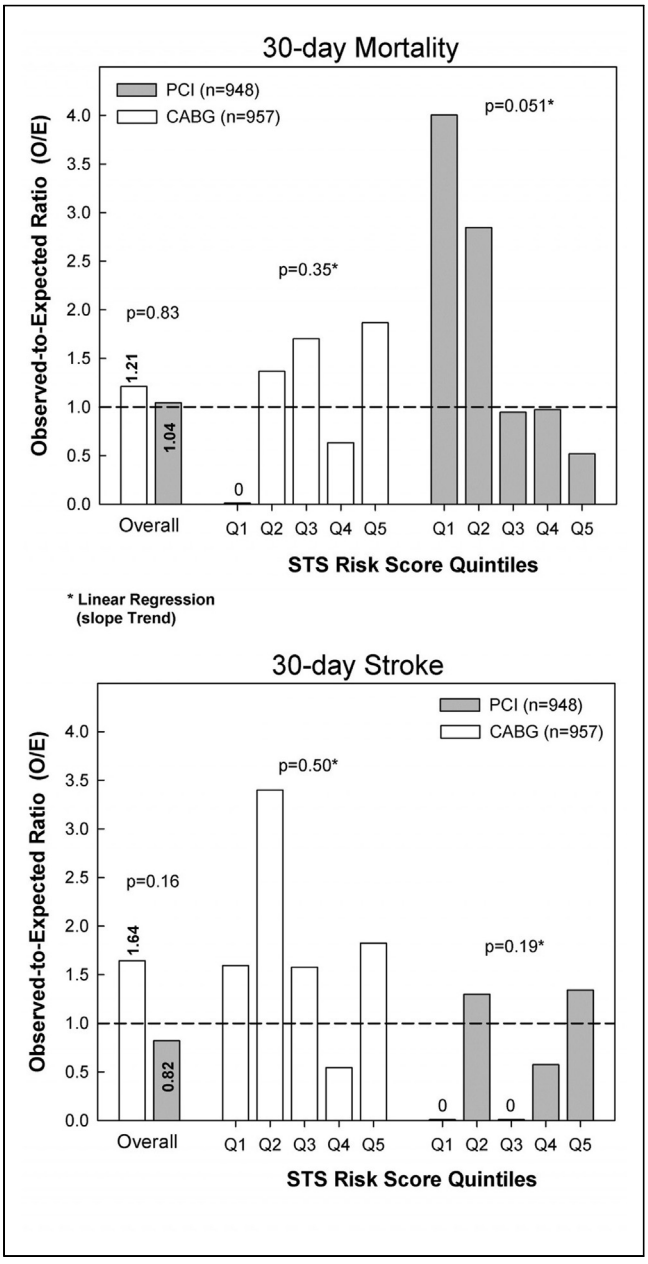
BACKGROUND Whether STS risk scores can accurately predict outcomes in patients with left main (LM) coronary artery disease undergoing coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) is unknown.

METHODS We compared the observed 30-day mortality and stroke rates to those expected from the corresponding STS risk models for patients undergoing LM revascularization by PCI with everolimus-eluting stents (n=948) and CABG (n=957). Comparisons were made by observed-to-expected ratios (O/E) and for quintile subgroups (Q1=low risk, Q5=high risk) within each treatment group.

RESULTS Randomized EXCEL trial groups had similar expected 30-day STS risk scores: mortality [mean; median (IQR): PCI - 0.91%; 0.62% (0.37%-1.06%) vs CABG - 0.86%; 0.62% (0.38%-1.01%); p=0.69], and stroke [0.77%; 0.59% (0.41%-0.91%) vs [0.76%; 0.62% (0.40%-0.95%)]; p=0.42]. Observed 30-day mortality rates were similar for CABG and PCI [10 (1.05%) vs 9 (0.95%); O/E: 1.21 vs 1.04, p=0.83] as were 30-day stroke rates [12 (1.25%)vs 6 (0.63%); O/E= 1.64 vs 0.82; p=0.16]. Subgroup analysis of 30-day mortality O/E showed that for patients with low STS mortality risk, observed mortality might be greater than expected in case of PCI and lower in case of CABG[Fig, top]. Stroke risk tended to be lower for PCI across most STS risk quintiles[Fig, bottom].



CONCLUSION In the EXCEL trial, STS CABG risk models predicted aggregate 30-day CABG and PCI mortality reasonably well, although CABG appeared safer in the lowest-risk patients while PCI appeared safer for higher-risk patients. Stroke risk tended to be less with PCI than for CABG.

CATEGORIES CORONARY: Cardiac Surgery