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THE OFFICIAL PUBLICATION OF THE CRITICAL LIMB ISCHEMIA GLOBAL SOCIETY

CLI Global Society at the AMPutation Prevention Symposium 2017

Leadership and members of the CLI Global Society were present at the 7th Annual AMPutation Prevention Symposium held August 9-12, 2017 in Chicago, Illinois, attended by over 800 attendees from 25 countries and 46 states.

The first annual *Alan T. Hirsch Memorial Keynote Address* "A Call to Action – The CLI Global Society" was presented by Dr. Barry T. Katzen, MD, FACC, FACR, FSIR. Dr. Katzen is the Founder and Chief Medical Executive of Miami Cardiac and Vascular Institute, a Founding Member and President of the Critical Limb Ischemia (CLI) Global Society and a pioneer in CLI therapy.

Dr. Katzen recognized the vast body of work of Dr. Hirsch who passed away earlier this year. "Dr. Hirsch was a consummate clinician who provided data driven, evidence-based care long before it was fashionable. He joined as a Founding Board member of the fledging CLI Global Society with his usual deliberation but ultimate incredible enthusiasm! His contribution to science, and specifically CLI, will be sorely missed."

Dr. Katzen called attention to the first angioplasty procedure, performed in 1963 by Charles Dotter, MD, "the Father of Interventional Radiology," which was performed on a patient with CLI with a non-healing ulcer of her foot. "Endovascular therapy today represents a field that includes multiple disciplines working collaboratively to advance this important area of less invasive therapy. The field has matured over the past decades bringing rapid technological advancements, increasing cost pressure on the healthcare system along with a need for improved clinical science, data and proof of benefit. The treatment of CLI is much more than endovascular therapy or surgery revascularization."

The CLI Global Society was formed in 2016 to address the unmet need of CLI. In the United States, lower extremity PAD manifests as CLI in nearly 1 million Medicare patients per year, with an estimated annual cost of over 3 billion dollars.[1] One in 190 Americans (1.6 million) living with loss of a limb. Unchecked, this number may more than double by 2050 to 3.6 million.[2]

The CLI Global Society's mission is to improve quality of life by preventing amputations and death due to critical limb ischemia. Dr. Katzen underscored that mission by addressing this unmet need must start with a definition of CLI. CLI was first formally defined in 1982 by the Working Party of the International Vascular Symposium as a condition in patients without diabetes with chronic ischemia as the major threat to a limb with ankle pressure <40 mm Hg in patients with rest pain and <60 mm HG in those with tissue necrosis.

The Rutherford classification was first developed in 1986 and revised in 1997 with CLI falling under Rutherford categories 4-6. The Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) was published in 2008 and defined CLI as all patients with chronic ischemic rest pain, ulcers or gangrene attributed to objectively proven arterial occlusion disease.[3] The AHA/ACC adopted the TASC II definition in 2016.[4] In 2014, the Society of Vascular Surgery (SVS) defined CLI as an objective classification of the threatened limb based on the degree of ischemia, wound extent, gangrene and infection. SVS developed the SVS Lower Extremity Threatened Limb Classification System based on grading of these 3 factors (The WIfi Classification).[5]

So why is CLI a problem? The CLI Global Society recognizes the following contributing factors to the challenge of CLI:

1. Lack of consensus on definition;
2. Lack of awareness within healthcare community and general public;
3. CLI morbidity and mortality are akin to the most aggressive cancer diagnoses;
4. Limited research;
5. Lack of consensus on best methods to prevent, diagnose, treat and rehabilitate;
6. Limited number of CLI specialists;
7. No diagnosis code for CLI;

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Dr. Barry T Katzen delivers the ignaugural Alan T. Hirsch Keynote Address at the AMPutation Prevention Symposium 2017 in Chicago, IL.

Flaws in the Objective Diagnosis of Critical Limb Ischemia

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Critical limb ischemia (CLI), the most advanced form of peripheral artery disease (PAD), is defined by all societal guidelines and consensus statements as the presence of tissue loss or gangrene with documented evidence of hypoperfusion.[1,2] Hypoperfusion has been traditionally assessed using the ankle brachial index (ABI) or ankle systolic pressure; however, other tests such as toe pressure or toe brachial index (TBI), $TcPO_2$, and skin perfusion pressure have also been used, though not widely. In 2014, in a single center study, we showed for the first time that approximately 30% of patients with documented CLI have near normal, normal, or non-compressible ABI.[3] Subsequently, using the data from IN.PACT DEEP Trial, we validated and extended our previous findings (Figure 1), showing that approximately one-third of patients with tibial disease had normal or non-compressible ABI.[4] Since then, others have reproduced, validated, and extended our previous work.[5]

While the exact reasons for normal or non-compressible ABI in patients with CLI is unknown, a few mechanisms have been postulated: (1) A significant proportion of patients with CLI are diabetic or have end-stage renal disease (ESRD); hence, because of heavy medial calcinosis, these arteries are partially or fully non-compressible, resulting in elevated or non-interpretable pressures. (2) There is extensive collateral flow below the knee; therefore, while the main tibial arteries are occluded, the collateral flow provides adequate pressure. (3) A significant portion of patients with CLI have isolated below knee disease; it is possible that ABI reflects pressure to proximal and mid ankle but provides

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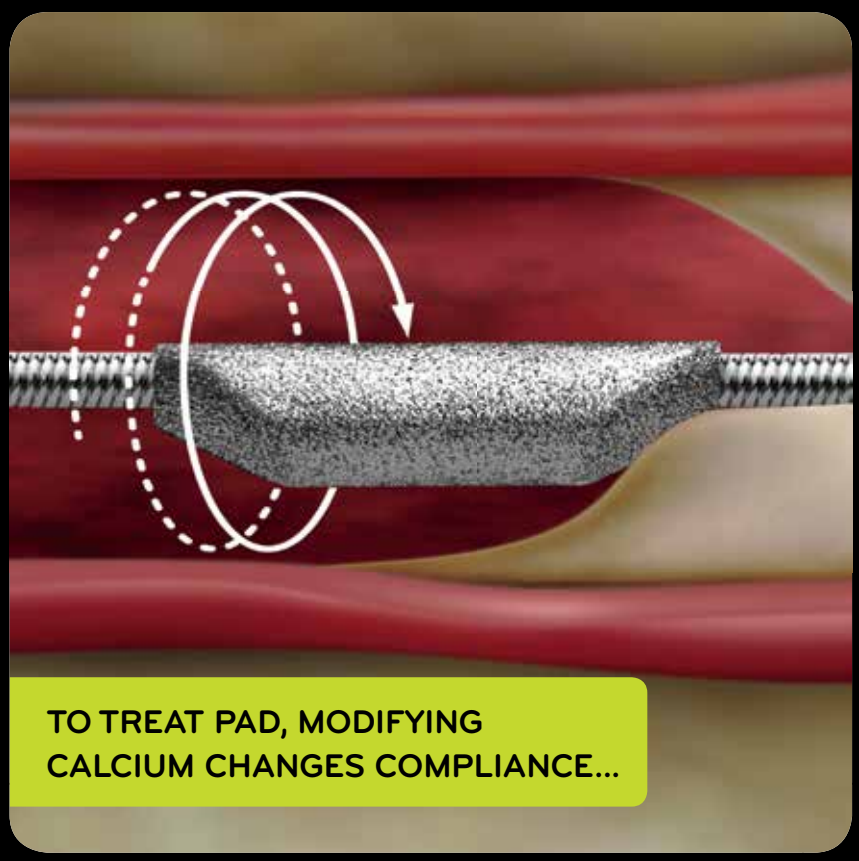

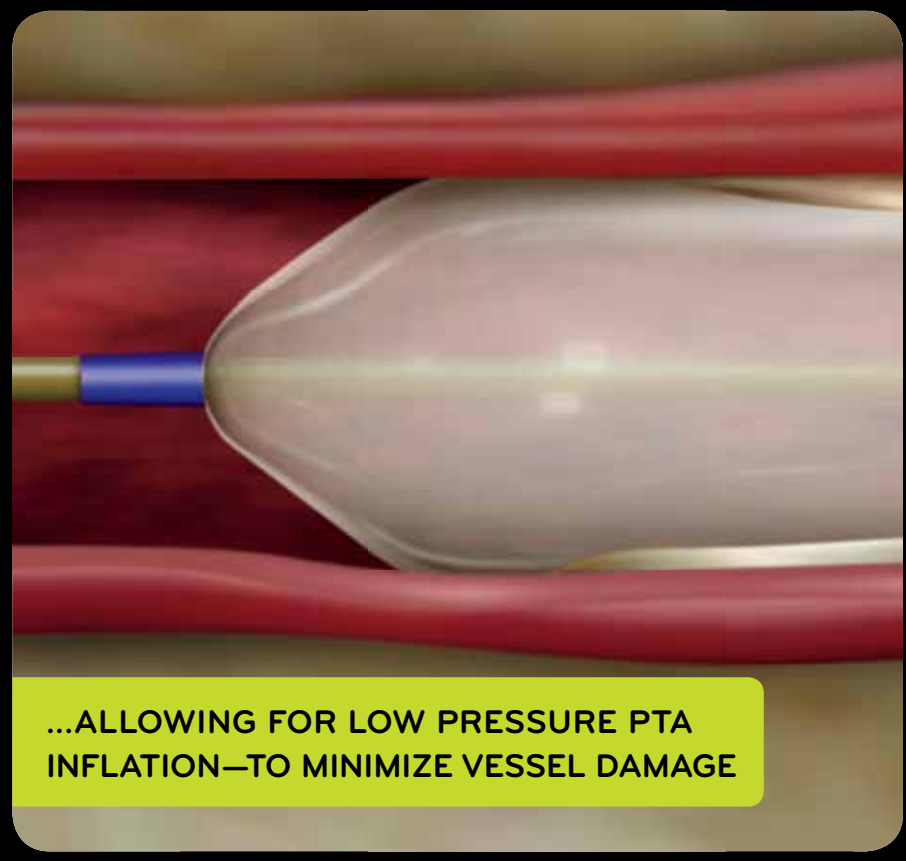

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Case Study: An Endovascular First Approach to CLI

Sabeen Dhand, MD
Presbyterian Intercommunity Hospital, Whittier, CA

Dr. Sabeen Dhand

An 80-year-old female patient presented to our hospital with gangrene of the first great toe of the right foot (Figure 1). She was being followed by her primary physician for multiple medical problems, including mild pain in the right calf and foot when walking, relieved at rest. The pain worsened during the previous several months, progressing to rest pain and erythema of the foot, and finally, development of gangrene involving the great toe. Her other relevant medical problems included prior myocardial infarction, atrial fibrillation, diabetes mellitus (Type 2), hypertension, hyperlipidemia, and chronic kidney disease (Stage IV). Although the patient was taking warfarin and aspirin, she was never started on pentoxifylline or cilostazol for management of her initial symptoms.

Given her renal insufficiency (Cr. 1.6, GFR 27), arterial duplex imaging was obtained of both lower extremities, which demonstrated occlusion of the femoropoliteal artery with trace reconstitution of the anterior tibial artery (Figure 2). No flow could be identified in the remaining infra-popliteal arteries. Based on spectral waveforms, no inflow disease was suspected. Additionally, no embolic disease was suspected clinically.

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Figure 1. Photograph of the patient's right foot demonstrating well-demarcated dry gangrene of the great toe. The patient also suffers from white discoloration of the forefoot, worst in the proximal first digit. All toes show nail and skin changes, as well as hair loss. No additional ulcers are identified. There is a mottled appearance of the foot, which is cool to touch. No infra-inguinal pulses are palpable on physical exam.

Disclosure: Dr. Dhand reports that he has been a consultant for Abbott.

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Key Findings of the Registry of First-Line Treatments in Patients with Critical Limb Ischemia (CRITISCH)

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Critical limb ischemia (CLI) represents the most severe form of lower extremity atherosclerosis and is associated with excessive cardiovascular morbidity and mortality and increased rates of limb loss. The severity of the disease and the intensive vascular care needed pose a significant socioeconomic burden for all western societies. Although claudicants still represent the majority of peripheral arterial disease (PAD) patients, it remains interesting that the costs for CLI healthcare accounted for 56% of all PAD reimbursement costs in Germany.[1] In a retrospective Medicare study, the mean cost of inpatient care in the year before major PAD-related amputation amounted to $22,405.[2]

Despite some evidence that an intensive medical therapy and aggressive risk factor modification might change the natural history of CLI, revascularization of the affected limb still remains the cornerstone of CLI treatment.[3,4] Unfortunately, many CLI patients will undergo major amputation as primary therapy, while in Germany, a retrospective insurance registry revealed that 44% of patients who received a primary amputation had not received at least a diagnostic angiography in the year prior to the procedure.[1]

Surgery, especially in cases of autogenous vein conduits, is associated with encouraging primary patency and increased amputation-free survival rates, despite the prolonged recovery and rather invasive nature of the procedure.[5] Endovascular revascularization offers an alternative minimally-invasive approach to surgery. The continuous development of the endovascular field over the past decades led to a paradigm shift in the treatment of peripheral atherosclerosis, and endovascular therapy replaced surgery as the first-line treatment strategy. However, the impact of many novel endovascular modalities in the treatment of CLI remains unclear, since in many recent trials, the majority of the enrolled patients were claudicants.[6]

Unfortunately, the Bypass Versus Angioplasty for Severe Ischemia of the Leg (BASIL) trial,[7] which compared the outcomes of plain angioplasty and open repair in CLI patients, still remains the only published randomized controlled trial. Nonetheless, there is a paucity of comparative data between the new technologies and bypass surgery.

Notwithstanding the scarce level 1 evidence about the different treatment options, previous studies did not include consecutive patients and did not evaluate endovascular revascularization or hybrid procedures as possible treatment options.[7,8] For this reason, we conducted a prospective, multicenter registry to examine the performance of all first-line treatment strategies.

The First-Line Treatments in Patients with Critical Limb Ischemia (CRITISCH) study is a prospective, interdisciplinary, multicenter registry evaluating the current practice of all available treatment strategies in 1200 unselected CLI patients treated in 27 vascular centers in Germany.[9] The single inclusion criterion was the presence of new onset CLI. CLI was defined as an ankle-brachial index <0.40 or ischemic rest pain, or both, with or without tissue loss in the presence of PAD (Rutherford classes 4–6). In cases with a non-calculable index, ankle pressure or transcutaneous oxygen pressure was measured. Only one limb per patient was included. Patients with acute limb ischemia, isolated aortic or iliac interventions, vascular trauma, and known clotting disorders or non-atherosclerotic occlusive disease were excluded from the registry. The study was validated via an external audit at participating centers. The recruitment started in January 2013 and was completed in September 2014. Follow-up was planned at 6, 12, and 24 months after the patient's enrollment. The applied treatment was left at the discretion of the treating physician following the principle of "best medical practice" and there was no restriction concerning the selected treatment option. The various treatment options were categorized into five groups. Group I included patients undergoing endovascular treatment. Group II consisted of patients treated with bypass surgery, and group III included patients who were treated by common or deep femoral artery surgical revascularization, with or without concomitant inflow or outflow endovascular intervention. Group IV included patients treated conservatively (i.e., prostaglandin intravenous therapy, sympathicolysis) and group V was comprised of patients who underwent major amputation without any revascularization attempt. The primary endpoint of the CRITISCH registry was amputation-free survival (AFS). Secondary endpoints were overall survival (OS), amputation-free time (AF), and freedom of any re-intervention or above ankle amputation of the index limb (RAO).

Endovascular therapy was the preferred treatment option in 53.5%, while bypass surgery, common/deep femoral artery open repair, conservative treatment, and primary major amputation were selected in 23.7%, 10.5%, 9.8%, and 2.5%, respectively…The main risk factors for amputation or death during the hospital stay were coronary artery disease, acute coronary syndrome the last 6 months, end stage renal disease stages 3 and 4 of CKD, and bypass surgery.

Endovascular therapy was the preferred treatment option in 642 patients (53.5%), while bypass surgery (group II), common/deep femoral artery open repair (group III), conservative treatment (group IV), and primary major amputation (group V) were selected in 284 (23.7%), 126 (10.5%), 118 (9.8%), and 30 patients (2.5%), respectively. Because of the lack of randomization, a multivariate multinomial logistic regression model provided estimates of the Odds Ratios (OR) for the selection criteria between bypass surgery and endovascular treatment depending on five binary covariates: chronic kidney disease (CKD), TASC II class C/D, diabetes, a previous peripheral vascular intervention (PVI) at the index leg, and the absence of run-off vessels. Bypass was preferred over endovascular revascularization in patients with normal renal function (OR: 2.00, 95% CI: 1.47–2.73), patients presenting with TASC II C/D lesions (OR: 8.99, 95% CI: 5.44–14.87), after previous PVI (OR: 1.40, 95% CI: 1.03–1.89), or with at least one patent tibial vessel (OR: 4.18, 95% CI: 2.73–6.40).

The main risk factors for amputation or death during the hospital stay were coronary artery disease (odds ratio, OR: 2.96), acute coronary syndrome the last 6 months (OR: 3.67), end stage renal disease (OR: 3.31), stages 3 and 4 of CKD (OR: 6.34), and bypass surgery (OR: 3.34).

In the framework of a preplanned interim analysis, we used a prospective confirmatory analysis to compare amputation-free survival using the endovascular approach to treatment using bypass surgery (Hazard ratio [HR] of Wald test <1.33). Our hypothesis was that endovascular therapy would be shown to be non-inferior to conventional bypass. The 12-month amputation-free survival after endovascular revascularization and bypass surgery was 75% and 72%, respectively. The non-inferiority of endovascular therapy versus bypass surgery was confirmed (HR: 0.91). The Wald test (upper bound of 1-sided (1-0.0058) confidence interval [CI]: 1.29; P=.003) confirmed a statistically significant non-inferiority of endovascular therapy compared to bypass surgery. An effect of the selected treatment strategy on time until death (HR: 1.14; 95% CI: 0.80 to 1.63; P=.453), major amputation (HR: 0.86; 95% CI: 0.56 to 1.30; P=.463), and re-intervention and/or above-ankle amputation (HR: 0.89; 95% CI: 0.70 to 1.14; P=.348) was not observed.

In regard to secondary prevention, univariate and multivariable statistical

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The Effectiveness of a Team Approach in Treating Critical Limb Ischemia

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Dr. Tursi graduated from Temple University Medical School, School of Podiatric Medicine and completed his surgical residency at Atlanta Hospital and Regional Diabetes Center in Atlanta, Georgia. He has extensive experience in complex foot and ankle traumatic injuries and the management of diabetic wounds and foot care. He is board certified and is a fellow in American College of Foot and Ankle Surgeons. He is the Chief of Foot and Ankle Surgery at Our Lady of Lourdes Medical Center and is part of the podiatric staff at Virtua and Inspira Health Systems.

Dr. Tursi is Hyperbaric Medicine trained and also earned the position of Assistant Clinical Professor at the University of Medicine and Dentistry of New Jersey and the University of Pennsylvania/Presbyterian Podiatric Residency Training Program. Dr. Tursi has served as a foot and ankle consultant to the Philadelphia Flyers for the last 25 years.

Dr. Walker is an Interventional Cardiologist and Founder, President, and Medical Director of the Cardiovascular Institute of the South in Houma, Louisiana. He is a Clinical Professor of Medicine at Tulane University School of Medicine, Louisiana State University School of Medicine in New Orleans, Louisiana.

Dr. Tursi and Dr. Walker share a case study that demonstrates the effectiveness of a team approach to treating critical limb ischemia (CLI).

Frank J Tursi, DPM, FACFAS

Craig Walker, MD

Peripheral arterial disease (PAD) is a highly prevalent, substantially under-diagnosed global disease that carries a significant risk of morbidity and mortality.[1] As of 2009, PAD was estimated to afflict 8 to 12 million people, but more recent numbers approach 18 million in the United States.[2] Mortality rates associated with this devastating disease rival or exceed those associated with most lethal cancers and coronary conditions, including breast cancer, colon cancer, and congestive heart failure.[3,4] Fowkes et al noted in Lancet that PAD afflicts > 202 million people worldwide, and as such, PAD has been stated to be both more prevalent and more lethal than HIV.[5] In regard to prognosis, one year following the diagnosis of PAD/CLI, 25% of these patients will be dead, while 30% will have undergone an amputation. At year 5, over 60% of those diagnosed with CLI will be dead. Additionally, within 5 years of the diagnosis of PAD/CLI, 20% will have sustained a non-fatal myocardial infarction (MI) or cerebrovascular accident (CVA), while 30% will have a fatal MI or CVA.[6]

Unfortunately, many patients presenting with PAD are not diagnosed until they exhibit severe ischemic symptomatology or advanced non-healing wounds of the lower extremities. During initial examination, it is vital that the PAD risk factors of each patient are identified. These include diabetics over the age of 50, diabetics under the age of 50 with comorbidities of hypertension or hyperlipidemia, renal disease patients, past or current smokers, patients with a past history of cardiovascular disease such as MI or CVA, patients over the age of 65, and all chronic wound patients.[7] Complicating the diagnosis of this devastating disease is the fact that 50–60% of PAD patients present without symptomatology [8] As we are aware, diabetic patients with severe neuropathy can undergo pedal amputations without the use of any anesthesia. With this profoundly impaired sense, is it realistic for us to believe that they will be able to recognize the symptoms of PAD, such as claudication?

The PARTNERS Study was conducted from June 1999 to October 1999 and reported in JAMA in 2001.[1] This study accumulated data from 27 sites, located within 25 cities, and looked at nearly 7,000 patients of 350 primary care physicians. Patients were identified as being at risk for having PAD, and a detailed history and ABI vascular test was performed. Those patents with an ABI of 0.9 or less, or those with a history of recent or prior interventions, were considered to be positive for PAD. Peripheral arterial disease was found in 29% of this group, with only 11% having any symptomatology. Another concerning finding of the PARTNERS study was that while nearly 83% of patients with PAD were aware that they had PAD, less than 50% of their own treating primary care physicians were aware that they did indeed have PAD.

Economic costs associated with PAD are astronomical, with estimates of $58 billion in annual hospital costs and associated costs of all vascular events and interventions in 2004. Annual outpatient medication costs and in-patient interventions were estimated to exceed $290 billion in 2010.[9,10] To illustrate the enormous benefits of limb salvage, not only must we consider the untoward psychological, personal, and financial effects of primary amputation, but the unfortunate fact that, typically, a patient undergoing a below-the-knee amputation (BKA) loses their contralateral limb in 2 years and dies within 5 years of this amputation. From an economic standpoint, the rehabilitative costs following major primary amputation are $500,000–$600,000 during the first 5 years, not including the costs of home renovations such as ramps, shower and bath grab bars, etc.[11] The following case history is an illustration of all the aforementioned data and statements.

A 75-year-old Caucasian male presented to my podiatry practice as an out-of-state referral from a revascularization specialist. The patient had presented initially with severe bilateral ischemic peripheral arterial disease and severely calcified vessel disease below the knee. His primary complaint was a painful, non-healing, gangrenous second digit of the left foot. The patient was a nonsmoker, lived an active lifestyle with no history of diabetes mellitus, cardiac, or renal dysfunction.

Prior to presentation to the referring physician and following the development of gangrenous changes of his left second toe, he had undergone an unsuccessful endovascular revascularization procedure and was referred to the referring revascularization specialist. Unfortunately, at that time, the patient sought a second opinion at a large academic hospital. Following an extensive work-up and additional unsuccessful endovascular work at that center, he was advised that his best option would be below-the-knee (BTK) amputation. In fact, he was given

psychological counseling to prepare for BTK amputation. At this point, he decided to travel to the referring revascularization specialist for a third opinion.

It was there that he was diagnosed with severe PAD and extensive infra-popliteal calcified vessel disease. The patient underwent CO_2 angiography and drug eluting stent placement in the peroneal artery followed by crossing of a long calcified anterior tibial occlusion and treatment of the dorsalis pedis with percutaneous transluminal angioplasty.

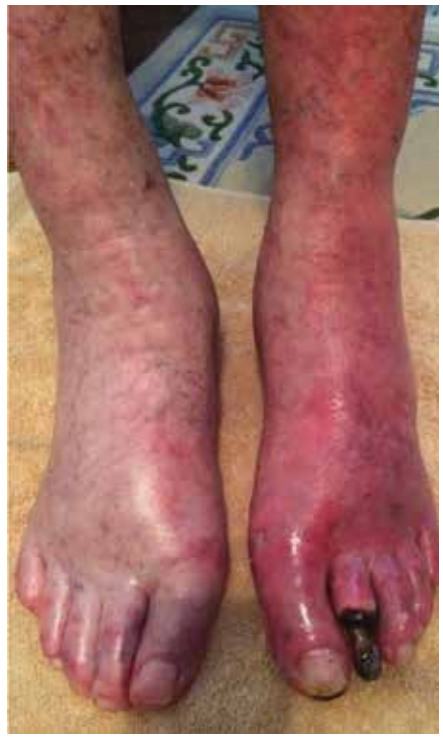

Figure 1. Initial presentation to podiatrist.

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Disclosure: Dr. Tursi reports that he is a Speaker/Consultant for Kerecis. Dr. Walker has no relevant disclosures.

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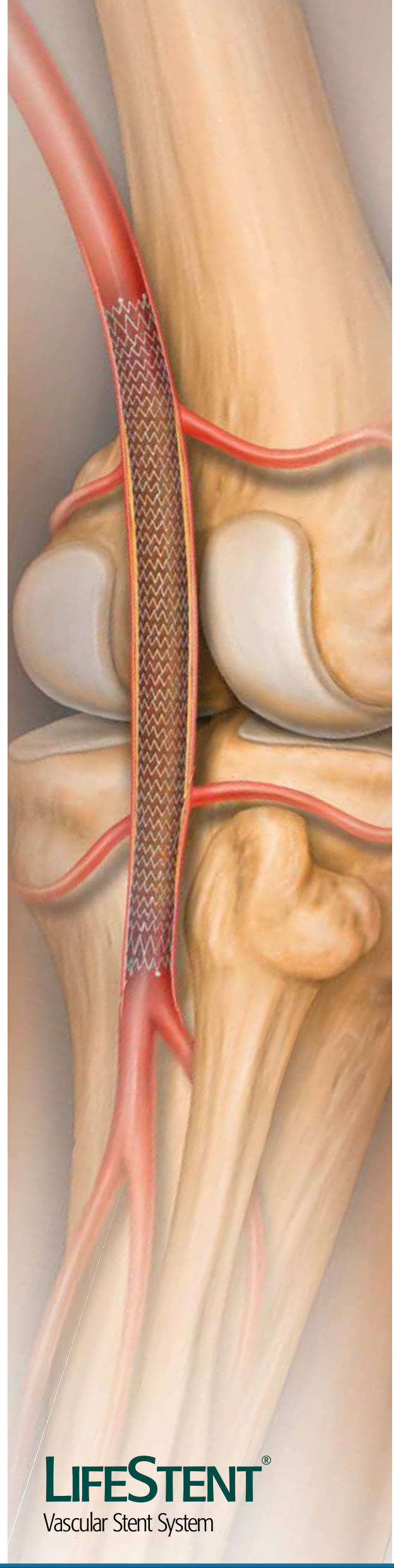

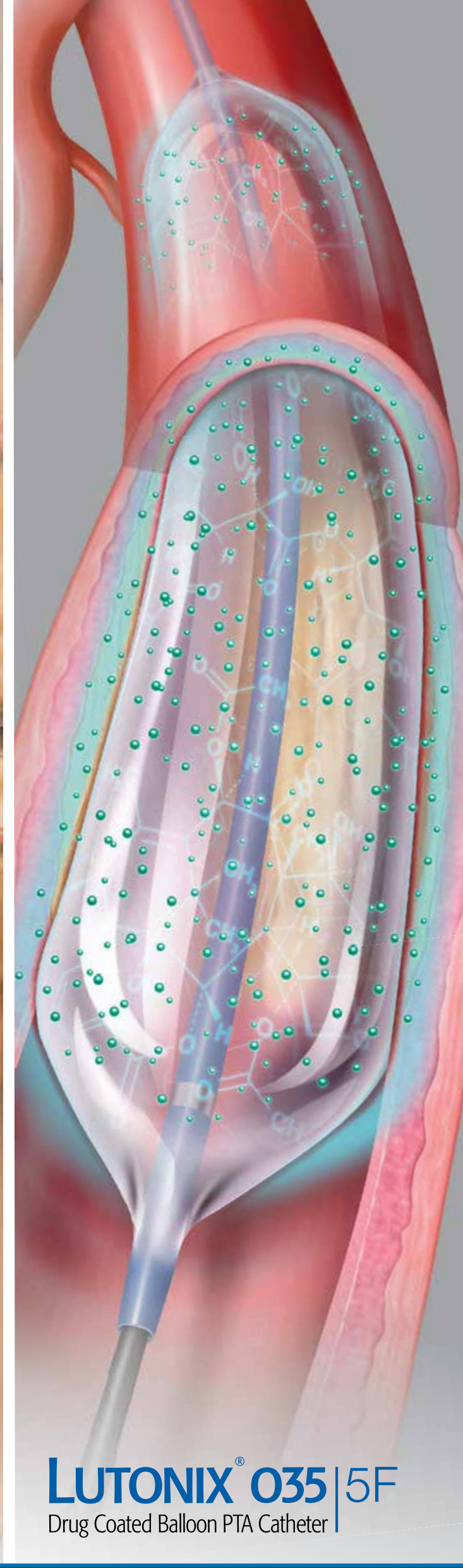

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little information regarding distal ankle and the foot perfusion. Because of these limitations, we have advocated the use of toe pressure or TBI for diagnostic purposes in patients with CLI.[6] While TBI and toe pressure have their own limitations, including the inability to measure toe pressures in patients with distal foot ulcers involving the great toe, they do offer information regarding perfusion in the distal foot. This is important because the majority of patients with CLI have distal foot disease. Unfortunately, the current guidelines only recommend TBI assessment in patients with non-compressible ABI.

Other modalities, such as $TcPO_2$ and skin perfusion pressure, are also currently available; however, these have many limitations that have been described before.[7] Importantly, these tools are not widely available and many are not currently reimbursed. Because of this, many clinicians and vascular experts have ignored the required perfusion assessment for CLI and have directly moved to cine angiography in patients with tissue loss or gangrene. However, this approach has not been widely accepted and most primary care physicians, podiatrists, and other allied health professionals still rely on ABI to assess perfusion in patients with tissue loss and gangrene. Because of the limitations of ABI, and since many of the tools above are only available in major academic centers or specialized vascular centers, patients with CLI frequently do not receive appropriate care, which has sometimes resulted in significant delay in revascularization or even amputation.

There are other diagnostic tools, such as fluorescence indocyanide green angiography, near infrared fluorescence imaging, or subcutaneous continuous oxygen monitoring, that are currently being evaluated.[8,9] However, they have not been widely accepted and data regarding their diagnostic sensitivity and specificity are sparse. Another tool that has been frequently advocated, especially for patients with non-compressible vessels, has been pulse volume recording (PVR). However, we recently evaluated the accuracy of ABI, TBI, and PVR in predicting tibial artery patency in patients with CLI and non-compressible ABI.[10] Among those with non-compressible ABI, the vessel was either occluded or severely diseased over 80% of the time (Figure 2). Unfortunately, PVR was also a weak predictor of vessel patency and over 50% of patients with occluded or severely stenotic tibial artery had normal PVR. A TBI < 0.70 was the most accurate in identifying tibial occlusion or stenosis in patients with non-compressible ABI.

GIVEN THE CHALLENGES DESCRIBED, WHAT IS THE BEST APPROACH TO PATIENTS WITH CLI?

We believe that all patients with suspected CLI should undergo an ABI and TBI assessment. ABI is typically reported as the higher of the anterior or posterior tibial artery, regardless of wound location or the affected angiosome. Therefore, the vascular specialist needs to personally interrogate the results to better understand the patency of anterior tibial and posterior tibial arteries and correlate this data with wound location (angiosome). Additionally, all patients should have toe pressure and TBI measured. If ABI is abnormal or TBI < 0.70, then cine angiography is indicated. Beyond diagnosis, obtaining perfusion data prior to revascularization will allow a better understanding of the quality of procedure and also serve as a way to monitor perfusion in follow-up, as there are high rates of restenosis in patients with CLI undergoing tibial angioplasty.[11] For primary care physicians, podiatrists, wound care specialists, and other allied health professionals with limited resources beyond ABI, prompt referral to a vascular specialist or center is likely the best option for patients with tissue loss or gangrene. A normal ABI in these patients should never be an indication of adequate perfusion and allow delay in revascularization.

Ultimately, clinical judgment and a multidisciplinary approach to patients and wounds should trump any tests. We have learned that time is limb and a rapid assessment and revascularization for CLI is paramount to amputation prevention. The current issue also highlights the need for the effort led by the CLI Global Society and other organizations to educate and improve the care of patients with this morbid condition. ■

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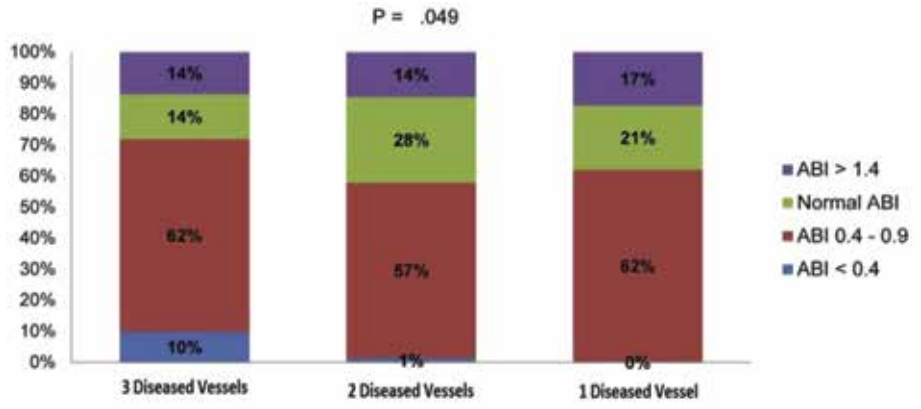

Figure 1. The association between tibial vessel patency and ABI. Among those with significant disease involving all 3 tibial vessels, 28% had normal or non-compressible ABI.
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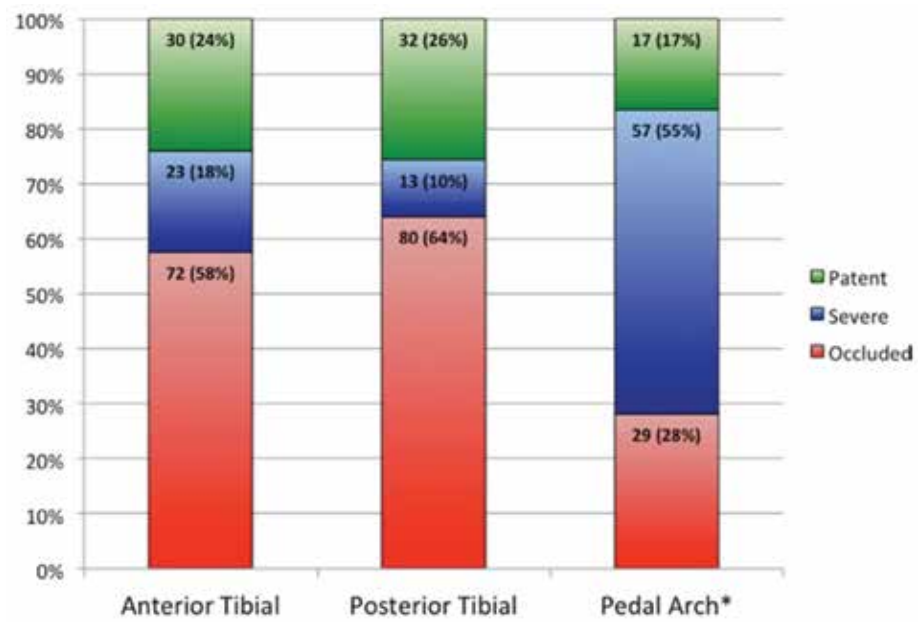

Figure 2. Prevalence of tibial artery patency in patients with non-compressible ABI. Among those with non-compressible anterior tibial (AT) ABI, nearly 80% had occluded or severely diseased AT. *[Adopted from Circ Cardiovasc Interv, 2017 May;10(5).]*

Beyond diagnosis, obtaining perfusion data prior to revascularization will allow a better understanding of the quality of procedure and also serve as a way to monitor perfusion in follow-up, as there are high rates of restenosis in patients with CLI undergoing tibial angioplasty.[11]

Disclosure: Dr. Shishehbor is a consultant and advisor to Abbott Vascular, Medtronics, Boston Scientifics, Terumo, and Philips. He is a member of the board of directors for CardioVascular Innovations (CVI), a not-for-profit 501(c) 3 organization.

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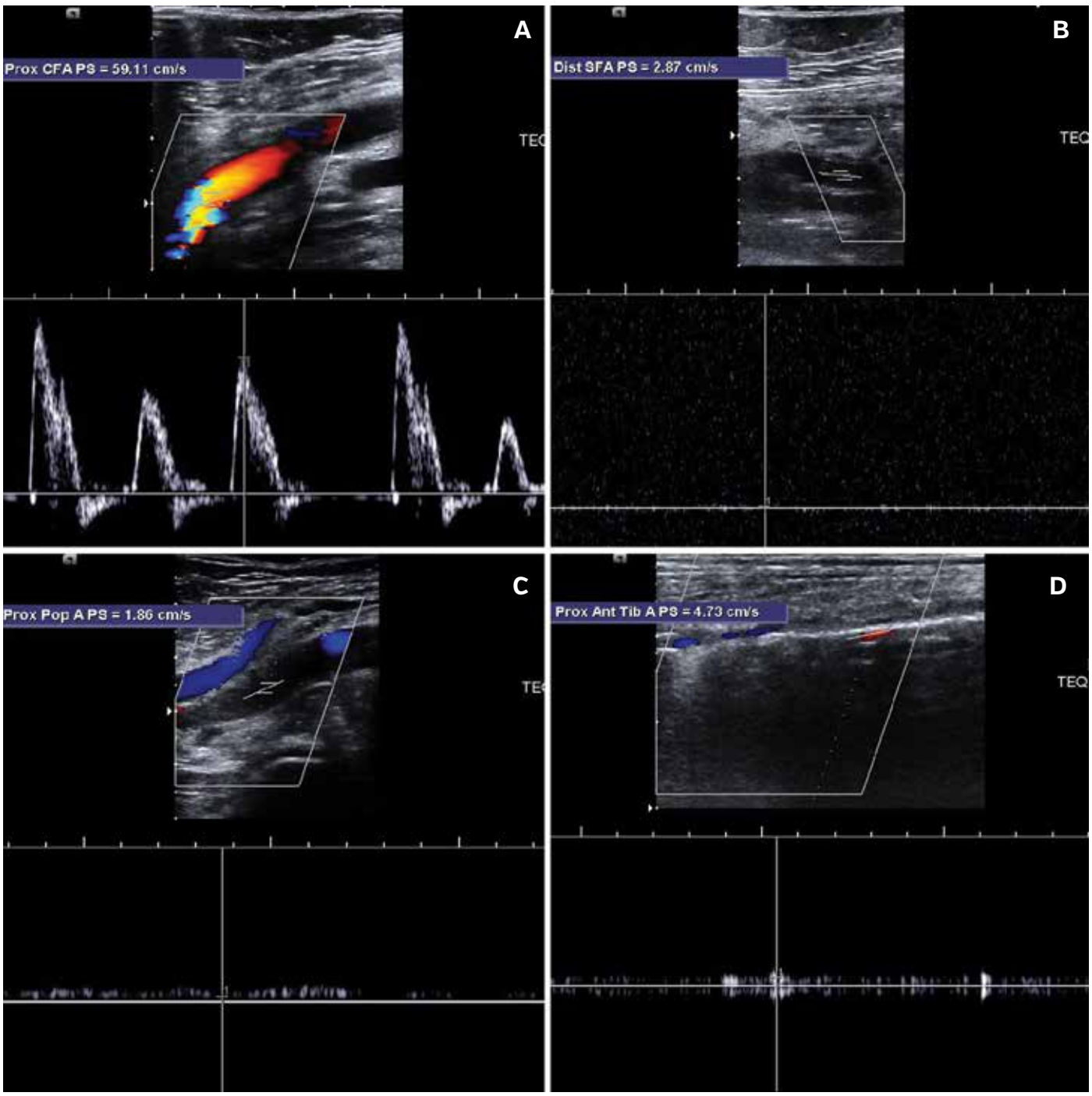

Figure 2. Arterial duplex study of the right lower extremity. (A) Biphasic waveforms with sharp systolic upstrokes are shown in the common femoral artery. (B) No significant flow is seen in the distal SFA, or (C) popliteal artery; and (D) there is trace reconstitution in the anterior tibial artery.

DHAND *from page 3*

The patient underwent lower extremity angiogram under moderate conscious sedation. A contralateral left groin access, up-and-over approach was utilized in order to determine if any aorto-iliac disease had been missed on the arterial duplex study. Initial arteriography was also performed with manual injection of carbon dioxide (primarily in the pelvis) to limit contrast load.

Diagnostic angiography revealed a long-segment occlusion of the femoropoliteal artery beginning approximately 5 cm from the origin of the superficial femoral artery (SFA). Numerous collaterals from the profunda artery were seen through the thigh and knee. There is faint reconstitution of the mid-anterior tibial artery, at the level of the mid-calf (Figure 3). The dorsalis pedis artery was faintly opacified (not shown).

For support, a 45 cm 6 French (Fr) Ansel sheath (Cook Medical) was advanced into the proximal left SFA. An angled 5 Fr catheter and stiff glidewire were used to recanalize the femoropopliteal artery, up to the suprageniculate popliteal artery. The system was downsized to an 0.018-inch wire (V18, Boston Scientific) and a Quick-Cross support catheter (Spectranetics). The 0.018-inch system was advanced into the infrageniculate popliteal artery in a subintimal plane. Brief attempts to cannulate the anterior tibial artery from this approach were not successful.

Pedal access via the dorsalis pedis artery was then obtained under ultrasound guidance. In our technique, after access, the 21-gauge needle is exchanged over a short 0.018-inch wire for the inner dilator of the Micropuncture sheath (Cook). Then an anti-spasm cocktail of 200 mcg nitroglycerin, 2.5 mg verapamil, and 2000 U heparin was injected followed by exchange of the inner dilator for a support catheter. In this case, the inner dilator was exchanged over a longer 0.018-inch wire (V18, Boston Scientific) and Quick-Cross support catheter. The system was advanced across the occluded anterior tibial artery and into the infrageniculate popliteal artery. The wire was directed into a 5 Fr end-hole catheter advanced from the left groin sheath. Once captured and externalized, through-and-through access was obtained.

Following floss access, plain old balloon angioplasty was performed in the dorsalis pedis artery (across access site) and anterior tibial artery with 2.0 x 150 and 2.5 x 300 mm balloons (Ultraverse, Bard; Figure 4). Angioplasty of the occluded femoropoliteal artery was performed with a 5.0 x 220 mm balloon (Ultraverse). Although in-line flow was restored to the anterior tibial artery, there was a significant irregular appearance of recanalized segments. Additionally, there was a dissection involving the proximal anterior tibial artery (Figure 4c). Given the extent of residual disease, it was felt that further balloon angioplasty (i.e., prolonged POBA versus drug-eluting balloon angioplasty) would not yield durable results. Therefore, primary stenting of the entire femoropopliteal segment and the proximal anterior tibial artery was performed. Multiple overlying stents were used, including a drug-eluting stent (Zilver PTX, Cook Medical) at the SFA origin and bare metal stents (Supera, Abbott) at the mid to distal femorapopliteal segments. A balloon-expandable drug-eluting 3 x 33 mm stent (Xience, Abbott) was used to treat the residual disease at the proximal anterial tibial artery. A final angiogram was obtained, demonstrating brisk inline flow to the dorsalis pedis artery via a robustly patent anterior tibial artery (Figure 5). The patient had a strong, palpable dorsalis

At our institution, peripheral arterial disease is treated utilizing a multidisciplinary approach. Patients who suffer from chronic wounds or obvious limb ischemia (i.e., gangrene) are referred by their primary care physicians to the hospital's wound healing center, where patients are seen by all three specialties: podiatry, vascular surgery, and interventional radiology. Wound care...is managed by podiatry and, sometimes, vascular surgery. An "endovascular-first" strategy has been adopted across the specialties.

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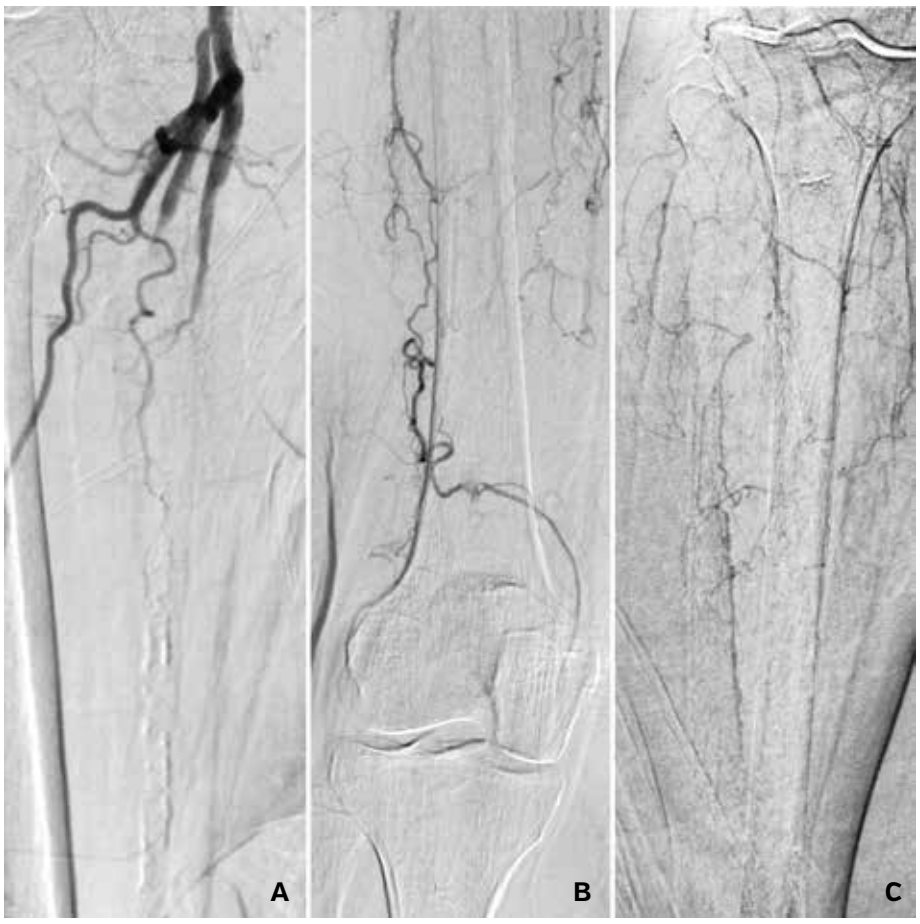

Figure 3. Left lower extremity angiogram: (A) Chronic total occlusion of the left SFA beginning approximately 5 cm from the SFA origin, (B) profunda collaterals noted in the thigh and knee, with no reconstitution of the popliteal artery, and (C) trace reconstitution of the mid anterior tibial artery.

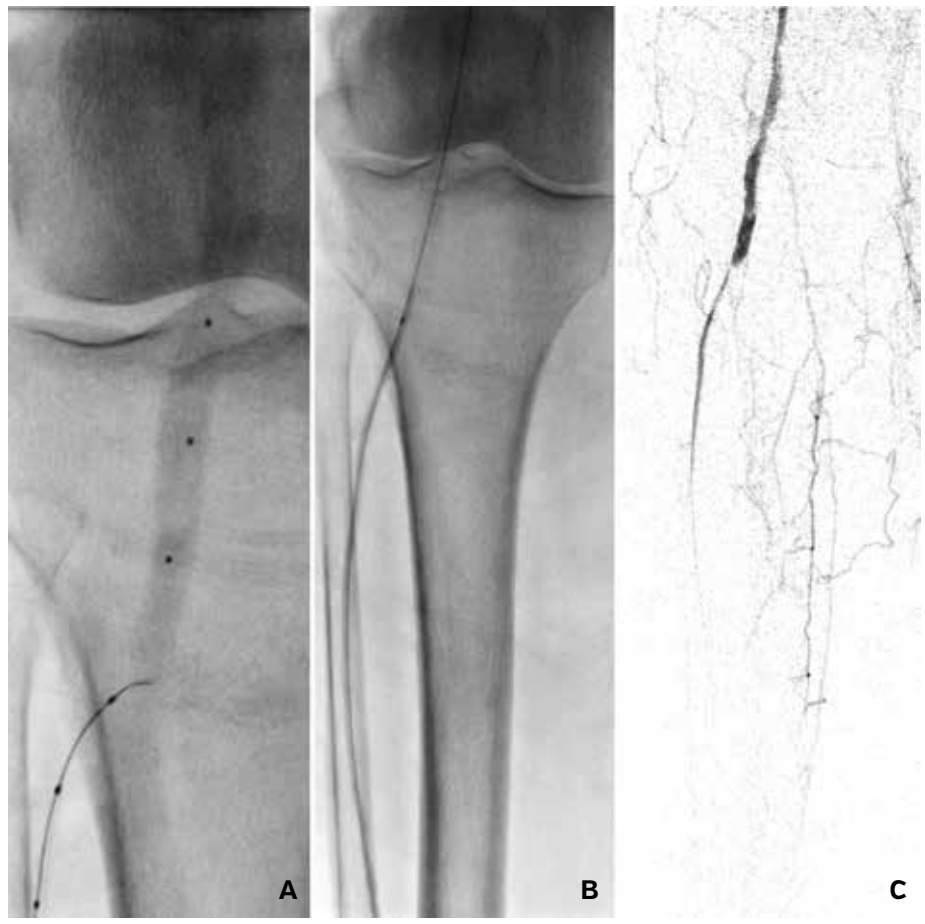

Figure 4. Intervention. (A) Obtaining floss access from the pedal approach, a support catheter is seen in the infrageniculate popliteal artery (from the up-and-over approach) and a second support catheter and 0.018-inch wire is visible crossing the occluded proximal anterior tibial artery. The wire is captured and externalized (not shown), followed by (B) angioplasty of the occluded segments and post angioplasty arteriogram, (C) demonstrating a dissection in the recannalized segment of the proximal anterior tibial artery. The post angioplasty arteriogram of the femoropopliteal artery is not shown.

pedis pulse at the end of the procedure. She underwent a toe amputation the following week uneventfully.

At our institution, peripheral arterial disease is treated utilizing a multidisciplinary approach. Patients who suffer from chronic wounds or obvious limb ischemia (i.e., gangrene) are referred by their primary care physicians to the hospital's wound healing center, where patients are seen by all three specialties: podiatry, vascular surgery, and interventional radiology. Wound care, including specialized dressings, debridement, skin substitutes, oxygen therapy, and vacuum-assisted wound closure, is managed by podiatry and, sometimes, vascular surgery. An "endovascular-first" strategy has been adopted across the specialties. The extremity angiograms are performed by interventional radiology with close vascular surgery support in cases of bypass or surgical emergencies.

The vast majority of our patients suffer from severe tibial disease, often with a single-vessel runoff. Although angiosomes are preferred, we typically attempt to achieve the best run-off possible, depending on what is identified on the initial diagnostic arteriogram. Several cases will require pedal access for recanalization, which all operators are comfortable performing. Additionally, most of the interventions are performed in one setting under moderate conscious sedation and rarely staged unless there is aortoiliac inflow disease (requiring bilateral groin access) or long procedure times. With the advent of drug-eluting balloons, recanalization without stenting is a preferred strategy. However, stenting is used if angioplasty alone does not obtain a fluoroscopically or clinically acceptable result. General anesthesia is used for select cases.

Most pre-procedural imaging is performed with an arterial duplex study. More recently, we try to obtain CT angiography run-off of the lower extremities for procedural planning, although this happens in <25% of our cases currently. Our most common obstacle for cross-sectional imaging is poor renal function in patients who are not already on dialysis.

During the wound healing process, both vascular surgery and interventional radiology follow patients in separate outpatient clinics, while the patient still goes to the wound healing center for medical management. Interventional radiology usually sees the patients 3–4 weeks after intervention, obtaining an arterial duplex study for baseline and follow-up. These patients are then usually seen every 3 or 6 months afterward, with biannual or annual screening arterial duplex studies, depending on the operator. If wound healing is not adequate, the patient either undergoes a repeat angiogram or is discussed in our monthly multidisciplinary vascular conferences.

Well-established, collegial multidisciplinary care has led to excellent outcomes in our patients suffering from critical limb ischemia. With the goal to prevent extensive amputation, the quality of life in the patients we manage is significantly improved. ■

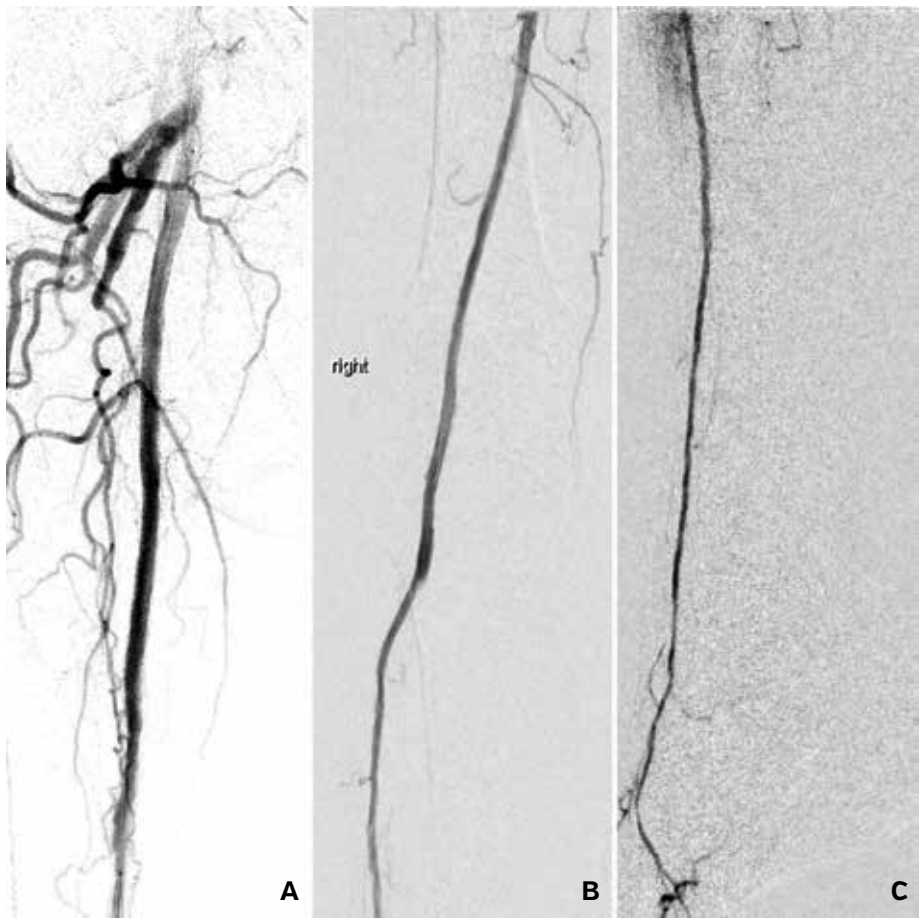

Figure 5. Final arteriogram after overlapping uncovered stent placements into the (A) SFA, (B) popliteal artery, and (C) anterior tibial artery. The lateral foot shows flow into the dorsal pedis artery, with a partially intact pedal loop. Delayed images demonstrate retrograde opacification of the plantar branches.

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STAVROULAKIS *from page 4*

analyses were performed in order to evaluate the association between statin therapy and the hazard of amputation and/or death. Although lipid-lowering therapy with statins has been among the most well studied pharmacologic therapies, the effect of these agents in CLI patients has not been well documented and current recommendations are extrapolated from other high-risk populations.[10] In the CRITISCH registry, statin therapy was applied in 445 individuals (37%), 371 (31%) patients received no statins, and 384 subjects were excluded from analysis, as they could not be allocated to any group in a reasonable manner (treatment crossovers). Patients on statins were more likely to be younger (P<.001) and to have a history of coronary heart disease (P<.001) or previous PVI (P<.001). Patients receiving statin therapy had a lower hazard regarding AFS (HR, 0.45; 95% CI, 0.34–0.63; P<.001) and death (HR, 0.40; 95% CI, 0.24–0.66; P<.001) as well as lower odds of major adverse cardio and cerebrovascular events (odds ratio, 0.41; 95% CI, 0.23–0.69; P<.001). Interestingly, statin therapy was not associated with reduced amputation rates (HR, 1.02; 95% CI, 0.67–1.56; P= .922).

Statin effect on amputation-free survival was consistent among diabetics (HR, 0.47; 95% CI, 0.31–0.70; P < .001), patients with CKD (HR, 0.53; 95% CI, 0.32–0.87; P =.012), and patients older than 75 years (HR, 0.40; 95% CI, 0.26–0.60; P <.001). Statin administration was also associated with an improved amputation-free survival in patients with antiplatelet medication (HR, 0.64; 95% CI, 0.41–0.99; P=.049) and without antiplatelet medication (HR, 0.26; 95% CI, 0.12–0.57; P=.001), and after both endovascular therapy (HR, 0.51; 95% CI, 0.34–0.76; P= .001) and bypass revascularization (HR, 0.38; 95% CI, 0.21–0.68; P=.001).

The results of the CRITISCH registry highlight that when physicians are free to individualize therapy for their CLI patients, they can achieve encouraging outcomes. Given the complexity of the disease and the increased comorbidity of CLI patients, an individualized approach seems more reasonable than a general recommendation. In this context, the future and ongoing trials should not only focus on the evaluation of the superiority/inferiority of a treatment option over another, but on the identification of those CLI patients who are better candidates for each treatment modality. Finally, our findings suggest that statin therapy in CLI patients is associated with increased amputation-free survival and lower rates of mortality and major adverse events regardless of the applied treatment strategy. However, we found no indication that statin therapy influences the fate of the affected limb, and further research is needed to assess areas of uncertainty in the secondary prophylaxis of CLI individuals. ■

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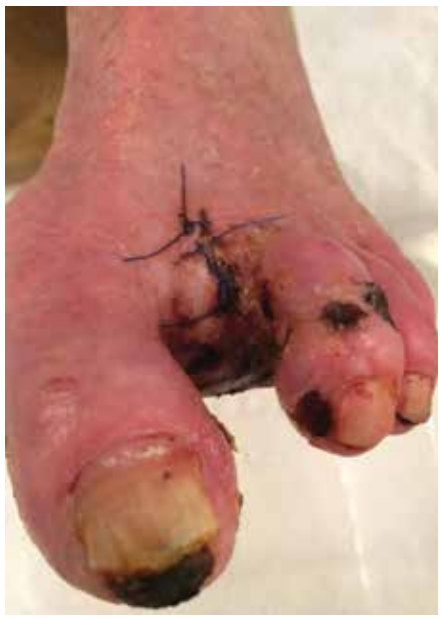

Figure 2A. Post-operative repair.

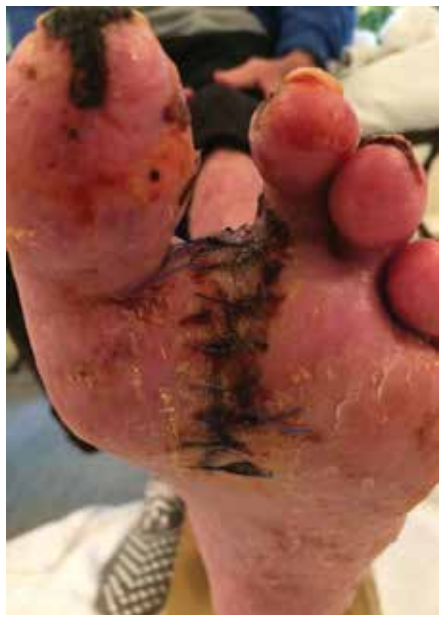

Figure 2B. Post-operative repair.

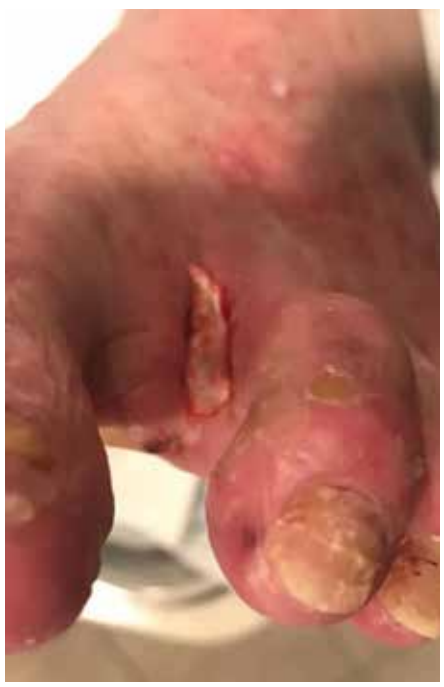

Figure 3. Application of Kerecis™ Omega3 acellular fish skin graft.

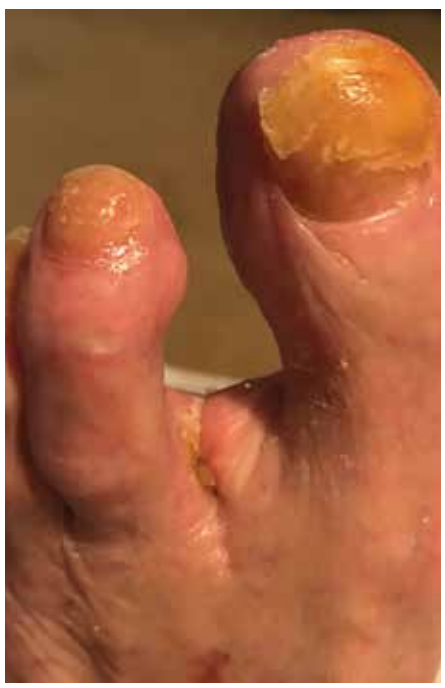

Figure 4. Healing 10 months after initial presentation to Podiatrist.

TURSI *from page 6*

He was then referred to my office for advanced wound healing treatment of his gangrenous 2nd digit (Figure 1). Following comprehensive history and physical examination, he was scheduled for a second digit amputation with exploration of the left second metatarsal phalangeal (MTP) joint. He also required an incision and drainage of the left second MTP, as he had developed a deeply seated abscess in that region. One of the most reassuring signs that he exhibited prior to incision was a visibly bounding dorsalis pedis (DP) artery pulse. The surgery was performed as described and his operative site was left open with local wound care performed while he was an inpatient. Prior to discharge, he was taken back to the operating room for delayed primary repair, which was performed following light wound debridement and extensive pulsatile lavage. (Figures 2 and 3).

Active surveillance in the outpatient setting ensued over the next 2 weeks, where he did encounter a small dehiscence of his dorsal incision site. This was treated with wound care visits, debriding necrotic tissues, and twice-daily Santyl dressing changes. Once the wound bed was clean and granular, we began using a Kerecis (Isafjordur, Iceland) Omega3 acellular fish skin graft as a skin substitute. A consultation with orthotics and prosthetics was also arranged for off-loading techniques and custom molded shoe implementation. He returned to his home state and wound care was continued by a local podiatrist with weekly application of the Kerecis Omega3 acellular fish skin graft (Figure 4).

One application of Kerecis had been performed prior to his transfer home, and 11 additional Kerecis grafts were applied over the following 2 months. Healing progressed nicely. Unfortunately, he developed a septic knee. He had a history of a total knee implant arthroplasty and apparently seeded infection to this region. The infection was treated with IV antibiotics, incision and drainage of the knee joint, and extensive pulsatile lavage. Once the septic arthritis was eradicated, treatment resumed on the left forefoot wound, which had regressed slightly. Sorbact with hypochlorous solution was initiated and with local wound care was continued until full wound healing had been achieved, approximately 10 months following surgery (Figures 5 and 6).

In conclusion, as physicians treating exclusively the foot, ankle, and lower extremities, podiatrists are often referred to as the gatekeepers of PAD. Podiatrists are typically the first physicians to have the chance to recognize and diagnose PAD, and with such an enormous opportunity, must be well versed in the risk factors, subjective complaints, clinical presentation, vascular testing, and treatment options. The earlier a patient can be referred to a revascularization specialist, the more likely that not only their limb may be saved, but their life as well. ■

Acknowledgement. We would like to thank Dr. David Trenner, MD for his contribution to patient treatment and follow-up.

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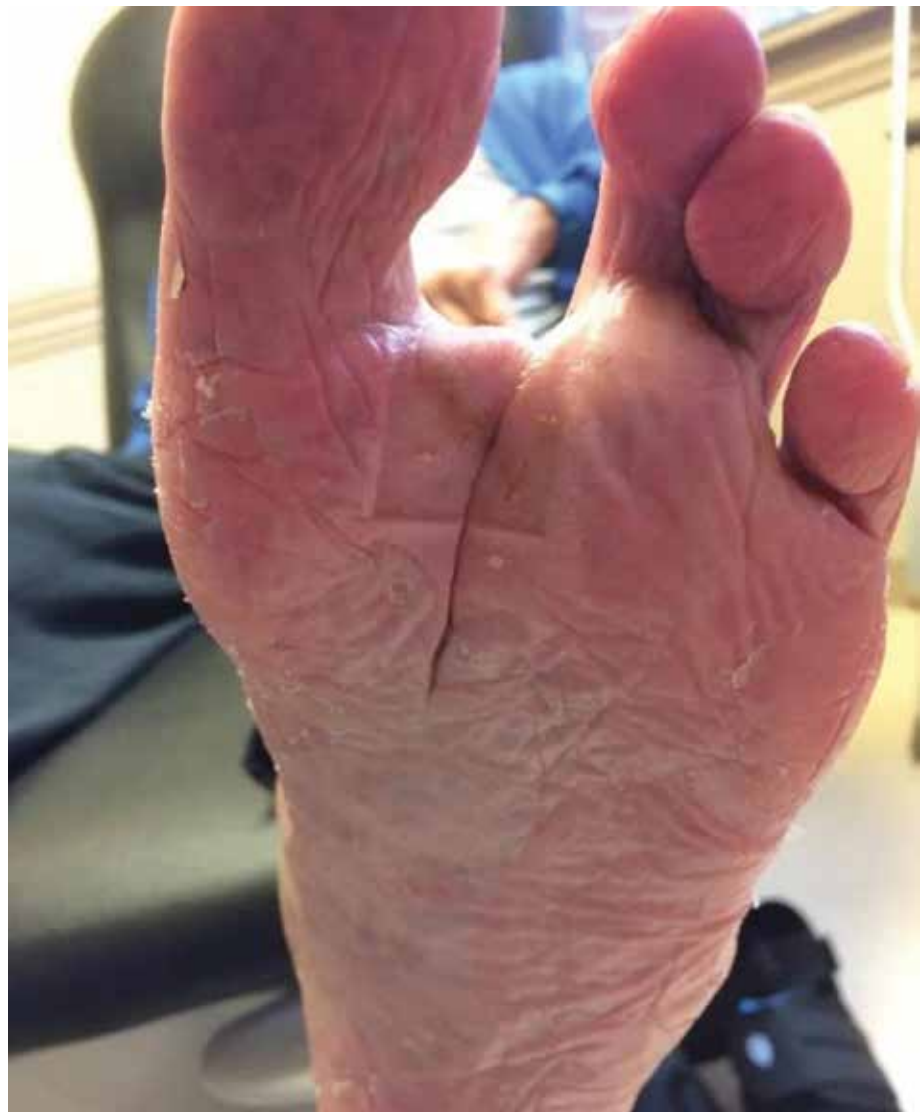

Figure 5. Healed at 10 months.

AMP 2017 *from page 1*

8. Costs for the treatment of CLI are among the greatest health care expenditures challenging the US today,[6] and;
9. In 2017, amputation often remains a first line treatment.

How can we fix the problem? The CLI Global Society recognizes and supports that a concerted effort can create change by:

- **Creating** a facilitated new definition of CLI;
- **Amplifying** public & health professional awareness of CLI;
- **Creating** a public & professional effort to prevent CLI;
- **Increasing** clinical cooperation and information sharing in the management of CLI;
- **Improving** the CLI standard of care for prevention, diagnosis, treatment and rehabilitation;
- **Reducing** time from symptom onset to provision of definitive care for CLI;
- **Reducing** variability in delivery of care that promotes preventable amputations;
- **Identifying** disparities in access and treatment to quality CLI care. Identify strategies to correct these disparities;
- **Advocating** for team-based programs that simultaneously address awareness, management, and treatment of CLI;
- **Partnering** with clinicians, hospitals, patients, and industry to have immediate impact;
- **Preventing** amputations and death due to critical limb ischemia.

What are current Society activities? The CLI Global Society consists of committees that are tasked with working on issues that include development of a unified definition of CLI, supporting the public health urgency of this disease by addressing CLI population health issues; analyzing technical alternatives to CLI revascularization procedures by supporting uniform quality metrics and developing resource based algorithms based on proven clinical practice; and education for patients, referring physicians, treating physicians and third party payers. The Society is deploying resources to support the mission. The Society has licensed longitudinal CMS claims data with a data set of patients from 2011-2014, along with 2010 data available to track the year before CLI. The Population Health Scientific Subcommittee is working with aligned organizations, experienced dataset and claims-based analysts while applying strong clinical oversight and input to ask the right questions. The goal is to identify trends and issues that can support the mission of CLI Global Society and CLI patients. Dr. Katzen passionately expressed that "this work will define rates and develop targets for public health initiatives around which we can rally support and measure outcomes. We are on the cusp of truly making a difference through the CLI Global Society's efforts in data collection, defining CLI as a disease state and employing advanced techniques to reduce both amputation rates and mortality from this devastating problem. This is truly an exciting time to be involved in this field!" ■

Over 100 attendees networked at the CLI Global Society Member Reception held in the historic Conrad Suite at the AMPutation Prevention Symposium 2017.

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Selected AMPutation Prevention Symposium 2017 Abstracts

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Comparison of Particulate Embolization after Femoral Artery Treatment with IN.PACT Admiral, Ranger, and Stellarex Paclitaxel-Coated Balloons in Healthy Swine

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Introduction. Drug-coated balloons (DCBs) have emerged as an effective treatment for patients with symptomatic peripheral arterial disease in the femoropopliteal arteries. They have been shown to be superior to balloon angioplasty (PTA) in large, multicenter randomized trials. After the introduction of the first DCB, the Bard Peripheral Vascular Lutonix .035-inch OTW DCB, there have been several entrants into the DCB market. However, multiple clinical and preclinical studies have illustrated there are differences in performance and safety between the different products. The various DCB technologies differ in their design of excipient coatings and the drug form (crystallinity) of the combinations. These design features can produce differences in effective drug delivery to target tissue while avoiding non-target effect (i.e. minimize emboli). In a previously published study, the Lutonix 035 and the Medtronic IN.PACT Admiral were tested and compared for downstream embolic events. The IN.PACT DCB illustrated increased downstream embolic debris and higher paclitaxel levels. The findings of embolic debris from DCB coatings are of potential importance and may be further compounded in patients with claudication and more complex critical limb ischemia (CLI) with limited flow reserve. Information regarding embolic debris may be important in the selection of DCB's for patient care.

Objectives. Different excipient/drug formulations unique to individual drug-coated balloons (DCBs) may influence embolic safety characteristics in distal non-target peripheral vascular territories through embolization of released particulates. A comparator study of three DCBs in commercial use, the IN.PACT Admiral, Boston Scientific Ranger, and Spectranetics Stellarex, in healthy swine was therefore performed to assess which balloon produces more downstream emboli and tissue reaction.

Methods. Three times over-lapping 80-mm DCBs for each device were assessed in 24 femoral arteries of 12 swine with 28-day follow-up for downstream embolic events and debris. IN.PACT Admiral was used as a control, as its downstream emboli and effect has been previously studied and published. Histologic analysis of arterial wall and skeletal muscle and coronary band downstream from the external or internal femoral arteries was performed. This analysis was supported by an analytic measurement of paclitaxel levels. The gastrocnemius, gluteal, and gracilis are skeletal muscle territories distal to the external femoral artery and the coronary corium (i.e., coronary band) is a highly vascularized structure that gives rise to the outer layers of the hoof wall and resembles the nail bed of a human finger.

Results. For all DCBs tested, regions of increased proteoglycan were accompanied by the loss of medial SMCs mainly extending nearly one-third to complete transmural involvement with restricted circumferential extension. Medial fibrin was present for all cohorts. The percentage of sections with downstream vascular changes in arterioles were greatest for IN.PACT > STELLAREX > RANGER (43%, 36%, and 25%, respectively). Embolic crystalline material was seen for all cohorts and followed a similar trend. Drug analysis in parallel tissues illustrated the highest paclitaxel concentrations in non-target coronary band tissues for STELLAREX>IN.PACT>RANGER (962.3 ng/g, 911.3 ng/g, and 822.5 ng/g, respectively).

All DCBs tested exhibited downstream effects of paclitaxel drug and/or downstream emboli. The IN.PACT control exhibited similar behavior as published from a previous study on downstream emboli. The new DCB's tested, STELLAREX and RANGER, exhibited downstream vascular changes and the STELLAREX DCB exhibited the highest downstream coronary band paclitaxel concentration at 28 days. The potential downstream embolic effects with certain DCB use may present a concern that may influence the selection of available catheter technologies.

Multicenter European Experience in the Use of the Indigo Vacuum-Assisted Thrombectomy Device in Acute Limb Ischemia

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Introduction. Percutaneous thrombectomy in patients with acute limb ischemia is a challenging task. Several devices have been approved for this indication, but their effectiveness remains a matter of debate. The aim of this study is to present the first European experience with a new aspiration thrombectomy catheter.

Objectives. The Indigo device (Penumbra) is a vacuum-assisted thrombectomy catheter that enables continuous thrombus aspiration. The catheter is available in 4 different sizes (3, 5, 6, and 8 French [F]).

Methods. A retrospective case review of all patients treated with the Indigo device between January 2016 and May 2017 in four European centers was conducted. Main inclusion criterion was acute ischemia of the lower limbs (<14 days). No further exclusion criteria were used. Main measure outcome was technical success defined as restoration of antegrade blood flow without the need of lysis or alternative thrombectomy/revascularization strategies. Secondary outcomes were any in-hospital major adverse events (myocardial infarction, stroke or death), need for blood transfusion and in-hospital reintervention.

Results. Sixty-five cases of ALI were included in this study. In all cases successful removal of the fresh clot was achieved using either an 8, 6, 5, or 3F Indigo aspiration-catheters or a combination, without the need for additional tPA lysis. The 3F catheter was able to extend into the arteries of the plantar arch. No perforations, dissection or neurovascular damage encountered in any of the cases. Technical success for thrombus removal was 100% for each treated vessel segment. No blood transfusions were necessary. One patient died during in-hospital stay due to heart failure and one patient suffered a myocardial infarction. In the post-operative follow-up re-occlusion occurred in 4% in 30 days due to re-thromboembolism from secondary causes.

Conclusions. In our experience, the Indigo device with its various range provided an easy, safe, robust and trackable thrombectomy to remove acute soft clot causing acute limb ischemia as far down as the arch of the foot. Bleeding risk was obviated because there was no need for lysis. There was no prolonged hospital stay experienced for patients with various comorbidities.

Distal Bypass for Critical Limb Ischemia: When Endovascular Fails

Cesar Eduardo Jimenez, MD, Hospital Universitario Clinica San Rafael, Bogotá, Colombia

Introduction. Critical limb ischemia (CLI) of the lower limbs is a very frequent and growing entity worldwide, already considered as an epidemic, given the increase in diabetes, unhealthy lifestyles, and increased life expectancy of the population. CLI is characterized by the presence of pain at rest and tissue necrosis, manifested by chronic ulcers that do not heal and necrosis of the foot or fingers. These patients have a very ominous prognosis with a high probability of limb loss and death. Treatments for CLI are based on the general condition of the patient, and the experience and availability of vascular surgeon resources. The diabetic and renal patients who usually present with CLI characteristically have severe infra-popliteal disease and to save the limb, require at least one of the three popliteal vessels below the foot to be able to maintain the viability of the limb and close wounds. Distal or ultra distal bypass were the first treatments for this entity, with good salvage and permeability indexes, but they have been stopped to the extent that endovascular techniques have been positioned as the first line of treatment in patients with CLI. A 20%–30% infra-popliteal percutaneous angioplasty fails for different reasons; major arterial surgery should continue to be considered an option in the management of patients with CLI. It is a complex and technically demanding procedure for a vascular surgeon, but well performed, is an excellent choice for limb salvage.

We present our experience in distal and ultra distal bypass in patients who were taken to percutaneous angioplasty as the first option for limb salvage but failed.

Objectives. The main objective of our work is to present our experience in limb salvage with distal surgical procedures and to determine the degree of limb salvage with these techniques. Secondary endpoints were morbidity and mortality associated with distal bypass.

Methods. We performed a retrospective analysis of patients undergoing popliteal bypass for limb salvage for two years (January 2015 to January 2017) at a referral hospital in the city of Bogotá for vascular pathologies. Inclusion criteria were patients with critical ischemia secondary to occlusive arterial disease of the popliteal, infrapopliteal, or both, who were taken to percutaneous angioplasty, but were not successful. The variables were age, sex, and type of bypass performed

(popliteal-pedis, popliteal to posterior tibial, popliteal to anterior tibialis). The risk factors studied were diabetes mellitus, coronary artery disease, hypertension, chronic obstructive pulmonary disease, and renal insufficiency on dialysis. Complications related to bypass were analyzed (myocardial infarction, pulmonary embolism, stroke, wound infection, early graft occlusion, bleeding requiring postoperative transfusion, and renal failure), the type of graft used, minor amputations performed at the time of the bridge, amputation at 90 days and 30-day mortality from the procedure. Follow-up was clinically and with duplex at the third postoperative month. In addition, it was evaluated which patients had percutaneous angioplasty associated with the bypass, as an additional measure to optimize flow before the revascularization. Variables data were collected in an excel database and analyzed retrospectively.

Results. We evaluated 18 patients with critical ischemia who underwent attempted percutaneous salvage angioplasty but failed. Average age was 70 years (minimum 52, maximum 85 years), with 44% (n=8) women and 55% (n=10) men. The associated comorbidities were renal failure on dialysis 11% (n=2), COPD 50% (n=9), diabetes mellitus 77% (n=14), HTA 83% (n=15), and coronary heart disease 77% (n=14). Bypass: popliteal to posterior tibial 16% (n=3), popliteal to anterior tibial 16% (n=3), popliteal peroneal 30% (n=6), and femorotibial 5.6% (n=1). Percutaneous angioplasty associated with vascular reconstruction was performed in a segment proximal to the occlusive lesion in 38% (n=7) of cases. Vascular reconstruction with autologous vein was performed in 83% of cases (n=15) and PTFE with vein patch in 16% (n=3); within this group, minor amputations were performed at the same time of the bypass in 61% of cases (n=11). Digital amputation was performed in 50% of cases (n=9) and 11% (n=2) were transmetatarsal amputation. Within the complications, there was no early occlusion of the graft requiring surgical or endovascular revision, acute myocardial infarction was present in 5.6% (n=1) of cases, no patient had pulmonary embolism or stroke, 16% (n=3) experienced intraoperative bleeding that required postoperative transfusion of blood, and 5.6 (n=1) had postoperative renal failure. Major amputation was required at 90 days in 16.7% (n=3) and 30-day mortality occurred in 5.6% (n=1). The permeability of the 3-month graft was 83%.

Conclusions. Open arterial surgery is still a very useful tool in limb salvage, failed angioplasty can occur, and vascular services should have other options to save the limb. Centers that claim to offer limb salvage must have surgeons with surgical and endovascular skills. Distal bypass offers a high limb salvage and low morbidity and mortality in our study.

One-Month Duplex Ultrasound Evaluation of Vessel Recoil After Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12-Month Target Lesion Revascularization

Theresa McGoff, BSN, Michael Sumners, DO, Osama Hallak, Fadi Saab, MD, Larry Diaz-Sandoval, MD, J.A. Mustapha, MD, Metro Health - University of Michigan Health, Wyoming, Michigan

Introduction. Late lumen loss by mechanical and biological recoil is a known mechanism of restenosis and late failure post peripheral endovascular intervention. Its evaluation by non-invasive methods such as duplex ultrasound has not been formally studied.

Objectives. To determine if vessel recoil at one month post endovascular revascularization predicts target lesion revascularization within 12 months of baseline procedure.

Methods. A retrospective review of 238 patients (356 tibial target lesions) from the PRIME registry that underwent tibial peripheral vascular intervention (PVI) for advanced peripheral artery disease (PAD) or critical limb ischemia (CLI) between January 2013 and August of 2016 were identified. Over a 12-month follow up, 58 lesions were identified that required target lesion revascularization (TLR) and were selected for analysis. The index PVI was reviewed and for each lesion the maximal balloon inflation size was recorded as the baseline measurement. Vessel size at each discrete lesion was evaluated by averaging three separate measurements (proximal, mid, and distal) of luminal diameter on duplex ultrasound at one-month follow-up. A control group that did not require TLR at 1 year of follow-up was otherwise randomly selected from the same 356 target lesion cohort and the same measurements were recorded. The TLR group included 53 tibial lesions, 50 of which were evaluable by duplex ultrasound (87%). The distribution included; 35 in the anterior tibial (66%), 12 in the posterior tibial (23%) and 6 in the peroneal (11%).

Results. Recoil and vessel diameter were significant predictors of re-intervention within 12 months, for every 10% recoil, odds ratio 12.76 (95% CI: 11.51-14.22), P<0.001. By multivariate analysis only recoil was a significant predictor of re-intervention within 12 months. A greater percentage of recoil was noted in distal vessels despite lower average inflation sizes.

Conclusions. Vessel recoil after tibial PVI evaluated at one-month duplex ultrasound may predict target lesion revascularization in advanced PAD and CLI patients over a 12-month follow-up. Multicenter analysis with a larger sample size is warranted to further validate findings.

Analysis of Radiation, Contrast, and Heparin Exposure for Clinical Trial Patients versus Non-Clinical Trial Patients

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Introduction. Standardly, patients receiving treatment for peripheral artery disease (PAD) and critical limb ischemia (CLI) undergo diagnostic and/or interventional procedures exposing them to increased levels of radiation, contrast dye, and heparin. If a patient enrolls in a clinical trial, very specific parameters for imaging and clotting time are dictated by the protocol. To date, no specific research has been done to compare the exposure experienced during a standard endovascular intervention compared to a patient enrolled in a research endovascular intervention.

Objectives. To determine if exposure to radiation, contrast, and heparin is increased for patients enrolled in a clinical trial versus patients treated per routine endovascular intervention for advanced PAD and CLI.

Methods. A single-center, retrospective review of peripheral endovascular procedures from the PRIME Registry yielded 666 Non-Research interventions and 137 Research interventions from January 2013 to March 2016. The two groups were analyzed for procedure time, radiation exposure (fluoroscopy time and dose), contrast dye exposure, total heparin dose, and peak activated clotting time (ACT).

Results. Non-Research, routine endovascular procedures, were found on average to have a significantly longer average procedure time ($P<.001$) and higher average fluoroscopy time and higher median fluoroscopy dose ($P=.008$, $P<.001$) compared to the research procedures. Research procedures showed an increased average contrast dose over Non-Research procedures ($P=.003$). Total heparin dose and ACT were not found to be significantly different between the two groups.

Conclusions. Despite protocols dictating the angiographic images needed for research protocols, research patients were not found to be at higher risk for radiation exposure and heparin dosing. However, the research patients were found to receive a larger average dose of contrast compared to patients not enrolled in clinical trial.

Occlusion Perfusion Catheter: A Universal Drug Delivery Device — Next Generation

Rex Teeslink, MD, Advanced Catheter Therapies, Chattanooga, Tennessee

Introduction. Advanced Catheter Therapies (ACT) has designed the Occlusion Perfusion Catheter (OPC) to function as a universal agent-delivery system that will accommodate any therapeutic agent, including pharmaceuticals, biologics, and live cells.

Objectives. To demonstrate the ability of the OPC to deliver an agent circumferentially and longitudinally into the media of the vessel wall, overcoming the limitations of a drug-coated balloon and/or stent.

Methods. The OPC is a five-lumen catheter designed with proximal and distal occlusion balloons, a center space-occupying balloon, an inflow port, an outflow port, and a guidewire lumen compatible with a standard 0.014 wire. It is a 5 French (Fr) catheter compatible with a 6Fr sheath. A fiberoptic pressure sensor is incorporated into the inflow lumen to monitor treatment chamber pressure. Occlusion balloons define the treatment region. The proximal and distal occlusion balloons are inflated simultaneously to control blood flow and create a treatment chamber. In addition, they serve to prevent systemic distribution of the agent. The fourth and fifth lumens are for inflow and outflow ports located within the established treatment chamber. The trapped blood is removed from the treatment chamber by flushing with saline. The space-occupying balloon can be inflated to minimize the amount of therapeutic agent required when indicated. This balloon never touches the vessel wall. After the blood has been evacuated, the therapeutic agent is delivered. A sensor monitor controls and optimizes pressure within the chamber for penetration into the media of the vessel wall, longitudinally and circumferentially.

Results. Confocal analysis of the vessel wall demonstrated delivery of fluorescent paclitaxel within media and adventitia, circumferentially and longitudinally. PK analysis demonstrated a straight line of 0.1 mcg/mL for 72 hours. According to Axel et al, the effective range of paclitaxel is 0.0085 to 0.85 mcg/mL to effect a 90% to 99% inhibition of human arterial SMC. Seven-day SEM demonstrated that paclitaxel delayed the healing effect. Twenty-eight-day histology demonstrated a normal endothelium. Live cell testing demonstrated that the OPC can deliver live cells with minimal mechanical damage at a wide range of pressures.

Conclusions. Pre-clinical testing conclusions: The OPC (1) delivers an agent circumferentially and longitudinally into the vessel wall; (2) delivers the effective range of paclitaxel for 90% to 99% inhibition of human arterial SMC, maintaining normal intimal endothelial function by noncoating; (3) delivers multiple agents; (4) supports multiple use in the same patient, above and below the knee; (5) controlled pressure within the chamber negates the requirement for accurate balloon-to-wall measurements; (6) delivers live cells with minimal mechanical damage to the cell membrane; (7) negates blood-agent admixture; and (8) minimizes systemic effect via flushing.

Mirror Distribution of Lesions in the Lower Extremities in Patients with Critical Limb Ischemia

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Introduction. Prevalence of critical limb ischemia (CLI) is still increasing. Symptoms for CLI are resting pain with or without small ulcers to gangrene. Doppler ultrasound is first diagnostic tool used in those patients; however, often performed in the symptomatic leg only. In angiography, which is the gold standard of lower-extremity vessel visualization, mirror occurrence of lesions in the arteries can be observed.

Objectives. The aim of the study was to estimate the distribution of lesions in patients with CLI.

Methods. This is an outpatient single center retrospective study of 87 consecutive patients with CLI who underwent diagnostic lower extremities angiography between January 2014 and December 2016. Distribution and mirror occurrence of lesions in the lower extremities arteries were estimated.

Results. In the registry, 52% patients were men, and mean age was 74±12 years. The occurrence of hypertension was 95%, hyperlipidemia 90% and diabetes 64%. Sixty-two percent of patients had history of coronary artery disease (25% post myocardial infarction), 56% prior PAD, and 18% history of stroke. Patients were treated with aspirin, thienopyridine-class antiplatelet agents and statins in 71%, 61%, and 69%, respectively. Fifty-four percent of patients had a history of PAD-related lower extremity interventions: endovascular intervention, bypass surgery, or amputation in 44%, 20%, and 15%, respectively. Most of the patients were in 4 Rutherford class (52%). Ulceration occurred in 45%. The mean rate probability of mirror lesion distribution for each vessel was 46%. The vessels with the highest percentage of mirror distribution were superficial femoral artery, anterior tibial artery, and posterior tibial artery with 60%, 57%, and 55%, respectively.

Conclusions. There is a trend for mirror distribution of lesions in patients with critical limb ischemia. Patients should be screened with bilateral Doppler examination, even if only one extremity is symptomatic.

From Vascular Intervention to Amputation: The Multidisciplinary Approach to Limb Salvage — A Case Presentation

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Introduction. Critical limb ischemia affects approximately 10 million people in the United States annually and there has been an increasing demand to facilitate and improve limb salvage approaches and therapies. The prevalence of comorbidities and risk factors, especially in patients with long-standing diabetes mellitus and peripheral vascular disease, increases the risk of major amputation to the affected lower extremity. This in turn leads to a decrease in quality of life, with a documented 40% higher risk of death in patients with diabetes mellitus after an amputation. We present a case of a 57-year-old, non-diabetic male with severe left lower extremity arterial occlusive disease and discuss the systematic, multidisciplinary approach from vascular intervention to surgical debridement.

Objectives. The case discussed in this investigation illustrates the importance of a streamlined, multidisciplinary approach to limb salvage and treating critical limb ischemia. It discusses the vascular intervention and the surgical procedure performed to the patient's left lower extremity in order to preserve adequate tissue to the left foot functional for ambulation.

Methods. The patient underwent an aorto-femoral runoff on 1/22/2017 with subsequent successful recanalization of the chronically occluded left external iliac artery and common femoral artery using PTA and stent placement as well as recanalization of the chronically occluded left SFA and popliteal artery using antegrade and retrograde access following PTA and drug-coated balloon with the Medtronic IN.PACT Admiral and three-stent implantation. On 4/3/2017, the patient underwent a 3rd toe amputation, wound debridement, and application of a bilayer wound matrix allograft to facilitate wound healing to his left lower extremity. The patient was subsequently followed up in the wound care clinic with weekly debridements, with a noted closure of all wounds on 6/16/2017, with minimal loss of tissue and minimal amputation to his left lower extremity.

Results. The patient presented in this study shows the progression of wound healing and limb preservation, initiating with a successful revascularization procedure and timely surgical amputation and wound debridement. It illustrates the use of an advanced biologic allograft to facilitate wound healing.

Conclusions. The authors in this investigation portray the importance of a multidisciplinary approach to limb ischemia and limb salvage. By streamlining a successful vascular intervention and surgical amputation and debridement, tissue loss can be minimized and lead to a functional limb necessary for ambulation, improving the patient's quality of life. A systematic team approach and coordination of care are essential to bring all disciplines together for optimal outcomes.

Implementation of Critical Limb Ischemia Clinic in an Office-Based Vascular Surgery Center

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Introduction. There are approximately 18 million American citizens suffering with peripheral artery disease (PAD), and of those individuals, an estimated 2 million have critical limb ischemia (CLI) which is the deadliest form of PAD. Predominantly in the elderly population, individuals with CLI have a high prevalence of multiple chronic comorbidities such as diabetes, hypertension, renal insufficiency, cardiovascular and cerebrovascular disease, and a history of smoking. Costing an estimated $43,000 per patient each year for clinical care alone, CLI is an economic burden. Hospitalization for an infected wound can escalate healthcare cost from $19,000 to $42,000, an increase of 121%. If the limb affected is unsalvageable, the cost for amputation (nationwide population) is an estimated $10.6 billion. However, an endovascular revascularization procedure requires the patient to recuperate at home, and two years status post procedure, approximately 80% of these patients are walking and 90% live alone. This is in contrast to data for amputation, which shows a two-year mortality rate of 30%-50%, with 36%-50% requiring another amputation.

Objectives. Our goal was to implement an office-based CLI clinic aimed at the preservation of limbs and preventing amputation in high-risk populations. After researching established CLI clinics and investigating the plan of care, we created an algorithm for early intervention with the CLI population in our office and surrounding community. Utilizing that algorithm and corresponding program plan, we hope to improve quality of life for the patients we serve with early assessment, diagnosis, and intervention by revascularization, while also creating PAD awareness within the community.

Methods. Our case study followed a 65-year-old male who presented with ischemic ulceration on the right foot with previous medical history of hypertension, coronary artery disease, dyslipidemia, and a left above-the-knee amputation with a significant history of smoking. He had a palpable femoral pulse but an absent popliteal or tibial pulse. Following angioplasty, the limb was revascularized to promote wound healing and salvage the right lower extremity.

Results. Our CLI clinic will prevent lengthy hospitalization, improve CLI patient outcomes, and reduce avoidable despair of underdiagnosed and undertreated vascular disease. The office-based vascular practice is a necessity for the advancement of evidence-based practice in the vascular realm.

Conclusions. The CLI clinic will improve awareness and the approach of PAD. Multiple studies show that aggressive revascularization is an essential component of prevention of amputations; nevertheless, evidence-based research is key to improving the care provided for patients with PAD who develop CLI.

Patients with Critical Limb Ischemia in the Outpatient Setting

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Introduction. Critical limb ischemia (CLI) is a significant morbid disease defined as a severe manifestation of peripheral arterial disease (PAD) and occurs in a chronic setting with the presence of claudication symptoms over a long period.

Objectives. The aim was to compare patients with and without CLI in baseline and long-term observation to indicate which factors should be paid particular attention.

Methods. This is a retrospective, single outpatient center registry of 96 consecutive patients with PAD, in whom endovascular procedure utilizing stents or angioplasty were performed from January 2015 to September 2016. Patients were divided into 2 groups: those with critical limb ischemia (CLI 1) (n=46) and those without (CLI 0) (n=50). We compared baseline characteristics and performed long-term observation analysis. Endpoint was the composite of death, myocardial infarction (MI), stroke, target vessel and target lesion re-intervention (TVR and TLR), amputation at 30 days, 3, 6, 9, 12, and 24 months.

Results. There were no significant differences in basic demographic and clinical characteristics between groups except higher occurrence of diabetes (72% vs. 52%, P<.05), end-stage renal disease (30% vs 8%, P<.05) and presence of ulceration (30% vs. 2%, P<.05) in the CLI 1 group. There was significant difference in exercising (50% vs. 20%, P<.05) in the CLI 0 group. There were no differences between cardio and cerebrovascular events at 30 days from discharge. At long-term observation there were no significant differences between groups regard to mortality, MI and stroke incidence. The risk of TVR (6% vs. 41%, P<.05), TLR (6% vs. 37%, P<.05) and amputation (0% vs. 9%, P<.05) was significantly lower in the CLI 0 group when compared to the CLI 1 group.

Conclusions. Critical limb ischemia occurs more often in patients with end-stage renal disease, in those on dialysis, and in patients with diabetes. Long-term observation demonstrated patients with CLI have more frequent and repeated endovascular procedures and amputations.

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VIVA - Vascular InterVentional Advances (VIVA 17)
Location: Las Vegas, Nevada
Website: www.vivapvd.com

September 11-15, 2017
VEINS 2017 – Venous Endovascular Interventional Strategies
Location: Las Vegas, Nevada
Website: www.vivapvd.com

September 16-20, 2017
CIRSE 2017: Cardiovascular and Interventional Radiological Society of Europe Annual Congress
Location: Copenhagen, Denmark
Website: www.cirsecongress.org

November 7–10, 2017
Cardiovascular Interventions 2017
Location: La Jolla, California
Website: www.cvinterventions.com

October 29-November 1, 2017
TCT 2017 – Transcatheter Cardiovascular Therapeutics
Location: Washington D.C
Website: www.tctconference.com

November 11-15, 2017
AHA Scientific Sessions 2017
Location: Anaheim, California
Website: www.scientificsessions.org

November 13-16, 2017
AIM Symposium (25th Annual Symposium on Current Issues and New Techniques in Interventional Radiology And Endovascular Therapy)
Location: New York, New York
Website: www.veithsymposium.org

November 17-18, 2017
AVID Symposium
(Advances in Vascular Imaging)
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Location: Sydney, Australia
Website: www.vervesymposium.com

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Location: Las Vegas, Nevada
Website: www.SCAI.org

February 3-7, 2018
ISET 2018
2018 International Symposium on Endovascular Therapy
Location: Hollywood, Florida
Venue: The Diplomat Hotel
Website: www.iset.org

March 10–12, 2018
American College of Cardiology Scientific Sessions (ACC)
Location: Orlando, Florida
Website: http://acc2018.com/

March 17-22, 2018
SIR 2018 / Society of Interventional Radiology Annual Scientific Meeting
Location: Los Angeles, California
Website: www.sirmeeting.org

April 5-7, 2018
9th Diabetic Limb Salvage Conference (DLS 2018)
Location: JW Marriott, Washington, DC
Website: www.dlsconference.com

April 25-28, 2018
SCAI 2017 – Society of Cardiovascular Angiography & Intervention
Location: New Orleans, Louisiana
Website: www.SCAI.org

May 22-25, 2018
EuroPCR
Location: Paris, France
Website: www.europcr.com

May 30-June 1, 2018
New Cardiovascular Horizons (NCVH)
Location: New Orleans, Louisiana
Website: www.ncvh.org

June 17-20, 2018
(C3) Complex Cardiovascular Catheter Therapeutics
Location: Orlando, Florida
Venue: Hilton Bonnet Creek/Waldorf Astoria
Website: www.c3conference.net

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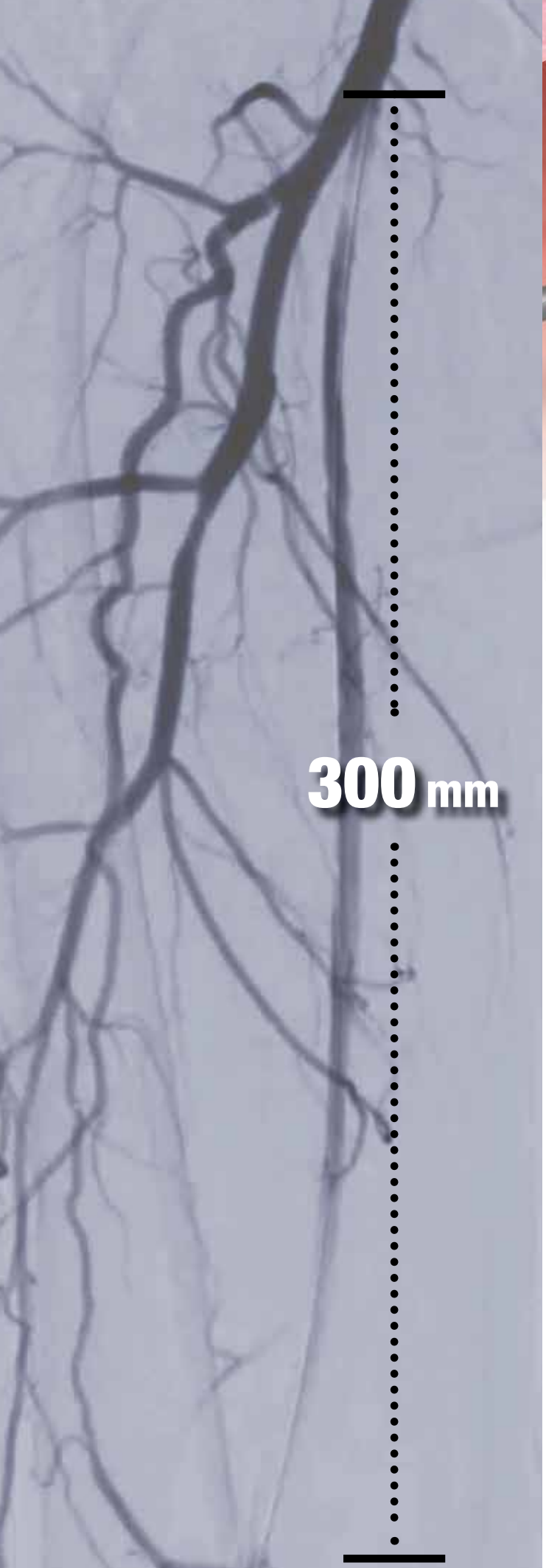
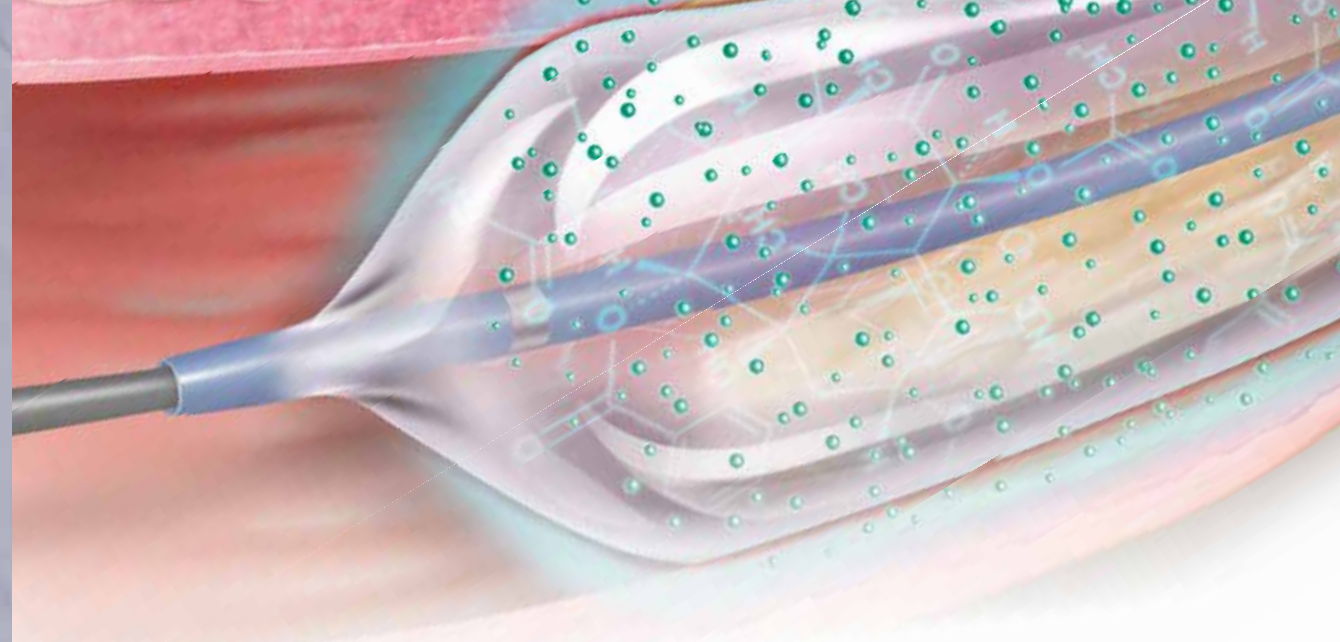
1. Jetstream Calcium Study





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