Selected Abstracts from the International Symposium on Endovascular Therapy (ISET)

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Abstract 1: Peripheral Aneurysm Coiling Using Large-Volume Ruby™ Coils: Results from the Multicenter Aneurysm Coiling Efficiency Trial

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Purpose: The Aneurysm Coiling Efficiency (ACE) trial aimed to demonstrate the safety and efficacy of soft, large-volume, bare platinum Ruby Coils (Penumbra Inc, Alameda, CA) in achieving high packing density, leading to complete aneurysm obliteration and stable vessel embolization.

Materials and Methods: The ACE trial was a prospective, multicenter study designed to capture data on the safety and efficacy of large volume coils in the peripheral vascular embolizations. Patients were identified from 15 centers between March 2012 and December 2016. Patients within the ACE registry were categorized into aneurysm embolization or vessel sacrifice subgroups. Primary outcomes included packing density with the number of coils implanted, time of fluoroscopic exposure, procedural device-related serious adverse events (SAEs), and occlusion status at 6 months with an optional 1-year outcome.

Results: A total of 78 cases were treated in 67 patients with peripheral aneurysms or malformations. The median age was 59 years (Interquartile Range (IQR) 48–71); 44.8% were female. In cases involving aneurysms (n = 26), a median of 6.5 coils (IQR 4–14) was deployed, achieving a median packing density of 26.8% (IQR 18.6–33.0) per case. Median fluoroscopy time was 29.0 minutes (IQR 21–36). At the 6-month follow-up, 90.9% (20 of 22) of cases had achieved stable or better occlusion grade compared with postprocedure and 100.0% (15 of 15) at the 1-year follow-up. No aneurysms were retreated during the followup period. In 52 procedures, vessel sacrifice or treatment of miscellaneous malformations was performed. A median of three coils (IQR 2-5) were placed in a median of 21.5 minutes (IQR 15–29) under fluoroscopy. At 6-month and 1-year follow-up, a total of 91.7% (22 of 24) and 100.0% (3 of 3) cases have demonstrated stable or better occlusion grade than postprocedure, respectively. Two lesions were retreated at 1-year follow-up. Common sites for embolization of this trial included were pulmonary (n = 5), splenic (n = 18), and gastroduodenal artery (GDA, n = 10). Compared with GDA patients in Maleux's study (1) wherein fibered (n = 15; mean ± standard deviation [SD] = 13.3 ± 5.2; P = 0.0134) were used, significantly fewer Ruby Coils were required to embolize the GDA. Only, 4.5% (3/67) of patients reported serious adverse events within 24 hours postprocedure; none were device related.

Conclusion: The Ruby Coil System efficiently achieves high packing density and stable occlusion in peripheral aneurysm embolization and vessel sacrifice. The 6-month and 1-year follow-up supported the long-term embolization stability in both cohorts.

Abstract 3: Submassive and Massive Pulmonary Embolus: Catheter-Directed Intervention versus Medical Management?

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Purpose: To use retrospective analysis of right heart strain measures before and after catheter-directed intervention in massive and submassive pulmonary embolus (PE) and compare outcomes with matched control participants New tools for catheter intervention allow for combination mechanical and chemical lytic therapy for massive and submassive PE. The authors hypothesize that when used in combination, clot aspiration devices and catheter-directed lytics substantially improve measures of right heart strain compared with standard medical management. Furthermore, timely catheter-based intervention on massive and submassive PE may provide a foundation for altering the course of pulmonary thromboembolic disease.

Materials and Methods: A retrospective study was approved by the institutional review board to investigate patient outcomes after catheter-based therapies comparing them with control participants. In the treatment group were 25 patients who underwent catheter-based therapy consisting of single or combination mechanical and chemical lytic therapy. A control group of 25 patients who were diagnosed with PE during the same time period was matched for relative clot burden, similar severity of disease (right ventricular–to–left ventricular [RV-to-LV] ratios), age, preexisting chronic obstructive pulmonary disease, and other pertinent risk factors. Control patients received standard of care medical management, including systemic anticoagulation only. All available pre- and postprocedural cardiac imaging, including CTA, and echocardiography were gathered and used to assess RV-to-LV ratios, as an indirect measure of right ventricular strain. Two blinded, fellowship-trained cardiothoracic imaging physicians (each with greater than 7 years of experience) evaluated the pre- and posttreatment computed tomography angiography (CTA) and echocardiography images. These blinded physicians acquired

RV-to-LV measurements from diagnostic CTA and echocardiographic images at all time points according to established methods. Measurements of RV and LV diameters pre- and posttherapy, as well as assessment of clot burden and location were recorded in an anonymized data table.

Results: Over a period of approximately 1 year, 25 patients at a single institution underwent catheter-based thrombolysis of submassive and massive PE. Two devices were used, either alone or in combination: (1) Indigo Mechanical Thrombectomy System (Penumbra, Alameda, CA) and (2) EKOS Acoustic Pulse Thrombolysis (BTG, London, United Kingdom). The total dose of administered tissue plasminogen activator was roughly uniform in both catheter-directed treatment groups, averaging 28 mg, and was administered either as a single bolus or as 12- to 24-hour infusion (average, 22 hours). Average preprocedure diagnosis was 1 day. Postprocedure imaging was performed at 48 hours after the initiation of medical management and systemic anticoagulation or after IR catheter-directed therapy (average postprocedure follow-up time-point, 1.8 days). Measurements of RV-to-LV ratios between the catheter-directed thrombolysis and medical management groups before and after therapy demonstrated a statistically significant reduction in RV strain, as measured by a change in RV-to-LV ratio. Specifically, the catheter-based group demonstrated an improvement in average RV-to-LV ratio of 25% at 48 hours ($P < 0.05$) versus the medical management group, which showed a slight average increase in this ratio (7%; $P < 0.1$). No adverse events were reported in either group.

Conclusions: Catheter-based management of massive and submassive PE shows improved RV-to-LV ratio, an indirect measurement of right heart strain, compared with medical management alone. A combination of widely available catheter-based devices, either mechanical aspiration or ultrasound-enhanced thrombolysis may be used in management of intermediate- and high-risk PE patients safely. If widely available, catheter-based therapy stands also to change the practices of interventional radiology physicians. The importance of catheter treatment could approach that of other cardiac emergencies such as ST elevation myocardial infarction, creating the expectation to provide emergent or semi-emergent response. Although RV-to-LV ratios are a useful and a widely available indicator of short-term right heart strain, better measures of cardiac strain and total pulmonary vascular reserve are needed to more precisely measure the long-term impact of invasive therapy and to understand the impact on disease progression to chronic pulmonary hypertension.

Abstract 4: XTRACT as a Potential Frontline Treatment in Peripheral Arterial Thromboembolism: Results from the PRISM Trial

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Purpose: The purpose of the trial was to examine the safety and clinical efficacy of XTRACT in a patient population with peripheral arterial occlusion. We report the outcome of the PRISM trial on the use of Penumbra/Indigo System as an initial and secondary approach for peripheral revascularization.

Materials and Methods: The PRISM trial is a single-arm, multicenter, and retrospective analysis of enrolled consecutive patients meeting the inclusion criteria of peripheral arterial occlusion (Thrombolysis in Myocardial Infarction [TIMI] 0–1) before treatment with the Penumbra/Indigo System. The primary endpoints were vessel patency immediately postprocedure as measured by TIMI scores, and the rate of serious adverse events (SAEs) within 24 hours of treatment with the study device.

Results: PRISM concluded with 79 patients enrolled. XTRACT was the primary treatment modality for 39 patients (49.4%); the remaining 40 patients (50.6%) were treated with XTRACT secondary to failure from CDT, other endovascular therapies, and distal emboli from preceding interventions. As the primary intervention, XTRACT was successful in 79.5% (31 of 39) of patients; as secondary therapy, 92.5% (37 of 40) of patients were successfully revascularized with XTRACT to TIMI 2–3. Overall, vessel patency (TIMI 2–3) was achieved in 87.2% (68/78) immediately after XTRACT and in 96.2% (76/79) of patients after additional adjunctive interventions. Procedural SAEs were reported in five patients (6.3%); none were device related.

Conclusions: Thrombectomy using XTRACT was safe and effective as both primary and secondary intervention in patients with peripheral arterial occlusions.

Abstract 5: A Unique Bioconvertible Inferior Vena Cava Filter: One-Year Results from the SENTRY Study

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Purpose: The safety and effectiveness of this bioconvertible Sentry inferior vena cava filters (IVCFs) were assessed in patients requiring temporary protection against pulmonary embolism (PE). The Sentry filter is designed to provide filtration for a 60-day period of transient PE risk and then open (bioconvert) to a nonfiltering configuration, obviating typical filter-related complications and with no requirement to retrieve the device.

Materials and Methods: At 23 clinical sites, 129 patients were enrolled with documented deep vein thrombosis (DVT) or PE or at temporary risk of developing DVT or PE and unable to use anticoagulation. The primary endpoint was clinical success at 6 months, including technical success of filter deployment, freedom from symptomatic PE through 60 days before filter bioconversion, and 6-month freedom from filter-related complications. Patients were extensively monitored

by radiography, computed tomography (CT), and CT venography at prespecified time points, including filtering configuration through 60 days, filter bioconversion after 60 days, and PE and filter-related complications through 6 and 12-months.

Results: The primary endpoint of clinical success at 6 months was achieved in 111 of 114 evaluable patients (97.4%, 95% confidence interval 92.5%–99.1%). A Sentry device was successfully deployed in all patients. The rate of symptomatic PE was 0% through 60 days (0 of 129), 6 months (0 of 126), and 12 months (0 of 117). The rate of symptomatic filter-related complications was 1.6% (2 of 129) through 12 months. During the first month, 2 patients developed symptomatic caval thrombosis, experiencing no recurrence after successful interventions. Through 12 months, there were no instances of filter tilting, migration, embolization, fracture, or perforation, and there were no filter-related deaths. The rates of successful filter bioconversion were 95.7% (110 of 115) at 6 months and 96.4% (106 of 110) at 12 months.

Conclusions: The results of this pivotal multicenter trial demonstrate that this next-generation, bioconvertible IVCF provided safe and effective protection against PE during the 60-day period of risk. The Sentry device had a very high rate of intended bioconversion, an unprecedentedly low rate of device-related complications through 12 months of imaging-intensive follow-up, and a noteworthy 0% symptomatic PE rate at every follow-up time point to 1 year.

Abstract 6: Clinical Outcomes and Debris Capture Analysis Using a Novel Filter During Atherectomy: WISE LE Study

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Purpose: The WISE LE study was designed to demonstrate the performance of the WIRION Embolic Protection System (EPS) in subjects undergoing lower extremity atherectomy for the treatment of peripheral arterial disease (PAD). The study includes a histopathologic analysis of debris captured by the filter during the procedures.

Materials and Methods: WIRION is a distal EPS consisting of an independent modular filter unit with a proprietary locking mechanism mounted on a rapid exchange delivery system that can be attached in any location along any 0.014-inch guidewire through a 6-Fr or larger guiding catheter. The filter is compatible with arterial diameters of 3.5 to 6 mm.

The WISE LE is a multicenter study, performed in the United States and Germany, on patients with PAD who are undergoing atherectomy with the use of the WIRION EPS in the femoropopliteal arteries. The primary endpoint is a composite of MAEs occurring within 30 days postprocedure, which is compared with an objective performance goal derived from historical atherectomy data. The secondary endpoints include device and clinical success and evaluation of the debris in the filter. Adverse events were adjudicated by an independent Clinical Event Committee. All filters were sent to an independent lab (NAMSA) for quantification and histology analysis of any captured debris.

Results: The study protocol specified enrollment of 153 patients with the primary endpoint successfully met if 18 (12.0%) or fewer MAEs occurred according to CEC adjudication. An interim analysis was performed in 103 patients, and the study was stopped for success at the interim given a single MAE.

The histopathologic analysis showed that the WIRION captured small-sized thrombi (<1 mm) in 97% of patients analyzed. Larger thrombi ranged 1 to 2 mm (20% of patients) or even larger (>2 mm) were captured in 14% of patients as well. In general, the thrombi exhibited presence fibrin material admixed with fibrous fragments along with some red blood cells and leukocytes. From 66% of patients, signs of microcalcification of the thrombi were detected.

Conclusions: The study was designed to demonstrate the successful and effective use of the WIRION filter with all atherectomy systems used in the study including directional, rotational, orbital, and LASER systems. The WIRION was demonstrated to be safe, easy-to-use device that can be used with all atherectomy system. Debris was captured in 97% of cases with larger than 1-mm debris in 20% of cases, demonstrating the highly clinical importance of using EPS during atherectomy in PAD.

Abstract 7: Atherectomy Devices for Peripheral Arterial Disease: Review of Current Device Data

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Purpose: Understand atherectomy indications and contraindications in peripheral artery disease (PAD). Review current data regarding atherectomy devices.

Materials and Methods: PAD affects more than 2 million Americans. Atherectomy is an adjunctive endovascular technique to reduce plaque burden in PAD patients. This review discusses current data available for atherectomy devices.

Results: Current designs include directional, rotational, laser, and orbital atherectomy devices. Directional atherectomy devices (SilverHawk, TurboHawk, and HawkOne) enable different excisional planes by rotating the device. The DEFINITIVE LE study demonstrated 78% primary 1-year patency using SilverHawk; 33% received postatherectomy percutaneous transluminal angioplasty (PTA) and 3.2% stenting. The newest HawkOne device targets lesions with different morphologies, including thrombus. Neointimal hyperplasia and restenosis from arterial wall injury inspired development of Pantheris, a directional device with optical coherence tomography, currently undergoing the VISION trial.

Rotational devices (Rotablator, Jetstream, and Phoenix) require no distal embolic protection because debris is small. The

ERBAC study demonstrated higher target lesion revascularization rates with rotational atherectomy (42.4%) and excimer laser (46.0%) when compared with angioplasty (31.9%). Excimer laser devices (Turbo Elite, Turbo-Tandem, and Turbo-Booster) use high-energy, monochromatic light to dissolve plaque. EXCITE ISR demonstrated that 6-month patency rates are higher with laser and PTA (73.5%) versus PTA only (51.8%). Orbital atherectomy systems (OAS) (Diamondback 360 and CSI Stealth 360) eccentrically sand plaque. New low-profile models (4 Fr) are more flexible, navigating highly tortuous calcified lesions. The CONFIRM registry reports lowered stenosis from 88% to ~10% with PTA and OAS. LIBERTY 360 (30-day results) demonstrated 90.7% freedom from major adverse events.

Conclusions: A wide array of atherectomy devices are available for the treatment of PAD patients. This review provides data supported guidance regarding which specific atherectomy devices are best equipped based on lesion specific morphology and characteristics.

Abstract 8: Eighteen-Month Personnel Monitoring Dosimetry Results Using a Suspended Radiation Protection System with Face Shield

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Purpose: To determine the radiation doses at the waist and eye for an interventionalist performing a wide variety of procedures over an extended period using the suspended protection system (SPS) (Zero-Gravity™, TIDI Products, Neenah, WI).

Materials and Methods: One interventionalist wore two personnel monitoring dosimeter badges (optical stimulating luminescence, Luxel+, Landauer, Glenwood, IL), one at the front waist and one on the cap near the left eye, when performing procedures using SPS. The SPS includes a 0.5-mm Pb-acrylic face shield encompassing an arc in the front and to the sides of the operator and a 1-mm Pb apron. Reports for 18 consecutive months were retrospectively reviewed, along with corresponding technical information for the same procedures, including fluoroscopy minutes, total patient dose-area-product (DAP), and fluoroscopic DAP. Background controls were subtracted out by the manufacturer using standard industry method. Data for the substantially fewer procedures in which the operator used a standard lead apron and different dosimeters are not included in this study.

Results: A total of 299 procedures were performed, including vascular and nonvascular interventions of the chest, abdomen, pelvis, and extremities (e.g., chemo- and radioembolization, transjugular intrahepatic portosystemic shunt, genitourinary and biliary interventions, others). The total deep dose equivalent (DDE) over 18 months were 0 mRem for the waist and 11 mRem (0.11 mSv) for the eye. The lens dose equivalent (LDE) was 11 mRem (0.11 mSv). Eye DDE is relevant to the brain. The average annual background exposure is 320 mRem (3200 μSv) or 80 mRem (800 μSv) without radon. This is compared with annualized left eye exposure of a practicing interventionalist using SPS in this study of 7.33 mRem (73.3 μSv). The annual occupational exposure limits to the lens of the eye are 15,000 mRem in the United States and 2000 mRem in Europe.

Conclusions: Eye exposures during clinical practice using the SPS were exceedingly low in this study, far lower than reports of mobile shields, and represent a 9% increase above background without radon. Waist dose was not detectable.

Abstract 9: Early Clinical Results Using the FLEX Scoring Catheter in 100 Femoropopliteal Chronic Total Occlusions

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Purpose: Current methods in the treatment of chronic total occlusions (CTO) present numerous clinical and technical limitations. There is strong unmet need for treatment methods that are cost-effective and lead to improved patient outcomes. Initial clinical results using the FLEX Scoring Catheter (VentureMed Group, Toledo, OH) as a vessel preparation device to treat femoropopliteal chronic total occlusions were evaluated.

Materials and Methods: The Flex Scoring Catheter is a 6-Fr, 0.18-inch guidewire-compatible device. The FLEX has three atherotomes that modify plaque during pull-back with Dynamic Scoring technology. FLEX can be rotationally controlled to create multiple linear scores preparing the vessel for treatment. The present study analyzed voluntarily provided case reports (24 operators in 15 hospital systems) of 100 patients presenting between December 2015 and September 2017 with femoropopliteal CTOs. After successfully crossing the CTO, the lesion was treated with the FLEX Scoring Catheter before a drug-coated balloon (DCB) or plain old balloon angioplasty (POBA). Luminal gain after administration of the FLEX and postprocedure was calculated, as well as the average opening and maximal balloon pressures.

Results: The average lesion length was 191 mm (range, 30–350 mm). The average luminal gain after FLEX was 31%. Residual stenosis after FLEX plus DCB or POBA was 7.9%. Technical success was 99%; one patient required predilation to allow for the FLEX catheter to pass. The FLEX catheter allowed for recanalization of the CTO before angioplasty in 99% of the cases. There were no vessel perforations or emboli. Ninety-six percent of the cases had no dissection; 4% of cases had minimal dissections. Provisional stent use was 19%. Moderate or severe calcification was recorded in 46% of the cases. DCB was used in 70% of the cases, at operator discretion. The balloon-opening pressures (defined as the

lowest pressure allowing for complete lesion effacement) averaged at 4.1 atm (range, 2–10 atm), and maximal balloon inflation pressures averaged at 9.4 atm (range, 4–16 atm).

Conclusions: The FLEX catheter performed safely with a high degree of technical success. It is effective in recanalizing CTOs with low rates of vessel dissection. Provisional stent use is low, and there were no flowlimiting dissections. Low (subnominal) balloon-opening pressures suggest significant change in vessel wall compliance after vessel prep with FLEX. The FLEX is used by interventionalists as a vessel preparation device, especially before DCB.

Abstract 10: One-Year Results of The BioMimics 3D Stent System in the MIMICS-2 Study

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Purpose: Endovascular treatment of femoropopliteal artery (FPA) disease is challenging because of high rates of restenosis and multiple forces in this vascular segment that present complex problems for stent design. The BioMimics 3D (three-dimensional) stent (Veryan, Horsham, UK) is a self-expanding Nitinol stent designed 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 leads to elevated wall shear in the stented segment and reduced neointimal formation. The unique design offers biomechanical compatibility through its ability to accommodate longitudinal shortening during knee and hip flexion. This study is designed to demonstrate the safety and efficacy of the BioMimics 3D Vascular Stent System in the treatment of FPA disease.

Materials and Methods: This prospective, single-arm, multicenter trial enrolled patients with symptomatic de novo occlusive disease of the native FPA. An independent angiographic core laboratory reviewed all angiograms and endpoint events were independently adjudicated. 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, in-hospital clinical and 1-year primary patency and clinically driven target lesion revascularization (CDTLR) outcomes.

Results: A total of 271 subjects were enrolled, with a mean age of 68 years, 66% male, 81% smokers, and 45% with diabetes. The core laboratory–reported mean 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 was 77.4%, and at procedure conclusion, 11.5%. Lesion success (successful stent implantation without device-related complications) and procedure success (lesion success without MAE) were 100%. There were no procedural or in-hospital stent fractures, abrupt closure, spasm, distal embolization, or perforation. Dissections greater than type C occurred in 1% of cases. One-year primary patency and CDTLR data will be available at the time of presentation.

Conclusions: 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. The 1-year results will confirm whether these results are associated with sustained safety and efficacy.