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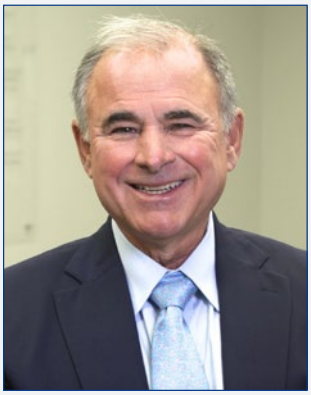

Craig M. Walker, MD, FACC, FACP
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Founder and President,
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Clinical Professor of Medicine,
Tulane University School of Medicine

Clinical Professor of Medicine,
Louisiana State University School of Medicine

Journal of Arterial, Venous, and Lymphatic Intervention

JAVELIN is an online, peer-reviewed journal that will focus on the diagnosis, medical treatment, and interventional therapy of arterial, venous, and lymphatic disorders. It will include case reports, step-by-step procedural instructions, new product introduction, recorded live cases, commentary on subjects of controversy, new breakthroughs in medical and interventional treatment, and submitted articles of interest. Articles will be archived for continued reference.

JAVELIN will have articles of interest to cardiologists, vascular surgeons, radiologists, nephrologists, wound-healing experts, podiatrists, family physicians, nurse practitioners, and internal medicine physicians. The “Fellows Corner” will focus on instructional cases and videos aimed at fellows and interventionists who are interested in continued basic education on peripheral vascular diagnosis, medical therapy, interventional techniques, and complication management.The “Fellows Corner” will include commentary from fellows in active training as well as a series on the basics of peripheral vascular intervention.

Advancements in diagnosis, treatment, interventional therapy, and wound healing for peripheral vascular disorders are progressing rapidly. JAVELIN will allow authors to utilize video images to enhance educational clarity and, if accepted, provide rapid turnover from the time of submission to peer review and subsequent publication. JAVELIN is now accepting articles for review and publication.

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Drug Transfer Efficiency of Commercially Available Drug Coated Balloons

Authors:
Kayla Lowry[1]; Trey Ursillo[1]; Saami K. Yazdani, PhD[1]
[1]Wake Forest University, Department of Engineering, Winston-Salem, NC

Category: Cardiovascular Disease

Background: Drug transfer from drug-coated devices have become a focus point in studying the treatment of vascular diseases. Devices such as, drug-coated balloons (DCBs) and drugeluting stents (DES) represent devices used to reduce restenosis rate and improve the long term outcome of patients. While both devices deliver antiproliferative drugs, primarily Paclitaxel (PTX) and Sirolimus (SIR), to the artery, each has a distinct method of doing so. DES use a polymeric coating allowing for a controlled release of the drug over a long period of time. In contrast, DCBs rely on an excipient-drug coating to aid in a quick release of the drug and the retention of the drug onto the arterial wall. The efficiency in which the process occurs can have an effect on the clinical outcome of the DCB. Therefore the goal of this study was to examine the drug transfer efficiency of three commercially available DCBs.

Methods: The transfer of the PTX coating of three commercially available DCBs (Lutonix: BD, NJ; IN-.PACT Admiral: Medtronic,CA; Stellarex: Spectranetics, CO) was evaluated using a validated bench-top system that incorporates harvested porcine carotid arteries. Each balloon was deployed in a single artery using the manufacturers' recommended delivery parameters for a duration of two minutes. The arteries were then placed in a closed system flow-circuit bioreactor for 15 minutes, 1 hour, and 24 hours (n=3 per time point per DCB). The arteries were subjected to pulsatile flow conditions using a culture medium. Following each time point, the treated arteries were removed and the arterial drug levels (pharmacokinetics) were measured using liquid chromatography-mass spectrometry. The percent of total PTX transferred from the DCB to the artery was calculated and data is expressed as mean standard deviation.

Results: The percent of PTX transferred from the DCB to the artery was calculated for each sample and averaged for each time point. For the Lutonix DCB the drug transfer percent was 0.53 0.59% for 15 minutes, 0.73 0.49% for 1 hour, and 0.018 0.002% for 24 hours. For the In.PACT DCB the drug transfer percent was 1.58 1.49% for 15 minutes, 1.20 1.05% for 1 hour, and 1.58 1.41% for 24 hours. Which was the largest transfer percent at 15 minutes and 24 hours in comparison to the Stellarex DCB, which had a drug transfer percent of 0.79 0.43% for 15 minutes,1.60 0.92% for 1 hour, and 0.99 1.096% for 24 hours.

Conclusion: Our results indicate a very small amount (<2%) of PTX is transferred from the DCB to the artery. Further studies are warranted to better identify where the remaining drug is located, as well as to perform parallel studies using clinically-relevant animal models.

Evaluation Of Left Ventricular Function After Revascularization Of Chronic Total Occlusion Of Left Anterior Descending Coronary Artery Using Speckle Tracking Echocardiography

Mahmoud S. Abdelmoneum, MD
Benha University Hospital, Cairo, Egypt
Category: Cardiovascular Disease

Category: Venous Disease

Background: Revascularization of a chronic total coronary occlusion (CTO) of left anterior descending (LAD) artery lead to recovery of the hibernating myocardium that will improve left ventricular (LV) function

Methods: This prospective observational study included 100 patients who were diagnosed by coronary angiography to had CTO of LAD. In accordance with established protocols, Using (2D-STE) was to measure global longitudinal strain (GLS) and LV functions. Follow-up of patients was done at day 1 and 3 months later after PCI.

Results: 100 patients included in this study, with a mean age 58.55 7.98 years. (GLS) and wall motion score index (WMAI) difference at baseline and follow-up shows a positivecorrelation with left ventricular ejection fraction (LVEF) changes at baseline and follow-up ($p<0.001$).Mean of baseline left ventricular end systolic volume (LVESV) was 61.52 15.14 and follow-up LVESV was 50.60 14.07 with statistical difference ($p=0.047$). Mean value of baseline GLS (-14.26 0.93) and follow-up GLS was (-18.66 0.92) ($p<0.001$).

Conclusion: Revascularization of CTO of LAD improves LV function. In patients undergoing CTO revascularization, change in longitudinal strain (LS) and GLS was more accurate and sensitive predictors for improvement LV function at 3 months follow-up.

Incidence of Rare Morphological Variant Stanford Type B Aortic Dissection Necessitating Bilateral Femoral Artery Cutdown Endovascular Repair

Caroline Cushman, BS[1], Andrew Ibrahim, BS[1]
James Montgomery, MD[2],
Dennis Eastman, MD[3]

School of Medicine, Texas Tech University Health Sciences Center, Lubbock, Texas, USA[1]
Department of Interventional Radiology, Covenant Medical Center, Lubbock, Texas, USA[2]
Department of Surgery, Covenant Medical Center, Lubbock, Texas, USA[3]

Category: Cardiovascular Disease

Introduction: Type B aortic dissections often follow a spiral pathology with ischemia of the contralateral kidney and iliac artery. We present a rare Type B aortic dissection with a rightsided linear pathology, where complete occlusion of the right renal artery and subsequent reduced flow to the ipsilateral right common iliac artery occurred. This dissection's unique trajectory and complications, including visceral, renal, and lower extremity ischemia, posed significant challenges, and required specialized intervention, rather than typical treatment strategies. While Type B dissections are often medically managed, this case is a striking example of the necessity of endovascular repair in complicated Type B aortic dissections.

Methods: We describe a 44-year-old female presenting with sudden-onset pain and a tearing sensation radiating from back to pelvis, accompanied by altered sensation in her right lower extremity. Past medical history included hypertension, peripheral vascular disease, obesity, and a history of substance abuse involving cocaine, nicotine products, and opiates. Due to the severity of her symptoms, prompt imaging was conducted, revealing a Type B aortic dissection extending from the left subclavian artery to the aortic bifurcation, and a descending thoracic aortic dissection with complete absence of blood flow to the right kidney, complete obstruction of flow in the right common iliac artery from the true lumen, reduced flow in the superior mesenteric artery.

At this time, decision was taken to perform endovascular repair. Imaging showed a Type B aortic dissection starting at the takeoff of the left subclavian artery. Bilateral femoral artery cutdown exposure and endovascular repair of the thoracic aortic dissection with placement of a Medtronic valiant thoracic stent graft from the innominate artery to the upper descending thoracic aorta was conducted. The procedure resulted in marked improvement in the size of the true lumen at the visceral aorta. Post-operative angiography revealed good flow into the celiac, superior mesenteric artery, left renal artery, and both iliac arterial systems, leading to stabilization of the patient's condition.

Discussion: The case exemplifies the rarity and severity of a right-sided linear Type B aortic dissection. In this patient, the rare morphology and severity of the dissection necessitated advanced interventions to alleviate malperfusion in the superior mesenteric artery, right renal artery, and right common iliac artery due to partial or complete obstruction of flow. In this case, complete renal infarction from false lumen thrombosis and obstruction by the dissection flap also occurred, further complicating treatment.

Thus, this case advocates for considering advanced interventional treatment modalities, such as bilateral femoral artery cutdown and endovascular repair in rare morphological variant Type B Stanford dissections in the context of infeasible medical management otherwise.

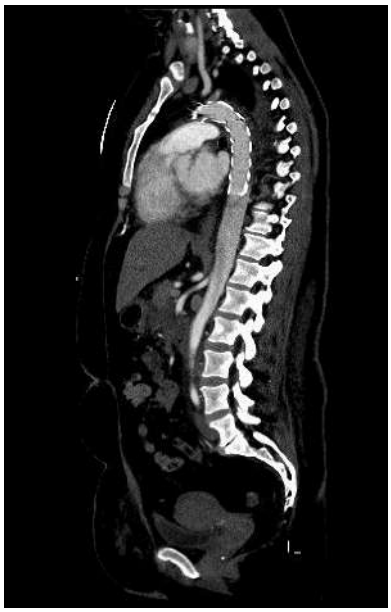


Figure 1: Placement of a Medtronic Valiant thoracic stent graft in the Type B aortic dissection extending from the innominate artery to proximal thoracic descending aorta.

Conclusions: At 1- and 24-hours, no observable differences were observed between arterial and AVF flow. Additionally, no observable differences were found between 1- and 24-hour time points in either flow group. Trends in the data suggest the AVF hemodynamics may increase retention of DCB-delivered paclitaxel in the arterial tissue compared to arterial tissue. Future investigation in the research includes modifying the bioreactor to resemble the AVF anatomy and physiology by fusing arterial and venous tissue.

Investigating the Therapeutic Efficacy, Safety, and Long-Term Impact of Sacubitril Valsartan in Treating Hypertrophic Cardiomyopathy

Shenghan Zhong[1]
Department of Cardiovascular Medicine, Chongqing Kanghua Zhonglian Cardiovascular Hospital, Chongqing, China[1]

Category: Cardiovascular Disease

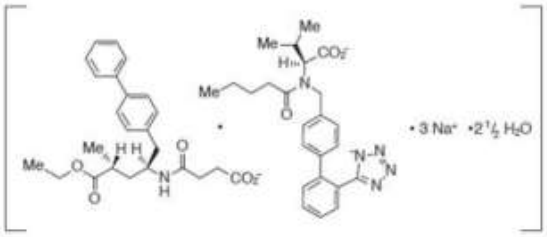
Background: This study aims to evaluate the efficacy, safety, and long-term effects of sacubitril/valsartan in treating hypertrophic cardiomyopathy using a hypertrophic cardiomyopathy rat model and in vitro cardiomyocytes. Hypertrophic cardiomyopathy presents a challenge in cardiac disease treatment. This research aims to explore the potential role of sacubitril/valsartan in treating hypertrophic cardiomyopathy, offering novel therapeutic strategies for this condition.

Methods and Materials: Experimental groups were established using a hypertrophic cardiomyopathy rat model (400 10g, n=9 per group), with the treatment group receiving sacubitril/valsartan and the control group receiving a placebo. In vitro cultured cardiomyocytes were exposed to different concentrations (0mg, 25mg, 50mg, 75mg, 100mg, 200mg, 500mg, and 750mg/kg/day) of sacubitril/valsartan. Measurements included myocardial hypertrophy, cardiac function indices, and cell assay data.

Results: The left and right myocardial hypertrophy index and myocardial cell diameter of the treatment group were lower than those of the control group, which were (1.04 0.21 vs 1.38 0.15), (0.34 0.08 vs 0.46 0.09), (15.23 1.67 vs 19.82 2.01) μm, respectively. The differences were statistically significant ($P < 0.05$). Echocardiography showed that the left ventricular end-diastolic diameter (LVEDD) and left ventricular end-systolic diameter (LVESD) in the treatment group were lower than those in the control group, which were (2.03 0.36 vs 4.26 0.54) mm and (1.74 0.83 vs 3.57 0.83) mm, respectively. The differences were statistically significant ($P < 0.05$). The levelsof troponin, myocardial kinase isoenzyme and lactate dehydrogenase in the drug treatedgroup were lower than those in the control group (234.56 31.24 vs 412.89 21.36) pg/ml, respectively. (67.98 10.56 vs 98.65 13.27) U/L, (124.78 31.24 vs 214.67 28.79) U/L, the differences were statistically significant ($P < 0.05$).

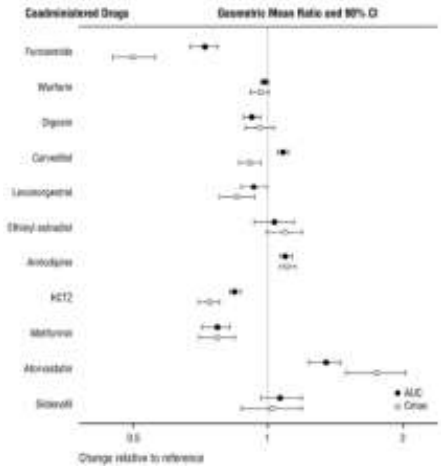
Conclusion: Sacubitril/valsartan exhibits promising therapeutic potential; however, further clinical studies are required to validate its exact efficacy in treating hypertrophic cardiomyopathy. These preliminary results offer hope for its potential as a treatment and provide a foundation for future clinical investigations.

Figure 1



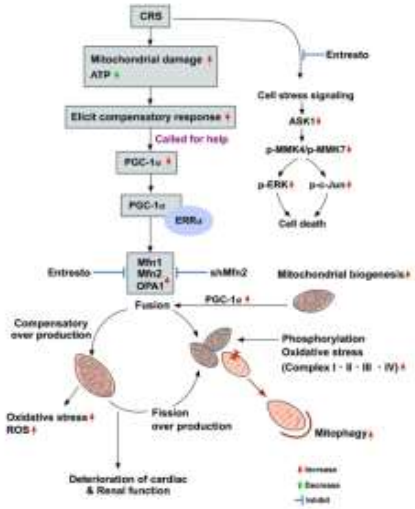
Conclusion: ENTRESTO is available as film-coated tablets for oral administration, containing 24 mg of sacubitril and 26 mg of valsartan; 49 mg of sacubitril and 51 mg of valsartan; and 97 mg of sacubitril and 103 mg of valsartan.

Figure 2



Effect of ENTRESTO on Pharmacokinetics of Coad ministered Drugs.

Figure 3



The mechanism of entresto for protecting the cardiomyocytes and preserving the heart function through regulating the oxidative stress

Liquid Delivery of Vascular Smooth Muscle Cell-Targeting RNA Aptamer for Treatment of Venous Neointimal Hyperplasia in Arteriovenous Fistula

Linda B. Liu[1]; Saami K. Yazdani, PhD[2]
Wake Forest University School of Medicine, Department of Biomedical Engineering, Winston-Salem, NC[1]
Wake Forest University, Department of Engineering, Winston-Salem, NC[2]

Category: Cardiovascular Disease

Background: The main cause of loss of patency in arteriovenous fistula (AVF) vascular accesses is venous neointimal hyperplasia, which is the accumulation of vascular smooth muscle cells (VSMCs) in the vessel intima. Perfusion catheters are a novel liquid drug delivery device that can administer therapeutic agents directly into the vascular wall (1). Aptamer 14 (Apt14) is an RNA "smart drug" that specifically targets VSMCs to inhibit their migration and has been shown to reduce neointimal formation in porcine arterial injury models (2). The purpose of this study was to determine the acute delivery efficacy of Apt14 delivery with a perfusion catheter via visualization of the depth of drug penetration in porcine venous tissue using a novel AVF benchtop model.

Methods: The AVF benchtop bioreactor consists of a circulation media reservoir, gear pump, transparent vessel housing, and a signal generator. Porcine jugular veins harvested from a local abattoir were used as the test vessels. The average flow rate and systolic/diastolic pressures measured in the bioreactor were 665 +/- 85 mL/min and 146/87 mmHg.

The delivery catheter used in this study was the occlusion perfusion catheter (OPC, Advance Catheter Therapies) which can isolate a treatment zone in the vessel using two occlusion balloons and allow pressure-driven liquid delivery into the target region (Figure 1). The OPC catheter has a built-in pressure transducer that enables monitoring in real-time of the delivery pressure in the treatment zone during infusion.

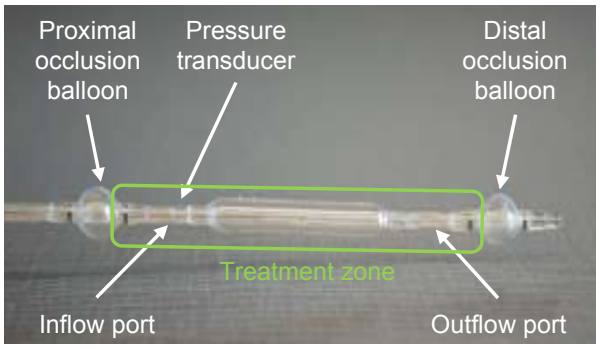


Figure 1: Diagram of the occlusion perfusion catheter.

We used a fluorescent formulation of Apt14 to enable visualization of the depth of delivery penetration via fluorescent microscopy. The aptamer solution was prepared at 100 nM and delivered at 0.4 atm for 2 minutes. After drug delivery, the OPC was withdrawn from the bioreactor, and the veins exposed to AVF-level pulsatile flow for 1 hour. Treated segments of the veins were removed after the time point, stained with phalloidin-Alexa Fluor 488 (Thermo Fisher Scientific) to visualize smooth muscle, and imaged. Depth of drug penetration was measured from the internal elastic lamina to the maximum depth of penetration and normalized to the thickness of the venous medial layer. All data are expressed mean standard deviation.

Results: Fluorescent microscopy showed that Apt14 delivery with the OPC resulted in successful acute retention of the drug in the medial layer of the porcine veins (Figure 2). Average depth of penetration was 13.65 5.02 μm (n = 3), which was 77 16% of the medial layer thickness..

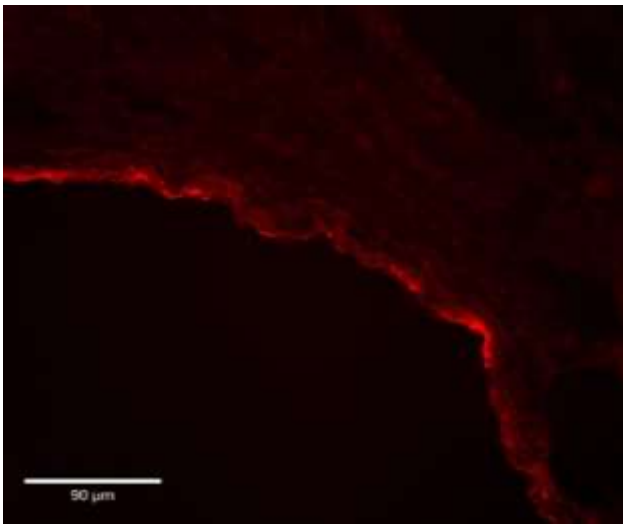


Figure 2: Representative fluorescent microscopy image of aptamer in venous tissue.

Conclusions: This study is the first to evaluate the liquid delivery of an RNA aptamer in venous tissue under simulated AVF flow. We demonstrated feasibility delivering a liquid therapeutic into porcine venous using a perfusion catheter. Future work will include measuring aptamer accumulation and optimizing delivery parameters, including drug concentration, pressure, and duration.

Long-term outcome of percutaneous endovascular stenting in external iliac artery endofibrosis

Mohsen Sharifi[1,2], Robert Snyder[1], Iman Sharifi[1] and Emily White[1]

Category: Cardiovascular Disease and Peripheral Arterial Disease

Background: External iliac artery endofibrosis (EIAE) is a rare vascular disease which has been traditionally seen in avid cyclists. The conventional approach has been surgery, although no high-quality evidence suggests superiority of surgery over percutaneous endovascular intervention. There are limited data on the efficacy of stenting in EIAE. Methods: Over a 14-year period, we treated 10 patients (13 limbs) with EIAE with stents. These patients had declined surgery. The mean follow up was 8.4 3.3 years. There were eight women. Five patients were competitive runners, three were cyclists, and two were triathletes. The mean age was 40.7 2.9 years and body mass index was 19.46 1.6. Intravascular ultrasound (IVUS) was used in eight limbs. Results: Procedural success was achieved in all. The recurrence of symptoms occurred in three patients at a mean of 9.3 2.1 months postindex intervention. The other seven patients remained symptom free. IVUS revealed a pathognomonic finding which we termed 'perfect circle appearance'. It results from symmetric or asymmetric hypertrophy of one or more layers of the arterial wall leading to negative remodeling, which creates a distinct echo dense structure contrasting itself from the luminal blood's echoluscent appearance. It is identical to IVUS images of diffuse venous stenosis with important implications in the treatment technique. Conclusions: We conclude that stenting in EIAE is safe and effective with a good long-term outcome. It can be an alternative to surgery, particularly in those patients who refuse a surgical approach. The IVUS image is pathognomonic and 'sine qua non' of EIAE.

Keywords: Balloon angioplasty, external iliac artery endofibrosis, intravascular ultrasound, rare diseases, stenting.

Background: External iliac artery endofibrosis (EIAE) is a rare vascular disease affecting young high-performance athletes.1–3 It has been traditionally reported in competitive cyclists, which, if left untreated, can lead to cessation or limitation of their activity.2,4,5 None of the traditional atherosclerotic risk factors for vascular disease are at play in the pathogenesis of EIAE and consequently the diagnosis may be delayed due to lack of awareness of providers. Often their symptoms are dismissed as 'neuropathy', 'arthritis', or 'psychiatric' in nature. The classic diagnostic tools such as ankle–brachial index (ABI) and imaging studies are often interpreted as 'normal'. The conventional approach to treatment has been surgery.3,6,7 This choice has not been based on good quality evidence but tradition, and the limited benefit of a few endovascular reports which had primarily used balloon angioplasty alone.8–10 These patients are young and very active and usually prefer alternatives to surgery. We herein report the long-term follow up of our experience with 10 patients (13 limbs) with EIAE who underwent percutaneous endovascular stenting.

Methods:

Study Population

From October 2006 through June 2020, we treated 10 patients with symptomatic EIAE with endovascular stents. There was a total of 13 EIAE as three patients had bilateral disease. They had all refused surgery. This study was approved by the Institutional Review Board of A.T. Still University under a consent exemption decision due to the retrospective nature of the investigation.

Patient selection and outcome measurement

The patients were identified retrospectively from our office computerized database and were followed prospectively for clinical outcomes. The patients' medical records includ- ing clinical histories, angiograms, and available intravascu- lar ultrasound (IVUS) studies were reviewed. Recorded information included: type of exercise, type and duration of symptoms, age at the time of procedure, body mass index (BMI), height, sex, bilaterality of disease, level of exertion to elicit symptoms, type of stents implanted, and restenosis rate. The mean follow up from the index operation was 8.4 ± 3.3 years.

To establish the diagnosis, the patients were to be rela- tively young athletes with the development of lower- extremity ischemic symptoms at high levels of exertion. They were then screened for evidence of stenosis in the external iliac artery by duplex ultrasound (and computed tomography angiography [CTA] if available). If there was a relative reduction, albeit small, in the diameter of the exter- nal iliac artery in comparison to the more distal arterial seg- ments, EIAE became highly suspected. These patients underwent invasive angiography. If any reduction in the angiographic diameter of the external iliac artery was noted as compared to more distal arterial segments, the diagnosis of EIAE was made. No provocative testing was performed during angiography. Some patients underwent IVUS imag- ing based on availability of IVUS at the time of angiogra- phy. The pathognomonic IVUS findings described below would make the diagnosis definitive. Although resting ABI was performed in all patients, its normalcy did not exclude EIAE. Furthermore, normal or mildly abnormal exercise ABI did not exclude the disease.

Percutaneous endovascular intervention was offered to these patients with full disclosure of limited information about the long-term outcome.

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[1]Arizona Cardiovascular Consultants & Vein Clinic, Mesa, AZ, USA 2School of Osteopathic Medicine, A.T. Still University, Mesa, AZ, USA

Corresponding author: Mohsen Sharifi, Arizona Cardiovascular Consultants & Vein Clinic, 3850 E. Baseline Road, Building 1, Suite 102, Mesa, AZ 85206, USA. Email: seyedmohsensharifi@yahoo.com; @drmohsensharifi

Results

Clinical Characteristics

Our study is in line with previous studies demonstrating that majority (more than 90%) of CFA bifurcations occur inferior to the mid femoral head. This study demonstrates right inferior epigastric artery is present below the mid femoral head only in 6% of our subjects and the anatomic zones are not significantly influenced by age, race, gender or cardiac risk factors. Also and of practical importance, if the right or the left common femoral artery bifurcation falls below the mid femoral head the likelihood that the other side will also fall below the mid femoral head in about 98%.

Percutaneous endovascular approach

The procedures were done in a retrograde ipsilateral approach in 10 limbs and in an antegrade contralateral approach in three patients. A 6-8 French sheath was uti- lized. All received 325 mg of aspirin before the procedure and 80 U/kg of heparin as bolus. Aspirin was at 81 mg daily for 6 months. The mean stent diameter and length were 8.54 ± 1.33 mm and 78.46 ± 17.25 mm, respectively. They were all self-expanding stents (Table 2). All underwent postdilatation with the same size balloons, or 2 mm larger (in later cases). The decision on stent sizing underwent a dynamic change as our experience increased. Initially we

Table 1. Clinical characteristics of patients at baseline ($N = 10$).

Characteristic	Value
Demographics	
Age, years	40.7 ± 2.9
Men	2 (20)
BMI	19.46 ± 1.6
Height, m	1.64 ± 0.023
Cyclists only	3 (30)
Runners only	5(50)
Triathletes	2 (20)
Leg symptoms	
Burning	6 (60)
Fatigue	8 (80)
Pain	5 (50)
Discomfort	4 (40)
Tingling or numbness	4 (40)
Bilateral	3 (30)
Left leg only	5 (50)
Right leg only	2 (20)
First onset of symptoms, years	7.3 ± 1.7
Time from onset of symptoms to diagnosis, years	1.4 ± 3.8
Mean length of follow up, years	8.4 ± 3.3
Comorbidities	
Diabetes mellitus	1 (10)
Hyperlipidemia	1 (10)
Hypertension	0
Smoker	0

Values are mean ± SD or number (%).
BMI, body mass index.

used the distal normal segment as the refer- ence and chose a stent with a 1:1 ratio for size selection. After witnessing the initial restenosis cases, we averaged the distal and proximal normal segment diameters and added 2 mm to this. The rationale to this approach is described in the Discussion.

There were two men and eight women. IVUS had been used in eight limbs. There were no immediate complications postprocedurally.

Recurrence of symptoms

There were three patients with recurrence of symptoms at 9.3 ± 2.1 months postindex intervention. The mean stent diameter was 6.7 mm in these patients (one 6 mm and two 7 mm stents). Two of them underwent a redo procedure with IVUS guidance and received a larger stent with high- pressure dilatation. The other patient declined further treat- ment as she had given up strenuous exercise for personal and lifestyle reasons. These patients had not undergone IVUS assessment at the index procedure. At a follow up of 3 years, no symptoms recurred in the two retreated patients.

At a mean follow up of 8.4 ± 3.3 years, the remaining seven patients had remained entirely asymptomatic. Four of them continued to perform high-level exertion as before and three had reduced their high-intensity activities due to lifestyle changes (and not symptoms), although they were still quite active by normal standards.

All patients had three uniform characteristics on imag- ing: With angiography, the caliber of the more caudal seg- ment, such as the common femoral artery, was always larger than the external iliac artery. Although this finding was often subtle, it was always present. It was also seen on careful evaluation of ultrasound images. The other findings were the ubiquitously present ‘perfect circle appearance’ on IVUS and the automatic central positioning of the IVUS catheter within the lumen as described below.

There was no death or limb loss at follow up.

Unique IVUS findings

In all eight limbs which underwent IVUS imaging, a clear and nearly perfect circular appearance of the diseased arterial segment was noted. We called this finding the ‘perfect circle appearance’ (Figure 1A). It was noted most visibly in the circle created by the external elastic lamina. In contrast, segments of external iliac artery without endofibrosis did not show this pattern (Figure 1B). The perfect circle appear- ance was a uniform finding in all eight limbs in this series that had undergone IVUS imaging (Figures 1 and 2). A review of the literature showed an identical pattern in cases who had published IVUS images (Figure 3A) without nec- essarily elaborating on the features.11,12 In fact, we could not find a published IVUS image of EIAE

Table 2. Stents utilized at the index intervention ($n = 13$).

Stent	*n* (%)
Absolute	3 (23)
EverFlex	2 (15)
LifeStar	3 (23)
Protégé	2 (15)
SMART Control	1 (8)
SMART Flex	1 (8)
Zilver	1 (8)

Absolute: Abbot Cardiovascular, Plymouth, MN; EverFlex and Protégé: Medtronic, Minneapolis, MN; LifeStar: Bard, Tempe, AZ; SMART Control and SMART Flex: Cordis, Santa Clara, CA; Zilver: Cook Medical, Bloomington, IN.

which did not have this pattern. This difference of appearance was easily distinguishable. Additionally, in EIAE, the IVUS catheter would often automatically acquire a central or near central position in the lumen (no matter how much the operator tried otherwise) as opposed to the normal segments where it would gravitate and stay to one side. Again, this finding was noted in all our cases as well as in all others who had concentric hypertrophy (Figures 1–3). In two case reports with eccentric hypertrophy of the vessel wall this central positioning was not seen.[13,14]

The angiogram of the patient in Figure 1 (IVUS images) is shown in Figure 4. It deserves particular attention. On visual assessment the extent of stenosis is around 60–70%, which may not be considered as flow-limiting in athero- sclerotic lesions. Similarly, on IVUS imaging, the extent of stenosis (intimal hyperplasia in Figure 1A) is mild to mod- erate. Ordinarily this lesion may not be considered for intervention in classic atherosclerotic lesions. However, there is clear 'negative remodeling' of the entire vessel wall, which in high-performance athletes would render it highly flow-limiting, as explained in the Discussion.

Statistical analysis

The reported continuous variables are shown as mean ± SD. Computations were performed using IBM SPSS soft- ware, Version 26 (IBM Corp., Armonk, NY, USA).

Discussion

The conventional approach for treatment of EIAE has been surgery.[3,15–18] Surgical literature has considered open operative reconstruction as the 'gold standard'. This designation has been made as no other alternative approaches, such as endovascular intervention, exist to date to compare it to. In a few balloon angioplasty-alone case reports, the short-term outcome was variable, with restenosis occurring early due to the high elastic recoil of the artery.[8–10] Stent placement has been more encouraging but the results were based on a handful of case reports with short follow ups.[17,18]

Therefore, the gold standard designation for surgery has been based on tradition and very limited data on alternative approaches rather than robust evidence and rigorous com- parisons.[3,15,16] There are no randomized data between per-cutaneous endovascular intervention and surgery.

Statistical analysis

Different surgical techniques have been described. The 'release only' suprainguinal surgical approach mobilizes the associated restrictive fibrous tissues and divides the tethering branches.[6] More commonly, end-to-end anasto- mosis following resection of the stenotic segment is done.[3,7] Other methods have included use of prosthetic conduits and application of panel grafts by using the lower-extremity superficial veins.[3,15,16] Endofibrosectomy with or without prosthetic or venous patch plasty has also been described.[3–5] Surgery is not without its complications. In one large series of surgical intervention in 27 limbs, three patients (11%) had occlusion or severe stenosis of the surgical site at 2.1 years requiring four redo surgical or interventional procedures.[19] Despite surgery, four patients (15%) had no long- term improvement in symptoms. There were three wound infections (11%) and one deep vein thrombosis (4%).

Venous patch dilatation was seen in one patient (4%) and five patients (19%) developed paresthesias due to damage to the lateral cutaneous nerve of the thigh.19 Stated differently, 53% of this surgical cohort had major or minor complications.[19] It is therefore premature, at least in our opinion, to consider surgery as the gold standard. Surgery should be regarded as the traditional treatment modality as there has been no comparison with endovascular approaches.

Characteristic IVUS features

An important finding of this study is the perfect circle appearance of EIAE on IVUS. It was seen in every single case in which IVUS was done. By reviewing the literature and published IVUS images, we have come to believe that this finding in the arterial circulation is both pathognomonic and 'sine qua non'.[11,12,20] In other words, if an external iliac artery segment shows this feature, EIAE is present and if it does not show it, the disease is absent.

The perfect circle appearance can be explained by the histopathologic findings. Wall thickening occurs in all layers usually but not necessarily in a circumferential fashion, although variations in the extent of thickening can occur.[15,18] In a series of four patients who underwent surgery, intimal

thickening was noted, mostly in a symmetrical fashion. The media and adventitia exhibited both symmetric and asymmetric hypertrophy.[20] Interestingly, no inflammatory process was noted. In the media, smooth muscle cells had proliferated in a circular pattern.[20] This pattern of hypertrophy across all layers remodels the vessel such that the cross-sectional area of the vessel wall on IVUS shows a well circumscribed structure which is highly echo dense, thereby distinctly contrasting itself from the luminal blood's echo- luscent area (Figures 1A, 2, 3A, and 3B). The macroscopic cross-sectional appearance of resected lesions (Figure

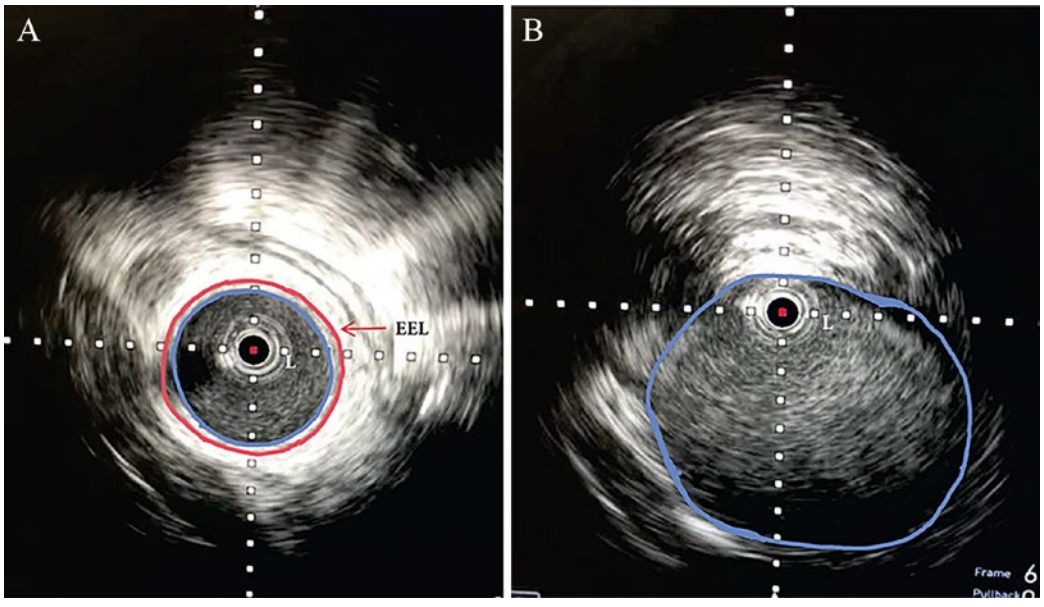

Figure 1. IVUS of a 35-year-old woman and avid runner with external iliac artery endofibrosis. The pathognomonic 'perfect circle appearance' is clearly visible. **(A)** The cross-sectional circumference created by the lumen and external elastic lamina is close to a uniform circle due to symmetrical and pan-layer hypertrophy. Note the dense echogenicity. The IVUS catheter (red dot) usually stays in the center without gravitating to one side as it becomes deflected by the rubbery texture of the endoluminal wall. The red circle shows the EEL and the blue circle delineates the luminal area. **(B)** A normal arterial segment just caudal to the diseased area shows an absence of hypertrophy and dense echogenicity and loss of the perfect circle appearance. The luminal diameter in **(B)** is considerably larger than that of **(A)**, even though the arterial segment is more caudal. The IVUS catheter frequently lays on one side of the lumen (here at 12 o'clock), and seldom in the center, whereas the catheter usually appears in the center of the perfect circle appearance **(A)**.
EEL, external elastic lamina; IVUS, intravascular ultrasound; L, lumen.

5A) has been previously reported.[20] Pan-hypertrophy of the vessel wall with resulting negative remodeling is readily apparent on inspection of these specimens. The rubbery consistency of the endoluminal wall is quite obvious (Figure 5A). A representative, full cross-sectional photomicrograph of the lesions is shown in Figure 5B. All layers are thickened and the central lumen is impinged upon. Variations in the extent of thickening can occur in different parts of the vessel wall. In this specimen (Figure 5B), there is disproportionate and eccentric adventitial thickening. The histopathologic findings are shown in Figure 5C. In this photomicrograph, the adventitia is preferentially infiltrated by smooth muscle cells and extensive fibrosis.

A consequential feature of concentric wall thickening is that the IVUS catheter frequently stays at or near the center of the lumen whereas in normal segments it usually gravi- tates to one side of the endoluminal surface (Figures 1–3). No matter how many times the operator purposefully changes the catheter position in the lumen, the released resting place of the IVUS catheter will be in the center. We believe this finding is due to the thickened, noncompliant and 'rubbery' wall which consistently deflects the catheter to the center, whereas the normal segment, by being softer, does not bounce the catheter away. In only two reported cases that had eccentric hypertrophy the IVUS catheter was not centrally located.[13,14]

Principal findings

The recurrence of symptoms was in those with smaller stents, without IVUS guidance and earlier in our experi- ence. High-pressure inflation was not used in these patients. We now recommend at least 2 mm over-sizing of a self- expandable stent followed by high-pressure inflation. Based on the perceived danger of vessel rupture seen in elderly patients with atherosclerosis, we were very con- servative in our earlier cases. We learned that this approach is not optimal for EIAE as the pathophysiology and histol- ogy are distinctly different than atherosclerotic stenosis. The response of EIAE to treatment appears to be similar to that of iliac

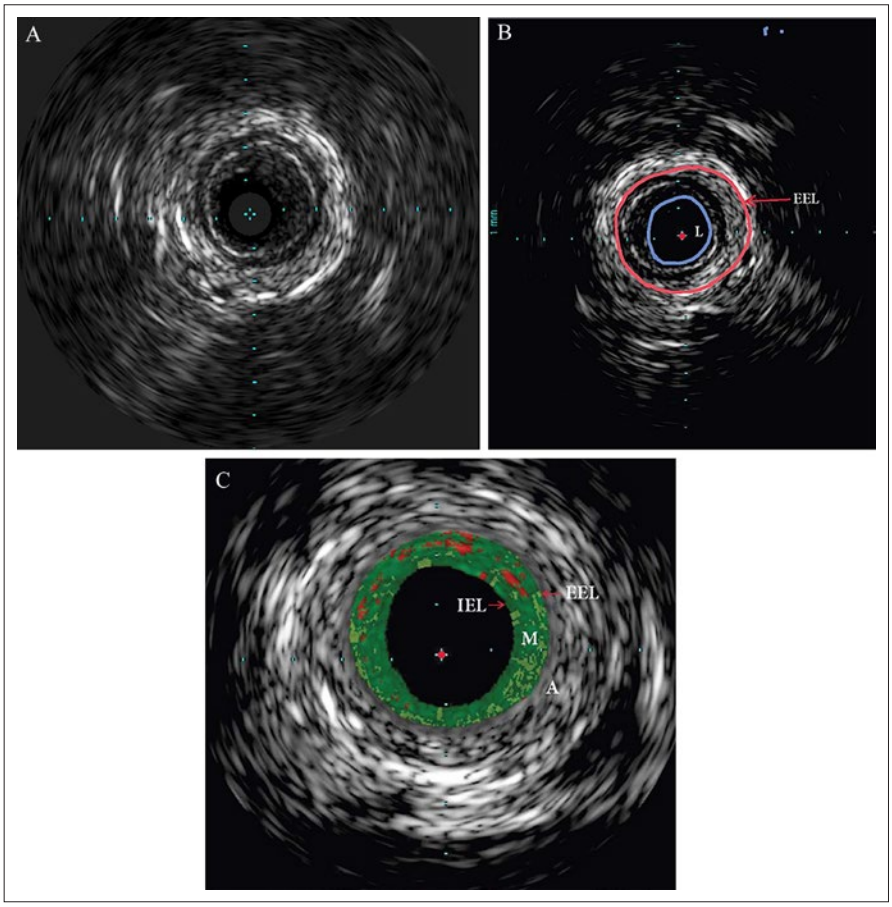

Figure 2. *IVUS showing external iliac artery endofibrosis in a 40-year-old woman who has been a triathlete for over 10 years.*

(A) *The perfect circle appearance and centralization of the IVUS catheter are present.* **(B)** *More hypertrophy is noted in this patient compared to Figure 1.The red dot shows the IVUS catheter, the red circle shows external elastic lamina, and the blue circle shows the lumen cross-sectional area.* **(C)** *Use of virtual histology (green layer) with similar cut frame demarcates the fibrotic and hypertrophic media, very clearly showing the inner and outer borders of the media.*

A, adventitia; EEL, external elastic lamina; IEL, internal elastic lamina; IVUS, intravascular ultrasound; L, lumen; M, media.

venous stenosis. Venous stenosis seldom responds to angioplasty alone and requires stenting, preferably with a strong radial force. The histopathologic appear- ance of both diseases is very similar. Hyperproliferation of smooth muscle cells within all vessel wall layers and

fibrosis is uniformly present. Macroscopic samples of EIAE show circumferential thickening of the vessel wall with a rubbery consistency (Figure 5A). We have noted the same perfect circle appearance in cases of diffuse iliac venous stenosis as well.[21] This has important clinical impli- cations suggesting that the two entities can be similarly treated. Extrapolating our findings from the treatment of venous stenosis, we can postulate that restenosis can be reduced with use of IVUS, a larger stent, and high pressure postdilatation, similar to the techniques used in endovenous intervention. Indeed, we have not had recurrence of symptoms in our more recent cases wherein the above measures were applied. Percutaneous treatment of EIAE is therefore differ- ent than that for atherosclerotic arterial stenosis and a larger stent should be considered.

The findings on computerized tomographic and mag- netic resonance angiography and external ultrasound may be subtle and not picked up by the reading radiologist. The images should be reviewed by the operator with a high index of suspicion. As a general guideline, if the external iliac artery caliber is smaller than that of the common or proximal superficial femoral artery on any form of imaging in the younger age group, EIAE should be highly suspected. The absence of calcification in the vessel wall is also important. Since symptoms occur at a high level of exertion, resting ABI is of limited value. Even exercise ABI was only mildly positive in 50% of the tested patients. Some case reports have reported on a significant but transient decline in ABI, especially during exertion.[4,9,17] These were probably due to the more advanced stage of the disease. ABI should be done at far higher levels of exertion than with a few minutes of walking on a treadmill. In general, we do not believe that a normal resting or exercise ABI would exclude EIAE and the necessity for treatment. Conversely, if ABI is abnormal, it would be an indicator of severity of disease. A limitation of this study was that exercise ABI was not performed in all patients. Consequently, the diagnosis of EIAE and necessity to intervene was not dependent on ABI.

In our series, EIAE was not limited to cyclists but was seen in runners (and triathletes) as well. In general, these patients are slim, of low BMI, and usually have a low normal or shorter height. Women were more affected in this study. This is contrary to some published reports in which men were more affected[3,19] and con- sistent with others showing a higher frequency in women.[20]

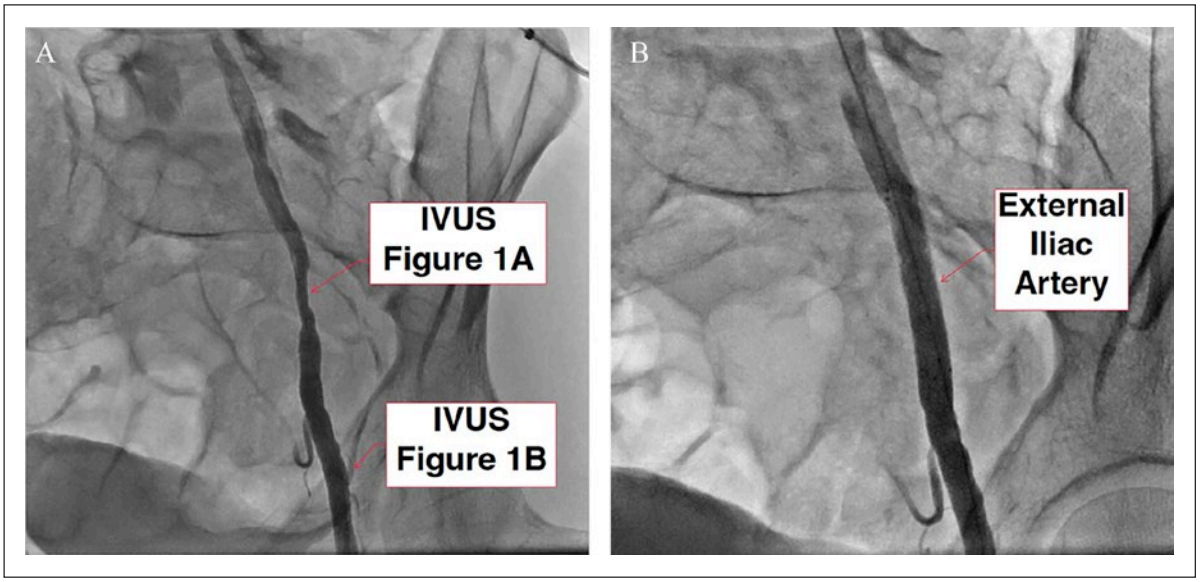

Figure 4. Angiographic images of a 35-year-old woman and avid runner (same patient as in Figure 1) with left external iliac endofibrosis prior to intervention **(A)** and poststenting **(B)**. The locations of IVUS images from Figure 1 are shown in **(A)**. Note: the stenosis was found to be a fixed lesion. There was no spasm or wire bias. Evaluation for fibromuscular dysplasia was negative.
IVUS, intravascular ultrasound.

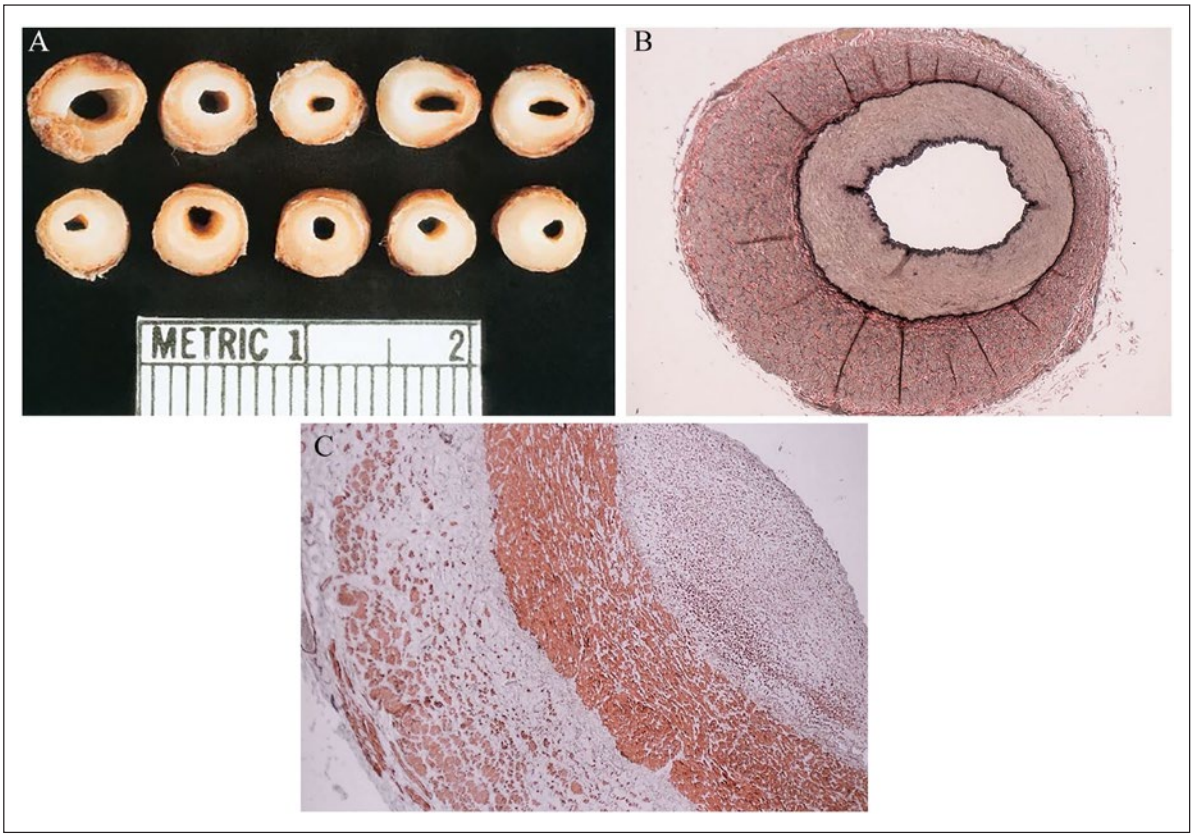

Figure 5. Macroscopic **(A)** and photomicrographic **(B)** samples of resected external iliac artery endofibrosis. Note thickening within all layers of the vessel wall with narrowing of the lumen due to negative remodeling. In **(A)**, the rubbery appearance of the vessel wall including the endoluminal surface is readily apparent. **(B)** Photomicrograph of a cross-sectional area of a sample from **(A)** shows eccentric medial and adventitial thickening and prominent adventitial hyperplasia. **(C)** Histopathologic photomicrograph of **(B)** shows the adventitia is replete, with extensive smooth muscle proliferation (actin-positive cells) separated by collagen (Verhoeff-van Gieson stain). Other layers also show hypertrophy (magnification ×25).
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Negative remodeling and flow limitation

At first glance, the lesions of the representative patients (Figures 1, 2, and 4) may be considered as moderate by our existing frames of reference.

Specifically, examination of the angiogram suggests a 60–70% lesion (Figure 4) and the intimal thickening in Figure 1A is mild to moderate and therefore not necessarily 'flow-limiting'. However, we believe that the IVUS find- ings show a highly flow-limiting lesion, which results from the negative remodeling process inherent in EIAE. This concept is elucidated in the following calculation.

The vertical diameter of the luminal area in Figure 1A is about 5.3 mm. In the distal segment (which in normal indi- viduals should be less than the proximal segment) it is about 9 mm (Figure 1B). The corresponding radii will be 2.65 mm and 4.5 mm, respectively. From Poiseuille's law, it follows that for a given perfusion pressure, any reduction in the radius of the cross-sectional area of a cylinder would lead to a reduction in the flow rate by the 4th power of the radius. In other words, a 50% reduction in the radius would drop the flow by 16-folds. In the instant case, the radius has dropped from approximately 4.5 mm to 2.65 mm (radius reduction to 59% of reference), thereby leading to an approximate 8.3-fold flow reduction. This reduction in overall luminal diameter is due to hyperproliferation of all components of the vessel wall which impinge on the effec- tive luminal cross-sectional area. Thus, the issue is not the extent of intimal thickness but the relative negative remod- eling and loss of the effective luminal cross-sectional area as one moves from a normal to an abnormal segment. An 8.3-fold reduction in flow, in a high-performance athlete at peak exercise, is undoubtedly 'flow-limiting'. In reality, the reduction in flow would be more as one has to compare the common iliac artery diameter (larger, and hence a steeper decline) than that between the external iliac artery and the common femoral artery. This example highlights that our existing frames of reference derived from the treatment of atherosclerotic lesions are not necessarily applicable to EIAE.

Conclusions

We conclude that in patients with symptomatic EIAE, stenting is effective and safe with a good long-term outcome. It can be an alternative to surgery, especially for those reluctant to have an operation. The finding of the perfect circle appearance on IVUS establishes the diagnosis. Centralization of the IVUS catheter would be an additional clue. Beyond 1 year following stenting, symptom recurrence is unusual. The technical considerations of endovascular treatment for EIAE are different than those of atherosclerotic arterial stenosis and are similar to percutaneous endovenous intervention for venous stenosis. A mul- ticenter, randomized clinical trial between surgery and endovascular treatment is required to evaluate the best treatment approach.

Declaration of conflicting interests

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ORCID iD

Mohsen Sharifi https://orcid.org/0000-0002-9471-3428

References

1. Weinberg I, Jaff M. Nonatherosclerotic arterial disorders of the lower extremities. Circulation 2012; 126: 213–222.

2. Peach G, Schep G, Palfreeman R, et al. Endofibrosis and kinking of the iliac arteries in athletes: A systematic review. Eur J Vasc Endovasc Surg 2012; 43: 208–217.

3. Howard A, Sinha S, Peach G, et al. Minimally invasive sur- gical repair of iliac artery endofibrosis. J Vasc Surg 2013; 58: 1657–1660.

4. Ceallaigh P, Burns P, McLaughlin R, et al. Complete exter- nal iliac artery occlusion in a 34-year-old cyclist. Eur J Vasc Endovasc Surg 2002; 23: 376–377.

5. Korsten-Reck U, Rocker K, Schmidt-Trucksass A, et al. External iliac artery occlusion in a young female cyclist. J Sports Med Phys Fitness 2007; 47: 91–95.

6. Schep G, Bender M, van de Tempel G, et al. Detection and treat- ment of claudication due to functional iliac obstruction in top endurance athletes: A prospective study. Lancet 2002; 359: 466–473.

7. Rousselet M, Saint-Andre J, L'Hoste P. Stenotic intimal thickening of the external iliac artery in competition cyclists. Hum Pathol 1990; 21: 524–529.

8. Wijesinghe L, Coughlin P, Robertson I, et al. Cyclist's iliac syndrome: Temporary relief by balloon angioplasty. Br J Sports Med 2001; 35: 70–71.

9. Fite J, Dilm J, Villalba J, et al. Management of a complicated triathlete's bilateral iliac artery endofibrosis. MOJ Anat Physiol 2018; 5: 186–190.

10. Ford S, Rehman A, Bradbury A. External iliac endofibrosis in endurance athletes: A novel case in an endurance runner and a review of the literature. Eur J Vasc Endovasc Surg 2003; 26: 629–634.

11. Campbell D, Andraska E, Rectenwald J, Gallagher K. Intravascular ultrasound imaging as a novel tool for the diag- nosis of endofibrosis. J Vasc Surg Cases 2016; 2: 59–61.

12. Eiberg J, Riazi H, Pedersen B. Intravascular ultrasound as a valuable tool in iliac endofibrosis diagnostics. Eur J Vasc Endovasc Surg 2022; 63: 906.

13. Flors L, Leiva-Salinas C, Bozlar U, et al. Imaging evaluation of flow limitations in the iliac arteries in endurance athletes: Diagnosis and treatment follow-up. AJR Am J Roentgenol 2011; 197: W948–955.

14. Lomis N, Miller F, Whiting J, et al. Exercise-induced external iliac artery intimal fibrosis: Confirmation with intravascular ultrasound. J Vasc Interv Radiol 2000; 11: 51–53.

15. Willson T, Revesz E, Podbielski F, et al. External iliac artery dissection secondary to endofibrosis in a cyclist. J Vasc Surg 2010; 52: 219–221.

16. Scavee V, Stainier L, Deltombe T, et al. External iliac artery endofibrosis: A new possible predisposing factor. J Vasc Surg 2003; 38: 180–182.

17. Maree A, Ashequl Islam M, Snuderl M, et al. External iliac artery endofibrosis in an amateur runner: Hemodynamic, angiographic, histopathological evaluation and percutaneous revascularization. Vasc Med 2007; 12: 203–206.

18. Venstermans C, Gielen J, Salgado R, et al. Endofibrosis of the external iliac artery. JBR-BTR 2009; 92: 184–185.

19. Peake LK, D'Abate F, Farrah J, et al. The investigation and management of iliac artery endofibrosis: Lessons learned from a case series. Eur J Vasc Endovasc Surg 2018; 55: 577–583.

20. Kral C, Han D, Edwards D. Obstructive external iliac arteriopathy in avid bicyclists: New and variable histo- pathologic features in four women. J Vasc Surg 2002; 36: 565–570.

21. Sharifi M, Javadpoor S, Bay C, et al. Outcome of stent- ing in the lower-extremity venous circulation for the treat- ment of deep venous thrombosis. Vasc Dis Manag 2010; 7: E233–E239.

The Impact of Vascular Motion on Acute Drug Retention

Trey Ursillo[1]; Kayla Lowry[1]; Mollie Phillips[1]; Catherine Allred[1]; Saami K. Yazdani, PhD[1]
[1]Wake Forest University, Department of Engineering, Winston-Salem, NC

Category: Cardiovascular Disease

Background: The treatment of peripheral artery disease (PAD) sometimes results in restenosis, requiring the use of drug-eluting stents (DES) or drug-coated balloons (DCB) to prevent neointimal hyperplasia. However, diseased arteries in the lower extremities are prone to extensive movement, which could lead to decreased acute drug retention. No study has examined the effects of severe deformation of arteries on drug retention, which is critical in the treatment of PAD in arteries that are exposed to frequent and varied movement. This study examined the effects of vascular motion on acute drug retention using both DCB and DES.

Methods: Two DCBs (Lutonix, n = 11; IN.PACT, n = 12) and one DES (Zilver, n = 12) were deployed in an artery using a benchtop bioreactor flow system in an incubator. The bioreactor system can produce twisting, bending, and compression movements that contort the artery, mimicking real movement in the knee. Three sets of movement parameters ("Stationary": no twisting, bending, or compression; "Normal": 16.8–18.1° twist, 25° bend, 3.2–3.5 mm compression; "Severe": 50–68° twist, 25–35° bend, 21 mm compression) were used for each DCB and stent. Paclitaxel concentrations were measured using pharmacokinetic analysis and compared between balloon type and stent, and between movement parameters using ANOVA and Tukey's HSD post-hoc analyses. All values are expressed as mean ± standard deviation.

Results: Movement produced by the bioreactor affected mean drug retention. Pharmacokinetic analysis indicated that mean paclitaxel concentration was lower in the normal and severe movement groups when compared to the stationary group for arteries treated with Lutonix balloons (Stationary = 403.5 ± 195.1 ng/mg, Normal = 14.9 ± 9.9 ng/mg, Severe = 19.2 ± 15.4 ng/mg; Stationary-Normal p = 0.007, Stationary- Severe p = 0.005). Additionally, mean paclitaxel concentration was lower in the severe movement group when compared to the normal group for arteries treated with the Zilver stent (Normal = 84.8 ± 32.7 ng/mg; Severe = 0.11 ± 0.06 ng/mg; p = 0.01). There was a decreasing but non-significant relationship between movement and mean paclitaxel concentration for arteries treated with IN.PACT balloons.

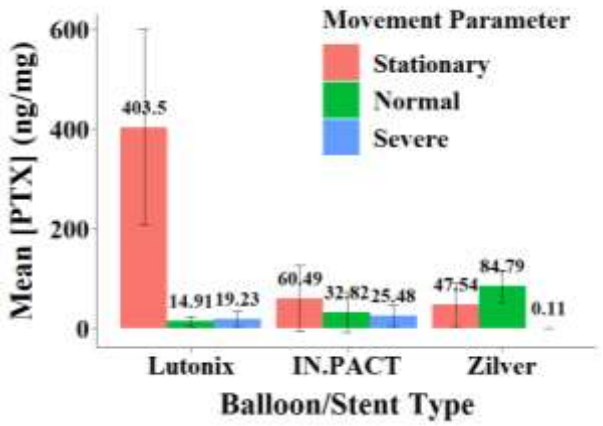

Figure 1: Mean paclitaxel concentration for arteries treated with each DCB and DES under different movement parameters.

Conclusion: Absorption of paclitaxel into the artery directly post-treatment is affected by movement in a DCB and DES; however, not all DCBs seem to be as affected by movement, and the effect of movement on drug absorption differs between DCBs and DES. More research is needed to understand the foundation of these differences, including examining which specific movements have the greatest effect on arterial drug absorption, and how arterial drug concentrations vary across different timepoints.

Retrievable Stent Therapy for CLTI: update on the DEEPER REVEAL Trial

S. Jay Mathews[1] (on behalf of the DEEPER REVEAL Investigators)
[1]Bradenton Cardiology Center, Manatee Memorial Hospital

Category: Critical Limb Ischemia

Background: The Bare Temporary Spur Stent System (Spur) is a novel device developed to meet the challenges of infrapopliteal arterial disease. The Spur stent uniform expansion of the scaffold and penetration of the vessel wall by the spikes may minimize dissections and prevent vessel recoil, thereby increasing acute luminal gain while leaving no scaffold in the body.

Objective: The intent of this study is to evaluate the safety and efficacy of the Spur for the treatment of infrapopliteal disease in subjects with CLTI.

Methods: The DEEPER REVEAL trial is a prospective, non-randomized, multicenter, single arm trial enrolling 130 subjects, comparing the safety and efficacy of the Spur in subjects with infrapopliteal CLI to a pre-defined performance goal based on percutaneous transluminal balloon angioplasty (PTA).

The primary efficacy endpoint is technical success defined as <30% residual stenosis, and the co-primarysafety endpoint at 30 days post procedure is freedom from the occurrence of major adverse limb events (MALE), defined as:

- Above the ankle amputation of the index limb
- Major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy/ thrombolysis) of the index limb involving the infrapopliteal arteries and peri-operative death (POD), defined as death within 30 days post procedure.

An interim analysis for futility is planned when 50% of subjects have reached 30 days follow up.

Results: The first subject was enrolled in October, 2022, with 81 subjects enrolled as of January, 2024. The interim analysis was performed in February, 2024, with the DSMB meeting on February 2024. The results are as follows:

- DSMB provided a letter of recommendation, approving continuation of the trial without modification.
- MALE occurred in 2.8% (2/69) subjects post procedure
- POD occurred in 2.8% (2/69) subjects post procedure

Conclusion: The Bare Temporary Spur Stent System is a novel device for the treatment of infrapopliteal disease in patients with CLTI. The DEEPER REVEAL trial is the first US-based trial to examine the safety and efficacy of this device. The study has been approved to proceed without modification by DSMB review after an interim analysis of the primary efficacy endpoint of technical success.

A Comparison of the Durability of Auryon and Turbo-Elite Laser Atherectomy Catheters In Real World Clinical Use

Matthew N. Sayegh, MD, Michael C. Anderson Ph. D., Maxwell M. Junda Ph. D.

Joseph J. Ricotta II, MD, MS, DFSVS, FACS

Florida Atlantic University, Boca Raton, FL, USA, Tenet Healthcare, FL USA, USA, Philips, Colorado Springs, CO, USA, Covalent Metrology, Sunnyvale, CA, USA

Category: Peripheral Artery Disease

Background: Two ultraviolet (UV) laser atherectomy systems are commercialized: Turbo-Elite (Philips, Colorado Springs, CO) and Auryon (Angiodynamics, Queensbury, NY). Turbo-Elite operates at 308nm wavelength, 130ns pulse duration. Auryon operates at 355nm wavelength, 10ns pulse duration. Both utilize catheters consisting of silica quartz glass optical fibers embedded in epoxy to deliver laser energy to peripheral artery treatment sites. Laser and optics publications have reported that short duration laser pulses are more likely to fracture optical fibers than long duration pulses. Fractured fibers scatter laser energy which may then damage embedding epoxy and adjacent fibers. It was hypothesized that the short duration laser pulse of the Auryon system will cause more catheter damage than the long duration laser pulse of the Turbo-Elite system.

Methods: Over a period of 3 months, n=31 each Turbo-Elite 1.4mm and Auryon 1.5mm catheters were used to treat peripheral lesions in 62 patients. Exclusion criteria and treatment parameters were not prescribed to facilitate a “real world” comparison. Laser fluence settings of 60 mJ/mm^2 were used for all catheters. A frequency of 60Hz was selected for all Turbo-Elite catheters, while Auryon catheters operate at a fixed frequency of 40Hz. Following treatment, catheter tips were cleaned and scanned using laser confocal microscopy at a third party laboratory. A reference plane was defined at each catheter’s distal tip, and a damage plane defined 2.5μm below the reference plane. Measurements of volume of catheter damage (μm3) below the damage plane, and number of optical fibers fractured below the damage plane of both catheter types were compared using 2-tailed t- tests.

Results: Despite being used for shorter number of laser pulses, Auryon catheters exhibited a significantly greater number of optical fiber fractures and catheter damage volume than Turbo-Elite catheters. Results (Mean (StDev)) are summarized in the table below.

Conclusion: These results are strong evidence that the short duration pulse of the Auryon laser causes optical fiber fracture and catheter tip damage in real world clinical use. The clinical ramifications of optical fiber fracture, resulting energy scattering and catheter tip damage are not known. This work represents a first known attempt to quantify and compare laser catheter durability in a clinical rather than laboratory setting. Limitations of this study include small sample size and single-user, single- center experience. The clinical significance of optical fiber fracture due to short laser pulse duration and its potential effects on atherectomy effectiveness merit further investigation.

	Auryon 1.5mm Catheters	**Turbo-Elite 1.4mm Catheters**	**p-value**
Laser catheters analyzed (n)	31	31	NA
Laser catheter build comparison	n=126 Ø72µm fibers embedded in epoxy	n=108 Ø61µm fibers embedded in epoxy	NA
Mean lasing (treatment) time (sec)	126 (44.7)	118 (47.5)	0.480
Mean laser pulses (#)	5,037 (1,788)	7,208 (3,263)	***0.002***
Mean Optical Fiber Fractures per catheter (#)	20.3 (27.7)	0.97 (3.26)	***0.001***
Maximum observed optical fiber fractures per catheter (#, %)	111 of 126 (88%)	18 of 108 (17%)	NA
Number of catheters exhibiting zero optical fiber fractures (#, %)	3 of 31 (10%)	23 of 31 (74%)	NA
Mean Catheter Damage Volume (fiber and epoxy damage) (μm^3)	44,590,783 (108,703,485)	367,524 (659,247)	***0.031***
Number of catheters exhibiting >4,000,000 μm^3 damage	16/31 (52%)	0/31 (0%)	NA

Long-Term Outcomes of Femoropopliteal Atherectomy Versus Non-atherectomy Interventions from Commercial Claims

William A. Gray, MD[1] and Belinda A. Mohr, Ph.D.[2]

[1] Main Line Health, GrayW@MLHS.ORG.

[2] Philips, San Diego, CA USA, Belinda.Mohr@philips.com

Category: Peripheral Arterial Disease

Background: Patients suffering from symptomatic peripheral artery disease (PAD) can be treated with multiple options, including standard percutaneous transluminal angioplasty (PTA) and atherectomy. This study compares long-term patient outcomes following treatment of femoropopliteal artery lesions with or without atherectomy in a contemporary cohort of commercially insured patients.

Methods: A comparative cohort claims database study from Optum's de-identified Clinformatics® Data Mart Database was conducted. The database represents administrative health claims for members of large commercial and Medicare Advantage health plans. Femoropopliteal endovascular procedures were identified via ICD-10-PCS and CPT procedure codes. PAD diagnoses and baseline comorbid conditions were identified via ICD-10-CM diagnosis codes. The first femoropopliteal endovascular intervention between January 2017 and September 2022 was identified, and patients treated in the inpatient and hospital outpatient settings with one year of continuous enrollment prior to the index were included. Patients with concomitant procedures, either in the same limb or contralateral limb, and with history of femoropopliteal procedures within the prior year of index were excluded. Treatment in the index vessel with stenting, drug-coated balloons, or percutaneous transluminal angioplasty was allowed. All atherectomy device types were included. Outcomes measured included major adverse limb event (MALE), amputation, surgical revascularization, endovascular revascularization, thrombolysis, limb- related readmissions, and mortality. MALE was defined as a composite of major amputation, endovascular or surgical revascularization, or thrombolysis. Propensity score inverse probability weights were used to adjust patient populations for comparison in Cox and fine-grey regression analyses.

Results: A total of 85,707 patients with their first femoropopliteal endovascular intervention in any site of service were identified, of which N=4,339 atherectomy and N=6,570 non-atherectomy patients were available for analysis after patient selection criteria were applied. Average follow-up time for all patients was 703 days (median 574 days). Patients who received atherectomy had a significantly lower risk of minor amputation (adjusted HR (aHR) 0.85, 95% confidence interval (CI) 0.72 - 0.99; p=0.043), surgical revascularization (aHR 0.65, 95% CI 0.53 - 0.79; p<0.001), and limb-related readmissions (aHR 0.89, 95% CI 0.80 - 0.99; p=0.025) at 5 years. The risk of repeat femoropopliteal endovascular interventions was significantly higher in the atherectomy cohort (aHR 1.13, 95% CI 1.05 - 1.21; p=0.001). There was no risk difference for MALE, major amputation, thrombolysis, or mortality at 5 years.

Conclusion: In the treatment of femoropopliteal artery lesions, the use of atherectomy is associated with a decrease in risk of minor amputation, surgical revascularizations, and limb-related readmissions despite an increased risk of endovascular revascularizations. The lack of granular information (e.g., lesion length, atherectomy type, etc.,) limits causal assessment of these differences

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Non-Guide Wire Crossing of a Flush Superficial Femoral Artery Occlusion with Laser Atherectomy and Extravascular Ultrasound Guidance: A Case Study

Anton Hnatov, BSc[1], Siddhartha Rao, MD[1]
Vascular Solutions of North Carolina, Cary, NC, USA[1]

Category: Peripheral Artery Disease

Background: Patients with peripheral artery disease (PAD) often present with difficult-to-cross chronic total occlusions (CTOs) in the superficial femoral artery (SFA). This study examines the use of extravascular ultrasound (EVUS) to assist in crossing a flush occluded SFA in a patient with multiple cardiovascular risk factors.

Methods: We present the case of a 75-year-old male with Rutherford Class III disease and life- limiting claudication. The patient had a past medical history of smoking, atrial fibrillation, coronary artery disease, congestive heart failure, a cardiac pacemaker, and bilateral PAD of the lower extremities. The patient was status post multiple revascularizations of the bilateral lower extremities, a failed left fem-pop bypass, and a right SFA stent. The left superficial femoral artery was flush occluded 300 mm proximal to distal with extensive postoperative scarring at the ostium. A 40 mm segment of the proximal to mid SFA was heavily calcified. Traditional retrograde and antegrade crossing attempts to pierce the proximal cap were unsuccessful. Under extravascular ultrasound guidance, a 1.5 mm Auryon laser catheter (AngioDynamics, Queensbury, NY, USA) was advanced without a guidewire into the proximal cap and used to intentionally perforate the cap over several runs. Angiography showed no dye extravasation. A wire/catheter combo was then able to be advanced into the SFA, and the wire was externalized and flossed at the level of the distal SFA. This allowed for subsequent therapy with balloon angioplasty and stent placement.

Results: Final angiography showed less than 30% residual stenosis, restoring normal Thrombolysis in Myocardial Infarction (TIMI)-3 flow along the entire treated segment. This result supports the efficacy of EVUS in the treatment of complex occlusions.

Conclusion: Integrating EVUS with traditional interventional tools offers a viable option for complex PAD cases, particularly when conventional methods are inadequate. This case highlights the potential of ultrasound-guided techniques to improve outcomes for patients with PAD.

The Impact of Malignancy Status on Coagulation Profiles in Patients with Peripheral Artery Disease Post-Revascularization

Samir Ghandour[1], MD, Shiv Patel[1], BS, Sasha P Suarez Ferreira1, MD, Katherine Morrow[1], MD, Ivy Lee[1], BS, Tasya Rakasiwi[1], BS, Fanah Hagos[1], RN, Anahita Dua[1], MD, MBA, MSC.
Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

Category: Peripheral artery Disease; Critical Limb Ischemia; Limb Salvage

Background: Malignancy is a known contributor to arterial thrombotic potential and mitigation of this risk may be achieved with targeted antiplatelet or anticoagulant therapy. The utilization of viscoelastic assays to determine thrombotic risk based on an individual's coagulation parameters has never been evaluated. This study aims to quantitatively investigate the variations in thromboelastographic parameters in patients presenting for operative treatment of peripheral arterial disease (PAD) with and without active malignancy.

Methods: A total of 229 patients with PAD post-revascularization were prospectively included in this study. Those receiving concurrent anticoagulant therapy at baseline were excluded. Thromboelastography (TEG) and platelet mapping (PM) were performed for each patient at baseline prior to operative treatment. A historical determination of the patient's malignancy status, as well as mono-antiplatelet or dual-antiplatelet therapy use, was documented. A Mann-Whitney- U test was used to determine the differences in baseline TEG (reaction time, R; clot kinetics, K; alpha angle, α-angle; maximum amplitude, MA) and PM (ADP and AA aggregation and inhibition) parameters between patients with active malignancy and no malignancy. A Wilcoxon-ranked test was used to investigate the differences in TEG and PM parameters between the different antiplatelet regimens within the malignancy cohorts.

Results: Seventeen patients (7.4%) had active malignancy. Compared to those without malignancy, patients with active malignancy had significantly shorter clot kinetic times ($p<0.01$), indicating an increased propensity to thrombose. Amongst those with active malignancy, those on mono-antiplatelet therapy (52.9%) had significantly shorter clot kinetics ($p<0.05$) than those on dual antiplatelet therapy (47.1%), indicating that increased antiplatelet medications did decrease platelet aggregation and subsequent thrombotic potential.

Conclusion: Patients with active malignancy display faster blood clot formation, further substantiating their hypercoagulability status. TEG-PM may potentially be able to identify "at risk" clotting profiles in this patient population, allowing for the targeted use of thromboprophylaxis to mitigate this personalized risk.

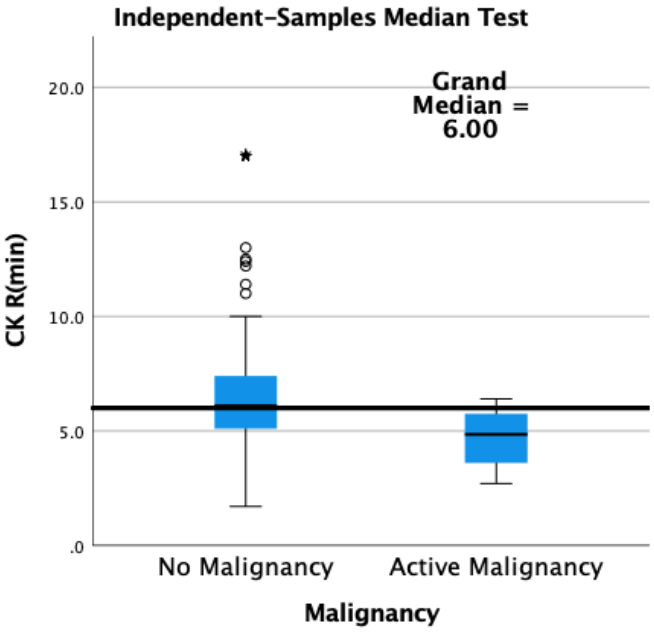

Figure 1. *Boxplot showing the differences in clot formation times (CK R) in minutes between patients with active malignancy and those without.*

Prospective Randomized Controlled Trial for the Efficacy and Safety of Using Different Doses of Recombinant Tissue Plasminogen Activator in Pulse-Spray Thrombolysis of Thrombosed Hemodialysis Arteriovenous Access

Nader Mohamed Mohamed Hamada and Mohamed Talat Mohamed Ibrahim
Vascular Surgery- Faculty of Medicine - Ain Shams University

Category: Venous

Background: Maintaining vascular access for the patient undergoing hemodialysis (HD) is a major source of hospitalization, patient morbidity, and physician frustration. Percutaneous methods of treating thrombosed arteriovenous accesses (AVAs) have evolved to become an effective alternative to surgical thrombectomy.

Results: The immediate post-procedure technical success was 100% in both groups.Vascular Surgery-Faculty of Medicine - Ain Shams University Category: Venous

The duration from access thrombosis till intervention in Group I ranged between 1day to 12 days with mean duration 4.81±3.016 days, and ranged between 1 day to 7 days in Group II with mean duration 4 ±2.098 days (P- value = 0.383). Clinical success was 81.25% in group I, and 93.75% in group II (P-value = 0.285), with mean period from thrombolysis till resuming HD from the same AV access 2.769 ± 1.878 days in group I, and 4.00 ± 2.726 days in group II (P-value =0.183). The mean in-room procedure time was 41± 14 minutes for group I and 42± 13 minutes for group II (P-value = 0.796)

No mortality cases reported, one case of group II developed diffuse upper arm hematoma which resolved completely after 8 days, and one case in group I developed small puncture site hematoma resolved after 2 days (P- value =1) and both cases treated with conservative measures, post-operative bleeding from puncture site occurred in two cases in group I and one case in group II (P-value = 0.544), bleeding stopped by manual compression. None of the patients had steal syndrome or infection.

The six weeks post -operative primary patency rates were 81.25% and 93.75% for group I and group II, respectively (P-value = 0.285).Assisted primary patency and cumulative patency weren't calculated in the study as none of the patients who had re-thrombosis of their AVAs underwent another trial of intervention.

Conclusion: Pulse-spray pharmacomechanical thrombolysis for treatment of the thrombosed AV access is safe, effective and durable. Using dose of 10ml rTPA yields higher clinical success and longer patency than using 6ml with no statistically significant increase in the rate of adverse effects.

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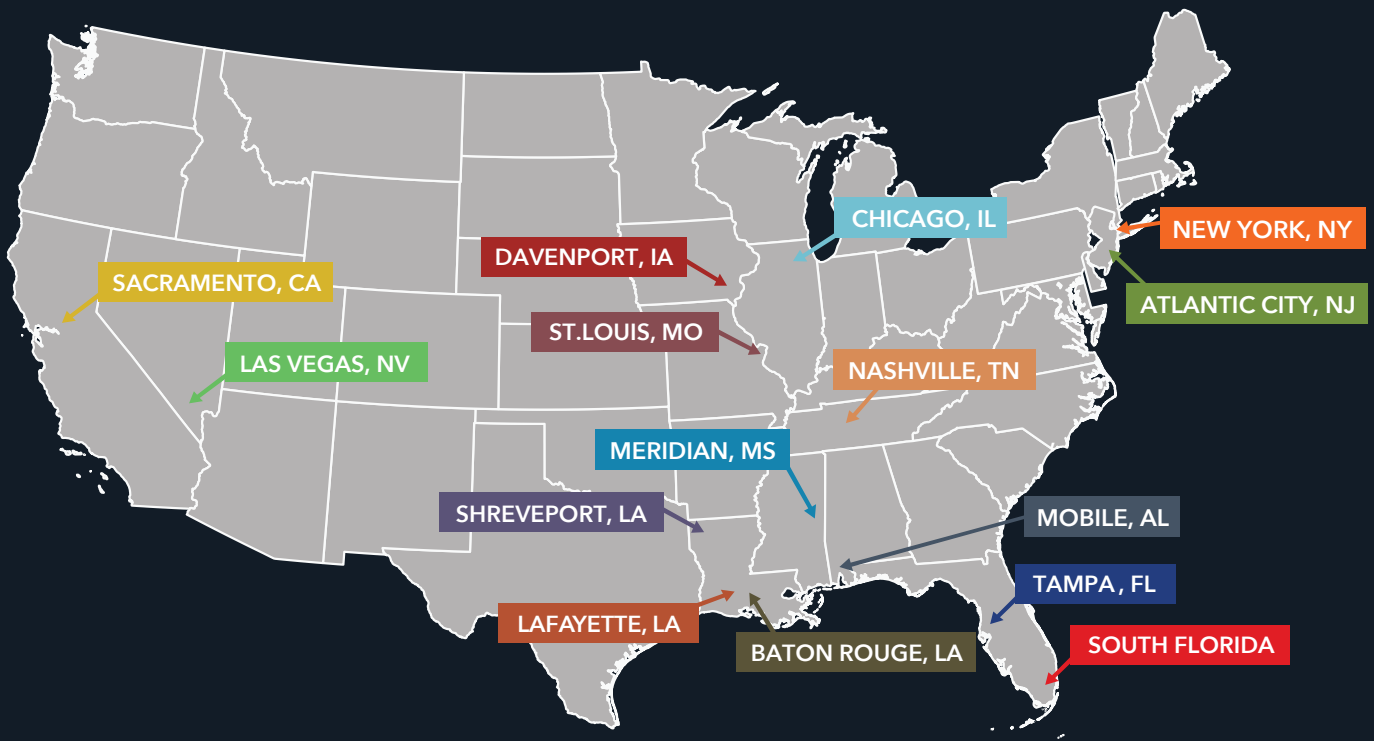

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