

## ABSTRACTS FROM THE 2016 CHICAGO ENDOVASCULAR CONFERENCE (CVC), CHICAGO, IL, JULY 18-20, 2016

### Title: Percutaneous Foam Sclerotherapy for the Management of Lower Extremity Venous Ulcers

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**Objective:** To determine the efficacy of image guided foam sclerotherapy for treatment of lower extremity venous ulcers in patients with severe chronic venous insufficiency who are CEAP classification C6.

**Materials:** This is a retrospective HIPAA compliant IRB approved review. A total of 38 patients underwent treatment for chronic lower extremity venous ulcers during a 3 month period. Treatment consisted of percutaneous foam sclerotherapy using 3% sotradecol prepared with the Tessari method. Injections were performed with a 25 gauge needle with ultrasound guidance. Target veins included dilated veins near an ulcer base as well as any dilated or incompetent perforator veins. Patients with reflux of the GSV or SSV concurrently underwent endovenous laser ablation. Patients underwent pre procedure evaluation with ultrasound duplex examination, history, physical, and assessment with CEAP and VCSS. Following treatment, patients underwent immediate post procedure wound care and compression dressing placement. Every patient underwent repeat evaluation at 2 weeks with additional treatment as necessary. Wound care and follow-up VCSS assessment was performed at 4 weeks and 12 weeks from initial treatment.

**Results:** There were 38 patients treated with a total of 51 lower extremities with venous ulcers. Endovenous laser ablation was performed in 68% of patients (n=26) and 63% of all lower extremities (n=32). All treated lower extremities (n=51) demonstrated interval wound healing and decreased serous drainage following sclerotherapy as well as a reduction in VCSS score. At 4 weeks, 67% (n=34) demonstrated complete healing. At 12 weeks, there was complete healing of 94% (n=48). An adverse event was seen in 1 patient secondary to extravasation resulting in dermal necrosis and an increased ulceration which subsequently healed following additional treatment. DVT was seen in 0 patients following sclerotherapy or endovenous ablation. Complete healing was seen in 94% at 12 weeks. There was a statistically significant drop in VCSS score at 12 weeks with an average decrease of 5.6 (p value < 0.001)

**Conclusions:** Percutaneous foam sclerotherapy is an effective technique. When performed in conjunction with endovenous ablation of saphenous veins, proper wound care, and compression therapy, percutaneous sclerotherapy is a first line treatment for promoting rapid healing of venous ulcers.

### Title: Successful Endovascular Treatment of Right Common Iliac Artery Occlusion and Left Common Iliac Artery Stenosis by Rendezvous Technique for Impella assisted CTO PCI with Improvement of Angina & Buttock Claudication - 'Novel' Retrograde Rendezvous Technique for Iliac Artery Intervention.

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**Objectives:** Description and oral presentation of a new technique for PVI of iliofemoral lesions.

A 67 year old vasculopath male with past medical history of hypertension, dyslipidemia, diabetes, CADs/pCABG '96: SVG to LADs/p BMS 4.0 x15 mm SVG to RCA 2008, S/p PCI proximal LAD Taxus 2.5, ischemic cardio-myopathy - EF 20 mm, > 45 deg angle), Ramus - 70% tubular stenosis and RCA - mid CTO. Graft angiography showed SVG to RCA had mild prox ISR then followed by 70%, RPDA distal to anastomosis had mild ISR with SVG to LAD - 100% occluded at ostium. There was no LIMA graft. His redo CABG mortality risk was assessed by EuroSCORE as 55.6%. After a multidisciplinary discussion, we decided that ramus 70% stenosis was amenable to revascularization with staged LAD CTO PCI if no improvement in symptoms after Ramus PCI. Patient's EF was less than 15% and Impella was indicated for high risk PCI. PVI was also planned for Leriche syndrome and for obtaining bilateral femoral access for Impella and CTO guidewires. We obtained bilateral femoral artery access with 10cm 7Fr sheath advanced over the wire into the vessel. Initial attention was on the right iliac occlusion. Using a stiff angled glidewire and a 5Fr Berenstein catheter, attempts were made to cross the right iliac occlusion luminally. This was unsuccessful so the wire was advanced into the proximal common iliac artery subintimally. The left femoral arterial sheath was exchanged for a 7Fr Ansel 2 sheath which engaged the right common iliac artery. A stiff angled glidewire crossed subintimally into the right external iliac artery. A 6x20mm EverCross balloon was advanced to the common iliac artery in an antegrade manner and a second balloon in a retrograde manner. The balloons were simultaneously inflated. This allowed the retrograde glidewire to advance into the abdominal aorta luminally (Rendezvous method). Successful percutaneous vascular intervention of the right common iliac artery with placement of 2 overlapping PTFE covered stents: The proximal common iliac artery was stented with a 10x38mm iCast covered stent deployed at nominal pressure. Distally, this was overlapped with a 7x22mm iCast covered stent deployed at high pressure. Attention was then turned to the left common iliac artery. The vessel was pre-dilated with an 8x20mm Powerflex Pro balloon inflated to nominal pressure and then stented with a 9x38mm iCast covered stent deployed at nominal pressure. The wires were removed and final angiography was performed. Balloon pre-dilation was followed by overlapping covered stent deployment as noted above. Following the procedure, there was excellent angiographic result with < 20% residual stenosis. After this, Impella assisted Ramus PCI performed without any complications. Clinical improvement was observed, with significant improvement in angina and buttock claudication. Right side ABI normalized to 0.9 at 2 month follow-up.

### Title: Evaluating the Safety and Efficacy of the Viance Crossing Catheter and the Enteer Re-Entry Catheter In Crossing Chronic Total Occlusions (CTO) in Patients with Peripheral Arterial Disease

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**Background:** Peripheral arterial disease affects (PAD) 8-12 million people across the country. The subset of patients with chronic total occlusions (CTO) has remained a challenge for the endovascular specialist with failure rates of up to 20-25%.

**Methods:** This was a multi-centered review of patients with CTOs treated with a Viance crossing catheter. Cases were analyzed for success rate and adverse events. Calcification, side branch involvement, and lesion length were analyzed to predict characteristics which maximize success.

**Results:** The overall success rate was 71.9% with mean lesion length of the successful cases being 155.75mm +/- 98.8mm and 177.1mm +/- 105.4mm in unsuccessful cases (p value 0.261). The success rates for iliac (n=10), superficial femoral artery/popliteal (n=100), and below the knee (n=29) were 70%, 78%, and 51.7%, respectively.

There were 56 cases with moderate-severe calcification, of which 62.5% were successful, as opposed to 78.3% in those without (p value 0.042). There were 44 cases with moderate-severe side branch involvement, of which 25% were successful compared to 78.9% for those without (p value 0.007).

**Conclusions:** The efficacy and safety of the Viance catheter in this larger cohort is comparable to previous studies. The presence of moderate to severe calcification and heavy collaterals were predictors of unsuccessful crossing whereas long lesion length was not a predictor of unsuccessful crossing. More importantly, there was no incidence of adverse events in this study.

**Title: Predictive risk factors for TLR in SFATarget Lesion Revascularization Post-Atherectomy in Peripheral Arterial Disease: Procedural and Histologic evaluation post OCT-guided Atherectomy**  
Jon George, MD, Cardiologist, Einstein Medical Center

**Background:** The VISION trial evaluated the first-in-class, optical coherence tomography (OCT)-guided atherectomy device, Pantheris, for its safety and efficacy in treating superficial femoral artery (SFA) and popliteal lesions. Designed to allow for optimal plaque debulking, while minimizing damage to the adventitial borders, the Pantheris atherectomy system achieved its safety and performance goals, and in addition allowed for a detailed assessment of tissue specimens retrieved from treated lesions, along with their detailed OCT-evaluation.

**Methods:** In the course of the VISION trial, DeNovo SFA lesions (n=198) were treated with OCT-guided atherectomy catheter using Pantheris. Excised plaque was analyzed to correlate OCT guidance of directional atherectomy with the avoidance of adventitial injury. In addition, multiple histologic attributes were assessed and quantified. In order to determine relative risk factors for lesion and procedural characteristics that contribute to TLR at 6 months, a regression analysis was performed for all measured components in TLR vs. non-TLR lesions.

**Results:** Comparative evaluation of the various attributes between non-TLR (n= 176) and TLR (n=12) lesions treated in the Vision trial delineated several risk factors related to: disease progression (pre-procedural stenosis, thrombus, lesion length, and lipid content), procedural (OCT visualization of plaque burden), and histologic (lipid content and medial removal). When compiled, the transformed calculated Z-scores for the selected attributes demonstrates a statistically significant value (p=0.034). Notably, less than 1% of adventitia was present within the atherectomy excised from all treated lesions.

**Conclusion:** These findings suggest that operator- dependent variables during revascularization, which can be objective with validated scores and can now be guided through the use of OCT in real time, may affect patient outcomes.

**Title: Retrospective Review of outcomes of Digital and forefoot Metatarsal amputation in diabetic foot**

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**Aims:** Diabetic patients have high plantar pressure due to peripheral neuropathy, joint arthropathy, and metatarsal head prominence. Despite a presumed adequate circulatory status, the majority of toe amputations

in diabetics often require revision to a more proximal level in the form of transtatarsal amputation (TMA). We aim to compare the outcome of diabetic patients with gangrenous toes who were managed initially either by digital amputation or by TMA

**Methods:** A retrospective audit of all patients who underwent either digital or TMA amputation in a tertiary referral center was performed from 2002 through 2015. Comorbid conditions, subsequent amputations, hospital stay, and need for readmission were noted.

**Results:** 190 patients underwent minor amputation during the study period. 126 patients were diabetic. 69 patients had digital amputation and 57 TMAs in diabetic patients. Demographics were similar in both groups. Progress to major amputation was 13% in the digital group and 17% in the TMA group in diabetic patients. 29% of digital amputations and 19% of TMAs in diabetic patients required minor amputations or revision procedures. Median length of hospital stay was 22 days for both groups. Need for re-admission was 50.5% in digital patients compared to 56.6% in TMA patients (p=0.399). There was no significant difference in quality of time spent without symptoms of disease or toxicity of treatment (Q-TWIST) between both groups.

**Conclusion:** Despite the relief of high vertical plantar pressure through TMA, a conservative approach of digital amputation seems to impart more favorable outcomes.

**Title: Target Specific Oral Anticoagulants Following Percutaneous Endovenous Intervention for Lower Extremity Deep Venous Thrombosis in Patients with Cancer**

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**Background:** In patients with cancer, deep venous thrombosis (DVT) is associated with a poor prognosis independent of each individual disease. To date the anticoagulant of choice has been low molecular weight heparins (LMWH). The 2016 anticoagulation guidelines update by the American College of Chest Physicians upholds that view and with respect to the use of target specific oral anticoagulants (TSOAC) cites paucity of data for their use in this setting. Subcutaneous injection of LMWH is inconvenient and cumbersome. We report on the medium-term outcome of patients with lower extremity DVT who underwent percutaneous endovenous intervention (PEVI) followed by administration of TSOAC.

**Methods:** A TSOAC was given to 88 patients with cancer within 2 hours of undergoing PEVI for extensive symptomatic lower extremity DVT. In 26 patients (30%), DVT was bilateral. On admission, 30 patients (34%) were on warfarin of whom 18 had therapeutic INR (60%). They underwent PEVI within 24 ± 8 hours of admission. Heparin was given to all and discontinued after completion of PEVI. Within 2 hours after PEVI, the maintenance dose of TSOAC was initiated and continued indefinitely. Rivaroxaban, apixaban and dabigatran were used in 43, 41 and 4 patients respectively. Warfarin was discontinued in those who were on it. The mean follow up was 26 ± 4 months. Patients were assessed for mortality, recurrent venous thromboembolic disease (VTE), post- thrombotic syndrome (PTS) and bleeding during this period.

**Results:** At follow-up, there were 8 deaths due to cancer. There was no recurrent VTE or bleeding in any patient. PTS developed in 6 patients (7%) with a mean Villalta score of 6.4 ± 1.4 (mild severity). All patients tolerated the anticoagulation regimen. The mean duration of hospitalization was 30 ± 6 hours.

**Conclusion:** In cancer associated DVT, PEVI followed by TSOAC is highly safe and effective. This approach leads to immediate relief of

symptoms, enhanced patient satisfaction, short hospitalization and no recurrent VTE. The incidence of PTS is low and only of mild severity.

**Title: Temporary Supra-Renal Caval Interruption using the Angel Catheter during Ilio-Caval DVT: First reported case in the United States outside clinical trials.**

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**Introduction:** Prevention of pulmonary embolism (PE), amongst patients with deep venous thrombosis (DVT) often involves retrievable inferior vena cava (IVC) filters. This is particularly true in patients that require surgery. Currently, retrievable IVC filters are available for IVCs whose diameter 32mm. Therefore, PE prevention in patients with an IVC diameter >32 mm remains an issue. In this report, we describe the use of a novel IVC filter device in such a scenario.

**Case Description:** A 33 year-old woman with a uterine fibroid presented with vaginal bleeding and leg swelling. Work up revealed an ilio-femoral DVT extending into the infra-renal IVC and a massive uterine fibroid causing extrinsic IVC compression with occlusion to the level of the renal veins. Her suprarenal IVC was patent but measured 34mm.

**Management Plan:** Hysterectomy was recommended; however there were concerns about thrombus migrating into the lungs after IVC compression was relieved. Angiovac thrombectomy and surgical thrombectomy were discussed but not feasible in this case. Temporary caval interruption with a filter was ideal but the only available option with an IVC diameter of 34mm was a bird nest filter, which is non-retrievable and would require suprarenal placement. Therefore, it was decided to seek compassionate use for an Angel catheter in the suprarenal IVC followed by hysterectomy. The Angel catheter is a novel IVC filter attached to a catheter and can be placed in the IVC irrespective of diameter. After FDA approval, the Angel catheter was deployed in the suprarenal IVC and hysterectomy was performed. Following surgery, the Angel filter was removed. Final venogram confirmed a patent IVC. Images 1-3 show the Angel catheter, IVC placement and tumor size.

**Conclusion:** The Angel catheter offered distal protection in this case and may have utility during either medical or mechanical treatment of DVT.

**Title: The Diagnostic Gap: Clinical under-treatment of fluoroscopy-based SFA revascularization**

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**Background:** Fluoroscopy-based diagnosis is a cornerstone for interventional medicine. Nevertheless, it has the inherent shortcoming of two-dimensional disease visualization. We postulated that limited plaque detection may lead to subsequent under-treatment.

**Methods:** In VISION trial 198 SFA lesions were treated with the first in class, OCT-guided atherectomy catheter, Pantheris which supports both, therapeutic intervention and real-time intravascular visualization. We investigated the difference between diagnostic lesion length as measured by fluoroscopy vs. the OCT-guided treated lesion length (defined here as a 'Diagnostic Gap').

**Results:** An average Diagnostic Gap (OCT length – fluoroscopy length) of 19.5mm was noted across all study lesions ( $p < 0.0001$ ). Subsequently, we analyzed the correlation between Diagnostic Gap values and occurrence of TLR at 6-month post revascularization. Even with low TLR rate in VISION study (6.4%, 12/188 lesions), a trend was observed (10.6 mm vs. 20.0 mm,  $p=0.15$ ) between the values of Diagnostic Gap and the occurrence of TLR at 6-month.

**Conclusion:** The clinical implications of under-treated plaque burden at the lesion edge is significant and has been linked to risk of TLR in coronary interventions. To the best of our knowledge, this is the first

clinical study to show the Diagnostic Gap and its correlation with TLR in PAD. These findings also suggest that real-time OCT-guided atherectomy may enable precise and complete plaque removal and thus improve long term patient outcomes.

**Title: The Relationship between Depression and Co-morbidities in Veteran Patients Undergoing Endovascular Interventions for Peripheral Artery Disease**

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**Background:** Little is known about the association between depression and peripheral artery disease (PAD) outcomes. If depression is a risk factor for the incidence and progression of PAD, it could be an important modifiable target for interventions to possibly improve outcomes of these patients. Age has been widely shown to greatly affect PAD outcomes, but it has rarely been looked at in conjunction with depression.

**Methods:** We analyzed Veteran patients enrolled in the Excellence in Peripheral Artery Disease (XLPAD; NCT01904851) registry undergoing endovascular revascularization of infrainguinal peripheral arteries between July 2005 and October 2014. Depression and age were established based on clinical information recorded in the electronic medical records.

**Results:** A total of 337 patients were analyzed; 88 (26.1%) had depression. Those with depression were younger ( $62.6 \pm 7.1$  vs.  $64.9 \pm 8.2$ ;  $p=0.015$ ) and white (75.0% vs. 60.6%;  $p=0.040$ ), without significant gender differences. A two-way ANOVA was conducted to examine the effect of age (middle vs. old) and depression (depressed vs. non-depressed) on co-morbidities for patients with PAD. There was a main effect for age,  $F(1,334) = 3.84$ ,  $p=.05$ , indicating the mean number of co-morbidities was significantly higher for older adults ( $M=2.7$ ,  $SD=2.0$ ) than middle age adults ( $M=2.3$ ,  $SD=1.8$ ). There was also a main effect for depression,  $F(1,334) = 12.17$ ,  $p=.001$ , showing the average number of co-morbidities for depressed patients ( $M=3.1$ ,  $SD=2.0$ ) was significantly higher than non-depressed patients ( $M=2.3$ ,  $SD=1.8$ ). The interaction between age and depression was non-significant,  $F(1,334) = 3.11$ ,  $p=.08$ . Among non-depressed patients, older adults compared with middle age adults had a higher instance of TIA, (3.6% vs. 1.2%;  $p=.043$ ) and chronic kidney disease, CKD, (14.9% vs. 5.2%,  $p < .001$ ). While amongst patients diagnosed with depression, older adults were less likely to of had a stroke than middle age adults (0.0% vs. 9.1%,  $p=.025$ ). Non-depressed middle aged adults also presented more often with CTO lesions (39.4% vs 27.3%,  $p=.012$ ) and predominantly had lesion thrombosis (42.2% vs. 29.3%,  $p=.005$ ). Depressed older adults presented more often with profunda femoris disease (5.7% vs. 2.3%,  $p=.04$ ) than depressed middle age adults. Overall major adverse cardiovascular and limb events at 12 months were similar in depressed and non-depressed patients for both middle and old age adults

**Conclusions:** Over a fourth of patients with PAD undergoing endovascular intervention have depression. These patients are younger, predominantly white, present with longer and more heavily calcified lesions, and undergo superficial femoral artery revascularization. Older adults with PAD that have depression had higher number of co-morbidities, but fewer occurrences of strokes, while those without depression have more instances of TIAs and CKD, but fewer co-morbidities. The 12-month clinical outcomes are similar for depressed and non-depressed patients. Depression and age have shown to effect PAD, which suggests that interventions to prevent or treat depression could have secondary benefits in reducing PAD risk or improving clinical outcomes and important to consider when treating PAD patients.

**Title: Transradial access for Endovascular therapy of Critical limb ischemia.**

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**Introduction:** The radial access is currently being used frequently in left heart catheterization because it has shown to decrease the incidence of vascular complications. In this case we are describing the use of radial access in peripheral PTA.

**Case:** A 52 years old female patient with PMH of HTN, HLP and Severe PAD with totally occluded infra-renal abdominal aorta just distal to the renal arteries and known right axillary femoral bypass with fem-fem bypass. This was presented with bilateral leg and foot pain at rest, diminished pulses and ulceration of the legs. ABIs were obtained and were abnormal (right leg: ABI: 0.27, TBI:0.12. Left leg: ABI:0.3, TBI:0.12). CTA showed total occlusion of the Axillo-fem-fem bypass, total infra-renal aorta with reconstitution of peripheral circulation at the level of external iliac arteries bilaterally. These findings confirmed by angiogram obtained by accessing right radial artery. Using the radial access in conjunction with ultrasound guided access to the right and left femoral arteries respectively, successful PTA and stents to the abdominal aorta using a self-expandable stent, right and left common iliac arteries using covered stents in a kissing fashion as well as treatment of the right and left external iliac arteries were successfully obtained. On 3 weeks follow-up, the patient's symptoms of claudication resolved, had good

pulses bilaterally, healing ulcers and favorable ABIs (Right leg: ABI:0.84, TBI:0.68, Left leg: ABI:0.82, TBI: 0.65).

**Discussion:** Iliac arteries lesions are usually treated by either retrograde ipsilateral femoral access or by contralateral femoral access with the crossover technique. However, sometimes the crossover technique may not be carried out due to total occlusion, severe tortuosity or calcification of the iliac arteries or because of a very acute angle of the aortoiliac bifurcation. In these cases where cannulation of ipsilateral common femoral artery may be impossible due to hypoperfusion of the common femoral artery an alternative approach is needed which is usually carried out from brachial access or radial access. However transradial access seems to be safer and preferred over the brachial access due to the complications associated with the brachial access. The brachial artery is usually avoided because it is an end artery, and its iatrogenic occlusion, for example, by local dissection or thrombosis, can lead to acute and limb-threatening ischemia of the forearm. In addition, it is situated close to relevant neural structures, and palsy is a dreaded complication. Finally, the fascia of the upper arm is tight, so bleeding episodes can lead to severe compartment syndrome requiring immediate surgery. Advantages of radial access for PAD intervention include: decrease in access site complications, more rapid ambulation, same-day discharge, and increased patient comfort. Relative contraindications to radial access include absent pulse, an abnormal Allen's test, Raynaud disease, the need for a dialysis shunt, or functioning shunts.

**Conclusion:** Transradial access for PAD intervention seems to be feasible and a promising technique with low procedure complication rates, which make this approach preferred over the brachial access that may lead to hazardous complications.