JAVELIN

Journal of Arterial Venous And Lymphatic Interventions

Supplemental Abstracts Issue

24th Annual
New Cardiovascular Horizons Abstracts

NCVH
New Cardiovascular Horizons

HIPG
Horizons International Peripheral Group

javelinjournal.org

May 28 - 31, 2024

NCVH

New Cardiovascular Horizons

25th ANNIVERSARY 1999-2024

25th Annual New Cardiovascular Horizons Conference

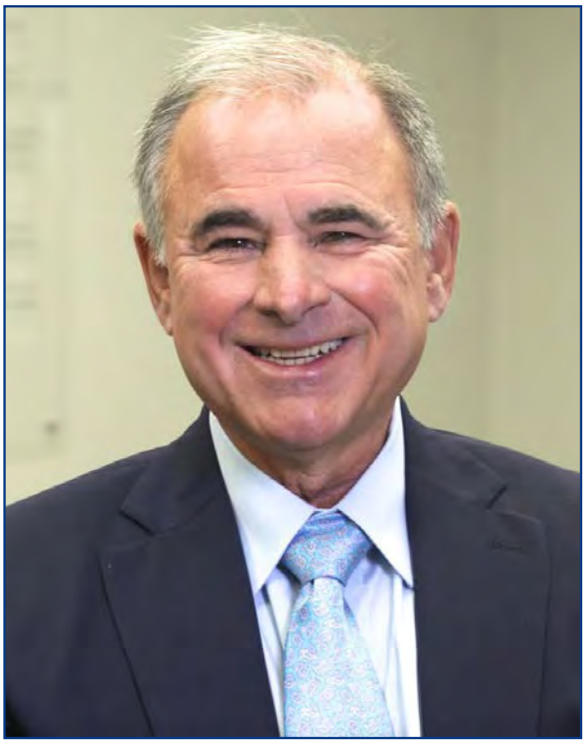
Craig M. Walker
Founder, Chairman

Join us next year to help us celebrate 25 years!

2024

May 28 - 31

337.993.7920 | registration@ncvh.org | NCVH.org



JAVELIN

Craig M. Walker, MD, FACC, FACP
Editor in Chief

Founder and President, Cardiovascular Institute of the South

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.

JAVELIN Editorial Board

Table of Contents

Abstract 1

Pharmacokinetic and Coating Analysis of 1st Generation FDA-Approved Drug Coated Balloons

Authors:

Catherine Allred[1], Mollie Phillips[1], Linda Liu[1], Saami Yazdani[1]

[1] Wake Forest University, Department of Engineering, Winston-Salem, NC 27101, US

Category: Peripheral Artery Disease, Drug Coated Balloon, Preclinical Benchtop Study

Category: Peripheral Arterial Disease

Intro: Peripheral artery disease (PAD) – characterized by calcified plaque buildup occluding arteries–is the leading cause of mortality globally. Drug coated balloons (DCB) have become the gold standard to treat PAD and incorporate an anti-proliferative coating onto percutaneous angioplasty balloons. DCBs rely on successful transfer of their surface coating onto the luminal surface of the artery, however, preclinical data has shown inconsistent drug transfer and retention. The aim of this study was to characterize the coating and acute transfer of three commercially available DCBs.

Methods: The coating and drug transfer of 1st generation FDA-approved DCBs (Lutonix and IN.PACT) were analyzed using an *ex vivo* biorelevant perfusion model. The *ex vivo* model utilized harvested porcine carotid arteries undergoing pulsatile flow conditions. The various DCBs were deployed into the bioreactor system and the amount of drug retention in arterial tissue was evaluated by pharmacokinetic analysis at 1 hour and 1 day post deployment. Scanning electron microscope (SEM) was used to compare the coating morphology, both dry and hydrated at 1 hour and 1 day post hydration of the various DCBs.

Results: Preliminary arterial paclitaxel levels were shown to be greater than 100 ng/mg in both the Lutonix and IN.PACT treated arteries at 1 hour post deployment (1 hr: Lutonix: 232 ± 138 ng/mg vs. IN.PACT: 126 ± 108 ng/mg, n = 5). At 24 hours post deployment, only the Lutonix treated arteries maintained similar PK values as the 1 hour time point, whereas the IN.PACT treated arteries decreased (24 hrs: Lutonix: 218 ± 136 ng/mg vs. IN.PACT: 65 ± 69 ng/mg, n = 5-6). SEM imaging revealed that the Lutonix and the IN.PACT DCB has uniform drug and excipient coverage of the balloon angioplasty. Additionally, in both the Lutonix and IN.PACT DCB, crystalline paclitaxel structure could be observed within the coating.

Conclusion: These preliminary results demonstrate that both 1st generation DCBs are able to deliver a considerable high amount of paclitaxel (> 100 ng/mg) to the target tissue. SEM imaging displayed crystalline structure within the coated paclitaxel.

Mechanical Thrombectomy With The Novel InThrill Thrombectomy Catheter for Portal Vein Thrombosis and Occluded TIPS: A Case Series

Jennifer Laporte, MD, Derek Mittleider, MD
Vascular & Interventional Physicians, Brevard Physicians Associates, Melbourne, FL

Category: Venous Disease

Background: Portal vein thrombosis (PVT) is commonly treated with anticoagulation alone, though rates of recanalization with anticoagulation vary widely. Failure to treat symptomatic PVT can result in complications associated with portal hypertension and hepatic decompensation as well as mesenteric ischemia and chronic cavernous transformation. Here, we present the novel application of the InThrill thrombectomy catheter (Inari Medical, Irvine, CA) to treat PVT and an occluded transjugular intrahepatic portosystemic shunt (TIPS). The 8-French InThrill thrombectomy catheter is designed to remove acute to chronic thrombus in 4-10mm diameter vessels via mechanical thrombectomy with its self-expanding nitinol coring element.

Methods: Four patients with PVT (n=3) or occluded TIPS (n=1) were treated with mechanical thrombectomy. The patients' past medical history, presentation, diagnosis based on computed tomography or esophagogastroduodenoscopy imaging, and prior treatments are listed in Table 1. One patient had a pre-existing TIPS that was newly thrombosed. Prior to thrombectomy, 3 patients received anticoagulation therapy, and 1 patient who was contraindicated for anticoagulation underwent argon plasma coagulation therapy. Thrombectomy was performed over-the-wire using an InThrill thrombectomy catheter with a 13-French ClotTriever sheath (Inari Medical) and a 16-French Introducer sheath (Cook Medical, Bloomington, IN). Four passes were performed with an aspiration through the ClotTriever sheath after each pass to yield greater than 90% thrombus removal from each patient. Angioplasty was performed after thrombectomy in all patients with TIPS placed in the three patients without pre-existing TIPS. Patency was confirmed with venography.

Results: Mechanical thrombectomy was technically successful in all patients, resulting in complete or near-complete resolution of PVT and occluded TIPS. All patients tolerated the procedure well. The average procedure time was 104 minutes with an average InThrill device time of 15 minutes. Three patients were discharged home, and patency and symptom resolution were maintained at the 2-month follow up. Patient #2 was discharged to rehabilitation and expired after presenting to the ER with a myocardial infarction and pneumonia 2 weeks post-procedure.

Conclusion: Mechanical thrombectomy with InThrill was feasible and effective in removing thrombus to restore patency in patients with PVT and occluded TIPS in a single session without thrombolytics. Long-term follow up in these patients as well as additional studies are warranted to validate its long-term effectiveness.

Patient #	Age/Sex	Past Medical History	Presentation	Diagnosis	Prior Treatment(s)
1	71 Male	-Beta thalassemia -Hypertension -Hyperlipidemia	-Acute burning upper abdominal pain, fullness, nausea, vomiting, and constipation	-Thrombosis of PV, SMV, and distal branches with associated mesenteric edema	-Heparin drip
2	67 Male	-Nonalcoholic steatohepatitis with portal hypertension -CHF -COPD -Type 2 diabetes -Thrombocytopenia -Sleep apnea -Chronic back pain -GI bleed	-Elevated pro-BNP and abnormal chest radiograph with findings concerning for multifocal pneumonia vs pulmonary edema	-Thrombosis of PV, large esophageal varices, erosive esophagitis, severe portal hypertensive gastropathy	-Apaxiban
3	62 Female	-Alcohol-related chronic liver disease -Portal hypertension -Bleeding esophageal varices -Gastric antral vascular ectasia -Recurrent GI bleed -Hypertension -Chronic gastritis	-Abdominal pain and shortness of breath for 3 days	-Occluded TIPS with abdominal ascites, right pleural effusion	-TIPS -Argon plasma coagulation 48 hours prior to InThrill
4	25 Female	-No significant medical history -Started oral contraceptives pills 2 months prior	-Severe abdominal pain for 6 days	-Thrombosis of PV, SMV, and distal branches with mesenteric edema	-Heparin drip

Table 1

Case summary. PV: portal vein; SMV: superior mesenteric vein; CHF: congestive heart failure; COPD: chronic obstructive pulmonary disease; GI: gastrointestinal; TIPS: transjugular intrahepatic portosystemic shunt.

Investigation of Effects of AVF Hemodynamics on Drug-Coated Balloon Treatment

Linda Liu[1]; Saami K. Yazdani, PhD[2]

[1]Wake Forest School of Medicine, Department of Biomedical Engineering, Winston-Salem, NC

[2]Wake Forest University, Department of Engineering, Winston-Salem, NC

Category: Cardiovascular Disease

Background: Since 2017, when drug-coated balloons (DCBs) first received FDA indication for use in dysfunctional arteriovenous fistula (AVF) hemodialysis accesses, their drug delivery performance in the AVF environment still have not been extensively studied. This vascular region experiences considerably higher blood flow rates and shear stress than the coronary and peripheral arterial systems, for which DCBs were originally designed. Therefore, an ex vivo bioreactor system was developed to simulate AVF hemodynamics using porcine carotid arteries to allow for studying the impact of these extreme hemodynamics on DCB performance and drug retention.

Methods: The bioreactor was developed consisting of a gear pump, uses a signal generator to create a pulsatile flow, and circulates DMEM media in a closed system. The test section was a freshly harvested porcine carotid artery. Commercially available IN.PACT Admiral Paclitaxel-coated DCBs were deployed in the carotid arteries under normal arterial flow or AVF flow. DCBs were inflated to 15-20% overstretch of the arterial diameter and deployed for 120 seconds. Vessels were collected 1 hour and 24 hours (n = 3 per experimental group) after drug delivery for liquid chromatography with tandem mass spectrometry (LC-MS-MS) pharmacokinetic analysis. Two-tailed unpaired t-tests were used to compare corresponding groups. All data are expressed as mean ± standard deviation.

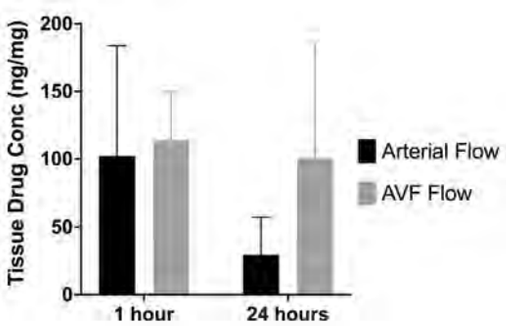


Figure 1: Tissue concentration of paclitaxel at 1- and 24-hours delivered under arterial and AVF conditions.

Results: The average arterial flow rate was 120 ± 18 mL/min and the systolic/diastolic pressures were 138/22 mmHg. The average AVF flow rate measured in the bioreactor system was 665 ± 85 mL/min, with systolic/diastolic pressures of 146/87 mmHg. At 1-hour, tissue drug concentrations in arteries treated under arterial flow vs. AVF flow were 102.22 ± 81.70 ng/mg and 113.82 ± 36.21 ng/mg, respectively ($p = 0.833$). At 24-hours, the tissue concentrations were 29.52 ± 27.91 ng/mg in arteries under arterial flow and 100.52 ± 86.28 ng/mg in arteries under AVF flow ($p = 0.246$). Under arterial flow, there was a 71.1% decrease in drug concentration ($p = 0.218$) from 1 to 24 hours. Under AVF flow, a 11.7% decrease was found ($p = 0.817$) from 1 to 24-hours.

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.

The DEEPER REVEAL Trial: the Bare Temporary Spur Stent System for the Treatment of Critical Limb Ischemia

S. Jay Mathews[1]

[1]Bradenton Cardiology Center, Manatee Memorial Hospital

Category: Critical Limb Ischemia

Background: The most advanced stage of peripheral arterial disease (PAD), is critical limb ischemia (CLI). CLI typically involves the infrapopliteal arteries and is associated with high rates of mortality, especially in patients who have undergone amputation; reported rates are up to 51% in one year.

Infrapopliteal arteries have proven challenging to treat with available treatment methods. This is due in part to the anatomical challenges of infrapopliteal disease, including calcification, lesion length, vessel tortuosity, and vessel recoil.

The Bare Temporary Spur Stent System (Reflow Medical, San Clemente, CA)[1] is a novel device developed to meet the unique challenges of infrapopliteal disease. The Spur stent is a self-expanding frame covered with spikes which is deployable and retrievable. As the stent is deployed, the 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 nothing behind.

The intent of this study is to evaluate the safety and efficacy of the Bare Temporary Spur Stent System for the treatment of infrapopliteal disease in subjects with Critical Limb Ischemia (CLI)

Methods: The DEEPER REVEAL trial is a prospective, non-randomized, multicenter, single arm trial enrolling 130 subjects. The study will compare the safety and efficacy of the Bare Temporary Spur Stent System 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-primary safety endpoint is freedom from the occurrence of major adverse limb events (MALE) and peri-operative death (POD), at 30 days post procedure. A powered secondary efficacy endpoint evaluating limb salvage and primary patency through 6 months will be analyzed provided the co-primary safety and efficacy endpoints are met.

The Bare Temporary Spur Stent System is for investigational use only.

Abstract 5

Impact of Vascular Motion on Drug-Coated Balloon Pharmacokinetics: Preliminary Results Using a Novel Ex Vivo Mode

Mollie Phillips[1], Catherine Allred[1], Linda Liu[1], Saami Yazdani[1]

Wake Forest University, Department of Engineering, Winston-Salem, NC 27101, US[1]

Category: Peripheral Arterial Disease

Background: Drug-coated balloons (DCBs) are commonly used to treat peripheral arterial disease (PAD); however, their outcomes vary with treatment sites. Within the periphery, there is a wide range of vascular motion, including twisting, bending and artery shortening. The impact of vascular motion on drug delivery and retention remains relatively unknown for DCBs. The goal of this study was to quantify drug uptake and retention of various DCBs deployed within arteries undergoing vascular motion.

Methods: Drug absorption and retention paired with arterial movement was assessed by treating porcine carotid arteries with DCBs (Lutonix, IN.PACT, Stellerax) in a novel ex vivo bioreactor. Specific movement parameters were used to accurately mimic peripheral motion. Following DCB treatment of the porcine carotid arteries undergoing peripheral motion, drug retention in the arterial tissue were quantified by pharmacokinetic at 24-hour post treatment. Scanning electron microscopy was also used to analyze characteristics of DCB coatings and arterial walls.

Results: We were successful in mimicking peripheral motion by twisting, shortening, and bending the harvested porcine carotid arteries. Preliminary PK data showed that following 24 hours of peripheral motion, tissue paclitaxel levels ranged between 14 to 33 ng/mg between the three various DCBs (IN.PACT: 32.9 ± 30.1 ng/mg vs. Lutonix: 14.91 ± 9.92 ng/mg vs. Stellarex: 28.29 ± 26.99 ng/mg, N = 3-8).

Conclusion: These preliminary data highlight the use of a novel bench-top system to assess the pharmacokinetics of DCBs undergoing peripheral motion. Ongoing studies will further characterize and isolate the impact of each vascular motion (twisting vs. elongation vs. bending) and characterize the coating of DCBs.

Angiographic Relationship Between Right And Left Common Femoral Artery Bifurcation, The Femoral Head And The Inferior Epigastric Artery For Optimal Vascular Access.

Alfred Samura, M.D.[1], Jean Gue, M.D[1]., Greg Miller, D.O.[1], Hunter, Krystal[1], Diana Martirosyan, M.D[1]., Sona Hurtz, M.D[1]., Ehson Aligholizadeh, M.D.[1], Amine Al Soueidy, M.D.[1], Angela Zheng, M.D.[1], Peter Galiano, D.O.,[1] Rachel Moshman, M.D.[1], Ayobamidele Balogun, M.D[1]. Janah Aji, M.D.[1]

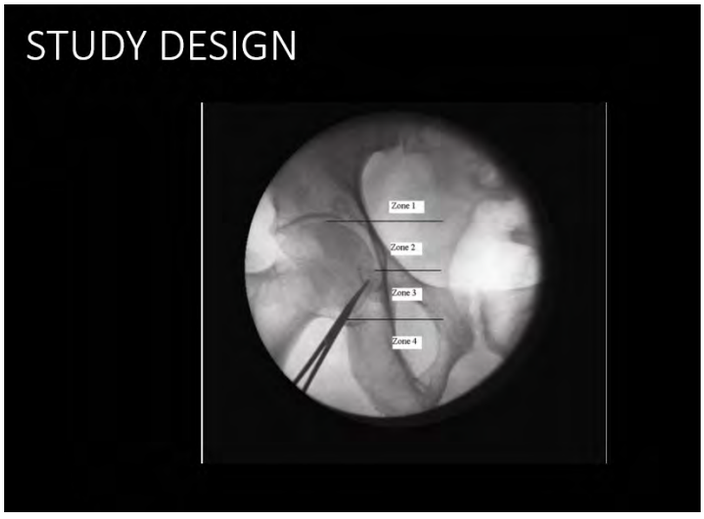
Cooper University Hospital, Camden, New Jersey, USA[1]

Category: Cardiovascular Disease and Peripheral Arterial Disease

Background: The common Femoral artery (CFA) is a familiar access site for endovascular procedures. Avoidance of the same entry site could be preferable during repeated procedures or some of the procedure could necessitate the need for bilateral femoral procedure .Knowing the anatomy of one of the CFA can help predict the bifurcation site of the contralateral side. We seek to compare left and right CFA bifurcation zones and the inferior epigastric artery (IEA) course using an anatomic fluoroscopic approach during arterial access. Specifically, can a known right CFA bifurcation level help predict left CFA bifurcation level.

Methods: Subjects were identified using case log records of patients with bilateral CFA angiograms between 2011 and 2016. 631 patients met criteria and were included in the study. The CFA and IEA were divided into four zones based on relationship with the femoral head.

Fig 1: Femoral artery bifurcation based on relationship with femoral head



Zone 1: above the femoral head

Zone 2: between the superior border of the femoral head and the mid femoral head

Zone 3: between the mid femoral head and the inferior border of the femoral head

Zone 4: below the inferior border of the femoral head

Results:

Table 1: Results of Right and left CFA bifurcation zones, and concordance between Left vs Right CFA Bifurcation zones. Right and Left IEA course, and concordance between left vs Right IEA.

	Right			Left			Concordance between L/R		
	N	n	Percent	N	n	Percent	N	n	Percent
CFA BF1	631	3	0.5%	631	0	0.0%	3	0	0.0%
CFA BF2	631	12	1.9%	631	14	2.2%	12	2	16.7%
CFA BF3	631	157	24.9%	631	198	31.4%	157	81	51.6%
CFA BF4	631	459	72.7%	631	419	66.4%	459	346	75.4%
CFA BF3 + CFA BF4	631	616	97.6%	631	617	97.8%	616	604	98.1%
CFA BF1 + CFA BF2	631	15	2.4%	631	14	2.2%	15	2	13.3%
Origin IEA1	631	242	38.4%	631	353	55.9%	242	191	78.9%
Origin IEA2	631	377	59.7%	631	273	43.3%	377	214	56.8%
Origin IEA3	631	11	1.7%	631	4	0.6%	11	1	9.1%
Origin IEA4	631	1	0.2%	631	1	0.2%	1	0	0.0%
ORIGIN IEA 3 + ORIGIN IEA 4	631	12	1.9%	631	5	0.8%	12	1	8.3%
ORIGIN IEA 1 + ORIGIN IEA 2	631	619	98.1%	631	626	99.2%	619	615	99.4%
IEA Reflection1	631	135	21.4%	631	222	35.2%	135	81	60.0%
IEA Reflection2	631	458	72.6%	631	394	62.4%	458	312	68.1%
IEA Reflection3	631	31	4.9%	631	8	1.3%	31	2	6.5%
IEA Reflection4	631	7	1.1%	631	6	1.0%	7	1	14.3%
IEA REFLECTION 3 + IEA REFLECTION 4	631	38	6.0%	631	14	2.2%	38	3	7.9%
IEA REFLECTION 1 + IEA REFLECTION 2	631	593	94.0%	631	616	97.6%	593	582	98.1%

CFABF: CFA bifurcation in zones 1,2,3,4

Origin IEA: Inferior epigastric artery originating in zones 1,2,3,4

IEA Reflection: Inferior epigastric artery changing course (reflecting) in zones 1,2,3,4

Table 2: Demographics of study subjects.

	Age (years)	BMI
N	631	631
Mean	67.33	29.34
Std. Deviation	11.15	10.39
Minimum	34	15.74
Maximum	93	248

	N	n	Percent
Male	631	411	65.1%
White	631	476	75.4%
HTN	631	595	94.3%
HL	631	565	89.5%
DM	631	334	52.9%
Tobacco	631	416	65.9%
CR GT 2	631	93	14.7%
ESRD	631	52	8.2%
PVD	631	245	38.8%

Table 3: Interaction of Risk factors with CFA bifurcation zones

	Right CFA BF1			Right CFA BF2			Right CFA BF3			Right CFA BF4			Pvalue
	N	n	Percent							N	n	Percent	
Male	3	2	66.7%	12	8	66.7%	157	107	68.2%	459	294	64.1%	0.930
White	3	3	100.0%	12	9	75.0%	157	112	71.3%	459	352	76.7%	0.425
HTN	3	2	66.7%	12	11	91.7%	157	151	96.2%	459	431	93.9%	0.134
HL	3	2	66.7%	12	11	91.7%	157	141	89.8%	459	411	89.5%	0.627
DM	3	2	66.7%	12	7	58.3%	157	74	47.1%	459	251	54.7%	0.384
Tobacco	3	2	66.7%	12	8	66.7%	157	96	61.1%	459	310	67.5%	0.546
CR GT 2	3	0	0.0%	12	1	8.3%	157	22	14.0%	459	70	15.3%	0.784
ESRD	3	0	0.0%	12	1	8.3%	157	11	7.0%	459	40	8.7%	0.868
PVD	3	1	33.3%	12	5	41.7%	157	56	35.7%	459	183	39.9%	0.814

	Left CFA BF2			Left CFA BF3			Left CFA BF4			Pvalue
							N	n	Percent	
Male	14	7	50.0%	198	125	63.1%	419	279	66.6%	0.341
White	14	10	71.4%	198	145	73.2%	419	321	76.6%	0.621
HTN	14	14	100.0%	198	187	94.4%	419	394	94.0%	0.635
HL	14	14	100.0%	198	182	91.9%	419	369	88.1%	0.149
DM	14	7	50.0%	198	99	50.0%	419	228	54.4%	0.577
Tobacco	14	10	71.4%	198	126	63.6%	419	280	66.8%	0.670
CR GT 2	14	1	7.1%	198	27	13.6%	419	65	15.5%	0.596
ESRD	14	0	0.0%	198	16	8.1%	419	36	8.6%	0.514
PVD	14	6	42.9%	198	80	40.4%	419	159	37.9%	0.803

Chi Square Test

Table 3: Interaction of Age and BMI with CFAs and with IEAs

Right CFA BF		N	Mean	StDev	Pvalue
Age (years)	1.00	3	69.330	7.638	0.935
	2.00	12	67.250	6.757	
	3.00	157	66.880	11.062	
	4.00	459	67.470	11.312	
BMI	1.00	3	30.800	7.665	0.988
	2.00	12	28.928	5.102	
	3.00	157	29.179	5.884	
	4.00	459	29.397	11.654	
One Way Anova					

Left CFA BF		N	Mean	StDev	Pvalue
Age (years)	2.00	14	66.000	10.303	0.409
	3.00	198	68.180	11.112	
	4.00	419	66.970	11.201	
BMI	2.00	14	29.877	7.311	0.639
	3.00	198	29.893	16.623	
	4.00	419	29.062	5.533	
One Way Anova					

Right Origin		N	Mean	StDev	Pvalue
Age (years)	1.00	242	67.269	11.291	0.387
	2.00	377	67.236	11.090	
	3.00	11	70.273	10.150	
	4.00	1	84.000		
BMI	1.00	242	28.873	5.512	0.803
	2.00	377	29.633	12.645	
	3.00	11	29.992	6.864	
	4.00	1	25.110		
One Way Anova					

Left Origin		N	Mean	StDev	Pvalue
Age (years)	1.00	353	67.286	11.133	0.560
	2.00	273	67.366	11.204	
	3.00	4	71.750	10.658	
	4.00	1	54.000		
BMI	1.00	353	29.530	12.977	0.817
	2.00	273	29.049	5.565	
	3.00	4	33.150	8.720	
	4.00	1	26.630		
One Way Anova					

Right Lowest Reflection		N	Mean	StDev	Pvalue
Age (years)	1.00	135	66.711	11.942	0.160
	2.00	458	67.262	10.813	
	3.00	31	69.097	11.429	
	4.00	7	75.714	14.545	
BMI	1.00	135	28.579	5.514	0.819
	2.00	458	29.556	11.680	
	3.00	31	29.505	6.567	
	4.00	7	29.201	5.926	
One Way Anova					

Left Lowest Reflection		N	Mean	StDev	Pvalue
Age (years)	1.00	222	66.820	10.854	0.624
	2.00	395	67.520	11.373	
	3.00	8	71.630	8.017	
	4.00	6	67.330	11.827	
BMI	1.00	222	28.430	5.443	0.324
	2.00	395	29.903	12.397	
	3.00	8	29.313	7.443	
	4.00	6	26.005	5.702	

Conclusions: 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%.

Abstract 7

The Effect Of Inclisiran In Patients With Prior Myocardial Infarction: A Post Hoc Pooled Analysis From The ORION-10 And ORION-11 Randomized Controlled Trials

Ulf Landmesser, Prof[1], David G. Kallend, MD[2], Wolfgang Koenig, Prof[3], Lawrence A. Leiter, Prof[4], Frederick J. Raal, Prof[5], Kausik K. Ray, Prof[6], R. Scott Wright, Prof[7], YannTong Chiang, PhD[8], Lorena Garcia Conde Orozco, MD[9], Gregory G. Schwartz, Prof[10]

Department of Cardiology, Charité-University Medicine Berlin, Berlin Institute of Health (BIH), DZHK, Partner Site Berlin, Germany[1]

DalCor Pharmaceuticals, Montreal, Quebec, Canada[2]

Deutsches Herzzentrum München, Technische Universität München, Munich, Germany, DZHK (German Centre for Cardiovascular Research), partner site Munich Heart Alliance, Munich, Germany; Institute of Epidemiology Medical Biometry, University of Ulm, Ulm, Germany[3]

Li Ka Shing Knowledge Institute, St. Michael's Hospital, University of Toronto, Toronto, Canada[4]

Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa[5]

Imperial Centre for Cardiovascular Disease Prevention, Department of Primary Care and Public Health, Imperial College, London, UK[6]

Division of Preventive Cardiology and Department of Cardiology, Mayo Clinic, Rochester, MN, USA[7]

Novartis Pharmaceuticals Corp, East Hanover, NJ, USA[8]

Novartis Pharma AG, Basel, Switzerland[9]

Division of Cardiology, University of Colorado School of Medicine, Aurora, CO, USA[10]

Category: Cardiovascular Disease

Background: The risk of future myocardial infarction (MI) is high among those who had a recent MI. As such, guidelines endorse more stringent low-density lipoprotein cholesterol (LDL-C) goals, along with ≥50% LDL-C reduction, among those with an atherosclerotic cardiovascular disease (ASCVD) event within the past 2 years (European Society of Cardiology/European Atherosclerosis Society) or at least two prior ASCVD events at any time (American Heart Association/American College of Cardiology).

Methods: In this post hoc analysis, 1643 patients with prior MI were randomized 1:1 to receive 300 mg inclisiran sodium (284 mg inclisiran) or placebo at baseline, Day 90, and 6-monthly thereafter, in addition to background statin and/or ezetimibe. Analysis was stratified by time from last MI prior to randomization (recent [>3 months – <1 year]; remote [≥1 year]). Percentage and absolute LDL-C change from baseline were assessed.

Results: Baseline characteristics were generally balanced between treatment arms and MI strata. Inclisiran produced substantial percentage, absolute, and time-adjusted changes in LDL-C from baseline compared to placebo (Table). There was no significant interaction of treatment and MI stratum on LDL-C changes. Treatment-emergent adverse events (TEAEs) were similar between treatment arms and between MI strata, except for a higher proportion of mild-moderate clinically relevant TEAEs at the injection site with inclisiran, regardless of MI status.

Conclusion: Twice-yearly dosing with inclisiran (after the initial and 3-month doses) provided effective and sustained LDL-C lowering, irrespective of MI status, and was generally well tolerated. Inclisiran may provide a therapeutic approach to lower LDL-C levels below those achieved with conventional oral agents in patients who have had a prior MI event and are at a very high risk of recurrent events.

Table:

Table 1 . LDL-C change from baseline (ITT population)* per time since last MI† by treatment arm in ORION-10 (NCT03399370) and ORION-11 (NCT03400800)

	Time since last MI			
	Recent (>3 months – <1 year)		Remote (≥1 year)	
	Inclisiran (n=52)	Placebo (n=70)	Inclisiran (n=757)	Placebo (n=764)
Percentage change from baseline				
Change to Day 510, %, LS mean (95% CI)‡	−49.4 (−58.9 to −39.8)	3.2 (−4.9 to 11.4)	−48.1 (−50.7 to −45.6)	2.3 (−0.2 to 4.7)
Between-group difference, Δ (95% CI)§	−52.6 (−65.1 to −40.1) *p*≤0.0001		−50.4 (−53.8 to −47.0) *p*≤0.0001	
Time-adjusted change after Day 90 and up to Day 540, %, LS mean (95% CI)¶	−47.1 (−53.6 to −40.6)	2.9 (−2.7 to 8.6)	−48.8 (−50.6 to −47.1)	3.4 (1.7 to 5.2)
Between-group difference, Δ (95% CI) §	−50.0 (−58.7 to −41.4) *p*≤0.0001		−52 (−54.7 to −49.8) *p*≤0.0001	
Absolute change from baseline				
Change to Day 510, mg/dL, LS mean (95% CI)‖	−55.2 (−63.9 to −46.5) *n=51*	−1.0 (−8.5 to 6.5) *n=69*	−53.6 (−55.7 to −51.5) *n=745*	−1.4 (−3.5 to 0.7) *n=758*
Between-group difference, Δ (95% CI)§	−54.2 (−65.7 to −42.7) *p*≤0.0001		−52.2 (−55.2 to −49.2) *p*≤0.0001	
Time-adjusted change after Day 90 and up to Day 540, mg/dL, LS mean (95% CI)‖	−50.9 (-57.5 to −44.3) *n=51*	−0.4 (−6.1 to 5.4) *n=67*	−51.5 (−53.1 to −49.8) *n=742*	0.2 (−1.5 to 1.9) *n=740*
Between-group difference, Δ (95% CI) §	−50.5 (−59.3 to −41.7) *p*≤0.0001		−51.7 (−54.0 to −49.3) *p*≤0.0001	

*ITT population comprised all patients randomized;

†Per the Case Report Forms, the information provided on MI history was limited to whether it took place <1 or ≥1 year prior to consent. An MI within 3 months of randomization was exclusionary;

‡Analyzed with a multiple imputation washout model assuming the possibility of missing data being missing not at random for patients receiving inclisiran who discontinued the study early;

§Inclisiran vs placebo, $p<0.0001$;

¶Analyzed using a control-based pattern mixture model;

‖Measured with a mixed-effects model for repeated measures that assumes missing data are missing at random.

CI, confidence interval; ITT, intention-to-treat; LDL-C, low-density lipoprotein cholesterol; LS, least squares; MI, myocardial infarction; SD, standard deviation.

Abstract 8

A Randomized Study To Compare Low-Density Lipoprotein Cholesterol-Lowering Effects Of Inclisiran With Usual Care Vs Usual Care Alone In Patients With Recent Hospitalization For An Acute Coronary Syndrome: Rationale And Design Of The VICTORION-INCEPTION Trial

Jeffrey L. Anderson, MD[1], Ann Marie Navar, MD, PhD[2], Neeraja Balachander, MBBS, PhD, MS[3], Nihar R. Desai, MD, MPH[4], Kirk U. Knowlton, MD[1]

Intermountain Medical Center, Intermountain Heart Institute, Salt Lake City, UT, USA[1]
UT Southwestern Medical Center, Dallas, TX, USA[2]

Novartis Pharmaceuticals Corp., East Hanover, NJ, USA[3]

Section of Cardiovascular Medicine, Center for Outcomes Research, Yale School of Medicine, New Haven, CT, USA[4]

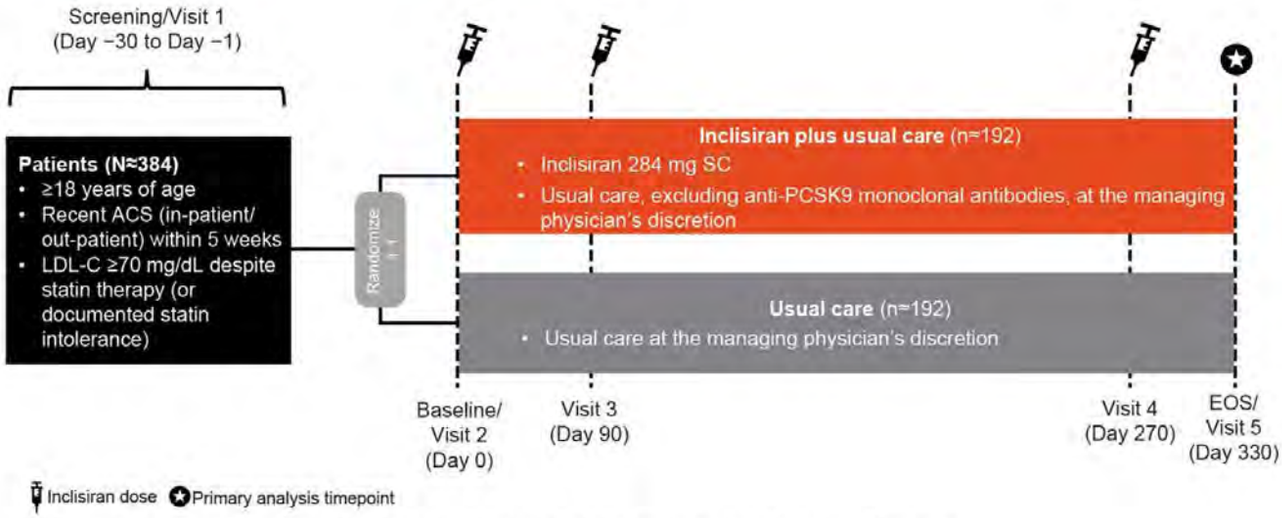
Category: Cardiovascular Disease

Background: Patients are at high risk for a recurrent cardiovascular (CV) event in the first year following acute coronary syndrome (ACS). Low-density lipoprotein cholesterol (LDL-C) is a modifiable risk factor for recurrent CV events. Despite the availability of lipid-lowering therapies (LLT), many patients fail to achieve guideline-recommended LDL-C <70 mg/dL in the year post-ACS. Early LDL-C evaluation and LLT intensification after recent ACS may reduce recurrent CV event risk. In prior Phase 3 trials, inclisiran plus maximally tolerated statin therapy effectively reduced LDL-C in patients with established atherosclerotic cardiovascular disease (ASCVD). As patients with an ACS within 3 months of screening were excluded from these trials, the efficacy of inclisiran in these patients is unknown. The objective of this study is to assess the LDL-C-lowering effect of inclisiran added to usual care, vs usual care alone, in patients recently hospitalized (in-patient/out-patient) for an ACS and with LDL-C ≥70 mg/dL despite statin therapy.

Methods: VICTORION-INCEPTION (NCT04873934) is a Phase 3b, randomized, parallel-group, open-label, multicenter, United States-based trial enrolling eligible patients to receive inclisiran plus usual care or usual care (Figure). Concomitant LLT and routine LDL-C assessment are at the discretion of the managing physician to mimic real-world clinical practice. The primary endpoints are percent change from baseline in LDL-C and the proportion of patients achieving LDL-C <70 mg/dL. Key secondary endpoints include absolute change from baseline in LDL-C, absolute and percentage change in LDL-C at each post-baseline visit, the proportion of patients reaching pre-specified LDL-C targets, absolute and percentage change in other plasma lipids, the intensity of background LLT, and safety and tolerability of inclisiran.

Conclusion: VICTORION-INCEPTION, an ongoing trial planned to complete in early 2024, will assess the effectiveness of inclisiran plus usual care for the management of patients with elevated LDL-C post-ACS despite receiving statin therapy.

Figure. Study design of the VICTORION-INCEPTION trial



Abbreviations: ACS, acute coronary syndrome; EOS, end of study; LDL-C, low-density lipoprotein cholesterol; PCSK9, proprotein convertase subtilisin/kexin type 9; SC, subcutaneous.

Abstract 9

Crossing Complex Infrapopliteal Lesions Utilizing a Front-End Cutting Technique: A Case Series with The Novel 1.5mm Phoenix Atherectomy System

Anton Hnatov, BSc[1], Trisha Tarra, PhD[2], Siddhartha Rao, MD[1]

Vascular Solutions of North Carolina, Cary, North Carolina, USA[1]

Philips North America, Cambridge, Massachusetts, USA[2]

Category: Critical Limb Ischemia

Background: Patients with critical limb ischemia (CLI) often present with complex, calcified infrapopliteal lesions. Atherectomy is a common endovascular technique employed to debulk difficult-to-cross or otherwise uncrossable lesions. The Phoenix Atherectomy System (Philips) is a front-end cutting rotational device that cuts, captures, and clears diseased tissue. The Phoenix 1.5mm catheter is a second-generation device with a low 4F profile designed to treat smaller lesions in the distal arteries.

Methods: We performed retrospective, single-center, case series of five patients who presented with CLI and whose complex and calcified infrapopliteal lesions were treated with the 1.5mm Phoenix Atherectomy System after prior failed crossing attempts were performed.

Results: Five patients with CLI who presented with complex, calcified infrapopliteal lesions that were treated with the 1.5mm Phoenix Atherectomy System after prior unsuccessful crossing attempts were included in this case series. The 1.5mm Phoenix catheter successfully crossed and debulked each infrapopliteal lesion. Each patient achieved TIMI grade 3 flow of the target lesion. There were no device-related procedural complications or deaths. These data demonstrate that the Phoenix Atherectomy System can be used to debulk complex, calcified infrapopliteal lesions to optimize endovascular therapy.

Conclusion: In this retrospective, single-center case series, the 1.5mm Phoenix Atherectomy System showed favorable results for the treatment of complex, calcified infrapopliteal lesions. The 1.5mm Phoenix Atherectomy device has the potential to improve outcomes for patients with CLI.

Pounce Thrombectomy System to Treat Acute and Chronic Peripheral Arterial Occlusions

Bruce H. Gray, MD[1]; Elias Wheibe[1]; Andrew B. Dicks, MD[2], Matthew Low, Joseph, Tingen, MD[2]

University of South Carolina School of Medicine-Greenville, Greenville, SC, USA[1]

Vascular Surgery, PRISMA Health, Greenville, SC, USA[2]

Category: Peripheral Arterial Disease

Background: Symptomatic limb ischemia can be life and limb threatening. The severity of ischemia, location of the occlusion and integrity of the distal circulation often dictate treatment approach. Mechanical thrombectomy (MT), aspiration thrombectomy (AT), and catheter-directed thrombolysis (CDTT) have been the mainstay of endovascular treatment. Each of these modalities are effective in removing fresh, less organized thrombus. As thrombus ages it becomes more adherent to the arterial wall and resistant to these therapies.

Methods: Using a retrospective analysis, we investigated the safety and efficacy of a novel arterial percutaneous thrombectomy system, Pounce thrombectomy System (Pounce, Surmodics, Minneapolis MN) in removing variable aged thrombus (acute/subacute/chronic). Our outcomes measures focused on procedural success, length of hospital stay, use of adjuvant therapy, 12 months follow up and any complications that associated with the use of Pounce thrombectomy.

Results: Forty-four consecutive patients who presented with acute (n=18), subacute (n=7), or chronic (n=19) lower extremity ischemia were treated and followed for a mean of 7 months. The peripheral occlusions were considered thrombus-dominant by the feel and ease of wire traversal. They were treated with Pounce thrombectomy system (PTS) with complimentary PTA/stenting when appropriate. The mean number of passes with PTS was 4.0 +/- 2.7. Sixty-five percent (29/44) were successfully revascularized in a single setting with only 2 requiring concomitant thrombolysis for incomplete thrombus removal from the PTS target artery. Fifteen patients (34%) additionally had thrombolysis for tibial thrombus that was not attempted with PTS. PTA +/- stenting after PTS occurred in 57% of limbs. Technical success was 83% and procedural success was 95%. Reintervention rate throughout follow-up was 22.7%. Major amputation occurred in 4.5%. Complications were limited to minor groin hematomas (n=3). Outcomes were equally effective in patients with pre-existing stents or de-novo arterial occlusions as evidenced with ankle brachial index improvement from 0.48 pre- to 0.93 post-intervention and 0.95 at latest follow-up ($p<0.001$).

Conclusion: PTS coupled with PTA/stenting is expeditiously safe and effective in patients with variable aged thrombus-associated lower limb occlusion.

Abstract 11

A New Trainee's Guide To Limb Salvage: Endovascular-First Treatment For Critical Limb Ischemia

Kristy Patel, MS4[1]; Micah Watts, MD, FSIR[2]

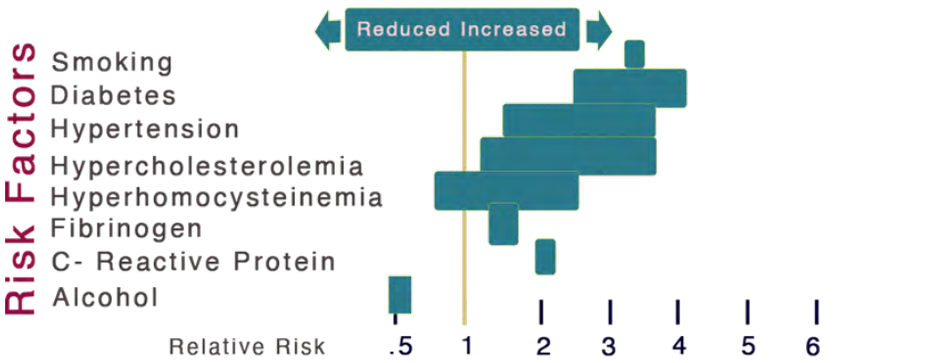
Rowan-Virtua, School of Osteopathic Medicine, Stratford, NJ USA[1]

The Vascular Institute at Atlantic Medical Imaging, Vineland, NJ USA[2]

Category: Limb Salvage

Background: A rising public health concern, peripheral arterial disease (PAD) causes the arteries in the extremities to constrict to such an extent that claudication and rest discomfort, commonly known as critical limb ischemia (CLI), can occur. PAD is a progressive atherosclerotic obstruction of noncoronary peripheral vessels that is seen mostly in the lower extremities. The most seriously affected by CLI are patients who greater than 65 years in age, smoke tobacco, have sedentary lifestyles, and have co-morbidities including diabetes, hypertension, chronic kidney disease, metabolic syndrome, and hyperlipidemia. An ankle brachial index (ABI) and other noninvasive tests are used to support this clinical diagnosis; patients with an ABI < .9 are diagnostic for PAD. A surgical approach vs. an endovascular approach are two therapy alternatives when the symptoms cannot be controlled clinically. The disease's substantial morbidity and mortality risk for many patients makes the latter advantageous for revascularizing the damaged arteries for limb salvage. Clinical presentation varies widely ranging from being asymptomatic to chronic limb threatening ischemia. Symptoms start to arise when blood demand exceeds its supply in active tissues; symptoms include claudication, atypical extremity pain, ischemic rest pain, or severe diffuse pain, nonhealing wounds/ ulcers, and skin discoloration/gangrene.

Figure 1: Risk Factors for PAD



Data from the Framingham Heart showing the odds ratio for developing intermittent claudication

Methods:

Clinical

- History
    - Identify risk factors including cardio-renal co-morbidities, tobacco smoking, and calorie-rich diets
    - Histories of older patients should include information about walking impairment, extremity pain, and presence of nonhealing wounds
- Physical Exam
    - Skin changes (e.g. thinning, discoloration, ulceration, or gangrene)
    - Ankle-Brachial Systolic Pressure Index (ABI)
    - Neurologic assessment
- Labs/Imaging
    - Routine labs
    - Duplex ultrasound
    - Vascular imaging to identify intervention targets and sites for ongoing surveillance following intervention; the gold standard is contrast arteriography including a complete bilateral study of the aorta, iliac, femoral, popliteal, and run-off vessels
- Education
    - Lifestyle modifications with smoking cessation, glucose control, statin, and exercise

Table 1: Rutherford classification used to categorize PAD into the degree of severity of ischemia

Grade	Category	Clinical Description	Objective criteria
0	0	Asymptomatic-no hemodynamically significant occlusive disease	Normal treadmill or reactive hyperemia test
	1	Mild claudication	Completes treadmill exercise; AP after exercise > 50 mmH but at least 20 mmH lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise, and AP after exercise < 50 mm Hg
II	4	Ischemic rest pain	Resting AP < 40 mmH, flat or barely pulsatile ankle or metatarsal PVR: TP < 30 mm Hg
III	5	Minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP < 60 mm Hg, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mm Hg
	6	Major tissue loss-extending above TM level, functional foot no longer salvageable	Same as category 5

AP: ankle pressure; PVR: pulse volume recording; TM: transmetatarsal; TP: toe pressure.

Table 2: Wound, Ischemia, foot Infection (WI-fI) used to predict disease severity, wound healing, and amputation risk

	Ischemia – 0				Ischemia – 1			
W-0	VL	VL	L	M	VL	L	M	H
W-1	VL	VL	L	M	VL	L	M	H
W-2	L	L	M	H	M	M	H	H
W-3	M	M	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

	Ischemia – 2				Ischemia – 3			
W-0	L	L	M	H	L	M	M	H
W-1	L	M	H	H	M	M	H	H
W-2	M	H	H	H	H	H	H	H
W-3	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

a. Estimate risk of amputation at 1 year for each combination

	Ischemia – 0				Ischemia – 1			
W-0	VL	VL	VL	VL	VL	L	L	M
W-1	VL	VL	VL	VL	L	M	M	M
W-2	VL	VL	VL	VL	M	M	H	H
W-3	VL	VL	VL	VL	M	M	M	H
	f-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

	Ischemia – 2				Ischemia – 3			
W-0	L	L	M	M	M	H	H	H
W-1	M	H	H	H	H	H	H	H
W-2	H	H	H	H	H	H	H	H
W-3	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

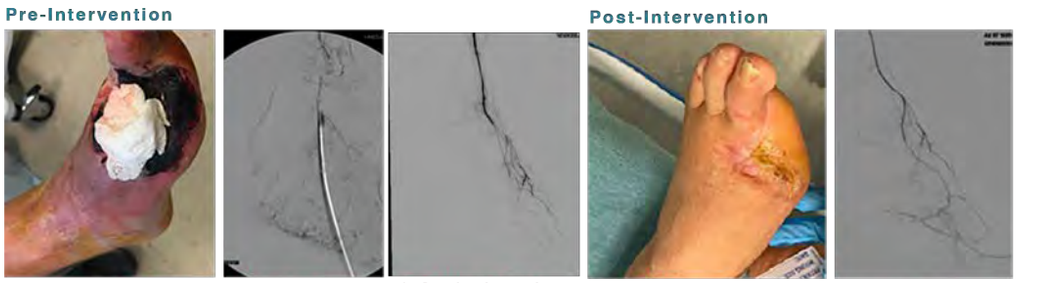
b. Estimate likelihood of benefit of/requirement for revascularization (assuming infection can be controlled first)

*fI, foot Infection; I, Ischemia; W, Wound.

Very low = VL = clinical stage 1
Low = L = clinical stage 2
Moderate = M = clinical stage 3
High = H = clinical stage 4
Clinical stage 5 would signify an unsalvageable foot

Clinical Case: 65-year-old type 2 diabetic with a nonhealing toe and ray resection from osteomyelitis complication.

Figure 2: Pre- intervention vs. post- intervention of DP revascularization



Procedure: Gain percutaneous arterial access. Navigate to the target lesion and perform an angiogram. Intervention with balloon angioplasty, atherectomy, and/or stent placement. Post-intervention angiogram. Reassess. Access site closure. Consider antiplatelet or anticoagulation therapy. Follow-up in 2-6 weeks with noninvasive testing. Regular wound care follow-up is critical in limb salvage patients to avoid future complications, including amputation and infection.

Results: The goal of endovascular treatment (EVT) for CLI patients is to maintain patency of treated lesion(s) until wound healing is achieved; after the healing phase, less amount of blood is needed to maintain tissue integrity. With the decreased need for blood supply, restenosis may be clinically silent.

Advantages vs Limitations of Endovascular Revascularization:

Advantages:

·Decreased procedural morbidity and mortality

·Ease of repeat intervention

·Ability to treat patients with severe clinical co-morbidities

·Ability to treat multiple targets

·Rarely prevents future attempt at surgical bypass

Limitations:

·Lower primary patency rates with increased need for repeat interventions

·Endovascular therapy may be limited by renal insufficiency

Conclusion: CLI is a complex, multifactorial disease process that varies in clinical manifestations and therapeutic options. For patients with surgical contraindications and substantial morbidity and mortality risks, EVT offers a less invasive, safer option for recanalizing their vasculature and salvaging limbs. Due to a lower patency rate compared to surgical therapy, it is important to maintain regular clinical care after revascularization to reduce the need for multiple interventions.

References:

1) Brazeau NF, Pinto EG, Harvey HB, et al. Critical limb ischemia: an update for interventional radiologists. Diagn Interv Radiol. 2013;19(2):173-180. doi:10.4261/1305-3825.DIR.5955-12.1

2) Dave, Bhargav & Shah, Rikin. (2018). Peripheral stent technology and current status for endovascular treatment of femoropopliteal artery disease: a clinical review. International Journal of Research in Medical Sciences. 6. 1474. 10.18203/2320-6012.ijrms20181743.

3) Dattilo PB, Casserly IP. Critical limb ischemia: endovascular strategies for limb salvage. Prog Cardiovasc Dis. 2011;54(1):47-60. doi:10.1016/j.pcad.2011.02.009

4) Hardman RL, Jazaeri O, Yi J, Smith M, Gupta R. Overview of classification systems in peripheral artery disease. Semin Intervent Radiol. 2014 Dec;31(4):378-88. doi: 10.1055/s-0034-1393976. PMID: 25435665; PMCID: PMC4232437.

5) Keefe, Nicole A., IR Playbook: A Comprehensive Introduction to Interventional Radiology. Springer Nature, 2019.

6) Mills JL Sr, Conte MS, Armstrong DG, et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification based on wound, ischemia, and foot infection (WIfI). J Vasc Surg. 2014;59(1):220-34.e342. doi:10.1016/j.jvs.2013.08.003

7) Murabito JM, D'Agostino RB, Silbershatz H, Wilson WF. Intermittent claudication. A risk profile from The Framingham Heart Study. Circulation. 1997;96(1):44-49. doi:10.1161/01.cir.96.1.44

Alarming Impact of COVID-Continued Supply-Chain Issues on Contrast Related Morbidity in Patients Undergoing CLI Procedures in Cardiac Catheterization Lab-Case Series of Contrast Reactions

Anthony Bruccoliere MBA[1], Anthony Pham[1], Ardalan Naghain[1], Kanishk Goel[1], Lewis Kelly[1], Juthipong Benjanuwattra MD[1], Marina Iskandir MD[1], Aliakbar Arvandi MD[1], Mac Ansari MD[1]Texas Tech Health Science Center PAD Center of Excellence, Division of Cardiology, Department of Medicine, Texas Tech University Health Sciences Center, Lubbock, TX[1]

Category: Peripheral Arterial Disease

Background: The COVID pandemic disrupted the supply chain and imposed several severe shortages in the post COVID world. In May 2022, there was a worldwide shortage of contrast among other things including the Iodine 270 mg/mL Visipaque. Due to the severe shortage, our catheter lab had depleted their stores of Iodine 270 mg/mL Visipaque and could only acquire the Iodine 320 mg/mL Visipaque. Following the switch, our patients experienced similar severe and life-threatening adverse reactions that could not be attributed to other causes.

Methods: A retrospective chart review of all reactions from procedures performed after the new contrast was adopted, between September-October 2022, was collected. Patient demographics, allergies, comorbidities, medications used (sedation), adverse reactions, and type of contrast were analyzed. Data was analyzed with control subjects.

Results: A total of 7 cases were identified. All cases utilized the Iodine 320 Visipaque. No other change was adopted to medication or procedure. Three patients experienced post-procedural vomiting. One patient with no psychological history experienced extreme agitation and aggression. Five patients required overnight admission due to severe postoperative shivering. Two of these patients required urgent warming measures and one recorded a life-threatening temperature of 106F requiring several cooling measures. One patient was readmitted to ICU on post-op day 2 with high-grade fever and chills. The common factor in all patients was the development of high-grade fever a few hours after administration of contrast. All patients recovered after receiving steroid and Benadryl.

Conclusion: Our experience clearly shows there were a number of adverse reaction cases immediately following the change in contrast used. Since no other factors or methods involved in procedures were changed, it is highly suggestive that these reactions were due to the use of Iodine 320 Visipaque. Once the supply of the original Iodine 270 Visipaque was restored, adverse reactions ceased, and none occurred in October or November. An independent investigation by the university pharmacy also concluded the same. Our case series exemplifies how COVID has and continues to affect patients beyond its disease course. Disruptions in the supply chain imposed by COVID force departure from preferred methods and adaptation to maintain continuity of care. As the global pandemic looms behind us, healthcare providers must continue to be proactive and adaptive to the long-term disruptions of healthcare caused by the ripple effects of COVID-19.

Abstract 13

Combination of Covered and Non-Covered Stents Serves as Viable Treatment Option of Aortoiliac Disease in Patients Deemed High-Risk for Surgery

Mitchell DeVolder, Vivie Tran, Maryam Niazi, Marina Iskandir, M.D, Aliakbar Arvandi M.D, Mohammad M. Ansari, M.D.Texas Tech University Health Sciences Center PAD Center of Excellence, Division of Cardiology, Department of Internal Medicine, Lubbock, TX

Category: Peripheral Arterial Disease

Introduction: Peripheral artery disease (PAD) is one of the most underdiagnosed pathologies in the United States. PAD generally follows an asymptomatic course which eventually causes pain, claudication and muscle atrophy. PAD occurs predominantly in the lower extremities and is one of leading causes of amputation. Effective treatments for PAD have been and continue to be developed including open surgical revascularization and percutaneous intervention. Percutaneous intervention utilizes stents to recanalize the occluded vessel. Many different stent types have been developed. In this case study we discuss the use of a combination of both covered and bare metal stents in the treatment of severe aortoiliac disease.

Case Presentation: Male age 42, with PMH of HTN and PAD presented with pain in his bilateral lower extremities when walking (claudication). Routine angiography showed evidence of stenosis of the distal aorta and the bilateral common iliac arteries worse on the left. The patient underwent PVI of his aortoiliac disease which was treated with a covered stent in the right common iliac and a combination of a covered and bare metal stents in the left common and external iliac, respectively. Utilizing the bare metal stent in the proximal left external iliac spared flow to the left internal iliac with collateral flow to the leg. The procedure was successful, and the patient was discharged home the next day.

Conclusion: Our case demonstrates the viability of percutaneous intervention utilizing a combination of covered and bare stents in a patient with advanced aortoiliac disease who is not a candidate for surgical intervention. This supports the need for the toolbox advantage in all PAD-CLI centers to carry both covered and bare metal stents to successfully treat all disease presentations.

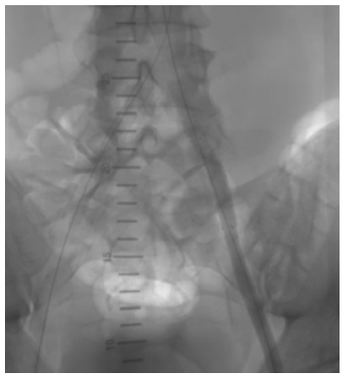


Figure 1. Bilateral common iliac occlusions pre-op

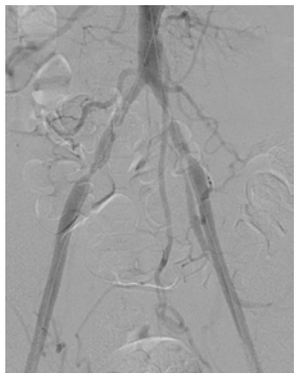


Figure 2. Reperfusion of right common iliac s/p successful stenting

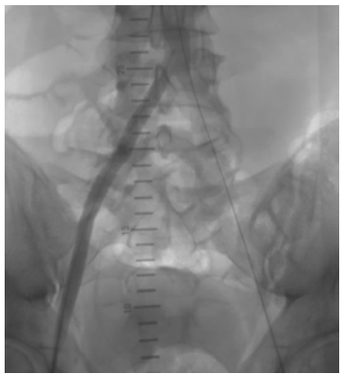


Figure 2. Reperfusion of left common iliac s/p successful stenting

Utility of Three-Dimensional (3D) Printing in Procedure Planning and Patient Education for Structural Heart Disease and Advanced Vascular Cases

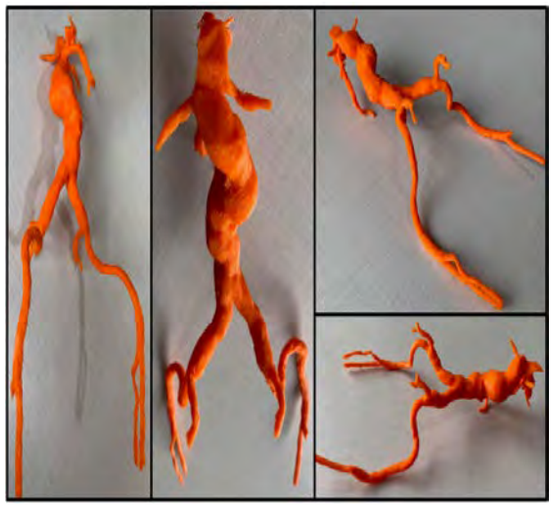
Cole Pollina, Seena Firouzbakht, Anthony Bruccoliere, Geoff Thomas, Ardalan Naghian, Elwin Rutayomba, Anthony Pham, Zeid Nawas, Marina Iskandir, Aliakbar Arvandi, Mohammad M Ansari
Texas Tech University Health Sciences Center PAD Center of Excellence, Division of Cardiology, Department of Internal Medicine, Lubbock, TX, USA

Category: Peripheral Arterial Disease

Background: Absence of models for procedure planning of EVAR, TEVAR, and TAVR with difficult anatomy presents numerous challenges in effective management and treatment. However, utilization of 3D printed models (via US, Echo, CT) are promising methods to enhance patient education and procedure planning. 3D printing has been widely described in medicine for training and planning. Via a complex EVAR, TAVR, and TEVAR case series, we demonstrate benefits in patient education and procedure planning.

Methods: For this purpose, three complex cases were selected. One EVAR with 6 cm AAA, one TEVAR having coarctation of aorta, and one TAVR with severe AS with bicuspid valve. Echocardiogram, abdominal US, and CT scan were performed. Diacom images were selected and independently verified by imaging the cardiologist and utilized for 3D printing at the Texas Tech 3D Printing Lab (Formlabs Form 3 SLA 3D). The models were then utilized for patient education, procedure planning.

Results: Prior to scheduling, our patients presented in the outpatient clinic to discuss treatment. Our initial explanation through images and intervention details was insufficient (5/10, 6/10, 6/10). Thus, we decided to aid patient education via development of a 3D printed model. After which patient rated understanding improved (9/10, 10/10, 10/10). Physician treatment strategy and device selection of the case and treatment pre- and post-3D printing improved as well (75% to 100%).



Conclusion: From our experience, the use of CT-generated 3D printed models facilitate procedural feasibility and patient understanding about their unique anatomy. The advancement of 3D printing technology is likely to provide safer, faster and more efficient procedure planning in the reconstruction of complex aortic pathologies in patients with complex structural heart and advanced vascular disease.

Abstract 15

The Utilization of Peripheral Intravascular Ultrasound Catheter Prior to Aortoiliac Disease Endovascular Intervention: A Case Presentation

Seena L Firouzbakht[1]; Subash Swarna[2]; Alyson Willis[3]; Steven Daley[4]; Mohammed M Ansari, MD; Marina Iskandir, MD Texas Tech University Health Sciences Center PAD Center of Excellence, Division of Cardiology, Department of Internal Medicine, Lubbock, TX, USA

Category: Peripheral Artery Disease, Endovascular Repair

Introduction: Treatment of severe aortoiliac disease in high-risk surgical patients by method of a minimally invasive procedure such as percutaneous endovascular aortoiliac intervention is a preferred approach as it reduces the patient's post-operative hospital stay and overall recovery time. With the wide availability of covered stents, the focus is mainly on the severe stenosis that may occur with aortoiliac disease. Although a specific area of occlusion can be treated, with many of these vessels being big vessels, speculated calcium may be ignored due to not calculating the proper inflow in the calcified disease. To identify potential calcification alongside with the stenosis, IVUS (Intravascular Ultrasound) catheterization may be considered prior to using endovascular or percutaneous intervention. However, IVUS catheterizations are typically not used to treat this condition. While many are well-versed in a .014 IVUS catheter normally, not as many are familiar with using a .035 IVUS catheter for peripherals. The implementation of IVUS catheterization provides accurate and high dimensional cross-sectional imaging of arterial vessels that can provide information of hidden lesion morphology, and improve PCI results.

Case Presentation: Female, age 61 with a PMH of CAD, follicular lymphoma, hepatitis C, HLD, prior MI, and PAD. She presented to the hospital with the complaint of bilateral leg pain with walking that starts in her buttocks and radiates down. Peripheral angiogram performed revealed sub-optimal blood flow through the iliac artery. An IVUS catheter advanced into the right iliac artery revealed severe calcification and narrowing of the blood vessel, confirming the reason for patient symptoms. After diagnosis of severe stenosis of the right iliac artery with IVUS, a covered stent was advanced through the right common iliac artery and successfully deployed which showed excellent results with no signs of dissection, perforation, or distal embolization. Severe stenosis with severe calcification of the right iliac arteries was treated with excellent results. The patient was discharged from hospital for clinic follow-up.

Conclusion: Although the routine angiography does not utilize IVUS, our case demonstrates that the implemented usage of the IVUS provides better detection of calcification disease that at times is undetectable by angiography. Usage of IVUS provides a more accurate diagnosis with the angiography, allowing for better treatment options. Our case study demonstrates that more implementation of the IVUS catheter can improve percutaneous intervention by significantly improving our ability to treat the disease.

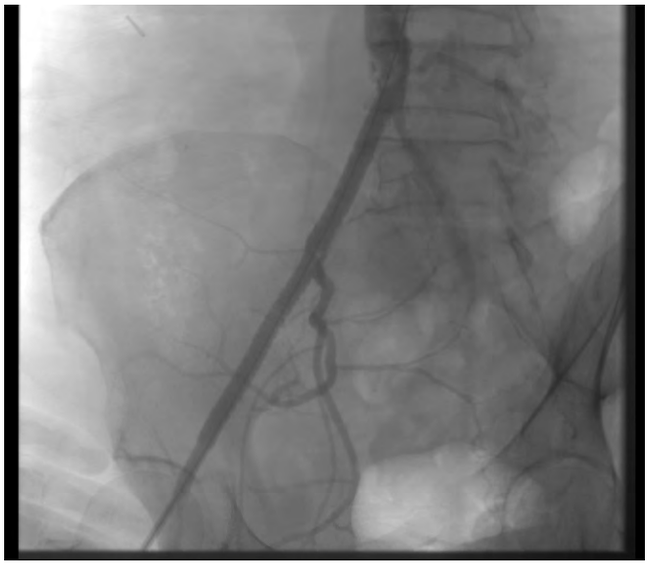


Figure 1: Pre-Procedure

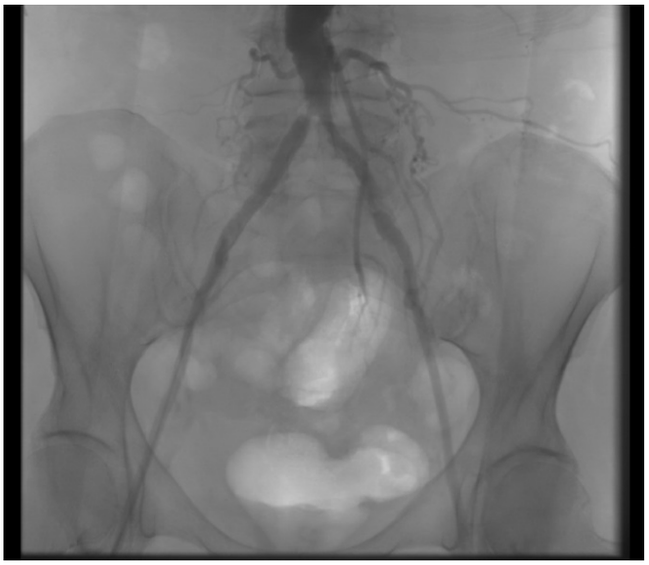


Figure 2: Post-Interventional Procedure

Abstract 16

Management of a Diabetic Foot Wound by Addressing Underlying Chronic Limb Ischemia: a Case Highlighting a Critically Overlooked Contributing Factor

Sachi Khemka, Vivie Tran, Bernardo Galvan, Katherine Holder, Mikal Ramon, Aliakbar Arvandi, M.D., Mohammad M. Ansari, M.D. Texas Tech University Health Sciences Center, Division of Cardiology, Department of Internal Medicine, Lubbock, TX, USA

Category: Podiatry/Wound Care

Background: Peripheral Artery Disease (PAD) affects over 200 million people worldwide and necessitates amputation in 3-4% of patients. Many procedures have been refined to mitigate the adverse events associated with PAD, but attention to early diagnosis of PAD in diabetic patients is frequently overlooked, rendering intervention in these patients less useful.

Methods: Male aged 77 with a history of PAD, CLI, CAD, DM type II, and HTN presented with right lower extremity Critical Limb Ischemia. He presented initially with a gangrenous right first and second toe that progressively worsened over the past two months and was attributed to the patient's diabetes.

Results: Treatment with antibiotic ointment and wound care provided no improvement. Peripheral angiogram was subsequently performed and revealed occlusion throughout the right lower limb prompting angioplasty. Atherectomy and stenting were performed to effectively revascularize the patient's lower extremity.

Conclusion: Intervention in CTO of the peripheral vasculature requires a specialized technique that is optimally effective when performed early and tailored to each individual patient. This becomes increasingly important in patients with PAD who have diabetes as a primary comorbidity. Diabetic foot wounds are customarily managed with wound care and antibiotics, but alternative intervention is necessary when a diabetic patient also has PAD. Lack of angiogram in a diabetic foot wound patient can lead to misclassification and delayed intervention to restore blood flow of an ischemic limb. In this case, correct diagnosis enabled treatment with a customized approach that led to favorable results and prevented further complications of PAD.

Gaps in Prevalence of Peripheral Arterial Disease Disparities: Education and Awareness among Minorities

Anthony Pham, Anthony Bruccoliere, Ardalan Naghian, Geoff Thomas, Cole Pollina, Kanishk Goel, Lewis Kelly, Steven Daley, Marina Iskandir, MD, Alkiabar Arvandi, MD, Mohammad M. Ansari, MD
TTUHSC PAD Center of Excellence, Division of Cardiology, Department of Internal Medicine

Category: Peripheral Arterial Disease

Background: PAD is one of the most underdiagnosed illnesses in the United States. Many affected individuals, especially minorities, are often unaware of its associated, developing risk factors leading to the progression of chronic limb threatening ischemia, amputation, diminished quality of life, and ultimately, death. Though literature has highlighted gaps in public knowledge of PAD, few have focused on explanations regarding disparities as to why this large discrepancy exists particularly among minority groups. Our study is to investigate the reasons and possible disparities behind this gap of awareness and education in PAD to create a data-driven understanding of the needs among minority populations.

Methods: A cross-sectional review of patients at the Texas Tech University PAD Center of Excellence diagnosed with PAD-CLTI was conducted. A survey questionnaire was performed evaluating patients' perception on their various determinants of care to determine possible barriers to healthcare access. Demographics and comorbidities including HTN, CAD, and DM were recorded and analyzed. This data was extracted from a larger group of surveyed patients.

Results: A total of 100 patient responses selected were recorded and analyzed; 55% were males and 45% were females. Additionally, 61% were non-Hispanics and 39% were Hispanics. Overall, comorbidities ranked highest among males with specific PAD risk factors (hypertension and diabetes) having higher prevalence among Hispanics. When asked which social determinants of health greatly impacted the patients' access to care, Hispanics listed language barriers as one of the major obstacles affecting their care and knowledge about PAD. Interestingly, Hispanic women reported an additional hurdle to access involving the lack of transportation to/from the clinic and healthcare providers.

Conclusion: As seen in our disparity study, gaps in the awareness and public knowledge of PAD may possibly be attributed to significant language barriers and transportation access that exist greatly among the Hispanic population. Increased awareness via community outreach and inclusion of language in major ethnic groups essential in bridging this discrepancy.

Abstract 18

Utilization of A Covered Stent In The Treatment Of Long Calcified Chronic Total Occlusion Of The Superficial Femoral Artery

Vivie Tran, Sachi Khemka, Mitch Devolder, Seena Firouzbakht, Marina Iskandir, M.D., Aliakbar Arvandi, M.D., Mohammad M. Ansari, M.D.Texas Tech University Health Sciences Center PAD Center of Excellence, Division of Cardiology, Department of Internal Medicine, Lubbock, TX, USA

Category: Critical Limb Ischemia

Introduction: Chronic total occlusions (CTO), or occlusion of an artery for at least 3 months, is characterized by symptoms of lower extremity pain or numbness, open ulcers, and dry gangrene. If left untreated, CTO can eventually lead to amputation of the affected limb. While typically found in stable chronic patients, CTO has a poor prognosis, with higher morbidity and mortality rates and adverse limb events. Patients who present with a completely occluded calcified CTO typically undergo bypass surgery. However, for those of older age, who have comorbidities, or are unfit for anesthesia, surgery is not a viable option, as these patients are high-risk for surgery. A recent study showed successful outcomes in patients with long and complex superficial femoral artery (SFA) lesions treated with a long Viabahn covered stent. We present a case of long lesion calcified CTO of SFA treated successfully with a covered Viabahn stent.

Case Presentation: Female aged 85, with a history of polycythemia vera and smoking history, presented with worsening pain and dry gangrene of the first two right toes and severe pain in the leg. Peripheral angiogram showed SFA occlusion, with 90% proximal stenosis and chronic occlusion to the distal left SFA with severe calcification. After reviewing the angiographic images, a decision was made to proceed with percutaneous vascular intervention of the left lower extremity. After successfully crossing the CTO, balloon angioplasty and atherectomy were performed. After multiple balloon angioplasties, the vessel was still lacking adequate flow due to multiple subintimal tears and microperforations in between the severe calcification. We then proceeded with a Viabahn covered stent placement, which successfully sealed all microperforations and intimal dissections, guaranteeing steady flow. The patient was discharged home and reported doing well with no pain or symptoms on follow-up.

Conclusion: Our case is a glaring example of the need for covered stents (Viabahn) to serve as an endoluminal bypass in the treatment of specifically long lesion long calcified CTO of SFA. Covered stent placement is still a viable option for high-surgical-risk patients with severe disease that is not amenable to plain balloon angioplasty or regular stenting.

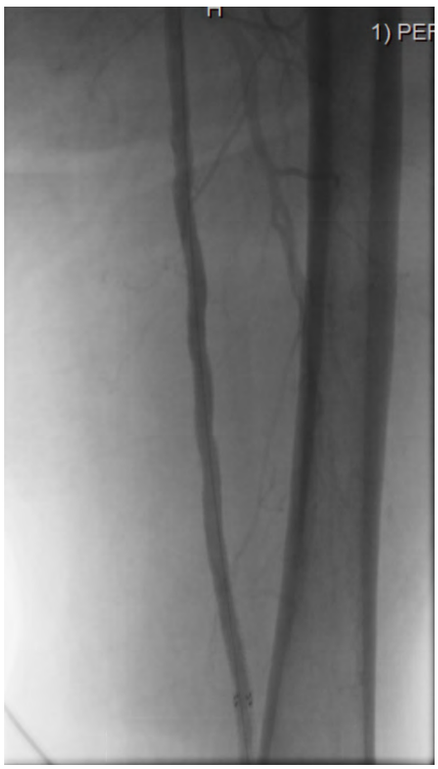


Figure 1: Angiogram of chronic total occlusion of superficial femoral artery

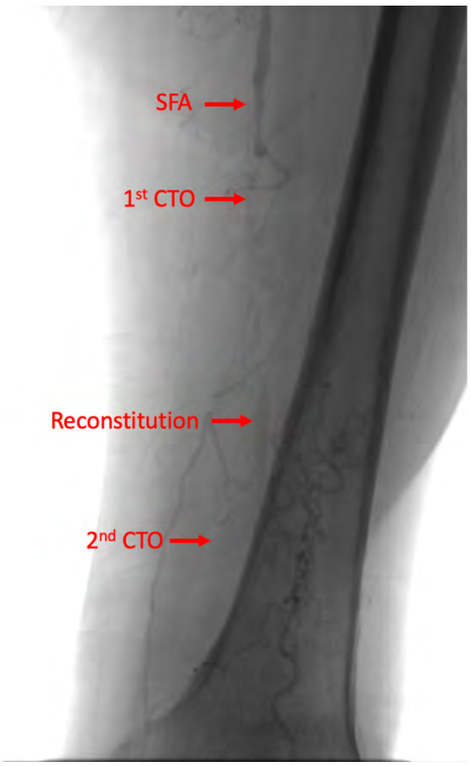


Figure 2: Angiogram of post-stent placement

Utilization of Intravenous Ultrasound in Treatment of May Thurner Syndrome

Alyson Willis, Alistair Disraeli, Subash Swarna, Marina Iskandir, MD, Aliakbar Arvandi, MD, Mohammad Ansari, MD Texas Tech University Health Science Center PAD Center of Excellence, Division of Cardiology, Department of Internal Medicine, Lubbock, TX, USA

Category: Venous Disease

Introduction: Chronic pulsatile compression of iliac vein by the right iliac artery is known to induce focal intimal proliferation and compression of the vein. This is a condition known as May Thurner syndrome. This results in impaired venous return and thrombosis. While surgery requires extensive dissection and morbidity, percutaneous intravenous stenting is the preferred. However, there seems to be an issue with appropriate diagnosis and stenting of the lesion/stenosis. This seems to originate from the difficulty in recognizing stenosis, which could be due to lack of a proper angiogram and non-utilization of intravascular ultrasound (IVUS). There are also multiple reports of inaccurate stenting or missing the stenosis region due to the same reason. We present a case describing the very same issue and how we correct it.

Case presentation: Female aged 65, with past medical history of DVT, HTN, DM, OSA, GERD, morbid obesity (BMI of 41), and prior known history of May Thurner syndrome. S/P common femoral and iliac vein stenting, presents with continued lower extremity swelling of left leg; now also experiences discomfort in the back and groin area. Patient reported a prior procedure at a different institution that went well but swelling did not improve. After the procedure, the patient started having pain as well. Routine compressions stockings did not help. The decision was reached to perform a venogram on the patient, which showed a disruption of flow and an improperly stented iliac vein. A Volcano Vision 0.035” IVUS catheter was advanced through the left iliac system and IVUS images were obtained which confirmed the inaccuracy of the prior stent placement. This confirmed the suspicion that the stenotic area that was on the ostium of the iliac vein was missed. We proceeded with initially performing a balloon dilatation followed by 16 x 160 mm Venovo stent placement. Post dilatation by 16 x 60 mm Atlas balloon was preformed. Repeat IVUS and angiography showed complete resolution of the issue. The patient tolerated the procedure well and was discharged with clinic follow up.

Conclusion: Our case clearly demonstrates the two main issues with stenting of the May Thurner Syndrome. The procedure is a viable option for patients with this disease. However, one must utilize IVUS for correct diagnosis and identification of the stenotic region. In order to effectively cover the stenotic region, starting prior to the stenosis and ending after the stenosis followed by adequate balloon dilation is required. Without IVUS, it is likely that the stent will be placed improperly. If any of the steps are missed, this procedure might result in suboptimal results causing more harm to the patient than helped, which our case describes well. IVUS catheter should be mandatory for such procedures, along with utilization of correct stenting technique.

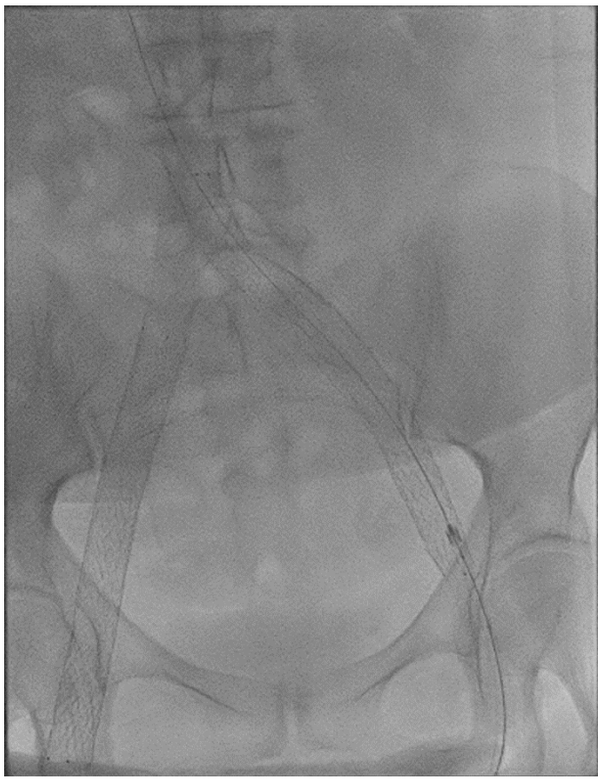


Figure 1: Visualization of left iliac stent and the utilization of balloon where the balloon dilation shows the missing stenotic region.

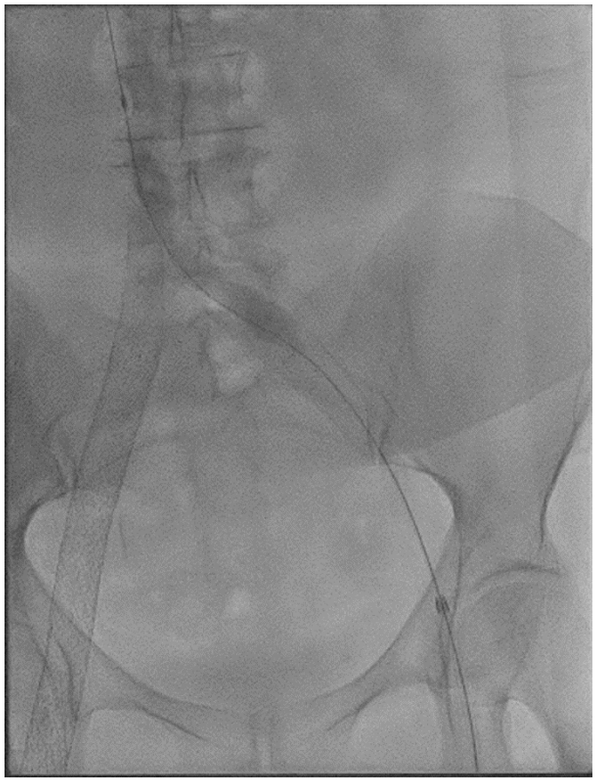


Figure 2: Visualization of corrective stent placement starting prior to the stenotic area from the edge of distal IVC correcting the previous problem.

JAVELIN

Journal of Arterial
Venous And Lymphatic
Interventions

Lafayette, LA
Hipgroup.org