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Neurological complications following PCI - incidence and trends during a period of transition from femoral to radial access. Observational data from the british cardiovascular intervention society PCI database

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Background: There has been a significant increase in use of transradial access (TRA) for PCI in the UK. Early on in the TRA learning curve, procedures are associated with more catheter exchanges, longer screening times and with more contrast use. These factors are all associated with increased risk of periprocedural neurological complications (NC). Using the British Cardiovascular Intervention Society PCI database we assessed changes in NC through a period of transition during which radial access became the dominant access for PCI.

Methods: This study includes data collected by the British Cardiovascular Intervention Society under the auspices of the Central Cardiac Audit Database. We performed a retrospective analysis of the BCIS database between January 2006 and December 2010. The data was split into 2 cohorts based on access site: either radial or femoral (mixed access site use and other access sites were excluded from the analysis). A NC was defined as a periprocedural TIA, ischemic stroke or hemorraghic stroke.

Results: Between 2006 and 2010 a total of 348,092 procedures were recorded exclusively using either transradial (TRA) or transfemoral (TFA) access. Over 5 years, the use of TRA for PCI increased from 17.1% to 50.8% of procedures. There was no difference in the incidence of NC during this period. Following multivariate analysis of the whole 5 year cohort, no difference in NC was observed between TRA and TFA (HR 1.005 CI 0.81-1.248; p=0.096).

Conclusions: These results are reassuring and suggest that a switch from TFA to TRA is not associated with any increased risk of periprocedural neurological complications.

Bioreabsorbable Vascular Scaffolds

TCT-33

Intracoronary Optical Coherence Tomography and Histology of Overlapping Everolimus-Eluting Bioreabsorbable Vascular Scaffolds in a Porcine Coronary Artery Model: The Potential Implications for Clinical Practice

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Background: The everolimus-eluting Bioreabsorbable Vascular Scaffold (Absorb) is a novel approach to treating coronary lesions. A persistent inflammatory response, fibrin deposition and delayed endothelialisation have been reported with overlapping first-generation drug eluting stents. We report optical coherence tomography and histological findings in a porcine coronary artery model after implantation of overlapping Absorb or second-generation everolimus eluting metallic platform stents (XIENCE V [XV]).

Methods: 41 overlapping Absorb and overlapping XV devices (3.0×12 mm) were implanted in the main coronary arteries of 17 non-atherosclerotic pigs with a balloon artery ratio of 1.1:1 (10% over-stretch). Implanted coronary arteries were evaluated by OCT at 28 (Absorb: n=11; XV: n=7) and 90 days (Absorb: n=11; XV: n=8), with immediate histological evaluation following euthanasia at the same time points. One animal from each time point was evaluated with scanning electron microscopy alone.

Results: 1407 cross-sections were analysed by OCT and 148 cross-sections assessed histologically. At 28 days in the overlap, OCT analyses indicated 80.1% of Absorb struts and 99.4% of XV struts to be covered (p<0.0001), corresponding to histological observations of struts with cellular coverage of 75.4% and 99.6% respectively (p<0.001). Uncovered struts were almost exclusively related to the presence of ‘stacked’ Absorb struts, i.e. with a direct overlay configuration. At 90 days overlapping Absorb and overlapping XV struts demonstrated >99% strut coverage by OCT and histology, with no evidence of a significant inflammatory process, and comparable % volume obstructions.

Conclusions: In porcine coronary arteries implanted with overlapping Absorb, strut coverage is dependent on the overlay configuration of Absorb struts at 28 days and not at 90 days. The potential clinical implications of increased strut thickness in the management of long lesions & coronary bifurcations may have important clinical (e.g. duration of antplatelet therapy) and design considerations (e.g. longer devices & the requirement of dedicated bifurcation devices to avoid overlapping the device) for current and future devices with bioreabsorbable platforms.

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ABSORB EXTEND: An Interim Report on the 12-month Clinical Outcomes from the First 250 Patients Enrolled

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Background: The safety and performance of the Absorb Bioreabsorbable Vascular Scaffold (BVS) System (Abbott Vascular, Santa Clara, CA) has been previously established in 131 patients from Cohort A and Cohort B of the First-in-Man ABSORB trial. Results out to 2 years have been presented in 101 patients from the ABSORB Cohort B trial. At 12 months, the MACE rate was 6.9%, with no scaffold thrombosis reported, which was sustained out to 2 years with a MACE rate of 9.0%. Following this trial, ABSORB EXTEND was initiated as a global continued access study (outside of the US) to expand experience with the Absorb BVS to different geographies. Additionally, patients were treated for longer coronary lesions than those in the ABSORB trial using either longer scaffold lengths or planned overlap of the Absorb BVS.

Methods: ABSORB EXTEND is a prospective, single-arm, open-label clinical study that is planning to enroll up to 1,000 subjects at up to 100 sites. Included are patients with lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.3 mm (as assessed by on-line QCA or IVUS). Treatment of a maximum of two de novo native coronary artery lesions, each in a different epicardial vessel, is permitted.

Results: Interim 12-month data in the first 250 patients enrolled in ABSORB EXTEND will be available for the first time in October 2012 and will provide additional data on the