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ABSTRACTS

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ABSTRACT 1

A Bewildering Case of Acute Renal Failure after Endovascular Repair of Abdominal Aortic Aneurysm

Author(s): Karthik Mekala, MD; Yashwant Agrawal, MD; Jacqueline Sennott, DO; Michelle DeGregorio, MD; Kirit Patel, MD; Abdul Halabi, MD

Affiliation(s): St. Joseph Mercy Oakland, Pontiac, MI, USA

Category: Cardiovascular Disease

Background: A 56-year-old male with a history of congestive heart failure, hypertension, hyperlipidemia, chronic kidney disease (CKD) stage 2, history of Abdominal Aortic Aneurysm (AAA) and recent history of Endovascular Aortic Aneurysm repair (EVAR) presented to the hospital with complains of dyspnea, worsening renal function and anemia. The patient was readmitted to the hospital 9 days after EVAR for similar complaints. Pertinent physical exam included basilar crackles and low-grade fevers. His WBC was 13.1 Thou/mcl, creatinine increased from 1.17 to 1.8, chest X ray showed left lower lobe opacity and underwent treatment for pneumonia. He did undergo ultrasound of kidneys which showed intact arterial flow to kidneys. He underwent an upper endoscopy which showed actively bleeding jejunal Dieulofoy lesion, his dual-antiplatelet therapy (DAPT) was withheld. The patient recovered and was discharged home. He however presented 5 days later with similar complaints. The patient was subsequently intubated due to pulmonary edema. He underwent a CTA of abdomen and pelvis which showed complete acute occlusion of the left renal artery and partial occlusion of the right renal artery.

Methods: We used a long 6F JR 4 from the right radial artery and performed an angiogram. The angiogram revealed a 99% stenosis of the left renal artery (LRA) and the right renal artery was not visualized. We had difficulty reaching the LRA with a long 6 F JR 4 guide catheter, hence we exchanged it for 100 cm 5F Multipurpose diagnostic catheter. After cannulation of the LRA, an angiogram showed a heavily thrombosed artery. We injected 8mg of Alteplase into the LRA and then placed a 300 cm Wholey wire into the LRA. We removed the Multipurpose catheter and predilated the lesion with an over the wire Cook Advance LP 5mmx40mm (135 cm) balloon. Then we deployed an Abbott Omnilink Elite stent 6mmx19mm. An angiogram was performed which revealed a small dissection in the mid LRA. We obtained left femoral artery access and placed a IM guide catheter into the LRA. We then predilated with a TREK RX 5mmx15mm balloon followed by Resolute Onyx 5mmx22mm stenting. An angiogram of the LRA revealed good angiographic results.

Conclusion: We describe a patient with chronic medical conditions including CKD who underwent a EVAR with GORE® EXCLUDER® Device for a large AAA was found to have worsening renal function, anemia, and pulmonary edema. Extensive work up revealed positive Heparin Induced Platelet Antibody, cardiopin antibody positive, and Serotonin release assay. Acute kidney failure is known complication of EVAR, however this case is unique, possible etiologies for worsening renal function include atheroembolic, unintentional coverage of the renal arteries, acute tubular necrosis, cardiorenal syndrome, cessation of DAPT due to anemia, contrast induced nephropathy and hematologic abnormalities.

References:
ABSTRACT 2

A Novel Technique for Removal of Impella® Device While Maintaining Vascular Access

Author(s): Christine L Shokrzadeh¹, Kaled Diab¹, Zulfiqar F. Cheema¹, Michael B. Silva, Jr¹., Charlie C. Cheng¹

Affiliation(s): University of Texas Medical Branch, Galveston, TX, USA¹

Category: Cardiovascular Disease

Background: The Impella® (Abiomed, Danvers, MA) is a temporary ventricular assist device for patients with severe CAD, left-sided heart failure, and cardiogenic shock. Traditionally, the Impella® devices are removed via surgical repair of the common femoral artery, or percutaneously with applied pressure at the access site to achieve hemostasis. However, hemostasis can be difficult to obtain with pressure due to large sheath size. Additionally, many patients are critically ill, precluding them from undergoing open femoral repair. We describe a novel endovascular approach to remove Impella® devices while maintaining vascular access, thus minimizing the need for open surgical repair.

Methods: The Impella® catheter is pulled back until the pump motor is at tip of the sheath. Two small holes are made on the catheter. The distance between the two holes is at least the length of the sheath. An angled wire is inserted at the proximal hole and advanced until its tip is at the distal hole. Holding both the wire and the catheter, the pump motor is advanced to the aortic bifurcation. The wire is advanced to the descending thoracic aorta. Then, the wire, catheter, and sheath are pulled back until the pump motor and sheath are out of the patient. Using the Seldinger technique, the Impella® and sheath are exchanged for a suture mediated closure device.

Figure 1. Hydrophilic angled wire, entering from the proximal hole on the catheter, and its tip are visible in the distal hole.
**Results:** This report illustrates three cases in which the patients underwent successful removal of the Impella® device while maintaining vascular access. Case 1 describes a patient who underwent Impella® insertion followed by inability to achieve groin hemostasis with manual pressure. Case 2 describes a patient with cardiogenic shock requiring full cardiopulmonary support with Impella® and ECMO (Extracorporeal membrane oxygenation). The patient was at high risk for hemorrhage and too unstable to transport to operating room. Case 3 describes a patient with cardiogenic shock who underwent PCI (percutaneous coronary intervention) and Impella® insertion. Subsequently, the patient developed a left ventricular thrombus.

**Conclusion:** The technique described here for removal of the Impella® while maintaining vascular access for placement of a suture-mediated closure device is crucial to reduce the risk of major bleeding and the need for open surgical repair in critically ill patients.
ABSTRACT 3

Acute Coronary Syndrome Secondary to Coronary Thrombosis in a Patient with Anomalous
Coronary Anatomy and Untreated Ulcerative Colitis

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Category: Cardiovascular Disease

Background: The overall prevalence of coronary anomalies ranges from 0.3 to 1.3% in the general
population1. Coronary artery anomalies do not appear to be associated with an increased risk of coronary
atherosclerosis. Frequently, the lack of support provided by guiding catheters limits the ability of crossing
culprit lesions with guide-wires and can make the delivery of balloons and stents more challenging2.
Retrospective cross-sectional studies show the incidence of thromboembolic events in inflammatory
bowel disease (IBD) patients has increased over the past decade and more arterial thrombotic events
have been observed3,4,7. Increased risk of coronary artery disease in IBD patients can be partly explained
by a hypercoagulable state5,6.

Methods: We present a case of a 60-year-old male with a chief complaint of chest pain. Patient has a
medical history of prior tobacco use, untreated ulcerative colitis (UC) and family history of coronary artery
disease. His electrocardiogram (EKG) showed sinus rhythm without abnormality, but his initial troponin
was elevated which prompted admission for the treatment of Non-ST elevation myocardial infarction
(NSTEMI). Cardiac catheterization was performed and showed acute coronary thrombus in his left
circumflex (LCx), but otherwise smooth epicardial coronary arteries. Patient received a synergy stent,
with subsequent Thrombolysis in Myocardial Infarction (TIMI) 3 flow. Patient was also noted to have
anomalous coronary anatomy with left circumflex off of his right coronary cusp, and posterior descending
artery draining to his right pulmonary artery. Hematology was consulted and felt that it was possible that
untreated ulcerative colitis (UC) may have been the inciting event of patient’s NSTEMI.

Results: The patient made a full recovery and is in the process of a full gastroenterology evaluation and
initiation of treatment for his IBD.

Conclusion: With otherwise angiographically normal coronary arteries, we speculate that a
hypercoagulable state due to untreated UC may be responsible for the occurrence of coronary artery
thrombus. We feel it is important to keep this in your differential diagnosis when evaluating patients with
ACS without a clear source. Additionally, in patients with anomalous coronary anatomy, PCI can have
increased complexity and further preparation should be considered.

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    woman with severe ulcerative colitis. ISRN Cardiol 2011;2011:134631
ABSTRACT 4

An Unusual Case of Left Atrial Appendage (LAA) Mass

Author(s): Arif Albulushi, MD¹, Faris Khan, MD¹, Khalid Al-Saidi MD¹ and Thomas R Porter, MD¹

Affiliation(s): University of Nebraska Medical Center, Omaha, NE, USA¹

Category: Cardiovascular Disease

Background: For patients presenting with cardiovascular implantable electronic device (CIED) infection, it is important to obtain cardiac imaging prior to an extraction procedure to evaluate for the presence of vegetations either on CIED leads or elsewhere in the heart.

Methods: A 71-year-old male with a history of carotid sinus hypersensitivity s/p dual chamber permanent pacemaker implantation 5 years ago. He presented with CIED infection after noticing skin breakdown over the pacemaker site with greenish discharge, and the decision was to proceed with device extraction. As part of the work up, he underwent TEE to assess for any pathology prior to the extraction. 2D TEE demonstrated a 0.8 x 0.9 cm echo density consistent with a mass lesion which was well circumscribed and mobile. On X-plane TEE, the mass, however, was possible adjacent to the aortic valve or near the aortic root and left atrial appendage. A cardiac CT was done that confirmed the presence of a prominent transverse pericardial recess without any thrombus or vegetation.

Results: Lesions that don’t follow the usual characteristics or are seen in odd locations, it is important to further clarify them by other imaging modalities. In our case, TEE images were concerning for a possible peri-aortic mass in a patient with positive blood cultures and possible endocarditis. However, the cardiac CT confirmed the diagnosis of prominent pericardial transverse recess. Generally speaking, the pericardium consists of an outer fibrous layer and an inner serous sac containing the heart. The serous pericardium is further divided into a visceral layer and a parietal layer. The former is reflected from the heart, along the great vessels, and onto the parietal pericardium. At these reflections and between the great vessels, recesses or sinuses are formed within the pericardial space. One of these recesses is the transverse recess. Clinically detectable pericardial fluid can accumulate in this space often the superior borders which hence force the space to extend beyond its normal boundaries. For this reason, pericardial recesses, can sometimes, create the appearance of a mobile mass on TEE!

Conclusion: Our case highlights the importance of careful examination of the LAA and adjacent structures during 2D TEE. If 2D TEE is inconclusive, additional studies such as, 3D TTE or cardiac CT may be indicated to further evaluate this lesion.
ABSTRACT 5

Aneurysm Anatomy-Based Strategy for Using Different Types of Aortic Endograft Systems

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Category: Cardiovascular Disease

Background: Stent grafts for Endovascular Aortic Aneurysm repair (EVAR) continue to evolve with regards to fixation, profile size and mechanism of deployment. The market provides a wide range of systems with small difference in Instructions for use, but with no clear cut off lines to justify their use for specific anatomies. In our institution we adopt a strategy to allow for choosing each type according to the anatomical criteria of infrarenal abdominal aortic aneurysm (AAA) and access vessels. The objective is to review and critique the strategy adopted in our service with regards to endograft type choice depending on patient’s anatomy.

Methods: We adopt a strategy that mandates the use of lower profile systems as “Endologix” (AFX2) system for smaller access vessels, for saccular AAAs and those with tight iliac bifurcations. We use “Medtronic” (Endurant ii) and “Bolton” (Triovance) systems for short and angulated necks. “Gore” (Excluder) is preferred with more angulated iliacs and with iliac branched devices. This is a retrospective analysis of elective EVAR cases performed using this strategy.

Results: Between July 2015 and March 2018 we performed 59 elective cases, 23 Endurant (39%), 26 AFX (44.1%), 8 Gore (13.6%) and 2 Bolton (3.4%). Technical success was 96.6%. Mean follow up was 16 months. Minimum diameter of aortic bifurcation was 10 mm for AFX and 20 mm for other grafts (p 0.041) and minimum aortic neck length for Endurant and Triovance was 8 mm and for AFX and Gore was 18 mm (p 0.035).

Conclusion: Different types of stent graft systems can be allocated for different anatomical indications for better results.
ABSTRACT 6

Health Literacy and Aortic Aneurysms: Implications for Cardiovascular and Vascular Surgical Practice

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Category: Cardiovascular Disease

Background: Little to nothing is known about the public’s knowledge of the risk factors, diagnostic procedures, and treatment options for abdominal aortic aneurysms (AAA). Although free preventive screening is available, millions of at-risk Americans remain unaware of their risk. Improved health literacy has been associated with increased screening, adherence with physician recommendations, compliance with medication regimens, and an improvement in overall health outcomes. This study aims to assess the level of AAA literacy among a large sample of participants in the 2017 national convention of the Veterans of Foreign Wars (VFW).

Methods: After consultations with an expert panel, 13 key words typically used by cardiovascular and vascular surgeons to describe the risk, diagnosis and treatment options for AAA were extracted from the primary screening tool used by the nation’s largest provider of free AAA diagnostic services. The National Institutes of Health (NIH) recommends that the readability of patient education materials be no greater than a sixth-grade reading level. A readability analysis of these words placed them at a grade level of 14.6. A self-administered, written assessment tool was developed to measure how many of these words were understood by those receiving AAA screenings. This tool allowed respondents to examine each of the words extracted from the current screening tool and then select a definitionally correct or incorrect equivalent word that reflected a readability score of the sixth grade.

Results: There were 570 completed questionnaires. 57.6% of the participants were female, 61.4% were 60 and above, and 32.6% were veterans. The average number of correct answers was 9.31 out of 13 (72% correct). Only 4.7% answered all questions correctly, with 29.1% missing 5 or more answers. The most frequently missed words were Asymptomatic, Screening, and Cholesterol (56.5%, 44%, and 41.4% incorrect). The most frequently known terms were Abdominal, Diagnosis and Genetic (96%, 95.3%, and 91.9% correct). The remaining words fell between these extremes. Those 60 years old and above scored significantly lower than younger respondents (p < .0001). A post hoc power analysis indicated that the power to detect the obtained effects of age at the .05 level was greater than .95. Gender and veteran status did not produce any significant differences.

Conclusion: These data suggest a communication gap between the words typically used by Cardiovascular and Vascular Surgeons and other healthcare professionals to talk about the risk factors, diagnostic procedures and treatment options for AAA and the at-risk population. The risk of a AAA increases with age. Thus, the age-related decline of health literacy regarding AAA deserves special attention by surgeons and others to help ensure that those at greatest risk fully understand the benefits and options for diagnostic screening.
ABSTRACT 7

Infective Endocarditis of MitraClip

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Affiliation(s): Cardiology, University of Nebraska Medical Center, Omaha, NE, USA1
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Category: Cardiovascular Disease

Background: The interventional repair of severe mitral regurgitation could be achieved with MitraClip (Abbott Vascular, Santa Clara, CA, USA) in patients with high surgical risk. Both the EVEREST II trial and the ACCESS EU registry illustrated the safety and efficacy of the device. Infective endocarditis (I.E.) after MitraClip procedure is rare and its management is a great dilemma.

Methods: We are reporting a 60-year-old female with a history of severe mitral regurgitation s/p MitraClip in 2015, CAD s/p CABG x6, CHF with EF 25%, recurrent GIB (gastric AVM), CKD and COPD on home O2. She presented with weakness and low-grade fever and was found to have UTI. She was placed on a course of oral antibiotics without improvement. Later, she was admitted to our center as her condition worsened, and she had +ve cultures for S.epidermidis and Enterococcus faecalis. Given a concern for I.E., a transesophageal echocardiography (TEE) was done and showed new vegetation on the MitraClip valve. She was determined to be not a good surgical candidate, and thus treated medically with a full course of Penicillin G, and she made a full recovery.

Results: MitraClip procedure for patients with severe mitral regurgitation is alternative option for those who are at high risk for surgical interventions. One of the rare complications of this procedure is I.E. Reviewing the literatures showed that there are only six cases reported so far for patients presenting with I.E. of MitraClip. The majority of those patients underwent surgical replacement of the infected valve and only two had medical treatment (one of the two died). The most common organism was S.aureus as the cause of I.E. Given the high surgical risk and advanced COPD, the decision was made to manage medically antibiotic course. This case highlights that patients with unfavorable surgical outcomes with bioprosthetic valve endocarditis, should be considered for medical therapy.

Conclusion: Management of Infective endocarditis in patients with MitraClip remains a challenge. The best outcome is obtained with surgical bail-out. However, since these patients were rejected conventional surgery in first place due to their high operative risk, medical treatment could be considered as alternative option.

Figure 1: TEE showing vegetation at the bioprosthetic mitral valve (MitraClip)
ABSTRACT 8

Outcome of Percutaneous LVAD Decommissioning via Amplatzer Plug for Patients Presenting With Significant Pump Thrombosis

Author(s): Arif Albulushi, MD¹, Marshall Hyden, MD¹, Jeffrey W. Delaney, MD¹

Affiliation(s): University of Nebraska Medical Center, Omaha, NE, USA¹

Category: Cardiovascular Disease

Background: Left ventricular assist device (LVAD) thrombosis is a serious sequela that can occur even with adequate anticoagulation. The usual treatment includes enhanced anticoagulation +/- thrombolysis and if unsuccessful, consideration for pump exchange.

Methods: We report 2 cases of LVAD pump thrombosis. The first one was a 68-year-old male in whom a HeartWare VAD was implanted in December 2016 for ischemic CMP who underwent inguinal hernia repair in August 2017. His Warfarin was held and bridged with heparin pre-op and restarted post-op while continued on heparin. 2 days post-op, he started to have SOB and CP with elevated pump power and flow. His LDH and bilirubin were elevated and he started to have hematuria, all concerning for pump thrombosis. He was started on Bivalirudin for anticoagulation and Dobutamine for decompensated HF. The next day he reported new onset right visual field loss and facial numbness which was transient but intermittently recurred over next 24 hours and the decision was to proceed with percutaneous device deactivation.

The 2nd patient was a 35-year-old male non-ischemic dilated cardiomyopathy in the setting of radiation from Burkitt's lymphoma who underwent HeartMate II LVAD placement as Destination Therapy in November 2014, which was complicated with pump thrombosis and underwent LVAD exchange in March 2017. He was recently admitted with right flank pain and was found to have new right sided renal infarcts with LDH >1000. He was placed on bivalirudin for suspected pump thrombus. His Echo showed improvement in his EF to 45% and he also had RAMP study with LVAD speed turned down to 6000 without any significant changes in his RA/PA/PW/PA sat/CO/CI.

Results: The decision was to proceed with percutaneous device deactivation using Amplatzer AVP II plug (St. Jude Medical) as shown in (Fig.1). The first patient did well after his procedure and 2 months later, he underwent successful heart transplantation. The 2nd patient did well after his procedure too. He was followed up for 3 months and he continued to do well. There are at least 4 cases reported in the literatures using this approach in high risk surgical patients. These cases illustrate that this procedure is doable with no much of complications.

Conclusion: These cases highlight the safety and feasibility of subcutaneous LVAD deactivation, which should be considered in high risk surgical patients
Fig. 1. Image A is showing contrast flow in LVAD cannula and image B is showing no contrast flow from aorta to LVAD after AVP II placement in patient 1. Image C and D are showing contrast flow before and after AVP II placement in patient 2. (arrows pointing to AVP II in inflow position and outflow position)
ABSTRACT 9

Predictors of Major Adverse Anatomical Events after Endovascular Abdominal Aortic Aneurysm Repair

Author(s): M ElKassaby¹², W Tawfick¹, H Sharaf El-Deen², I Awad², S Ateya² and S Sultan¹

Affiliation(s): National University of Ireland, Galway, Ireland¹
Mansoura University, Mansoura, Egypt²

Category: Cardiovascular Disease

Background: Anatomical considerations for Endovascular Aortic Aneurysm Repair (EVAR) represent the main factor determining its feasibility. Although EVAR is a minimally invasive intervention compared to open repair, it still has no proven long-term superiority. Endoleak is by far the most common complication post EVAR. Alongside with other anatomical adverse events, it has been linked to the pre-operative aneurysm anatomy. In this study, we were aiming to identify the predictors for major adverse anatomical events (MAAE) post EVAR.

Methods: This is a prospective observational cohort study. Between Jan 2012 and March 2014, we recruited 100 patients undergoing EVAR for non-ruptured infra-renal AAA in Galway University Hospital. Follow up continued till March 2017

Results: There were 73 (70.9%) males and 30 (29.1%) females. Mean age was 74.43 (range 62 to 90) years. Maximum transverse diameter of the on pre-operative Computed Tomography Angiogram (CTA) ranged from 30 to 120 mm. Thirty-days mortality was 1%. The most commonly detected endoleak post-operatively was type II with an incidence of 14.6% (N=15). There were 3 cases of graft thrombosis, upward migration and downward migration of implanted devices (one for each), and they all required re-intervention. There were 10 cases (9.6%) of aneurysm sac expansion. 4-year survival was 87.4% with a mean of 43.06 months (95% CI 40.41-45.72). 4-years primary and secondary clinical success was 77.7 and 87.4% respectively. Multi-variate logistic regression analysis of demographics, comorbidities, anatomical factors and intra-operative details for prediction of MAAE identified female gender, aneurysm maximum transverse diameter, shorter neck length and iliac angulation to be significant predictors of MAAE.

Conclusion: Although females are less common to suffer from AAA, they seem to do worse with EVAR. Hostile anatomy is strongly associated with long-term development of endoleaks and device malfunction.
ABSTRACT 10

Procedural Challenges in Coronary Angiography via Radial Access in a Patient with Arteria Lusoria Presenting with Dysphagia Lusoria

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Category: Cardiovascular Disease

Background: A combination of absent brachiocephalic trunk and anomalous circumflex artery with a retroesophageal right subclavian artery is an extremely rare finding. This anatomical variation can clinically manifest as dysphagia, chest pain, chronic cough, and acute ischemia. Left heart catheterization and coronary angiography via radial access in such cases can be particularly challenging and currently limited data is available.

Methods: A 42-year-old female presented to the outpatient Cardiology clinic for symptoms of chest pain. Patient complained of increasing episodes of chest pain radiating towards her back and neck along with having episodes of palpitations, dizziness, near syncope and episodic dysphagia. Physical examination revealed a regular heart rhythm with no vascular bruits. A stress test previously a year ago was normal. An echocardiogram was also normal. EKG revealed normal sinus rhythm and incomplete right bundle branch block. She remained symptomatic with a growing concern of underlying coronary artery disease and was subsequently scheduled for a diagnostic cardiac catheterization via radial access to delineate her coronary anatomy.

Results: The presence of a retro-esophageal right subclavian artery arising from descending aortic right, in association with an anomalous circumflex artery arising from the right coronary cusp with absent innominate artery is an extremely rare finding when found as a combination. Radial angiogram can be particularly challenging from a procedural standpoint as significant vessel tortuosity and abnormal catheter angulation may be encountered. Non-selective aortic arch injection may help delineate the anatomy. No previous findings of coronary angiogram with such anatomic variations via radial approach have been reported so far. Decision to continue radial procedure vs switching to femoral approach were contemplated upon with concerns that routine femoral catheterization may fail to depict this important anatomical variation. Multi-purpose, WR, JL3.5 and FR4 catheters along with long exchange wires were used systematically to negotiate the anatomical variations and to complete the angiogram radially (Pictures to be uploaded). Angiographically normal epicardial coronary arteries were seen. Chest CTA later confirmed the anatomical findings.

Conclusion: Left heart catheterization and coronary angiogram via radial access in presence of combination of absent brachiocephalic trunk with a retro-esophageal right subclavian artery and anomalous circumflex artery arising from the right coronary cusp is particularly challenging from a procedural standpoint as significant vessel tortuosity and abnormal catheter angulation may be encountered. Choice of anatomically appropriate diagnostic and guide catheters with specific catheter maneuvers is imperative in these radial angiographic procedures specially in cases with poor bilateral femoral artery patency.
ABSTRACT 11

Sickle Cell Disease Associated Pulmonary Arterial Hypertension

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Affiliation(s): Center for Cardiovascular Diseases, Texas Southern University, Houston, Texas, USA¹

Category: Cardiovascular Disease

Background: The purpose of the present study is to understand the prevalence of pulmonary arterial hypertension (PAH) amongst patients with Sickle Cell Diseases (SCD), the pathophysiology of this disease process, accepted diagnostic modalities, and the peculiar treatment protocols.

Methods: Review of published articles on the subject matter. Pulmonary arterial hypertension can be screened non-invasively by applying echocardiography to measure tricuspid regurgitation velocity (TRV - normal value <2.5 m/sec) in combination with estimated right arterial pressure, considered to be a valid estimate of systolic pulmonary arterial pressure (PAP)¹. The definitive diagnosis of PAH is by right heart catheterization. The diagnosis is possible if the TRV is 2.9-3.4 m/sec and likely if it is >3.4 m/sec² (see Tables 2 and 3).

Results: Pulmonary hypertension (PH) is relatively common in SCD and should be considered both in the broader picture of PAH in patients without SCD, with the view that SCD pathophysiology affects the pathogenesis, classification, and prognosis of this disorder.³ It is estimated that PAH affects approximately 10% of adult patients with SCD, particularly those with the homozygous genotype.³

About half of SCD-related PH patients have precapillary PH with potential etiologies of (1) a nitric oxide deficiency state and vasculopathy consequent to intravascular hemolysis, (2) chronic pulmonary thromboembolism, or (3) unregulated hypoxic responses secondary to anemia, low oxygen saturation, and microvascular obstruction.³ The other half, have postcapillary PH secondary to left ventricular dysfunction (Group 2 - see Table 1).

Pulmonary hypertension is defined as mean pulmonary pressure ≥25 mm Hg at rest as determined by right heart catheterization, according to the World Symposium on PH.⁴ Some authorities consider that PAH within the range between 21 and 24 mm Hg may identify subjects with reduced exercise capacity and poor outcomes.⁵

Clinically, PAH is divided into 5 broad categories (see Table 1)⁶ and in 2013, the decision was made, at the Fifth World Symposium on PH, to move PAH associated with chronic hemolytic anemia including SCD from Group 1 to Group 5 - pulmonary hypertension with unclear or multiple etiologies.⁷ Pathologically, all three layers of the pulmonary arterial wall – intima, media, and adventitia – are differentially affected in the various groups of PAH. (see Figure 1)⁹ and according to the site of primary initiation of elevated pulmonary arterial pressure (PAP) - as precapillary PH, postcapillary PH, and chronic thromboembolic PH (CTEPH).

Management of adults with SCD-related PH is based on anticoagulation for those with thromboembolism; oxygen therapy for those with low oxygen saturation; treatment of left ventricular failure in those with postcapillary PH; and hydroxyurea or transfusions to raise the hemoglobin concentration, reduce hemolysis, and prevent vaso-occlusive events that cause additional increase in pulmonary pressure.

Conclusion: SCD patients with PH have a markedly higher risk of death than those without. Patients with hemodynamically significant pulmonary hypertension (see Table 4) should be referred to specialized centers, for proper evaluation, diagnosis and management protocols specifically directly towards ameliorating the classified etiologies. (see Figure 2).
References:
Table 1. Classification of pulmonary hypertension according to the World Symposium on Pulmonary Hypertension

<table>
<thead>
<tr>
<th>Group</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pulmonary arterial hypertension</td>
</tr>
<tr>
<td>2</td>
<td>Pulmonary hypertension due to left heart disease</td>
</tr>
<tr>
<td>3</td>
<td>Pulmonary hypertension due to lung diseases and/or hypoxia</td>
</tr>
<tr>
<td>4</td>
<td>CTEPH</td>
</tr>
<tr>
<td>5</td>
<td>Pulmonary hypertension with unclear or multifactorial mechanisms</td>
</tr>
</tbody>
</table>

Table 2. Tricuspid regurgitation velocity as a predictor of right heart catheterization documented pulmonary hypertension in patients with SCD

<table>
<thead>
<tr>
<th>TRV, m/sec</th>
<th>No. in category</th>
<th>mPAP ≥25 mm Hg</th>
<th>N (%)</th>
<th>Reference</th>
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</thead>
<tbody>
<tr>
<td>≥2.5</td>
<td>96</td>
<td>24 (25.0)</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>2.5 ≥ 2.9</td>
<td>26</td>
<td>8 (30.8)</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>≥2.9</td>
<td>74</td>
<td>10 (13.5)</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>≥3.0</td>
<td>22</td>
<td>14 (63.6)</td>
<td>9</td>
<td>9</td>
</tr>
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</table>

Table 3. Prevalence of right heart catheterization–documented pulmonary hypertension in SCD population screening studies

<table>
<thead>
<tr>
<th>No. of adult SCD patients in population</th>
<th>No. excluded from study</th>
<th>Population for calculating prevalence</th>
<th>Mean age (y)</th>
<th>Received RHC/No. TRV ≥ 2.5 m/sec</th>
<th>N (%) with pulmonary hypertension</th>
<th>Reference</th>
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</thead>
<tbody>
<tr>
<td>445</td>
<td>47</td>
<td>398</td>
<td>34</td>
<td>96/109</td>
<td>24 (6.0)</td>
<td>9</td>
</tr>
<tr>
<td>80</td>
<td>0</td>
<td>80</td>
<td>33</td>
<td>26/32</td>
<td>8 (10.0)</td>
<td>10</td>
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<tr>
<td>531</td>
<td>0</td>
<td>531</td>
<td>36</td>
<td>81/243</td>
<td>55 (10.4)</td>
<td>12</td>
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</table>

Table 4. Hemodynamic classification of pulmonary hypertension associated with SCD

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Year Reported</th>
<th>No. with precapillary pulmonary hypertension</th>
<th>No. with postcapillary pulmonary hypertension</th>
<th>Reference</th>
</tr>
</thead>
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<tr>
<td>United States</td>
<td>2003</td>
<td>11</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>France</td>
<td>2011</td>
<td>11</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>Brazil</td>
<td>2012</td>
<td>3</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>United States</td>
<td>2013</td>
<td>31</td>
<td>24</td>
<td>14</td>
</tr>
<tr>
<td>United States and United Kingdom</td>
<td>2014</td>
<td>14</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>70 (52.6%)</td>
<td>63 (47.4%)</td>
<td></td>
</tr>
</tbody>
</table>
Figure 1. Schematic representations of pulmonary hypertension. (A) Schematic cross-sectional representation of a normal pulmonary arteriole and a pulmonary arteriole affected by pulmonary hypertension. (Adapted from Pugliese et al.8) (B) Schematic representation of site of initiation of elevated pulmonary arterial pressure of precapillary pulmonary hypertension, postcapillary pulmonary hypertension, and CTEPH. L.V., left ventricle; PH, pulmonary hypertension; R.A., right atrium; R.V., right ventricle.

Figure 2. Proposed algorithm for evaluation of pulmonary hypertension related to sickle cell disease. 6MWD, 6-minute walk distance; ANA, anti-nuclear antibody; CXR, chest X-ray; EKG, electrocardiogram; LFTs, liver function tests; mPAP, mean pulmonary artery pressure; NT-pro-BNP, N-terminal pro–brain natriuretic peptide; PAWP, pulmonary artery wedge pressure; PH, pulmonary hypertension; PVR, pulmonary vascular resistance; SCD, sickle cell disease; TRV, tricuspid regurgitation velocity. Note: Echocardiography should be performed while patients are clinically stable. PAH therapy is to be considered on the basis of a weak recommendation and very low-quality evidence. Reprinted with permission of the American Thoracic Society. The American Journal of Respiratory and Critical Care Medicine is an official journal of the American Thoracic Society.
ABSTRACT 12

Successful Percutaneous Endovascular Repair in a Very Large Abdominal Aortic Aneurysm With Severe Neck Angulation

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Curtis L. Anderson, MD-PhD2

Affiliation(s): Larkin University, Miami, FL, USA1
Florida Endovascular and Interventional, Miami, FL, USA2

Category: Cardiovascular Disease

Background: Abdominal aortic aneurysm (AAA), defined as a focal diameter >3.0cm, is a relatively common manifestation of vascular disease in older adults, with a prevalence of up to eight percent in men over the age of 50 and an estimated 1,000,000 individuals living in the United States. However, the majority of detected asymptomatic AAAs are small (<4.0cm) and those measuring >5.5cm account for less than 0.4 percent. Endovascular aneurysm repair (EVAR) is a minimally invasive approach, which has been successfully used for over 25 years and has demonstrated lower morbidity and mortality with similar long-term outcomes compared to open surgical repair. EVAR historically includes surgical femoral artery cutdown and repair, however, the more recently described percutaneous endovascular aneurysm repair (PEVAR) utilizes a pre-close technique and has demonstrated a lower incidence of vascular access site complications. Feasibility of EVAR depends on the anatomical characteristics of the AAA including but not limited to neck length, neck width, iliac axis, and neck angulation, the latter of which is the most important determinant factor of outcome post EVAR. Reported instruction for use (IFU) limitations to perform conventional EVAR are neck length <1-1.5cm, proximal neck width >28mm, and severe infrarenal neck angulation >60 degrees.

Methods: We present an obese 84-year-old Hispanic male with an incidental asymptomatic unruptured 9.5cm fusiform infra-renal abdominal aortic aneurysm with 90-degree neck angulation, 3.1 cm proximal neck width, and aneurysms of the bilateral common iliac and left internal iliac arteries. The patient initially presented to our institution from an assisted living facility after sustaining an unwitnessed ground level fall. After negative initial workup with non-contrast computed tomography (CT) brain and cervical spine the patient reported vague abdominal discomfort to the emergency physician, which lead to the subsequent diagnostic contrast enhanced CT abdomen and pelvis. The patient was admitted under the care of the interventional radiology service and underwent PEVAR using Endologix Unibody stent-graft system (Endologix; Irvine, CA) utilizing a bilateral pre-close femoral artery access with the Perclose Proglide SMC device (Abbott; Chicago, IL). A type I B endoleak was initially noted and was treated successfully during the procedure.

Conclusion: Upon review of the current literature, AAA treatment with EVAR is well documented, however, guidelines on the management of incidental very large AAA (≥ 6cm) and severe neck angulation (>60 degrees) is an area of current debate. Only one documented case of AAA >9.5cm in diameter with severe neck angulation treated with the combination of thoracic and abdominal endografts has been reported. In our case, PEVAR was a viable option to treat an incidental very large AAA despite multiple complex anatomical factors.
ABSTRACT 13


Author(s): Yoshihiro Imai, MD\(^1\), Takehiro Yamashita, MD, PhD, FACC\(^1\), On Topaz, MD, FACC, FACP, FSCAI\(^2\)

Affiliation(s): Hokkaido Ohno Memorial Hospital, Sapporo, Hokkaido, Japan\(^1\)
Duke University School of Medicine, Durham, NC, USA\(^2\)

Category: Cardiovascular Disease

Background: Thin-cap fibroatheroma (TCFA) and red thrombus are suggested as a high risk of embolic complications during percutaneous coronary intervention (PCI). Intracoronary aspiration procedures occasionally result in either an insufficient thrombus removal or provide no significant effects on TCFA. Herein, we describe a hypothesis-generating case example of angina pectoris where excimer laser coronary angioplasty (ELCA) and intracoronary aspiration removed both plaque and thrombus synergistically followed by drug-eluting stent (DES) implantation which achieved a successful revascularization without embolic complications.

Methods: Informed consent to involve this patient in this report was given to him. A 76-year-old male had undergone an emergency coronary angiography for acute chest pain 1 year prior demonstrating a noncritical stenosis at his proximal right coronary artery (RCA) (Fig. 1), which resulted in a conservative treatment. The patient received an optimal medical therapy including aspirin and statins along with antihypertensive and antidiabetic agents. However, a follow-up coronary computed tomography angiography at 1 year demonstrated an eccentric tight stenosis with a “Napkin- ring sign” which is known as an independent risk for an occurrence of acute coronary syndrome (ACS) (Fig. 2).\(^{[1]}\) Given these findings and the fact that we were only dealing with a single vessel, it was decided to treat this lesion using PCI. During the procedure, coronary angiography demonstrated a critical stenosis at the proximal RCA, which was evaluated as tighter than previous with no stenosis on his left coronary system (Fig. 3). Optical frequency domain imaging (OFDI, FastView; TERUMO, Tokyo, Japan) delineated a TCFA proximally with red thrombus distally, both of which suggested that this lesion was a high risk for embolic complications during PCI (Fig. 4A1, A2). To avoid these risks, ELCA was applied combined with intracoronary aspiration before DES implantation. Laser athero-ablation was performed using a 1.4 mm Vitesse-Cos RX catheter (Spectranetics, Colorado Springs, CO) with an incremental energy setting, starting with 40 mJ/25 Hz and completing with 60 mJ/40 Hz, followed by intracoronary aspiration using a 7F Eliminate catheter (TERUMO, Japan), which resulted in unique OFDI appearances (Fig. 4B1, 2–D1,2). The red thrombus was vaporized by ELCA in an energy-intensity dependent manner and was subsequently removed by intracoronary aspiration (Fig. 4B1–D1). The fibrous cap of TCFA was dissected with the material beneath the cap ablated by ELCA and extensively removed by intracoronary aspiration (Fig. 4B2–D2). After treating the stenosis with intracoronary aspiration, D1 (Fig. 4) lumen had an area of 14.3 mm\(^2\) with 7.0 mm\(^2\) that of D2 (Fig. 4), indicating greater than 50% residual plaque in the lesion which has been shown to be an independent risk factor for restenosis.\(^{[2]}\) To reduce this risk of restenosis, implantation of a 4.0 mm 18 mm Resolute Integrity stent (Medtronic, Minneapolis, MN) was performed, followed by post dilatation with 4.5 mm 15 mm Hiryu plus balloon (TERUMO, Japan) at 20 ATM, resulting in an optimal angiographic result without flow compromise (Fig. 4E). The final OFDI delineated that a large and clear lumen was obtained with minimal inter-strut protruding tissues observed (Fig. 4E1 and E2). The aspirated material was macroscopically yellowish white and the microscopic findings were consistent with an atherosclerotic plaque component (Fig. 5). This combined synergistic strategy of ELCA-aspiration-DES yielded a successful outcome.

Results: Using computed tomography and OFDI, the lesion in this case exhibited 5 distinct features—a High-Grade Stenosis, Low Hounsfield Units, a Napkin Ring Sign, Spotty Calcium, and a TCFA. According to past studies,\(^{[3,4]}\) these features presented a danger of promoting ACS in the future and a high risk of distal embolization during the PCI procedure, so it was decided to treat this lesion in a timely manner using...
an aspiration strategy. Following careful consideration, it was resolved to maximize the effect of an embolus removal strategy by performing ELCA antecedent to an aspiration procedure. This procedural strategy was adopted because past studies\[5,6\] have indicated that, when compared with standard balloon predilatation, routine thrombus aspiration for ST elevation myocardial infarction (STEMI) does not reduce pre-stent thrombus burden and fails to improve longer- term clinical outcomes while, in terms of thrombolysis in myocardial infarction (TIMI) flow grade and myocardial blush grade (MBG), another study\[7\] demonstrated that thrombus aspiration with distal protection was superior when compared with aspiration alone. Although these studies\[5–7\] related to STEMI, the combination of these evidences clearly indicated that even after aspiration the risk of a significant amount of residual embolic material remaining meant using the best available protection procedures to prevent such embolic complications. Attempts were made to check for any previous reports addressing the efficacy of using an aspiration procedure in patients with stable coronary artery disease but none were found. Additionally, there were no reports to support a synergistic embolus removal strategy by combining laser athero- ablation and aspiration but, in this case, post procedural serial OFDI findings clearly demonstrated that the application of antecedent laser athero- ablation maximized the effect of our embolus removal strategy. This strategy—using a combination of ELCA, aspiration and DES implantation—resulted in a clear and smooth lumen without any inter-strut tissue protrusion, which should also minimize the need for target lesion revascularization over the long term.\[6\]

**Conclusion:** A synergistic embolus removal strategy combining ELCA, Aspiration, and DES implantation is a promising option for the treatment of high-risk plaque with potential embolic complications.

**References:**
Figure 1: An emergency right coronary angiogram 1 year prior.

Figure 2: Coronary computed tomography angiography at 1-year follow-up showing an eccentric tight stenosis with a "Napkin-ring sign" at proximal RCA. RCA = right coronary artery.

Figure 3: Baseline coronary angiography demonstrating a critical stenosis at the proximal RCA, with no stenosis on his left coronary system. RCA = right coronary artery.
Figure 4: Coronary angiography (A–E) and OFDI findings (A1,2–E1,2). OFDI = optical frequency domain imaging.

Figure 5: Macroscopic (upper) and microscopic (lower) findings of the aspirated material. The material appeared yellowish white. Microscopic image showed fibrin cakes with typical cholesterol clefts and foamy macrophages as a feature of atherosclerotic plaque.
ABSTRACT 14

Unusual Presentation of Pheochromocytoma in Patient Requiring Ventricular Assist Device Support

Author(s): Arif Albulushi, MD, Nashwa Abdulsalam, MD, Douglas Stoller, MD

Affiliation(s): University of Nebraska Medical Center, Omaha, NE, USA

Category: Cardiovascular Disease

Background: Current generation LVADs provide continuous circulatory flow resulting in changes to sympathetic tone in patients. Pheochromocytoma, a rare neuroendocrine tumor, also alters sympathetic tone and cardiac hemodynamics, and how pheochromocytoma and LVAD physiology interact is unknown.

Methods: A 70-year-old male with refractory VT underwent LVAD implantation as bridge therapy for future transplantation. An incidental adrenal nodule was noted during the initial evaluation. Subsequent workup and further imaging with SPECT-CT revealed markedly elevated metaneprine levels and adrenal enhancement all consistent with pheochromocytoma (Figures 1 and 2). He was admitted 5 days prior of his adrenalectomy. Phentolamine was given intraoperatively, and blood pressure managed with low dose vasopressin and epinephrine as needed depending on mean arterial pressure. The patient tolerated the procedure without complication other than requiring diuresis.

Results: Current generation of (LVADs) provide circulatory support that is almost nonpulsatile which are also associated with marked increases in muscle sympathetic nerve activity through a baroreceptor-mediated pathway. Moreover, restoration of pulsatile flow through modulations in pump speed leads to increased distortion of the arterial baroreceptors with a subsequent decline in the sympathetic nerve activity. Pheochromocytoma also alters the cardiovascular physiology via the sympathetic nervous system, and the interplay here is unique especially in the setting of LVAD support. Our patient was admitted five days prior of adrenal surgery. His BP was optimized with phenoxybenzamine; however, we faced some difficulties in assessing his orthostatics. We couldn’t use the guideline directed medical therapy in our case for this reason. As a result, he didn’t receive his routine diuretics neither he got IV fluids. This case was a challenging especially intraoperatively, as there wasn’t a great consensus on dealing with LVAD patient who are going adrenalectomy. However, with the help of multidisciplinary teams including cardiac anesthesia, hear failure team, LVAD team and surgical oncology we have a favorable outcome. The patient remained in the hospital post operatively for couple of days and he made a full recovery.

Conclusion: Pheochromocytoma resection in patients with LVAD is feasible and safe. However, traditional assessment of sympathetic tone is challenging and may require invasive measurement.
Figure 1: CT abdomen showing right adrenal tumor

Figure 2: MIBG scan showing increased activity of right adrenal gland raising suspicion of pheochromocytoma
ABSTRACT 15

The Lutonix® Global Drug-Coated Balloon Registry Real World Patients with Below-The-Knee Disease – Interim 12 Month Outcomes

Author(s): Robert E. Beasley, MD

Affiliation(s): Mount Sinai Medical Center, Miami, FL, USA

Category: Critical Limb Ischemia

Background: The most common clinical presentation of peripheral artery disease (PAD) comprises intermittent claudication but about one third of patients will progress to critical limb ischemia (CLI) characterized by rest pain and/or tissue loss, which is the most severe limb manifestation of PAD. Paclitaxel-coated balloons are safe and effective in treating PAD. This ongoing multicenter registry study is designed to assess the safety and effectiveness of the Lutonix® 014 Drug-Coated PTA Dilatation Catheter (DCB) for the treatment of stenosis or occlusion of native below-the-knee (BTK) arteries in a real world clinical practice.

Methods: This registry trial enrolled 365 real world patients presenting with claudication or critical limb ischemia (Rutherford Category (RCC) 3-5). Patients with significant stenosis (≥70%) or occlusion of one or more native artery(s) below the tibial plateau and above the tibiotalar joint and the target vessel(s) reconstitute(s) at or above the ankle with inline flow to at least one patent inframalleolar outflow vessel were included. Patient is participating in an investigational drug or device study which has not yet reached its primary endpoint or had a non-controllable allergy to contrast were excluded. All patients were treated per standard of care when using the Lutonix® DCB. The DCB procedure was performed per the IFU. Follow-up visits, through 24 months, were also done per standard of care. Primary endpoints are:

Safety: Freedom from BTK MALE+POD at 30-days (Freedom at 30-Days from the composite of all-cause death, above-ankle amputation or major reintervention, i.e. new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis of the index limb involving a BTK artery.)

Efficacy: TLR at 6 months (Defined as clinically-driven target lesion reintervention (TLR)).

Results: Interim results on 365 patients will be presented. Majority of the patients were RCC 5 (65.8%), 64.0% were diabetic, 86.8% were hypertensive and 62.4% had dyslipidemia. Mean lesion length was 121±97.9mm, calcification was present in 68.2% and 24.4% with severe calcification. Lesion locations were 6.9% popliteal, 20.6% TP trunk, 51.1% AT, 22.3% PT, 22.8% peroneal. Freedom from Primary Safety Events at 30 days was 98.6%. Primary efficacy of Freedom from TLR at 12 months was 76.0%.

Conclusion: These interim 12-month outcomes suggest the Lutonix® DCB 014 is safe and effective for the treatment of BTK arterial disease.
ABSTRACT 16

Operative Management of Non-Iatrogenic Pediatric and Adolescence Peripheral Arterial Trauma: An Experience from Challenged Resource Setting

Author(s): Ahmed Mousa, MD1,2*; Ossama M. Zakaria,3,4, Emad Hokkam3, Tamer A. Sultan6, Ibrahim Hanbal1, Amr M. El-Gibaly6, Abdul Rahman S. Al-Mulhim2, Mohamed Y. Daoud2, Haytham Al-Arfaj2, Ahmed M. Odeh2, Mohamed A. Nienaa2, Foad Sadek7, Mohamed A. Farhan2, Mohamed Abd EL-Hamid1. Mahsoub M. Amin1, Alaa Sharabi1, Omar M. AL-Haieg1, Mohamed A. Bayomi1, Mohamed A. Nasr8

Affiliation(s): Al-Hussain University Hospital, Cairo, Egypt1
King Faisal University, Al-Ahsa, Saudi Arabia2
Suez Canal University, Ismailia, Egypt3
Faisal University, Saudi Arabia4
Menoufia University, Menoufia, Egypt5
Hanse Klinikum Stralsund, Stralsund, Germany6
King Fahad Hospital of the University, Dammam, Saudi Arabia7
Al-Azhar University, Assiut Branch, Assiut, Egypt8

Category: Limb Salvage

Background: To evaluate the management experience and outcome of pediatric and adolescence peripheral arterial trauma in a resource challenged settings.

Methods: Surgical treatment of pediatric and adolescent patients who presented with non-iatrogenic peripheral arterial injuries. A thorough study of each patient record was performed including the original demographic data, symptoms and clinical examination including the hard and soft signs of arterial injury. All selected patients were children and adolescents from 2 years to 18 years old presented with an isolated peripheral arterial injuries. Excluded from the study, those patients with massive vascular injury associated with other severe orthopedic or muscular trauma (crush injury).

Results: One hundred and forty-nine cases were treated for isolated extremity arterial trauma. There were 93.3% male patients, and 6.7%, age ranged from 2 years to 18 years, mean age of 14.4 ±3.2 years (mean ±SD). Seventy-six patients (51%) were having lower extremity arterial trauma, while 73 patients (49%) were having upper extremity injuries. Primary repair with end-to-end anastomosis was performed in 77 patients (51.7%), while an interposition reversed saphenous vein graft was initially performed in 72 patients (48.3%). Technical success of was achieved in (91%). However, 7 patients of these treated with end-to-end anastomosis was complicated with pseudoaneurysm formation at the anastomotic site that was discovered on the 2nd to the 4th postoperative day. Fasciotomy was performed for 10 patients, and the fasciotomy wound was closed with a split thickness skin graft. Moreover, general non-specific postoperative complications were recorded in 6 patients including postoperative fever, drug allergy and urinary tract infection as well as venous access site infection. Surgical technique-related complications included pseudoaneurysm formation in 7 patients (9%) mainly due to suture dehiscence as a result of severe infection. Interposition graft thrombosis in 10 patients (6.7%). Peripheral ischemia was noticed in 23 patients (15.4%), 16 in the lower limb and 7 in the upper limb. Two patients (3%) required above knee amputation. Two patients (3%) were expired.

Conclusion: Pediatric and adolescent peripheral arterial injuries although not frequently encountered during the practice and training of junior general and pediatric surgeons should be considered as a trigger for mortality and morbidity among this age group especially in the third world countries. Therefore, it is highly recommended that all postgraduate general and pediatric surgeons integrated training programs must entail more details about this crucial problem.

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### Table 1: Patient demographics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Frequency</th>
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</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>Standard Age 14.4 ±3.2 (3-302)</td>
<td></td>
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<tr>
<td>Gestational age 32-43 (33±8)</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
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<tr>
<td>Male</td>
<td>36</td>
</tr>
<tr>
<td>Female</td>
<td>27</td>
</tr>
<tr>
<td><strong>Mechanism of injury</strong></td>
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<tr>
<td>Blunt</td>
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</tr>
<tr>
<td>Road traffic accident</td>
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<tr>
<td>Sports injury</td>
<td>10</td>
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<tr>
<td>Building collapse</td>
<td>20</td>
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<td>Penetrating</td>
<td>41</td>
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### Table 2: Anatomical site of arterial injury

<table>
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<tr>
<th>Anatomical site of injured artery</th>
<th>No.</th>
<th>%</th>
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<tbody>
<tr>
<td>Lower Limb Injury</td>
<td>76</td>
<td>51</td>
</tr>
<tr>
<td>Superficial femoral artery</td>
<td>60</td>
<td>79</td>
</tr>
<tr>
<td>Popliteal artery</td>
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<td>14.5</td>
</tr>
<tr>
<td>Posterior tibial artery</td>
<td>5</td>
<td>6.5</td>
</tr>
<tr>
<td>Upper Limb Injury</td>
<td>73</td>
<td>49</td>
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<td>Brachial</td>
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### Table 3: Operative management of arterial injuries at presentation

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<tr>
<th>Procedure</th>
<th>No.</th>
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<td>Primary repair with end-to-end anastomosis</td>
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<td>51.7</td>
</tr>
<tr>
<td>Interposition vein graft</td>
<td>72</td>
<td>48.3</td>
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<tr>
<td>Reoperation</td>
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<td>9</td>
</tr>
<tr>
<td>Fasciotomy</td>
<td>30</td>
<td>20</td>
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<td>Amputation</td>
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Table 4: Summary of our results in relation to the literature

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</thead>
<tbody>
<tr>
<td>NO.</td>
<td>194</td>
<td>1.138</td>
<td>222</td>
<td>1928</td>
<td>2844</td>
<td>94</td>
<td>102</td>
<td>106</td>
<td>116</td>
<td>155</td>
</tr>
<tr>
<td>Age (mean ± SD)</td>
<td>14.4 (3.2)</td>
<td>10.7 (4.4)</td>
<td>9.6 (4.1)</td>
<td>11 (6)</td>
<td>14.7 (2.6)</td>
<td>12.1 (5)</td>
<td>10.7 (4.3)</td>
<td>9 (5)</td>
<td>12.7 (4.1)</td>
<td>12 (7)</td>
</tr>
<tr>
<td>Sex, (male/female)</td>
<td>139/10</td>
<td>838/300</td>
<td>148/47</td>
<td>1350/78</td>
<td>17/1</td>
<td>162/32</td>
<td>75/27</td>
<td>80/26</td>
<td>82/34</td>
<td>122/33</td>
</tr>
<tr>
<td>Type of injury</td>
<td>Blunt Trauma</td>
<td>72.4% (108)</td>
<td>58% (660)</td>
<td>66% (146)</td>
<td>76% (1465)</td>
<td>18% (3)</td>
<td>44% (41)</td>
<td>31% (32)</td>
<td>38% (40)</td>
<td>42% (49)</td>
</tr>
<tr>
<td></td>
<td>Penetrating Trauma</td>
<td>26.6 % (41)</td>
<td>42% (478)</td>
<td>23% (51)</td>
<td>24% (463)</td>
<td>78% (14)</td>
<td>56% (53)</td>
<td>68% (70)</td>
<td>72% (76)</td>
<td>58% (67)</td>
</tr>
<tr>
<td></td>
<td>Building Collapse</td>
<td>21.5% (20)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>6% (1)</td>
<td>7% (7)</td>
<td>8% (8)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Anatomical site of injury</td>
<td>Upper Limb</td>
<td>49% (73)</td>
<td>36% (406)</td>
<td>60% (134)</td>
<td>58% (30)</td>
<td>NA</td>
<td>37% (35)</td>
<td>36% (37)</td>
<td>34% (36)</td>
<td>37% (43)</td>
</tr>
<tr>
<td></td>
<td>Lower Limb</td>
<td>51% (76)</td>
<td>19% (212)</td>
<td>29% (65)</td>
<td>42% (21)</td>
<td>94% (17)</td>
<td>32% (31)</td>
<td>30% (31)</td>
<td>13% (14)</td>
<td>25% (29)</td>
</tr>
<tr>
<td>Operative treatment</td>
<td>Primary repair with end-to-end anastomosis</td>
<td>51.7% (77)</td>
<td>NA</td>
<td>12% (27)*</td>
<td>17% (13)*</td>
<td>6% (1)*</td>
<td>27% (25)*</td>
<td>20% (21)*</td>
<td>49% (52)*</td>
<td>25% (26)*</td>
</tr>
<tr>
<td></td>
<td>Interposition vein graft</td>
<td>48.3% (72)</td>
<td>NA</td>
<td>24% (54)*</td>
<td>24% (18)*</td>
<td>39% (7)*</td>
<td>33% (31)*</td>
<td>1% (1)*</td>
<td>14% (15)*</td>
<td>26% (27)*</td>
</tr>
<tr>
<td>Reoperation</td>
<td>9% (7)</td>
<td>NA</td>
<td>22.2% (10)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Fasciotomy</td>
<td>15% (10)</td>
<td>NA</td>
<td>23% (51)</td>
<td>NA</td>
<td>39% (7)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>10% (15)</td>
</tr>
<tr>
<td>Amputation</td>
<td>3% (2)</td>
<td>1.4% (16)</td>
<td>7% (3)</td>
<td>NA</td>
<td>6% (1)</td>
<td>3% (3)</td>
<td>7% (7)</td>
<td>1% (1)</td>
<td>2.6% (3)</td>
<td>6% (9)</td>
</tr>
</tbody>
</table>
Figure 1: Primary repair with end-to-end anastomosis of the ulnar artery

Figure 2: Repair with interposition reversed saphenous vein graft
ABSTRACT 17

A Comparative Review of the FLEX Catheter® in the Treatment of Femoropopliteal Lesions of Differing Lengths

Author(s): Jason A. Yoho, MD¹; Louis Lopez, MD²; John Pigott, MD³

Affiliation(s): Heart and Vascular Institute of Texas, New Braunfels, TX, USA¹
Allen County Cardiology, Saint Joseph Hospital, Fort Wayne, IN, USA²
Jobst Vascular Institute, Promedica Healthcare Systems, Toledo, OH, USA³

Category: Peripheral Artery Disease

Background: Treatment of femoropopliteal lesions, especially those longer than 8 cm, can be complex potentially requiring multiple devices for a successful intervention. The need for innovative improvements in treatment options for long lesions is imperative. Early clinical results of the FLEX Catheter (VentureMed Group, Toledo, Ohio) in real world patients were retrospectively reviewed by lesion length subsets to determine the feasibility and safety of the device.

Methods: The FLEX Catheter was engineered to create continuous and controlled depth longitudinal micro-incisions along the length of the lesion, prepping the vessel for angioplasty. The FLEX is a one-size-fits-all device that utilizes an expandable basket equipped with 3 atherotomes that follows the contour of the vessel wall. Voluntarily provided case reports from 326 real world patients (85 operators in 54 hospital systems) were analyzed. Lesions were pre-treated with the FLEX, followed by a drug coated balloon (DCB) or plain old balloon angioplasty (POBA), at operator’s discretion. Angiograms were performed pre-procedure, post FLEX, and post procedure to visually measure stenosis.

Results: The data was separated into subsets by lesion length; (1) less than or equal to 8 cm and (2) longer than 8 cm (See Table 1). In (1) the average lesion length was 4.3 cm (0.2 – 8 cm) and 18.6 cm (8.5 – 41 cm) in (2). The pre-existing average stenosis for the 8 cm or less subset was 88.7%, and 93.8% for the latter. Sixty percent of the longer lesions were chronic total occlusions (CTO). Technical success, defined as lesion (stenosis or CTO) crossing and luminal gain post FLEX, was 99% overall. Luminal gain post treatment with the FLEX averaged 26.7% for the shorter subset, and 26.8% in the longer. The opening balloon pressure (lowest pressure allowing complete lesion effacement) was 4.3 and 4.4 atm respectively. Residual stenosis at the completion of the procedure was 10.2% for (1) and 9.6% for (2). Provisional stent use was low, and no flow-limiting dissections, perforations, or embolization occurred.

Conclusion: The FLEX Catheter performed with a high rate of technical success in real world lesions. The luminal gain achieved, by the FLEX alone, was consistent regardless of lesion length. Low opening balloon pressures suggest the pre-treatment of the vessel by the FLEX positively improved vessel compliance. There were no flow-limiting dissections or emboli, and a low rate of provisional stents (19% overall) after angioplasty. The FLEX is a viable option to interventionalists in the treatment of femoropopliteal lesions of differing lengths.
Table 1: Summary of Femoropopliteal Lesion Data

<table>
<thead>
<tr>
<th></th>
<th>Less Than or Equal to 8 cm</th>
<th>More than 8 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%) or Mean (Range)</td>
<td>N (%) or Mean (Range)</td>
</tr>
<tr>
<td>Number of Cases:</td>
<td>122</td>
<td>204</td>
</tr>
<tr>
<td>Average Age:</td>
<td>70</td>
<td>72</td>
</tr>
<tr>
<td>ISR:</td>
<td>7 (6%)</td>
<td>19 (9%)</td>
</tr>
<tr>
<td>Average Lesion Length (cm):</td>
<td>4.3 (0.2 – 8)</td>
<td>18.6 (8.5 – 41)</td>
</tr>
<tr>
<td>Chronic Total Occlusions</td>
<td>25 (20%)</td>
<td>122 (60%)</td>
</tr>
<tr>
<td>Pre-Stenosis (%):</td>
<td>88.7 (60 – 100)</td>
<td>93.8 (50 – 100)</td>
</tr>
<tr>
<td>Post FLEX Stenosis (%):</td>
<td>62 (5 – 90)</td>
<td>67 (10 – 100)</td>
</tr>
<tr>
<td>Luminal Gain Post FLEX (%)</td>
<td>26.7 (0 – 95)</td>
<td>26.8 (0 – 85)</td>
</tr>
<tr>
<td>Opening Balloon Pressure (atm)</td>
<td>4.3 (2 – 12)</td>
<td>4.4 (2 – 12)</td>
</tr>
<tr>
<td>Maximal Balloon Pressure (atm)</td>
<td>8.4 (4 – 20)</td>
<td>9.4 (3 – 18)</td>
</tr>
<tr>
<td>DCB Use:</td>
<td>90 (73%)</td>
<td>151 (74%)</td>
</tr>
<tr>
<td>Provisional Stent Usage:</td>
<td>20 (16%)</td>
<td>42 (21%)</td>
</tr>
<tr>
<td>Minor Dissections (Grade: A, B)</td>
<td>5 (4%)</td>
<td>12 (6%)</td>
</tr>
<tr>
<td>Flow-Limiting Dissections:</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Moderate / Severe Calcium:</td>
<td>62 (51%)</td>
<td>113 (55%)</td>
</tr>
<tr>
<td>Residual Stenosis (%):</td>
<td>10.2 (0 – 50)</td>
<td>9.6 (0 – 60)</td>
</tr>
<tr>
<td>Luminal Gain Post Procedure (%)</td>
<td>78 (40 – 100)</td>
<td>84 (25 – 100)</td>
</tr>
<tr>
<td>Technical Success</td>
<td>121 (99%)</td>
<td>202 (99%)</td>
</tr>
</tbody>
</table>
ABSTRACT 18

A Peripheral Simulating Ex Vivo System for Pharmacokinetic Evaluation of Intravascular Drug Delivery Devices

Author(s): Onree Wilson¹, Trevor Rayl¹, Megan Erwin, BS¹, Claire Cawthon, MS¹, Jennifer Sexton, MD², William L. Pomeroy III, MD², Saami K. Yazdani, PhD¹

Affiliation(s): University of South Alabama, Mobile, AL, USA¹
Department of Cardiology & Vascular Surgery Biloxi, MS, USA²

Category: Peripheral Artery Disease

Background: Currently, in vivo evaluation of vascular devices is an expensive and time-consuming proposition. The design cycle can often be years as evidenced by the recent clinical trial results of drug eluting stents (DES) and drug eluting balloons (DEB). One of the most important safety and efficacy concerns regarding these devices is the drug release profile and drug retention. To this end, an ex vivo system has been developed in which the pharmacokinetic (PK) evaluation of the vascular devices can be evaluated in living arteries without the need of pre-clinical models. The system is capable of reproducing peripheral vascular motion, specifically twisting and elongation-shortening.

Methods: The novel peripheral vascular simulating bioreactor was developed consisting of computer controlled pulsatile flow pump equipped with pressure and flow sensors. The system is controlled via an Arduino™ microprocessor with stepper motors controlling twisting and elongation-shortening. The test section was a freshly harvested porcine carotid artery. The ex vivo system can be positioned within a CO₂ incubator. As a proof of concept, ex vivo arteries were treated via a perfusion catheter that delivered paclitaxel locally within the ex vivo system. PK analysis was then performed at 1 hr., 1 day and 3 days post-treatment and compared to historical pre-clinical data.

Results: A total 18 vessels were analyzed for paclitaxel concentration. The results demonstrated a decline of drug retention within the ex vivo system at 1 hr (41.2±46.1 ng/mg), 1 day (12.8±11.11 ng/mg), and 3 days (10.53±3.42 ng/mg). Drug concentration levels at the 1 hr. time point were similar to historic in vivo studies.

Conclusion: These results demonstrate a viable platform for evaluating drug release kinetics of interventional vascular devices in an ex vivo setting. Further studies are warranted to determine if vascular peripheral motion alters pharmacokinetic profiles of local drug delivery devices. We assert that this system can dramatically reduce the time and expense associated with in vivo testing of vascular devices, particularly to measure and quantify vessel drug retention.
ABSTRACT 19

BioMimics 3D Stent System: 1-Year Results of the MIMICS-2 Study

Author(s): Craig M. Walker, MD1, Timothy M Sullivan, MD2, Thomas Zeller, MD3 Masato Nakamura, MD4

Affiliation(s): Cardiovascular Institute of the South, Houma, LA, USA1
Minneapolis Heart Institute, Minneapolis, MN, USA2
Universitaets-Herzzentrum, Freiburg-Bad Krozingen, Bad Krozingen, Germany3
Toho University Ohashi Medical Center, Tokyo, Japan4

Category: Peripheral Artery Disease

Background: Endovascular treatment of femoropopliteal artery (FPA) disease is challenging; high rates of restenosis and multiple loading forces are problematic for innovative stent designs to overcome. BioMimics 3D® Vascular Stent System (Veryan, Horsham UK) comprises a Nitinol stent with unique 3D helical centerline to generate swirling blood flow and improve biomechanical performance. Pre-clinical and earlier clinical study data (MIMICS-RCT) with subjects randomized to BioMimics 3D or straight control stents, have demonstrated that swirling blood flow elevates wall shear stress in the stented segment, reducing neointimal formation. The helical stent design accommodates longitudinal shortening of the FPA during knee and hip flexion. MIMICS-2 study is designed to demonstrate the safety and effectiveness of BioMimics 3D in a larger population to support US premarket approval (PMA) application.

Methods: This prospective, single arm, multicenter trial with 3-year follow-up, enrolled patients with symptomatic de novo occlusive disease of the native FPA. Core laboratories reviewed DUS, angiography and X-ray imaging; clinical events were independently adjudicated. The primary safety endpoint was 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 effectiveness endpoint was 12-month primary patency. We present index procedure through one-year results including primary patency, revascularization rate, clinical and functional outcomes and stent integrity.

Results: 271 enrolled subjects had a mean age of 68 years, 66% male, 81% smokers and 45% diabetics. Core lab reported mean lesion length was 81.2 ± 38.4 mm and vessel diameter were 5.2 ± 0.9 mm; 46% of lesions were moderately to severely calcified and 30% were total occlusions. Technical success (% of lesions with ≤ 50% residual, in-stent, stenosis); lesion success (successful stent implantation without device-related complications) and procedure success (lesion success without MAE) were all 100%. Primary safety and effectiveness endpoints were met: freedom from MAE through 30 days was 99.6% (268/269) and the Kaplan-Meier estimate of freedom from loss of primary patency at 12 months was 81.9%. Freedom from CDTLR at 12-months was 88.4% by KM estimate. In 254 subjects with matched assessments, 85% showed an improvement of ≥1 Rutherford category at 12 months, with a mean change from baseline of -1.9 ± 1.1. No stent fracture was reported (0%; 0/229).

Conclusion: MIMICS-2 outcomes at one year confirm the safety and effectiveness of the BioMimics 3D stent with unique helical centerline.
ABSTRACT 20

Blue Toe Syndrome: Mimicking Acute Limb Ischemia

Author(s): Amit Nanda, MD; Rami N Khouzam, MD, FACC, FACP, FASNC, FASE, FSCAI

Affiliation(s): University of Tennessee Health Science Center, Memphis, TN, USA

Category: Peripheral Artery Disease

Background: Cholesterol embolism syndrome occurs when there is embolization of a primary atherosclerotic plaque from a proximal large-caliber artery to distal small to medium arteries. This causes end-organ damage by mechanical plugging and induces an inflammatory response. Blue toe syndrome is one of the most common dermatologic manifestations of cholesterol crystal embolization, whereby an atherothrombotic microembolism causes transient focal ischemia. In a prospective study of 1579 patients undergoing coronary angioplasty in the US, clinical evidence of cholesterol embolization was found in 1 patient (0.06%). This case helps bring to light this rare condition following coronary or peripheral angioplasty, in an effort to avoid confusing this syndrome with acute limb ischemia.

Results: A 76-year-old male with history of coronary and peripheral vascular disease had undergone a recent percutaneous peripheral angioplasty for severe bilateral iliac disease. Upon follow up, he complained of worsening left lower extremity pain and discoloration of his left toes for the past 5 days (Figure 1). His distal extremity pulses were not palpable. He was admitted to rule out recurrent limb ischemia and potential need for another peripheral angiogram and angioplasty. A non-invasive work up, including an arterial ultrasound, did not reveal significant limb vascular stenosis. It was determined that the constellation of his symptoms was secondary to cholesterol embolization. The patient was started on a high intensity statin, along with his dual antiplatelet therapy. Six weeks later, he was noted to have complete resolution of left lower extremity pain and major improvement of discoloration of his toes (Figure 1).

Conclusion: Cholesterol embolization syndrome often presents as a combination of signs and symptoms specific to end-organ damage and a systemic inflammatory response. Definitive diagnosis is established by histo-pathological confirmation through biopsy. There is no specific therapy for this disorder. The mainstay of therapy includes supportive care for end-organ damage and modification of risk factors such as smoking, hypertension, and serum cholesterol. Due to the absence of any clinical or diagnostic studies specific for the diagnosis of cholesterol embolization, there should be a high index of suspicion when a patient presents with lower extremity skin changes following any vascular procedure.
ABSTRACT 21

**CEAvsCAS.com: Internet Debate on Management of Carotid Artery Disease**

**Author(s):** Shira Strauss, MD¹; Michael Yacob, MD¹; Prasad Jetty MD¹

**Affiliation(s):** Division of Vascular and Endovascular Surgery, The Ottawa Hospital and the University of Ottawa, Ottawa, ON, Canada¹

**Category:** Peripheral Artery Disease

**Background:** Carotid artery disease (CAD) is narrowing of the carotid vessels, which may lead to transient ischemic attack and stroke. It has three treatment modalities—carotid endarterectomy (CEA), carotid artery stenting (CAS), and best medical therapy (BMT)—yet no consensus on its optimal management. Mixed interpretation of data, rapid evolution in technology and expertise, and improvements in pharmacotherapy have led to varied treatment guidelines across specialties and organizations. The Internet is a popular source of information for Canadians seeking medical advice, and patients searching for ways to treat CAD online may struggle to find a clear answer.

**Methods:** 10 CAD-related keywords were searched in Google Canada. Returned links were assessed for publication date, medical specialty and industry affiliation, presence of RCT data, differentiation by symptomatic status, and favored treatment. Website quality and readability were rated using the DISCERN instrument and Gunning Fog Index.

**Results:** 54 unique sites were identified. 18 (33.3%) were produced by medical societies or individual physicians, 11 (20.4%) by government organizations, nine (16.7%) by laypersons, and one (1.9%) was industry-sponsored. Common specialty affiliations were vascular surgery (11 sites), neurology (7 sites), and internal medicine (6 sites). 26 sites (48.1%) distinguished symptomatic from asymptomatic, 14 (25.9%) did not, and 14 (25.9%) were excluded due to focus on stroke of various etiology. A large proportion (38.9%) of sites received poor quality ratings (total DISCERN score<48). Among sites that favored CEA, CAS, or both equally, there was no significant difference in average total DISCERN scores, F(2,44)=0.167, \( p=ns \), or readability (GFI), F(2,44)=0.011, \( p=ns \). GFI score was significantly higher in sites with high DISCERN scores (\( p=0.015 \)), indicating higher quality sites required more advanced readership.

A majority of sites overall (57.4%) and vascular-affiliated (72.7%) favored CEA. In contrast, radiology- and cardiology-affiliated sites equally favored CEA or CAS (Figure 1). Excluding stroke sites, none advocated for best medical therapy alone. “Carotid stenting” was the only keyword to yield a site majority favoring CAS. Google search trends indicated that “carotid endarterectomy” was searched more frequently than “carotid stenting” (Figure 2).

**Figure 1. Website Treatment Preferences By Specialty**
Figure 2. Google CAD search trends since 2009 by keyword

Conclusion: CAD websites are often produced by government organizations, medical societies, or physicians, especially vascular surgeons. Sites range in quality, readability, and differentiation by symptomatic status. Google searches of CAD-related terms are more likely to yield sites favoring CEA. Further research should determine website influence on patient treatment decisions.
ABSTRACT 22

Comparison of DES and PTA in Patients With Infra-Popliteal Peripheral Arterial Disease

Author(s): H Patel¹, R Vasudev¹, M Kumar¹, P Shah¹, U Rampal¹, F Shamoon¹, M Bikkina¹, H Virk¹

Affiliation(s): New York Medical College at St Joseph’s Regional Medical Center, NJ, USA¹

Category: Peripheral Artery Disease

Background: Drug-Eluting Stents (DES) and Percutaneous Transluminal Angioplasty (PTA) both are accepted endovascular treatment options for infra-popliteal Peripheral Artery Disease (PAD). DESs have demonstrated improved patency and freedom from target lesion revascularization compared with Bare Metal stents or PTA; however, the effect on clinical outcome parameters, such as wound healing and limb salvage remains unidentified.

Methods: We collected patient’s data that underwent infra-popliteal arterial intervention between January 2011 and February 2014 in our institution. Study end points analyzed were primary vessel patency (defined as >/= 50% stenosis), target vessel revascularization, target limb major and minor amputations, and all-cause mortality at 14 months. Differences between two groups were analyzed using chi-square test for categorical variables and t-test for continuous variables. Statistical significance was considered for P values less than 0.05 in a 2-sided test.

Results: Our final cohort consisted of total of 83 cases, n=42 in DES group and n=41 in PTA group. Mean age was 71.6 years (range 49-95). 54% of patients were diabetic (n=45) and 61% (n=51) were current or past smokers. Primary vessel patency in DES group was 69% (29/42), which was significantly higher as compared to 36% (15/41) in PTA group (p=0.04, odds ratio 3.867, 95% Confidence interval (CI): 1.5-9.6). Target vessel revascularization in DES group was 24% (10/42) as compared to 32% (13/28) in PTA group (p=0.47, odds ratio 0.67, 95% CI: 0.26-1.77). Target limb amputation was 10% (4/42) in DES group as compared to 24% (10/41) in PTA group (p=0.085, odds ratio 0.33, 95% CI: 0.09-1.14). All-cause mortality was 10% in both DES and PTA group (p=1, odds ratio 0.97, 95% CI: 0.23 - 4.19).

Conclusion: Primary vessel patency was superior with DES as compared to PTA in patients with infra-popliteal PAD; however, we found no difference in target vessel revascularization, target limb amputation rates or all-cause mortality between these 2 treatment modalities.
ABSTRACT 23

Dissections in Peripheral Vascular Interventions: A Proposed Classification Using Intravascular Ultrasound (iDissection Classification)

Author(s): Nicolas W. Shammas, MD¹, MS; James T. Torey, PA-C²; W. John Shammas, BS¹

Affiliation(s): Midwest Cardiovascular Research Foundation, Davenport, IA, USA¹
St. John Hospital and Medical Center, Detroit, Michigan, USA²

Category: Peripheral Artery Disease

Background: Dissections following interventions in the infrainguinal arteries occur very frequently and are mostly under-appreciated on angiographic imaging. Media and external elastic lamina injury can contribute to loss of patency, and intravascular ultrasound (IVUS) can identify this type of injury. The circumference of injury also has been proposed to be a predictor of outcome. We therefore propose a classification combining depth of injury from intima to adventitia with circumference of dissection.

Methods: The iDissection classification exhibits six dissection grades (A1, A2, B1, B2, C1, and C2). The letters reflect the depth from Intima (A) to media (B) to Adventitia (C). The numbers reflect the circumference (< 180 degrees and ≥180 degrees). The patterns are displayed in the Figure below. The discrepancy between angiographic (using NHLBI classification) and IVUS imaging (using iDissection) is currently being evaluated in the iDissection prospective protocol with 2 IVUS core labs and 1 angiographic core lab.

Results: The 6 dissections patterns are shown below:

Conclusion: The iDissection identifies 6 patterns of dissections in peripheral arterial interventions that takes into consideration the depth and circumference of the dissection. Outcome data is needed to validate this classification and its clinical utility (Manuscript in print in JIC 2018; 30(4)).
ABSTRACT 24

Endovascular Management of Bilateral Spontaneous Superficial Femoral Arteriovenous Fistulas

Author(s): Amit Nanda, MD; Rami N Khouzam, MD, FACC, FACP, FASNC, FASE, FSCAI

Affiliation(s): University of Tennessee Health Science Center, Memphis, TN, USA

Category: Peripheral Artery Disease

Background: Arteriovenous fistulas (AVFs) are anomalous direct communications between the arterial and venous systems that bypass the normal anatomic capillary beds. Penetrating trauma and iatrogenic injury following percutaneous catheterization are the main causes of AVFs. AVFs are clinically relevant because they cause vascular steal, leading to arterial ischemia. AVF patient may become significantly symptomatic with detrimental sequelae. We present a case of bilateral spontaneous AVFs of the superficial femoral artery (SFA), diagnosed during work up for peripheral arterial disease.

Results: A 71-year-old man with a history of multiple sclerosis presented with severe claudication, progressive discoloration and hypoesthesia of bilateral lower extremities, which had worsened insidiously over the past few months. A few days prior, he developed wounds on his medial malleoli believed to be ischemic. He developed severe claudication and rest pain. He denied trauma or surgery of the legs. Patient endorsed remote history of tobacco abuse. He denied diabetes, hypertension or dyslipidemia. No family history of coronary or peripheral vascular disease. Examination revealed bluish to purple discoloration of bilateral feet (figure 1). Bilateral venous ultrasound ruled out any evidence of venous thrombi. HgA1C was normal. Ankle-Brachial Index (ABI) was 0.72 for the left leg and 0.84 for the right leg. Due to lifestyle limiting claudication, rest pain and abnormal ABI, a bilateral lower extremity peripheral angiogram was performed. It showed high-grade stenosis of the distal left SFA along with an AVF communicating between the SFA and the femoral vein (figure 2). Identical findings were noted on the right lower extremity. The high-grade stenosis along with the AVFs were contributing to the patient’s symptoms, likely due to a vascular steal phenomenon. Endovascular therapy for the bilateral high-grade stenosis and the AVFs was the best initial approach. Orbital atherectomy, percutaneous balloon angioplasty and, finally, placement of covered stents (VIABAHN), were performed bilaterally. Post-intervention angiography revealed complete coverage and obliteration of the AVFs (figure 2). After the procedure, the patient’s claudication had improved, with healing of the wounds.

Conclusion: Spontaneous AVF of the SFA is a rare clinical entity. Lower extremity AVFs are commonly iatrogenic, primarily due to percutaneous groin access. AVFs may be congenital or result from penetrating injuries. Our case represents a rare, incidental discovery of bilateral spontaneous AVFs without any obvious etiology. Clinical presentation of AVFs varies based on anatomic location, duration and nature of the trauma. A chronic fistula may lead to limb discrepancy, venous hypertension, arterial insufficiency and high output cardiac failure. Early diagnosis and efficient management is warranted. Treatment options range from non-invasive ultrasound and guided compression for asymptomatic cases to surgical ligation or endovascular techniques either by transvenous embolization or by stent grafting for symptomatic patients.
Figure 1.

Figure 2.
ABSTRACT 25

Femoropopliteal Arterial Dissections Post Atherectomy: An Intravascular Ultrasound Assessment and Correlation with Angiographic Findings. Results of the iDissection Study

Author(s): Nicolas W. Shammas, MD, MS¹, James T. Torey, PA-C²; W. John Shammas, BS¹; Susan Jones-Miller, MS¹; Gail A. Shammas, BSN, RN¹

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Category: Peripheral Artery Disease

Background: Dissections frequently occur post percutaneous intervention of the infrainguinal arteries and are generally classified angiographically using the NHLBI coronary classification. We hypothesize that dissections occur more frequently than observed on angiography when imaged by intravascular ultrasound and more severely as classified by the iDissection classification previously published.

Methods: In this prospective pilot study, a total of 15 patients were evaluated by intravascular ultrasound (IVUS) following treatment of femoropopliteal de novo or no-stent restenosis using atherectomy by a single investigator at a single center. Jetstream XC (n=13; Boston Scientific) and B-laser (investigational device in US, Eximo Medical) atherectomy devices were used as well as Eagle Eye Platinum ST IVUS catheters (Philips, San Diego, CA). Cine and IVUS images were obtained at baseline, after atherectomy and following adjunctive balloon angioplasty. Angiographic and IVUS images were adjudicated by core laboratories. Demographic, angiographic and procedural variables were analyzed in relation to the presence and severity of dissections as seen on IVUS and cine angiography.

Results: A total of 15 patients were enrolled. The mean age was 70.6 ± 8.0 years. Diabetes and claudication were present in 60% and 73% respectively. Mean pre-lesion, post atherectomy and post adjunctive angioplasty severity were present in 71.4%, 38.1% and 19.7% respectively. Using PACCS classification for calcium grading, grades 4, 3, 1, and 0 were 40%, 20%, 26.7% and 13.3% respectively. Lesion length was 108.5 ± 43.1 mm. A total of 46 dissections were identified on IVUS post atherectomy compared to 8 dissections on angiogram (p=0.0025; ratio 5.75 to 1). Post adjunctive angioplasty there were 39 dissections on IVUS vs. 11 on angiogram (p=0.0208; ratio 3.55 to 1). Of these dissections, 13% and 30.8% were ≥ 180 degrees in circumference post atherectomy and adjunctive balloon angioplasty respectively. Also, 39.1% and 38.5% involved the media and/or adventitia as seen on IVUS post atherectomy and adjunctive balloon angioplasty respectively. Balloon pressure and inflation time, limb ischemia, and degree of calcium did not correlate with the severity of dissections on IVUS. Longer lesions correlated with more dissections post atherectomy on IVUS (p=0.0330) but not on angiogram (p=0.2790). Dissection lengths were not different between atherectomy and adjunctive balloon angioplasty as seen on IVUS.

Conclusion: Dissections post atherectomy are widely present and severity is grossly underappreciated on angiogram. The significance of these dissections remains unclear in the age of drug coated balloons and the role of repair of these dissections with scaffolding (tack or stents) is unknown. A multicenter registry correlating these findings with clinical outcomes is needed.
ABSTRACT 26

Local Liquid Drug Delivery of Paclitaxel with a Novel Keratose Excipient

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Category: Peripheral Artery Disease

Background: Peripheral Artery Disease (PAD) is one of the leading causes of morbidity in the US. Drug-eluting stents are the standard treatment of PAD; however, drug-eluting stents have been shown to be ineffective. This is mainly due to high rates of strut fractures leading to restenosis. This has led to the development of non-stent drug delivery systems to deliver anti-proliferative drugs, like paclitaxel, to diseased peripheral arteries. One such novel drug delivery system is the perfusion catheter, which provides local liquid drug delivery between two occlusion balloons. The use of excipients can aid in the retention of paclitaxel. Keratose, an extracted form of keratin derived from human hair, is a promising excipient due to its ability to provide a tunable release of various drugs as a function of keratose concentration and its biocompatibility. The goal of this project was to evaluate the ability of keratose to aid in the delivery and retention of liquid paclitaxel using a perfusion catheter in an in vivo rabbit model.

Methods: Paclitaxel tissue levels were measured up to 14 days following treatment with a perfusion catheter delivering paclitaxel with a keratose excipient in the iliac artery of healthy rabbits (10 rabbits, 20 vessels). Pharmacokinetic evaluation using high performance liquid chromatograph-mass spectroscopy (HPLC-MS) was performed to quantify arterial drug retention at 1 hour, 1 day and 3 days, 7 days, and 14 days. Histology evaluation and morphometry analysis were also performed at 3 days, 7 days, and 14 days following treatment.

Results: Paclitaxel with keratose was successfully delivered to arterial segments using the perfusion catheter. Pharmacokinetic analysis of paclitaxel with keratose demonstrated arterial paclitaxel levels up to 14 days. The 1 hour, 3 days, 7 days, and 14 days vessel paclitaxel concentrations were 1.29±0.51, 0.061±0.014, 0.045±0.025, 0.016±0.048, 0.0071±0.0022 ng/mg respectively. Histomorphology data indicate a decrease in neointimal thickness and media area.

Conclusion: These findings demonstrate the ability of keratose to facilitate controlled release of paclitaxel and deliver therapeutic paclitaxel levels in vivo, highlighting local liquid drug delivery as a treatment for PAD and keratose as a novel excipient for paclitaxel retention. Further studies are warranted comparing keratose to commercially available excipients.
ABSTRACT 27

Lutonix Drug-Coated Balloon Long Lesion Study - 24 Month Outcomes

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Category: Peripheral Artery Disease

Background: The safety and effectiveness of Drug-Coated Balloons (DCB) have been shown in relatively short and less complex lesions. The US currently approved DCBs reported a mean lesion length of 8.0-10.2 cm with the majority of the lesions are TASC II A and B. There is a continued need to evaluate the safety and effectiveness of DCB in longer and more complex disease. This multi-center, single arm study was designed to demonstrate the efficacy and safety of the Lutonix DCB for the treatment of long (≥ 14 cm) TASC II Class C and D lesions in the SFA.

Methods: Patients presenting with claudication or ischemic rest pain Rutherford Class Category (RCC 2-4), TASC II Class C or D, lesions ≥14 cm in length, and vessel diameters between ≥ 4 and ≤ 7 mm in the native femoropopliteal artery were enrolled. Patients were excluded if the use of the Lutonix DCB per the current Instructions for Use (IFU) was contraindicated. Use of laser, atherectomy or cryoplasty during the index procedure was not permitted. Patient follow-up was up to 2 years.

Results: One hundred eighteen (118) patients were enrolled. The majority of patients were RCC 3 (69.0%). All but one (1) patient had a TASC II Class C or D lesion (77.1%/22.0%, respectively). Mean lesion length was 212.5±68.3, longest lesion treated was 450mm, and 51.2% were chronic total occlusions (CTOs). Calcification was present in 88.1% (21.2% had severe calcification) and 36.4% were diabetics. Ninety-five (95%) of the lesions were located in the SFA. Freedom from composite of all-cause peri-procedural (≤30 day) death, index limb amputation (above or below the ankle) and index limb re-intervention was 82.3% [73.9%, 88.2%] at 1 year and 70.5% [60.8%, 78.2%] at 2 years. Freedom from TLR at 2 years was 75.6% [66.2%, 82.7%]. For the Rutherford, ~80% of subjects Improved by at least one Category and >60% of subjects Improved by at least 2 Categories at 2 years.

Conclusion: The Lutonix DCB is safe and effective in treating long complex femoropopliteal lesions with excellent freedom from TLR at 2 years.
ABSTRACT 28

Office Based PAD Evaluation and Supervised Exercise Therapy (SET) covered by Medicare (Michigan Model)

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Category: Peripheral Artery Disease

Background: “Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)”. This is now a Medicare covered benefit.

“A SET program must be conducted in a hospital outpatient setting or in a physician’s office and under the “direct supervision” of a physician, or physician assistant, nurse practitioner, or clinical nurse specialist who must be trained in both basic and advanced life support techniques. Physical therapists not practicing in these settings are not covered at this time. The requirements of the SET program are available at the link below. https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx Currently, CPT Code 93668 covers Peripheral Arterial Disease Rehabilitation. At this point we are unsure whether a new code will be developed or code 93668 will be revised. We are expecting more information when CMS releases the final National Coverage Determination contractor instructions and will share that information as it becomes available.”

Methods: Key points in the 2014 clinical evidence update included:

“Management of intermittent claudication”

Exercise programs

- Supervised exercise is associated with increases in MWD (Maximal Walking Distance) compared with home-based or other unsupervised exercise programs.
- Supervised exercise is associated with greater increases in walking distance in people with aortoiliac disease than either stenting or optimum medical care.
- Supervised exercise appears to be more cost effective than either angioplasty alone or supervised exercise plus angioplasty in people with IC due to femoropopliteal occlusion.”


**For therapeutic services furnished in the hospital or CAH or in an on-campus outpatient department of the hospital or CAH, as defined at 42 CFR 413.65, “direct supervision” means that the physician or nonphysician practitioner must be present on the same campus where the services are being furnished. For services furnished in an off-campus provider based department as defined in 42 CFR 413.65, he or she must be present within the off-campus provider based department. The physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. The physician or nonphysician practitioner does not have to be present in the room when the procedure is performed.”

All ultrasound vascular testing must be performed by a Registered Vascular Technologist or in an Accredited Vascular Lab.

Results: The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover supervised exercise therapy (SET) for beneficiaries with intermittent claudication (IC) for the treatment of symptomatic peripheral artery disease (PAD). Up to 36 sessions over a 12 week period are covered if all of the following components of a SET program are met:
A The SET program must:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;
- be conducted in a hospital outpatient setting, or a physician’s office;
- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and
- be under the direct supervision of a physician (as defined in 1861(r)(1)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) who must be trained in both basic and advanced life support techniques.

B Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. At this visit, the beneficiary must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

C Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time. A second referral is required for these additional sessions.

D SET is non-covered for beneficiaries with absolute contraindications to exercise as determined by their primary physician.

Conclusion: PAD affects 12-20% of Americans age 60 and older, and the incidence of PAD increases considerably with age.

Supervised exercise therapy has been demonstrated to be an effective therapy to lessen the symptoms of claudication and improve walking distance in patients with PAD in numerous trials. Stakeholders like the American Heart Association (AHA) have long recommended supervised exercise as a first-line, non-invasive, low risk therapy for individuals with PAD who suffer from claudication. Despite the disease burden and the substantial evidence supporting supervised exercise therapy as a safe and effective treatment for PAD, it is currently covered by Medicare.
ABSTRACT 29

The Defining Based on Beneficial Uses of Intracavernosal Platelet Rich Plasma Product in the Presence of Clopidogrel (Plavix) on Erectile Function in Diabetic Rats

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Category: Peripheral Artery Disease

Background: Increasing evidence of a link between erectile dysfunction (ED) and cardiovascular disease suggests a shared vascular etiology with endothelial dysfunction as a plausible underlying biological mechanism. The presence of ED could be a warning of vascular disease in different arterial territories. Greater microvascular than macrovascular endothelial dysfunction as a potential contributor to ED and an underlying mechanism linking ED and cardiovascular disease. Men with diabetes are at greater risk of ED which is commonly associated with cardiovascular disease. Platelet-rich plasma (PRP) includes a high concentration of platelet growth factors which to cause angiogenesis and the nerve regeneration from whole blood and to improve clinical outcomes. Clopidogrel bisulfate (Plavix™, Sanofi/Bristol-Myers Squibb) is a thienopyridine class inhibitor of P2Y12 ADP platelet receptors and widely prescribed for patients with cardiovascular disease. The previous study showed that clopidogrel could effectively delay the development and progression of atherosclerosis. In this study, we aimed to evaluate the effect of intracavernous injection of PRP and clopidogrel on erectile and vascular function in streptozotocin (STZ)-induced diabetic rats.

Methods: Sprague-Dawley rats (n=30) were divided into two groups: Control and STZ-induced diabetes (45mg/kg, i.p., 8 wk). In vivo erectile responses were repeated after intracavernosal injection of PRP or clopidogrel and their combination. The clopidogrel relaxant response of corpus cavernosum (CC) and aorta was obtained from organ baths. The expression and localization of eNOS, HIF-1α, VEGF, and nNOS were determined in penile and aorta tissue.

Results: Diabetic rats demonstrated decreased ratio of intracavernosal pressure (ICP) to mean arterial pressure (MAP) (0.2±0.09; p<0.001) and total ICP (2032±313mmHg; p<0.01) after intracavernosal administration of PRP (0.4±0.01; 2806±445mmHg; p<0.05) and clopidogrel (0.4±0.08; 2646±263mmHg; p<0.05) partially restored. Interestingly, combined intracavernosal administration completely improved decreased ICP/MAP and total ICP (0.9±0.1; 5573±409mmHg). Clopidogrel directly caused marked relaxation in all CC and aortic tissues. The alterations of protein expression were partially recovered by the combined treatment.

Conclusion: Our study for the first time showed that PRP combined with clopidogrel treatment improves diabetes-related vascular and erectile function by lowering ADP-induced clotting. The restorations of eNOS and VEGF in the vascular and erectile endothelium could be involved in the antithrombotic actions in diabetic patients. The Future studies are needed to elaborate on regenerative medicine with clopidogrel on diabetic vascular complications.
ABSTRACT 30

Treatment of Failing Saphenous Vein Lower Extremity Bypass Grafts Utilizing An Image-Guided Atherectomy Catheter

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Category: Peripheral Artery Disease

Background: Up to 40% of lower extremity arterial bypass grafts will develop stenosis that may ultimately lead to graft failure. The current primary endovascular treatment of a failing graft utilizes balloon angioplasty, with its risks of dissection and perforation. Open repair is more durable but is associated with increased morbidity and is still associated with a high incidence of recurrence. There have been reports of plaque and neointimal tissue removal using atherectomy devices, but the potential of vein graft perforation, places the patient at a high risk of a poor outcome. The need for autogenous tissue to repair or replace the graft, the anesthetic considerations, and increased morbidity, and mortality, creates a situation for the application of a safe and efficacious image directed atherectomy device. The objective of this study was to assess the utility of an OCT-image-guided atherectomy device in treating severely diseased saphenous vein graft lesions.

Methods: In an observational study, patients with venous bypass grafts who presented to the clinic with claudication and foot pain were examined with ultrasound to assess the level of vessel stenosis. Those with evidence of stenosis that impacted the durability and patency of the graft were approached to schedule OCT-guided atherectomy (Pantheris catheter, Avinger, Inc.). With patient consent, the procedure was conducted with the intent to remove sufficient tissue to restore blood flow, as evidenced by inline flow to the foot. Follow-up visits were conducted in the clinic at regularly scheduled intervals post-procedure.

Results: The 14 patients who participated in this study had a mean age of 79 years and were predominantly male (62%). The source of 13 of the venous grafts was autologous; one was cadaveric. The time to presenting of symptoms after the initial venous graft ranged from 2 months to 16 years (mean 20 months. Mean length of the graft occlusions was 155 mm and the majority had >75% stenosis at the time of the procedure. Atherectomy with OCT-guidance was performed successfully in all 14 patients, with no adverse events during the procedure or recovery. At follow-up, all patients had a reduction in the level of graft stenosis, as determined with Duplex imaging, with 67% of patients having <20% stenosis and 33% having 30% to 40% stenosis post-procedure; one patient was lost to follow-up. OCT imaging identified occlusions that did not appear on angiographs and reduced the volume of contrast used, which was particularly important in patients with chronic kidney disease where contrast-induced injury is possible. Use of OCT imaging, combined with CO2 angiography reduced the amount of contrast infused to 10 cc.

Conclusion: OCT-guided atherectomy is a safe and effective treatment option for restoring blood flow in failed venous bypass grafts.
ABSTRACT 31

Use Of Directional Atherectomy To Treat Peripheral Lesions Above And Below-The-Knee: Pilot Experience With The New Design Of An Optical Coherence Tomography-Guided Device

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Category: Peripheral Artery Disease

Background: Use of optical coherence tomography (OCT) to guide atherectomy of peripheral arterial lesions have the potential to reduce injury to un-diseased parts of the vessel wall. Pathology studies and intravascular imaging showed the majority of plaque in peripheral artery disease is eccentric while large parts of the vessel wall within a stenotic lesion remain un-diseased. Intravascular imaging in directional atherectomy permits avoidance of deep wall layers while focusing on plaque. Blood flow management is necessary for clear imaging using the light energy that forms the basis of OCT. The first-generation OCT-guided atherectomy catheters facilitated two balloons to limit blood interference of the OCT component of atherectomy devices, but they added a level of complexity to the procedure and device handling. A design revision uses one balloon positioned adjacent to the OCT component to not only reduce blood flow but also position the cutter head for tissue excision.

Methods: With patient consent, atherectomy of peripheral lesions was performed under OCT guidance with two models of a redesigned atherectomy device (Pantheris 3.0, Avinger, Inc., Redwood City, CA). One model has the standard-length nosecone of 6 cm and the other has an extended length nosecone of 9 cm that is able to hold almost twice the volume of tissue as the standard model. Atherectomy was performed in all patients, followed by drug-coated balloon angioplasty.

Results: Directional atherectomy was performed in a total of 11 patients, 4 with the extended length nosecone. The lesions averaged 64.7 mm (range 3 to 150 mm) in vessels with an average diameter of 5.3 mm; 43% were severely calcified. All lesions were located in the superficial femoral artery, with two patients having an additional lesion in the popliteal and below the knee trifurcation level. Prior to the procedure the extent of stenosis averaged 84% (range 60% to 100%); after use of the atherectomy device the stenosis was 11% (range 0 to 20%), being reduced further to 6% (range 0 to 10%) after adjunctive angioplasty. Technical success rate was 100%. The devices could be advanced to locations needed, even lesions below the knee. With the extended nosecone, the cutter was able to reach the trifurcation region in a contralateral (crossover) approach.

Conclusion: Blood management was sufficient with one balloon component enabling real-time lesion analysis and guiding the cutter blade towards plaque and away from un-diseased wall parts. The extended tissue collection component reduced the number of times the device had to be removed to expel the tissue, thus permitting more tissue collected with fewer re-insertions of the device compared to the standard nosecone. Following this initial experience, an additional 20 patients have had lesions treated.
ABSTRACT 32

When Pedal Access is the Only Way to Save a Limb!

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Category: Peripheral Artery Disease

Background: Critical limb ischemia is associated with high rates of amputation and death. Peripheral arterial disease (PAD) is highly prevalent reaching up to 20% of the general population. PAD develops into critical limb ischemia (CLI) in 1-2% of the general population and is associated with high rates of amputation and mortality. Revascularization has been shown to prevent amputation in 80-90% of patients with CLI but on occasion traditional access or surgical bypass may not be achievable. We present 3 cases of CLI where pedal access was the only feasible option.

Methods and Results: 81-year-old female with CAD, CKD, and current smoker, had 3 recurrent acute limb ischemia (ALI) 6 to 8 weeks apart. Is on (clopidogrel, aspirin and Coumadin). Recently had AngioJet embolectomy and stenting including Viabhan stents to her right SFA, nitinol self-expanding stents to right popliteal followed by DCB and PTA to right peroneal, the only runoff to her right lower extremity. AT and posterior tibialis (PT) are both occluded.

It was speculated that recurrent ALI was secondary to poor runoff. Recanalization of one tibial runoff would improve her outflow and possibly reduce the ALI recurrence.

74-year-old patient with type II DM, HTN, right metatarsal amputation and 2 prior right lower extremity bypasses (femoropopliteal bypass and a profunda femoris to posterior tibialis bypass) presents with a non-healing right foot stump ulceration.

Angiography revealed a long femoropopliteal occlusion from the origin of the SFA to the proximal tibial vessels with collaterals faintly filling the pedals. Prior bypass grafts were occluded. A challenge is posed given that SFA is flush occluded, popliteal artery is occluded and a trans-collateral approach is not feasible.

A 50-year-old female with CAD, type II DM, and CHF. Presents with chronic non-healing right foot ulcer, despite treating the right SFA disease with AngioJet embolectomy and Viabhan covered stent after a subacute presentation. On aspirin and ticagrelor.

CTA of lower extremity showed a totally occluded left external iliac and left CFA, the right CFA was occluded at the origin extending to the P1 segment of the right popliteal. Her right anterior tibialis was occluded distally, right posterior tibialis had 50% disease, and right peroneal had 60% at its ostium.

Conclusion: These 3 cases illustrate the importance of the pedal access. Several studies have shown that pedal access is feasible and can be performed with high success. Adequate training however is needed to achieve desired results. Through a pedal access, total occlusions are likely to be crossed easier, distal embolization is captured by the pedal sheath, and various techniques can be done including atherectomy, stenting and embolectomy. Access can be obtained either with angiographic or duplex ultrasound guidance, although we believe the latter is more likely to be successful particularly in hibernating pedal vessels.
ABSTRACT 33

Utilizing Antibiotic Irrigation in Septic Ankle Arthrodesis: A Case Study

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Category: Podiatry and Wound Care

Background: Tibiotalar joint infection is a serious problem that presents a significant challenge to podiatric physicians. In this case report, we will explore this challenging limb salvage case utilizing a septic ankle arthrodesis technique, with simultaneous antibiotic irrigation for reduction of bacterial burden and biofilm.

Methods: A 67-year-old morbidly obese African American female with past medical history significant for metastatic endometrial cancer, hyperthyroidism, bilateral knee osteoarthritis, peripheral neuropathy, type 2 diabetes, hypertension, peripheral vascular disease, deep vein thrombosis (DVT), hypertriglyceridemia, hyperlipidemia, nicotine dependence and prior partial right fourth and fifth ray amputations. Presented with an extensive non-healing wound to the anterior aspect of the right ankle due to an open reduction with internal fixation of an ankle fracture sustained in a fall; which resulted in osteomyelitis of the fibula. The wound measured approximately 10 cm x 7 cm x 1 cm with exposed bone and tracking directly into the ankle joint. She had an angiogram with intervention prior. Furthermore, she was found to have a DVT, which was treated medically (Lovenox- Sanofi, Bridgewater, NJ). She underwent several debridements, placement of antibiotic beads, and IV antibiotic therapy, which lead up to our definitive procedure. Thorough surgical debridement and antibiotic irrigation is important in wound bed preparation and infection control. Utilizing a circular external ring fixator (Stryker Hoffmann Limb Reconstruction Frame- Kalamazoo, MI), one steinmann pin, smooth and olive 0.062 k-wires, antibiotic irrigation (Bactisure- Zimmer Biomet, Warsaw, IN), and bone stimulator (Exogen- Durham, NC), we performed a removal of hardware, resection of the distal fibula and septic ankle arthrodesis. The patient was advised that she was at a high risk for limb loss, and that this was a final effort to provide the patient with a stable, functional limb for ambulation.

Results: The infection was resolved, and partial ankle fusion was achieved. Ultimately, the patient requested an above knee amputation to initiate chemotherapy for her metastatic endometrial cancer.

Conclusion: This was a challenging limb salvage case with numerous prior surgical interventions in a patient with metastatic cancer. She had a small anterior wound that was treated with local wound care postoperatively. Per Oncology, she couldn’t undergo chemotherapy until the surgical wound was resolved. She elected to undergo a right above knee amputation six months after her surgery. We were able to demonstrate that the use of an external ring fixator with antibiotic irrigation during septic ankle arthrodesis was an effective tool in achieving ankle fusion. Also, various studies support the use of external bone stimulator in accelerating bone healing.
ABSTRACT 34

A Rare Cause for Venous Insufficiency: Congenital Anomaly of the Inferior Vena Cava

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Category: Venous Disease

Background: Congenital anomalies of the inferior vena cava are rare (IVC). The IVC develops primarily between the sixth and eighth gestational weeks involving the formation of several anastomoses between three paired embryonic veins: subcardinal, supracardinal, and postcardinal. Numerous variations in the basic venous plan of the abdomen and pelvis can result in these anomalies. Patients with these anomalies can present with chronic venous insufficiency, varicose veins, venous ulceration, or lower extremity deep vein thrombosis (DVT).

Methods: A 44-year-old female with a history of smoking, right lower extremity DVT while on oral contraceptives, and factor V Leiden mutation presented for a lower extremity venography due to bilateral lower extremity swelling, varicose veins, and discomfort, more prominent in the left than on the right side. She had an outpatient venous ultrasound which showed chronic non-occlusive DVT in the right common femoral vein. Venous insufficiency was noted in the bilateral common femoral vein, sapheno-femoral junction, and the left great saphenous vein. A Magnetic Resonance Venography showed abnormal venous drainage in the lower extremity and possible May-Thurner Syndrome versus anomalous venous circulation. Venography revealed anomalous venous return from the left iliac vein into the hemiazygous vein and right common iliac vein into azygous vein. The azygous and hemiazygous veins were draining into the superior vena cava and then into the right atrium. The IVC was noted to be absent. Extensive collaterals were noted with multiple paraspinal and vertebral veins draining to azygous system. Severe stenosis was noted throughout the hemiazygous system and at the junction of the left common iliac vein and hemiazygous vein.

Results: Secondary to sequential severe stenosis in left common iliac and hemiazygous vein, we performed balloon angioplasty sequentially and follow up angiography revealed some resolution of stenosis. We then placed two Cordis S.M.A.R.T.® stents 14mmX80mm self-expanding stents followed by post-dilatation with Advance® LP balloons. Patient recovered well and was started on Eliquis and Clopidogrel for 6 months followed by Eliquis long-term.

Conclusion: Azygos continuation (AC) is a rare anomaly with an overall prevalence of 0.6%. We present here a patient with chronic right lower extremity DVT and bilateral lower extremity venous insufficiency who was found to have an absent IVC, anomalous venous circulation from the lower extremity into the azygous system. Current literature suggests that congenital anomalies in IVC circulation predispose patients to DVT, venous ulceration, and insufficiency as the venous system fails to properly drain the lower extremities in spite of the compensatory collaterals.

References:
ABSTRACT 35

Very Short Peripheral Catheter for Reduction of Catheter-Related Thrombophlebitis

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Category: Venous Disease

Background: Short peripheral catheter thrombophlebitis (SPCT) is the major complication associated with the use of short peripheral catheters (SPCs) in intravenous procedures, affecting up to 80% of all patients receiving IV therapy. Recently, we demonstrated that SPCT is initiated by a prolonged mechanical interaction between the catheter cannula and the endothelial layer of the catheterized vein. Here we introduce and examine a novel design of a SPC—very short peripheral catheter (VSPC) which has a significant shorter cannula to minimize the contact between the catheter and the vein wall. The evolution and severity of SPCT resulting from indwelling of VSPC vs. a commercial SPC was studied and quantified in swine ear veins model using quantitative MRI techniques followed by histopathology analysis.

Methods: 15 Female swine were used. Each ear was randomly assigned to either our 20G 10mm length VSPC or 20G commercially used SPC (30 mm length). Each animal underwent two MRI scans through the study- 4 and 12 days following catheters insertion procedure. MRI scan included the following sequences: quantitative T2 mapping, and T1 pre and post gadolinium- injection. At the end of the second MRI scan the animal was sacrificed and its ears were harvested for a comprehensive blinded histopathology analysis.

Results: MRI results suggests that the T2 values of the SPC groups were higher than the VSPC ones (with average of 65ms Vs. 54ms) for all the tested animals. This finding implies on higher extent of edema identified in the region of the SPC site. The difference was mainly evident in the second MRI scan which was carried out 12 days following procedure. The T1- weighted imaging revealed the most significant difference between the catheters groups as the averaged signal intensity in each time point was about 1.5 times higher in the SPC samples (Figure 1). The histological findings showed marked stretching, focal damage and severe inflammation along the vein which was catheterized with the SPC. All morphological parameters indicative of vascular integrity was better in the VSPC samples.

Figure 1: Examples of T1 post gadolinium images of VSPC (two left panels) and SPC (two right panels) at the second MRI scan. “hot” intensity colors are mainly distributed surrounding the vein catheterized by the SPC

Conclusion: The MRI and the histopathological findings suggest that the VSPC catheter type is safer to use when comparing to the SPC catheter. Both the MRI parameters were found significantly higher in the SPC group indicating on higher extent of edema and inflammation compared to the VSPC group. The VSPC was able to dwell within the vein for all the period of the experiment with no evidence for catheter slipping out of the vein.
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