BACKGROUND Clinical trial data show overall favorable outcomes of paclitaxel-eluting stents for the treatment of femoro-popliteal (FP) occlusive disease. However, the external validity of trial results may be restricted to less complex FP lesions, and limited data on outcomes of pacliaxel-eluting stents in real world practice have been published.

METHODS This study is a retrospective analysis of data of all the patients who received Zilver® PTX® for FP lesion from February 2013 to October 2014 at MedStar Washington Hospital Center in Washington, DC. The primary endpoint of this study was primary patency, defined as a peak systolic velocity ratio < 2.0 by Doppler ultrasound, or angiographic diameter stenosis < 50%, or freedom from clinically driven target lesion revascularization.

RESULTS A total of 78 patients received Zilver® PTX® for FP lesions in the pre-specified time period. Of them, 63 had follow-up data and were included in this study. The mean patient age was 66.3±9.4 years, and 57.1% of the patients were men. Participants had a high prevalence of diabetes (49.2%), hypertension (93.7%), hyperlipidemia (93.7%), previous coronary revascularization (52.4%), or previous peripheral arterial disease (77.8%). Critical limb ischemia was present in 25.4% of the patients, Trans-Atlantic Inter-Society Consensus (TASC) class C or D in 76.2%, in-stent restenosis (ISR) in 36.5%, and total occlusion in 69.8%. The mean lesion length was 218.9±128.3mm, the mean number of stents was 2.02±1.0, and total stent length was 189.0±128.5 mm. Mean follow-up was 270.4±190.3 days. Primary patency rate at 1 year was 66.7% by Kaplan-Meier survival curve. When compared with patients with primary patency at follow-up, those with an adverse outcome had higher prevalence of TASC II class C or D lesions (100% vs. 68.8%, p=0.013), and were more likely to have ISR (66.7% vs. 27.1%, p=0.012), longer lesion (291.3±138.7 vs. 195.7±117.1, p=0.011), and incomplete coverage of the lesion (full coverage of lesions: 40% vs. 77.1%, p=0.011).

CONCLUSIONS Post marketing use of Zilver® PTX® for the treatment of FP lesions is associated with lower patency rates compared with clinical trial data. This may be related to the high prevalence of TASC II class C or D lesions and ISR in real world practice. Future studies should be more representative of contemporary clinical practice.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Femoropopliteal artery, Paclitaxel-eluting stent, Restenosis, in-stent

TCT-787

Evaluation of Cell Proliferation in Adaptive Neointimal Remodeling Following Arteriovenous Fistula in a Large Animal Model

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BACKGROUND Arteriovenous fistula (AVF) dysfunction caused by venous intimal hyperplasia persists as a significant threat to AVF long-term patency. Beyond conventional vascular planimetry we aim to evaluate the use of cell proliferation markers in neointima in a swine model of AVF.

METHODS Femoral AVF were surgically performed in nine swine by anastomosis. AVFs were followed for 3(n=3) and 90(n=6) days. At termination, AVFs were harvested and histological and planimetric analysis was performed. Immunohistochemistry for cellular proliferation was performed at the anastomosis levels as well as the arterial (A) and venous (V) anastomosis side.

RESULTS At 3 days, AVF displayed matching dimensions between V and A with a vascular area of 13.2±4.3mm2 in A and 15.1±9.4 mm2 in V. By 90 days, the vascular area on V increased by approximately 4-fold (58.6±42.5 mm2) while A increased by less than 3-fold (37.3±9.4 mm2). These planimetric ratios remained consistent in the proximal A and distal V at 3 (A=14.3±4.1 mm2;V=36.8±14.8 mm2) and 90 days (A=40.2±12.8 mm2;V=68.6±28.2 mm2). At 3 days, percent area of stenosis (%AS) at the anastomosis was minimal (A=1.8±1.5%; V=5±6.1%). However at 90 days, V demonstrated markedly increased %AS (21.9±16.5%) compared to A (6.9±2.9%), reflecting V being arterialized. As expected, cell proliferation counts were high at 3 days evidenced by a high Ki67 index in V (159.2±134.7 cells/mm2) and highest values were recorded in the V distal outflow side. Ki67 counts significantly decreased at 90 days (35.2±22.4 cells/mm2).

CONCLUSIONS Proliferation markers (Ki67) provide valuable assessment of vascular response. The AVF swine model provides an ideal scenario where conventional planimetry data describes the structural outcome while proliferative markers provide a dynamic picture of the biological vascular response.

CATEGORIES OTHER: Pre-Clinical/First In-Human Studies

KEYWORDS Animal model, AV fistula, Neointimal hyperplasia

TCT-788

The PRISM Study: Interim results for the novel Penumbra/Indigo thrombectomy system for acute ischemia in the peripheral and visceral vasculature

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BACKGROUND There are serious risks associated with untreated peripheral and visceral arterial thromboembolism. The Penumbra/Indigo System is a novel, highly trackable and efficient aspiration system in the peripheral vasculature. Reported herein are the initial results from the PRISM trial, the first multicenter study designed to obtain safety and effectiveness data in confirmed peripheral or visceral artery occlusion.

METHODS A total of 55 patients have been enrolled in this retrospective trial. In cases of failed thrombolysis, acute ischemia, or patients with distal emboli due to a prior intervention, thrombectomy using the Penumbra/Indigo System was implemented. The primary sites of occlusion were the popliteal (38.9%), peroneal (9.3%), superficial femoral (18.5%), posterior tibial (7.4%), profunda femoris (3.7%), superior mesenteric (3.7%), anterior tibial (9.3%), renal (3.7%), common femoral (1.9%), and brachial (1.9%) arteries.

RESULTS The mean patient age was 70.4 ± 12.9 years. At baseline, 96.1% (49/51) patients reported an angiographic TIMI score of 0-1, and 4 patients were unable to be assessed. Before any intervention was performed, 37.7% (20/53) of patients received only thrombolytic therapy, 9.4% (5/53) received only mechanical intervention, 7.5% (4/53) received both therapies, and 45.3% (24/53) had no prior treatment and were treated with the Penumbra/Indigo Systems as frontline. Median time from symptom onset to procedure was 5.0 days (IQR 2.0-24.0). Post-procedure, 96.1% (49/51) of patients were successfully revascularized to TIMI 2 (39.2%) or TIMI 3 (56.9%). Six patients had SAEs, none related to the device.

CONCLUSIONS Experience with the Penumbra/Indigo System demonstrates that using thrombo-aspiration for peripheral and visceral thromboembolism can lead to promising results in safety and effectiveness. This validates possible use across a wide range of applications in the peripheral vasculature.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Peripheral, Peripheral arterial disease, Thrombectomy

TCT-789

Comparison of stent-based revascularization strategies for femoropopliteal peripheral artery disease in diabetics and non-diabetics

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BACKGROUND There are limited data on outcomes of stent-based treatment of femoropopliteal peripheral artery disease (PAD) in patients with diabetes mellitus (DM).

METHODS Consecutive patients between January 2006 and March 2015 enrolled in the observational Excellence in Peripheral Artery Disease (XLPAD) registry (NCT01904851) were analyzed. Index limb procedures of patients with stent implants were included in the analysis. Outcomes tracked were major adverse limb events (MALE; target limb revascularization, surgical revascularization, and unplanned above-ankle amputation in target limb) and major adverse