PURPOSE To describe the management and treatment of iatrogenic pseudoaneurysms (PSAs) by interventional radiology (IR) at a single institution.

MATERIALS AND METHODS 50 patients with iatrogenic PSAs were identified from 2014 until 2016. Patients included 31 (62%) males and 19 (38%) females with mean age of 65 years (range: 34-92 years). Initial treatments were requested by cardiology (n=35), interventional radiology (n=9), vascular surgery (n=3), neurosurgery (n=1), the intensive care unit (n=1), and podiatry (n=1). Site, PSA volume, neck diameter, sheath size and closure device used during initial procedure, treating service, time from initial puncture to treatment, volume of thrombin used, number of treatment sessions required, advanced techniques used, clinical success, and complications were recorded.

RESULTS PSAs were located in the common femoral (n=38), profunda femoris (n=5), external iliac (n=3), brachial (n=1), superficial femoral (n=1), popliteal (n=1), and dorsalis pedis (n=1) arteries. Mean pseudoaneurysm volume was 27 cm3 (range: 0.4-230 cm3). Mean pseudoaneurysm neck diameter was 0.4 cm (range: 0.06-2.3 cm). Mean sheath size used during inciting procedure was 7 French (range: 5-8 French). 36 (72%) patients had no closure device used, 7 (14%) had a closure device, and in 7 (14%) closure device usage was not documented. Mean time from initial puncture to treatment was 490, 267, and 206 hours by vascular surgery, cross-sectional radiology, and IR, respectively. Mean volume of thrombin required was 720 units. 11 patients had at least 2 interventions and 2 patients required 3 treatment sessions for a total of 62 patient encounters. Mean number of treatment sessions required was 1.5 (range: 1-3). 58 (94%) treatments were by IR, 3 (5%) by vascular surgery, and 1 (1%) by cross-sectional radiology service. Advanced interventional techniques were required in 13 patients including arteriography with balloon-assisted thrombin injection in 5, open surgery in 4, arteriography with stent deployment in 2, arteriography only in 1, and arteriography with coiling in 1. Clinical success was ultimately achieved in all patients. No minor or major complications occurred.

CONCLUSION Interventional radiology provides rapid and effective management and treatment of iatrogenic pseudoaneurysms without complication.

CRT-300.17

Jetstream Atherectomy In Treating Denovo Or Non-stent Restenotic Femoropopliteal Disease: One-year Results From The Jetstream Navitus™ System Endovascular Therapy Post-market Registry (JET Registry)

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BACKGROUND The JET Registry is a real-world, prospective, multicenter registry designed to assess patient outcomes following the use of JetStream atherectomy (JS) for the treatment of de-novo or restenotic lesions in the femoropopliteal (FP) artery.

METHODS The JET Registry completed enrollment of 241 subjects at 37 U.S. investigational sites. Patients were enrolled if they had de novo or restenotic (non-stent) lesions in the FP artery, ≥70% stenosis or occlusion confirmed by angiography, lesion length ≥ 4.0 cm, at least one patent runoff vessel, and a baseline Rutherford category of 1-3. The primary effectiveness endpoint was binary restenosis at 12 months as defined by duplex ultrasound (DUS) derived peak systolic velocity ratio >2.5. Secondary endpoints included procedural success (≤ 30% residual diameter stenosis following atherectomy +/- adjunctive therapy), and major adverse events (MAE) through 30 days as defined by amputation, death, target lesion/vessel revascularization (TLR/TVR), or angiographic distal embolization (DE) that required a separate intervention. Adjunctive stenting was left to the operators' choice.

RESULTS A total of 241 subjects were enrolled (mean age 67.1 ± 9.8 years and 66% male). Diabetes was present in 41.1% of patients. Mean lesion length was 16.4 ± 13.6 mm, de novo lesions comprised 91.9%, and pretreatment percent stenosis was 91.1 ± 9.8%. Embolic protection and adjunctive stenting was used in 22.4% and 34.8% of cases, respectively. Mean procedure time was 73.4 ± 37.5 min. Post JS stenosis was 44.4 ± 20.0% and post adjunctive treatment 9.8 ± 11.4%. Site reported procedural success was 98.3%. At 30 days, the MAE rate was 2.3% (5/219), including 2 TLR/TVR and 3 DE. At 12 months (n=177); 80.1% and 81.7% were free from MAE and TLR/TVR, respectively, by Kaplan-Meier analysis, and 77.2% (44/57) were free of restenosis.

CONCLUSION A high procedural success rate is seen with the JS device in treatment of FP obstructive lesions with a favorable low TLR/TVR and restenosis rates at 1 year. Although patency rate is in line with other atherectomy devices, the data is limited by the reduced rate of DUS follow up at 1 year.

CRT-300.18

Supera Stent Outcomes In Above-The-Knee Interventions: Effects Of Compression And Elongation (Sake-Compel) Sub-Study

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INTRODUCTION The interwoven nitinol stent design, Supera (Abbott Vascular) has been shown to have superior radial strength and fracture resistance as compared to traditional nitinol stents, resulting in higher patency rates at 6 and 12 months. Recently, a single-center study, SAKE, of consecutive real-world patients at our institution revealed a primary patency rate of 96.9% at 6 months and 85.8% at 12 months based on clinical need for intervention. However, detailed sub-analysis of the SUPERB trial, revealed variances in patency based on compression or elongation of the stent during deployment. We set out to evaluate the patency of the stent within the SAKE study based on these deployment characteristics.

METHODS We retrospectively evaluated the medical charts of 80 patients (98 limbs) with Rutherford class 2-5 symptoms who received SUPERA stents in the SFA and/or popliteal artery for high-grade obstructive disease and/or chronic total occlusion from March 2010 through May 2011 as part of the SAKE study. We identified 76 limbs that met criteria for adequate evaluation of compression and elongation of the stent(s) during deployment. These patients were followed for patency (primary endpoint) and the need for re-intervention (secondary endpoint) over a mean follow up of 15 months. Vascular complications including hematoma, bleeding, and amputation were monitored for safety endpoints. Compression/Elongation was defined as follows based on previous sub-analyses: Moderate Compression (-40 to -21%); Minimal Compression (-20 to -11%); Nominal (-10 to 10%); Minimal Elongation (11 to 20%); Moderate Elongation (21 to 40%); and Severe Elongation (>40%). Clinical significance of findings were determined using analysis of variance (ANOVA) or t-test.

RESULTS Of 80 patients that received Supera stents, there is a linear correlation between primary patency and stent elongation or compression at 15 month follow up. Best patency rates (85.19% primary patency and 92.59% assisted primary patency) and lowest reintervention rates (14.8%) were achieved with stent compression, followed by nominal deployment or minimal elongation, and worst outcomes (64.71% primary patency; 82.35% assisted primary patency; and 35.3% reintervention) with stent elongation to moderate or severe degree.

CONCLUSION Patency rates and reintervention rates are variable based on deployment characteristics of the Supera stent. Best outcomes are achieved with compression of the stent during deployment.

CRT-300.19

Evaluation of Safety and Efficacy of Ranger Paclitaxel-Coated Balloon in a Swine Femoral Artery Model

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OBJECTIVE Drug-coated balloon (DCB) have emerged as a therapeutic alternative in the treatment of peripheral vascular disease. The aim of this study was designed to evaluate the safety and efficacy of a Ranger DCB in a swine femoral artery model.

METHODS The femoral arteries of 42 swine were treated with low pressure balloon inflation either 1x clinical dose (single inflation, 2 mg/mm^2 paclitaxel) or 3x dose (2 overlapping DCBs, each with 3 mg/mm2 paclitaxel) or control (uncoated) balloons. We performed histologic analysis of arterial wall and downstream skeletal muscle and coronary band at 7, 30, and 90-days. Scanning electron microscopy (SEM) evaluation of 1x dose DCB and control balloons were performed at 7 and 30-days. Pharmacokinetic analysis comparing other available DCBs (In. Pact and Lutonix) to 1x Ranger DCB was also performed.