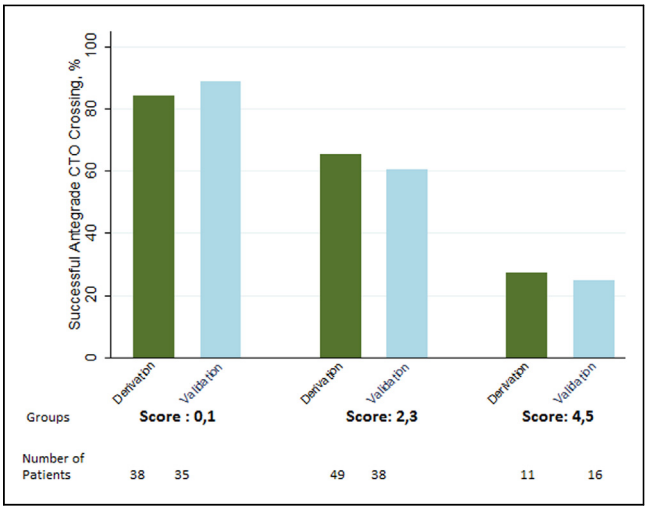
P<0.05), diameter ≥2.5 (OR: 2.8; 95% CI: 1.04-7.5; P<0.05) and a central stump (OR:1.19, 95% CI: 0.44 - 3.3; P=0.74) were included in the multivariate model. One point was assigned to severe calcification at the entry portion, blunt stump, diameter ≤ 2.5mm and length ≥ 100mm; 2 points were assigned for length ≥200 mm. Lesions were categorized into 3 groups based on their total score: i) easy (score 0-1); ii) intermediate (score 2-3); iii) difficult (score 4-5). The rates of successful crossing in the derivation and validation cohort respectively were: 84.6% and 88.2% for the easy crossing group; 65.3% and 60.5% for the intermediate group; 27.3% and 25% for the difficult crossing group.



CONCLUSION The infrapopliteal CTO crossing score suggests that specific angiographic characteristics can be used to predict the success of antegrade wire crossing. This score may be useful for defining an optimal antegrade vs. primary retrograde crossing approach.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-762

The BioMimics 3DTM Stent System in the Femoropopliteal Arteries of Patients with Symptomatic Peripheral Arterial Disease: Clinical and Angiographic Performance in the MIMICS-2 Study

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BACKGROUND Endovascular treatment of femoropopliteal artery (FPA) disease is challenging due to unique forces in this vascular segment, limiting stenting to designs that minimize focal deformation and providing longitudinal flexibility. The BioMimics 3D stent (Veryan, Horsham UK) is a self-expanding Nitinol stent with unique 3D helical centerline geometry to generate swirling blood flow. Preclinical studies and an earlier clinical study (Mimics) have indicated that the introduction of swirling blood flow reduces neointimal formation. This study is designed to demonstrate the safety and efficacy of the BioMimics 3D stent in the treatment of FPA disease.

METHODS This prospective, single arm, multicenter trial enrolled patients with symptomatic de novo obstructive or occlusive disease of the native FPA. An independent angiographic core laboratory reviewed all angiograms, and all events were adjudicated by independent committee. The primary safety endpoint is a composite of major adverse events (MAE) comprising death, any target limb major amputation or clinically-driven target lesion revascularization (TLR) at 30 days. Primary efficacy is stent patency at 12 months. We present procedural and in-hospital clinical outcomes.

RESULTS 271 subjects were enrolled, with a mean age of 68 years, 66% male, 81% smokers and 45% diabetics. Lesion length was 81.2 ± 38.4 mm and vessel diameter was 5.2 ± 0.9 mm; 46% had moderate to severe calcification and 30% were total occlusions. The baseline diameter stenosis (DS %) was 77.4% and final stent DS% was 11.5%. Lesion success (defined as successful stent implantation without device related complications) and procedure success (defined as lesion success without MAE) were 100%. There were no stent fractures, abrupt closure, spasm, distal embolization or perforation. Dissections > type C occurred in 1% of cases.

CONCLUSION The unique design of the BioMimics 3D stent for treatment of FPA was safe and achieved excellent procedure success without procedural complications or stent fracture. Longer-term results will confirm whether these results are associated with sustained safety and efficacy.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-763

Comparative Assessment of Infrainguinal CTO Crossing Devices

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BACKGROUND Chronic total occlusions (CTO) account for 40-50% of peripheral artery disease lesions. Several approaches are used for CTOs including wire catheter and crossing device based techniques. This study evaluated the practice patterns of crossing devices in a real world registry and technical/procedural success of various crossing devices. (Viance, Crosser, TruPath, and Frontrunner).

METHODS We analyzed data from the Excellence in PAD (XLPAD) registry between 2005-2016. We included all patients in which crossing devices were used to cross CTO lesions. We studied clinical records including lesion characteristics and procedural information. Primary endpoints were defined as procedural and technical success.

RESULTS Of 1366 CTO procedures, 31% (n=425) used crossing device to cross CTO lesions. 90% of these CTO lesions were femoropopliteal and 10% were below the knee. Crossing devices were used as the initial approach in 57%, while in 43% its use was provisional after an initial catheter-wire approach. The most common crossing device was Viance (46%), followed by Frontrunner (27%), TruPath (14%), and Crosser (13%). Table 1 presents patient and clinical characteristics by crossing device. There was no significant association between crossing device types and procedural complications or procedural success rates for femoropopliteal (FP) or below the knee (BTK) CTOs. Compared with all other crossing devices, technical success rate for FP lesions was significantly higher with Viance (91%, p=0.04). There was no difference in technical success rates by crossing device type in BTK CTOs.

Table 1. Clinical characteristics by crossing device	Viance (n=196)	TruPath (n=59)	Frontrunner (n =115)	Crosser (n=56)
Sex (Males)	171 (87%)	52 (88%)	110 (96%)	41 (73%)
Age (Years)	65±10	67±11	63±9	68 ± 9&,$
Race/ethnicity White	120 (61%)	40 (68%)	74 (65%)	50 (89%)
Black	44 (22%)	10 (17%)	36 (32%)	3 (5.5%)
Hispanic	11 (6%)	9 (15%)	4 (3%)	3 (5.5%)
Rutherford class (1-6)	3.3 ±0.8 €	3.0± 0.9	3.2±0.8	3.3±0.9‰
CLI presentation	50 (26%)	11 (18%)	22 (19%)	14 (25%)
ABI	0.75±0.21‼	0.73±0.18§	0.71±0.21	0.80±0.27‰

Note. & Crosser > Viance; $ Crosser > Frontrunner; € Viance >Turepath; ‼ Viance >frontrunner; § Truepath > Frontrunner; ‰Crosser > Truepath; P < 0.05 was set a statistical significance and 2-sided t-test was conducted for a paired comparison.

CONCLUSION In a real world, multicenter registry we showed that crossing devices were used approximately 1/3rd of the time to cross infrainguinal CTOs. Viance, the most frequently used crossing device also had the highest technical success compared with all other devices for FP CTO, while there was no difference in BTK CTO lesions.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-764

Usefulness of the Novel Ultrasonography Guided Central Wiring Technique in Endovascular Therapy for Chronic Total Occlusion of Femoro-popliteal Arteries

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BACKGROUND The success rate of endovascular therapy (EVT) for long chronic total occlusion (CTO) of femoro-popliteal (FP) arteries has improved because of devices development. However, patency rate after EVT has not been improved remarkably. The current study demonstrated that minimum stent area (MSA) were independent predictors for restenosis. The under expansion after self-expanded stents deployment was a problem. We had experienced under expansion in subintimal approach for EVT. Our aim was to investigate the usefulness of the novel Ultrasonography (US) guided Central Wiring Technique (CWT) in EVT for long F-P CTO lesions.

METHODS Between January 2015 and May 2016, we performed 53 cases of long F-P CTO lesions with CWT, lesion length was more than 150mm. We used 8 MHz linear transducer (Aprio 500 premier, TOSHIBA, Japan) which was set as our original preset for EVT. We performed US guided wiring with our original method. Operator controlled the guidewire as penetrated the center of CTO lesions. We assessed the procedure results, intravascular ultrasound (IVUS) findings and patency rate.

RESULTS Mean age was 73.8±9.4 y.o. and female was 14 cases (26.4%). Technical success rate was 100%. All cases were only antegrade approach. There was no cases which was needed retrograde approach. Dose of radiation was 275.0 ± 379.8 mGy. Dose of contrast media was 87.3±100.5ml. Mean stent diameter was 6.5±0.7mm, length was 157.5±102.3mm. Primary patency at one year was 90.6%. In IVUS findings, rate of all true lumen tracking was 50 cases (94.3%). There was a negative correlation between the central rate of guidewire position (diameter from central to guidewire / vessel radius ×100) and MSA.

CONCLUSION The US guided CWT with our original method was less invasive treatment and improved primary patency in EVT for long FP CTO lesions.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-765

Prevention of Restenosis with Adventitial Delivery of Torisel via Mercator MedSystems Bullfrog Catheter in Femoral Arteries of Swine

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BACKGROUND Restenosis following endovascular treatment is associated with inflammatory and proliferative responses produced in the artery wall at the time of the procedure which may be ameliorated through delivery of anti-inflammatory or anti-proliferative compounds into the adventitia of the vessel at the time of treatment. The present study aimed to assess the pharmacokinetic profile and vascular response to locally delivered sirolimus analog Torisel (temsirolimus, Pfizer) using the Mercator MedSystems Bullfrog Micro-Infusion Device (Emeryville, CA) to balloon overstretched superficial femoral arteries (SFA) in swine.

METHODS Sixteen SFAs of 8 swine were balloon overstretched (1.28±0.16:1 balloon to artery ratio) on day 0 followed by infusion of 357ug Torisel via the Bullfrog catheter at each site and harvested at 1 hour (n=4), 3 days (n=4), 7 days (n=4) or 28 days (n=4). An additional three control animals had bilateral SFA balloon overstretch (1.17±0.08:1 balloon to artery ratio) followed by saline infusion and harvested at 3 days (n=2), 7 days (n=2) or 28 days (n=2). Blood was collected for circulating Torisel evaluation and tissue was harvested for histological analysis and Torisel concentration.

RESULTS There were no adverse events, signs of toxicity, mural injury or evidence of thrombosis following Torisel or saline administered via the Bullfrog catheter. Quantitative analysis of Ki67-positive nuclei showed cellular proliferation in the control vessels peaking at Day 7 and a Torisel treatment-related decrease in average proliferation values on Day 3, Day 7 and Day 28 that were substantial and consistent along the vessel length. Circulating Torisel concentration peaked at 1 hour post-infusion, were near zero by Day 3 and below limits of quantitation by Day 7. In the treated vessels, Torisel concentration decreased by an order of magnitude from one hour (8440±6956ng/g) to 3 Days (624±398ng/g) and continued to decrease through Day 28 (122±73ng/g) yet remained present at detectable levels.

CONCLUSION Torisel has demonstrated ability to inhibit cell proliferation when delivered locally via the Bullfrog catheter which is proven to be a safe, efficient and effective delivery mechanism.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

CORONARY POSTERS WEDNESDAY

Abstract nos: 796 - 834, 836 - 839, 841 - 851

TCT-796

Percutaneous coronary intervention in left main coronary artery disease concomitant with acute coronary syndrome. Clinical results at a long-term follow-up

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BACKGROUND Left main coronary artery (LMCA) disease is encountered in approximately 6% of coronary angiograms and in 4% of acute coronary syndromes (ACS). The survival of patients with LMCA disease presenting with acute ACS it's lowest in those with cardiogenic shock. Percutaneous coronary intervention (PCI) in ST-segment elevation (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI) due to LMCA disease were not been sufficiently studied. The main objective of this study was to evaluate the efficacy and safety of PCI in patients with concomitant LMCA disease and ACS at a long-term follow-up.

METHODS We prospectively included 178 consecutive patients (70.1 ± 10.5 years, 71.9% male) with concomitant LMCA and ACS disease treated with PCI between June 2006 and April 2016. We evaluated the occurrence of major adverse cardiovascular events (MACE) defined as cardiac death, nonfatal myocardial infarction, target lesion revascularization (TLR) and stent thrombosis after 10-year clinical follow-up (median 56 months).

RESULTS 80.9% of patients were presented as NSTEMI and 19.1% as STEMI. 42.7% were diabetic patients and 23.3% had Killip class 3-4 at presentation. An intra-aortic balloon pump was needed in 11.2% of the cases and thromboaspiration was required in 9.3% of cases. The most frequently bifurcation technique employed in LMCA was "provisional stenting" in 67.6% of cases and final "kissing balloon" was done in 59.4% of procedures. We implant zotarolimus eluting stent in 77% of patients and complication rate in the procedure was 1.3%. Global rate of in-hospital mortality was 6.7%. During follow-up, MACE rate at 10 years was 18.8% (13.6% cardiac death, 1.3% nonfatal myocardial infarction, 5.2% TLR and thrombosis rate 0%). We observed significant differences in the occurrence of MACE in patients with STEMI (p=0.03), moderate-severe left ventricular systolic dysfunction (p=0.001), Killip class 3-4 at presentation (p<0.001) and patients treated with first generation of drug eluting stents (p=0.02).