TCT-456
Electrochemical Study For The Evaluation Of Corrosion Of A New Ceramic Stent
Lucila Navarro¹, Julio Luna², David Vetcher¹, Victor P. Mole³, Gustavo Duffo³, Ignacio Rintoul⁴
¹INTEC (Universidad Nacional del Litoral-Conicet), Santa Fe, Santa Fe, ²Clinica de Nefrologia y Enfermedades Cardiovasculares, Santa Fe, Santa Fe, ³Comision Nacional de Energia Atomica, San Martin, Buenos Aires

Background: Metallic coronary stents are placed in a high chloride environment that plays an important role on the corrosion behavior of the implant. Corrosion of stents presents two main risks: release of metallic ions into the tissue and deterioration of the mechanical properties of stents. Release of heavy metal ions could lead to inflammatory mediators and promote in-stent restenosis.

Methods: We evaluated the corrosion resistance of a ceramic stent (CST) developed with an innovative surface treatment that involves a multistage immersion in different solutions performed at INTEC-Universidad Nacional del Litoral and compared it with a plain stainless steel stent (SST), and a chromium-cobalt stent (Cr-Co). The stents were evaluated with potentiodynamic polarization studies, unexpanded and after balloon expansion at 12 bars. Ten stents were studied in each group. The corrosion potential (Ecorr) was measured under a virtual open circuit condition, with respect to a reference electrode; and the corrosion current (Icorr) by a potentiodynamic polarization curve measurement that involved scanning the potential (mV) at a rate of 0.5 mV/s to a final potential of 1.4 V. Micrographic pictures were taken before and after the electrochemical analysis to evaluate the type of corrosion. Statistical analysis: assays were done in duplicate: ANOVA and a multiple range test by Duncan’s variation were performed.

Results: The potentiodynamic curves of CST stents exhibited an anodic current density significantly lower than SST and Cr-Co stents: The Ecorr was -0.39 volts (V) for SST stents, -0.617 V for Cr-Co stents and -0.523 V for CST stents (p<0.05). The Icorr was of 9.8 E-7 Ampere/cm² for SST stents, 1.4 E-9 A/cm² for Cr-Co stents and 3.6 E-10 A/cm² for CST stents (p<0.05). Micrographic pictures showed only light signs of corrosion on the CST surface; as a changed on the surface color due to oxide deposition. A microscopic study exhibited a clear intergranular corrosion and SST stents showed a high tendency for pitting corrosion with loss of portions of stent struts.

Conclusions: Surface modified ceramic stens showed a better corrosion behavior when compared with stainless steel stents and Cr-Co stents.

TCT-457
Endothelialization of the Multilayer Flow Modulator Versus Single-Layer Arterial Stents
Sherif Sultan¹, Edel P. Kavanagh¹, Antoine Alves², Niamh Hynes¹
¹Western Vascular Institute, Galway, Ireland, ²NAMSA, Chasse-sur-Rhône, France

Background: The Multilayer Flow Modulator (MFM) (Cardiatis, Isnes, Belgium) is a self-expandable mesh of braided cobalt alloy wires used for treatment of aortic aneurysms. Because the endothelialization kinetics of the device are poorly understood, they were investigated and compared with those of two single-layer control stents in porcine coronary arteries.

Methods: A total of 19 stents were implanted in the left and right iliac and carotid arteries of 5 adult pigs, with each animal receiving two MFM devices plus a balloon-expandable stainless steel stent (SST) and a self-expandable nitinol stent (NS). One animal did not receive an SS. An animal was sacrificed every week for up to five weeks for device explantation, at which time analyses were conducted on the explants and/or vessels by gross examination, histology, scanning electronic microscopy, and immunohistochemistry.

Results: All 19 stents were successfully delivered. At 1 week, endothelialization and neointimal covering were slightly more advanced for the MFM device than for the two single layer-stent controls. For all devices, non-significant traces of inflammation or thrombosis were noted, and there were no signs of local intolerance. Through 5 weeks, the proximal and distal edges of the MFM device were often not fully integrated into the artery wall, indicating that the endothelialization process was not totally complete.

Conclusions: Overall, the MFM device was found to develop a thin layer of endothelial cells sooner and was associated with less significant neointimal development than the two single-layer control stents. At 1 and 2 weeks, surface cell proliferation confirmed the positive integration of the MFM device into vessels, with continuing neointimal development over the duration of the study. Further studies are needed to assess the long-term safety and effectiveness of the MFM device.

TCT-458
Delayed healing is operator procedure dependent and likely determined by smooth muscle cell proliferation rather than direct endothelial drug sensitivity
Anouchska Autor¹, Nikola Faber¹, Stefan Speer¹, Ilona Krabbendam-Peters¹, Richard W. van Duijn¹, Heleen v Beusekom²
¹Thorax Center, Erasmus MC, Rotterdam, Netherlands

Background: Drug eluting stents (DES) have been associated with delayed vascular healing and late stent thrombosis. Newer DES are more gentile to the vascular wall. Preclinical studies present contradicting results regarding endothelialization in DES. The injured rabbit iliac model shows delayed healing whereas the uninjured swine coronary model shows mainly endothelial (EC) dysfunction. We studied differences in arterial smooth muscle cells (SMC) and EC behavior in presence of paclitaxel and DES drugs in vitro and in vivo.

Methods: In vitro drug sensitivity was determined by population doubling time in presence of Pachtaxel (P), Sirolimus (S) or Everolimus (E) (0;0.1;10;1000nM) using rabbit aorta SMC (RSMC) and EC (REC), and porcine coronary SMC (PSMC) and EC (PEC). In vivo EC restoration was studied in rabbit iliac and porcine coronary arteries using a model of controlled prior injury (B/A ratio 1.2-1.3) followed by stenting (S/A ratio ~1:1:1), using S, Biolimus and bare metal stents.

Results: In vitro: Regression analysis showed that drug, dose and species are independent predictors of population doubling time. Univariate analysis showed RASMC behavior differed from PCSCM in presence of P and E (p<0.001 both) but showed a trend for S (p<0.005). A trend for S was observed for RSMC proliferated slower than PSMC but REC proliferated faster and were less sensitive to P and E than PAEC (p<0.05 both). In vivo: Endothelialization was slower in rabbit iliac than porcine coronary arteries. Regression Analysis (P<0.001; R²=0.85) showed that delayed healing depended on species, FU time, the extent of prior injury and stent induced injury (S/A ratio) and not DES drugs and histologic injury score. The rabbit model (R²= 0.40 vs swine R²= 0.9) needs additional parameters and as yet unidentified parameters seem to determine EC healing. We hypothesize that SMC injury during implantation determine healing rather than EC proliferation as indicated by in vitro data.

Conclusions: Endothelialization is mainly operator procedures dependent (prior and stent induced injury) than direct drug sensitivity. In vivo data indicate that SMC behavior may be a better predictor for delayed healing than EC.

TCT-459
Minimalist Approach to the Right Heart Catheterization from Forearm: 4 French Feasibility and Clinical Experience
Pradeep K. Yadav¹, Nathan Hill¹, William Weiss¹, Gerson Rosenberg¹, Ian C. Gilchrist²
¹Pennsylvania State University, Hershey, PA, ²Penn State University, Hershey, United States

Background: Sheath size is one of the factors for vascular access complications and hence smaller size catheters are more desirable; however, they carry the concern for procedural failure due to mechanical properties of the catheter wall and decreased drug accuracy of the pressure readings. A potential disadvantage of the 4 French (Fr) catheter is degradation in pressure signal fidelity due to the small lumen diameter. We measured the in vitro response of 4 Fr, 5 Fr, and 7 Fr catheters to a rapid step change in pressure. In vivo procedural feasibility was also analyzed in patients who underwent right heart catheterization (RHC) using 4 Fr catheters at our institution.

Methods: The natural undamped frequency and damping ratio of three different catheters 4 Fr Arrow, 5 Fr Arrow and 7 Fr Edwards Swan-Ganz were measured using the “pop test”, in which the catheters are simultaneously positioned in an enclosed system, then subjected to a sudden step change in pressure, resulting in oscillation of the catheter transducers. A second-order differential equation was used to calculate the 3dB frequency response of these catheters. For in vivo feasibility, retrospective analysis of all patients who underwent RHC using 4 Fr catheters, over the last two years at our institution was performed. Need for access site switchover, use of venography or 0.018” hydrophilic guide wire were assessed.

Results: The 4 Fr, 5 Fr, and 7 Fr frequency responses were 39.3, 45.8, and 35.9 Hz, respectively, considered adequate for blood pressure signal accuracy. A qualitative comparison of simultaneous measurements of a simulated pulse pressure showed no discernible differences among catheters. Retrospective analysis of the cathlab database over two year period identified 35 cases of RHC with 4 Fr catheters via a forearm vein. Twenty-one (60%) were done successfully with fluoroscopic guidance only, 14 (40%) required venography (n=10, 28%) and / or guide wire (n=11, 31%).

Conclusions: Frequency response of 4 Fr catheter is comparable to conventionally used 5 Fr and 7 Fr catheters. Right heart catheterization is feasible with 4 Fr catheters via a forearm vein, without any need for access site switchover.