Critical limb ischemia (CLI) is an underdiagnosed and undertreated deadly disease that requires proper diagnostic imaging and increased awareness. Between 2000 and 2010, the world's population increased by 12.6%, and the prevalence of peripheral arterial disease (PAD) has increased twice as much over this period. In the United States (US) and the European Union (EU), more than 3.8 million patients suffer from CLI and this number is expected to increase by 23% over the next 10 years. These alarming statistics can be attributed to an explosion in the diagnosis of diabetes and decreasing mortality from cardiovascular disease. A more alarming statistic is that more than 50% of amputations occur without any prior vascular intervention in the year prior.

Efforts to estimate the true prevalence of CLI in population studies are challenging because the CLI diagnosis is clinically established by a constellation of lower extremity features, including ischemic rest pain and non-healing ischemic wounds or gangrene, and requires the objective measurement of ankle or toe pressures. Few prior population-based studies have used such symptom- and examination-based clinical criteria to define CLI incidence or prevalence. Validation studies suggest that use of administrative codes for CLI diagnosis may underestimate the true prevalence by 25%. Given these factors, it can be estimated that between 1 million and 3 million Americans have CLI.

Adding to the poor prognosis after diagnosis of CLI, patients with this disease receive a diagnosis of CLI, the mortality risk is 24% over 1 year and 60% over 5 years. Fewer diseases connote a higher mortality rate. Among 22 different types of malignancy, only six have a 5-year mortality rate higher than that of CLI. A study by the CLI Global Society showed that mortality rates at 4 years differed by Rutherford Class presentation with 41% (Rutherford 4), 55% (Rutherford 5), and 68% (Rutherford 6), whereas major amputation rates at 4 years were 6% (Rutherford 4), 9% (Rutherford 5), and 30% (Rutherford 6). Overall, the high incidence of CLI in combination

Continued on page 14
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Images courtesy of Syed Hussain, MD, Christie Clinic, Vein and Vascular Care Center
Treatment of Calcified Common and Deep Femoral Arteries

Michael S. Lee, MD, FACC, FSCAI
UCLA Medical Center, Los Angeles, California

Percutaneous vascular intervention (PVI) is a safe and effective treatment option for symptomatic peripheral artery disease. The ideal treatment strategy for common femoral artery (CFA) disease is controversial. Common femoral endarterectomy (CFE) has been considered the standard of care for over half a century given that the CFA is easily accessible surgically, technically feasible, and provides durable patency. However, CFE may not be a good option in some patients, especially if they have multiple comorbidities or are elderly. A large registry from the National Surgical Quality Improvement Program database reported a 30-day mortality and morbidity rate of 15%, including a mortality rate of 3.4%. Surgery is also associated with infection and paraplegia. Furthermore, CFA disease is commonly accompanied by involvement of the iliac or superficial femoral arteries which are not revascularizable during CFE. PVI represents an alternative for patients who do not want surgery for various reasons, including personal preference or those who are poor candidates for surgery. PVI of the CFA is minimally invasive, non-surgical, and can be performed on an outpatient basis with same-day discharge. In contrast, CFE often requires at least an overnight hospital stay. The large diameter of the CFA makes it an appealing vascular territory to treat with PVI. Compared with CFE, PVI also provides the ability to revascularize other vascular beds including the iliac and superficial femoral arteries. PVI of the CFA can be performed via the radial or brachial artery because of the proximal location of the CFA, which decreases the risk of vascular access complications and bleeding. In the TECCO trial, the stent group provided lower rates of 30-day morbidity and mortality compared with the surgery group in patients with CFA disease (12.5% vs. 26%, odds ratio: 2.5; 95% confidence interval: 0.9–6.6; P = .05). The length of stay was also lower in the stent group (3.2 ± 2.9 days vs. 6.3 ± 3 days; P < .001). Delayed wound healing was more commonly observed in the surgery group (16.4% vs. 0%). At 2-year follow-up, there were no differences in sustained clinical improvement and the rates of primary patency, target lesion revascularization, and target extremity revascularization.

There are several aspects of the CFA which increase the technical complexity of PVI. Osteoid metaplasia, a mature bone structure, was commonly observed in CFA disease. Severe calcification of the CFA decreases the acute procedural success rate. Balloon and stent catheters may not traverse severely calcified lesions. Calcified lesions are also difficult to fully dilate and may require high pressure balloon inflations, which increase the risk of dissection, slow flow, and perforation. Dissection of the CFA may require stenting, which is undesirable at a flexion point.
SAVAL Update: Overcoming Recoil and Restenosis in the Treatment of Complex Tibial Disease

Patrick J. Geraghty, MD
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SAVAL STUDY DESIGN

The SAVAL trial is a two-phase study comparing patency and safety of the SAVAL DES compared with PTA in the treatment of infrapopliteal arteries.

Table 1. Patient Eligibility for SAVAL*

<table>
<thead>
<tr>
<th><strong>Patient Eligibility for SAVAL</strong></th>
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<tbody>
<tr>
<td>1. Chronic, symptomatic lower limb ischemia (Rutherford categories 4 or 5)</td>
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<tr>
<td>2. Stenotic, restenotic, or occlusive target lesion(s) in the tibioperoneal trunk, anterior tibial, posterior tibial, and/or peroneal artery(ies)</td>
</tr>
<tr>
<td>3. Stenosis that is ≥ 70% (based upon visual angiographic assessment)</td>
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<tr>
<td>4. Total target lesion length ≤ 140mm.</td>
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</table>

*Patient must have all 4 symptoms for trial eligibility.

WHAT MAKES THE SAVAL TRIAL UNIQUE?

The SAVAL clinical trial is the only large study investigating a purpose-built, self-expanding, sustained-release paclitaxel BTK DES. It is the first study of peripheral vascular intervention granted the FDA Breakthrough Devices Program designation (formerly the Expedited Access Pathway program).

The randomized study design will provide a rigorous comparison of this novel BTK device to the current standard of treatment (PTA). Of note, patient recruitment for SAVAL was designed to be international from the outset, with a goal of enrolling patients in the United States, Japan, and Europe.

Study Status: The SAVAL trial is actively enrolling subjects in its first phase.

Acknowledgement: I thank Alexandra J. Greenberg-Worisek, PhD, MPH, (Boston Scientific) for providing medical writing assistance.

Disclosure: Dr. Geraghty reports Consulting/Advisory Board: BSC, BD/Bard; Equity Holder: Euphrates Vascular.
The Halo One™ Thin-Walled Guiding Sheath reduces arteriotomy size compared to standard peripheral guiding sheaths of the same French size, which can help to minimize access site complications.\(^1\) A unique size offering makes Halo One™ Thin-Walled Guiding Sheath the only thin-walled guiding sheath with lengths suitable for distal peripheral interventions.\(^2\)

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\(^2\) Shaft lengths of 45, 70, and 90 cm are available in 4F and 5F sizes only. As of April 2020.

The Halo One™ Thin-Walled Guiding Sheath is indicated for use in peripheral arterial and venous procedures requiring percutaneous introduction of intravascular devices. The Halo One™ Thin-Walled Guiding Sheath is NOT indicated for use in the neurovasculature or the coronary vasculature.

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Utilization of Tibio-Pedal Artery Minimally Invasive Approach to Treat Complex Below Knee Disease in a High Transfemoral Risk Patient

Zola N’Dandu, MD, and Jonathan Bonilla, MD
John Ochsner Heart and Vascular Institute, Ochsner Medical Center-Kenner, Kenner, Louisiana

With the evolution of endovascular techniques, historically untreated patients have options. Tibio-pedal artery minimally invasive (TAMI) approach is safe and feasible when avoiding transfemoral access complications.1-3

CASE REPORT

A 66-year-old male with a past medical history of hypertension, hyperlipidemia, insulin-dependent diabetes mellitus Type 2 for more than 20 years, coronary artery disease previously treated with multivessel percutaneous coronary intervention (PCI), ischemic cardiomyopathy with ejection fraction of 35%, morbid obesity with body mass index (BMI) of 52, and sleep apnea presenting with chronic limb threatening ischemia (CLTI), presented with necrotizing fasciitis requiring an urgent debridement for infection control. His non-invasive vascular workup included an abnormal ankle brachial index (ABI), an abnormal arterial ultrasound, and tissue oximetry.

He had a right transradial aortogram with selective right leg angiogram. His angiogram revealed adequate inflow with patent aorto-iliac, common femoral, superficial femoral, profunda, and popliteal vessels. Distally he had a chronically occluded (CTO) right anterior tibial (ATA) with a hibernating dorsalis pedis artery (DPA), which faintly filled from a peroneal (PER) collateral, 90% tibial peroneal trunk (TPT) stenosis, multiple 75% lesions in the proximal and mid posterior tibial artery (PTA), and a patent lateral plantar artery (LPA) (Figure 1).

Anticipating a high risk of complications related to transfemoral access, we decided to proceed with TAMI approach with transradial guidance. A 4- to 5-Fr Glidesheath Slender (GSS) (Terumo Medical) was inserted in the right radial artery for visualization of the proximal vessels. We placed a 2.9-Fr Cook pedal (Cook Medical) sheath in the ATA and advanced a 0.018-inch CXI (Cook Medical) support catheter over a 0.018-inch Command ST (Abbott Vascular) wire. The CXI catheter and wire were advanced through the course of the ATA intraluminally except for the ostium of the ATA where the wire entered a subintimal...
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space. Thereafter, we gained access in the right PT with a 4- to 5-Fr GSS sheath to serve as an antegrade access to cross the ATA CTO (Figure 2). A 0.018-inch CXI support catheter was telescoped within a 4-Fr Berenstein (Boston Scientific) catheter with a 0.018-inch Command wire advanced into the proximal ATA (Figure 3). The antegrade equipment was advanced into the distal ATA. The retrograde CXI catheter was pulled back in the distal AT where the antegrade wire was inserted for externalization. Subsequently the antegrade CXI catheter was externalized through the retrograde 2.9-Fr sheath placed in the distal ATA (Figure 4). The 0.018-inch Command wire was exchanged for a 0.014-inch ViperWire (Cardiovascular Systems, Inc.) guidewire to perform atherectomy using a 1.5 mm Classic CSI Diamondback 360 catheter in the PTA, TPT, and ATA (Figure 5). Thereafter, based on extra vascular ultrasound (EVUS) measurements, we performed balloon angioplasty of proximal DPA, ATA, and PTA with a 3.5- x 300-mm balloon (Ultrasound BD Bard), and TPT with a 4.0- x 60-mm Lutonix

With the evolution of endovascular techniques, historically untreated patients have options. Tibiopedal artery minimally invasive (TAMI) approach is safe and feasible when avoiding transfemoral access complications.

Figure 3. Arrow (A) retrograde ATA access, (B) retrograde wire looped at ATA ostium, (C) retrograde PT access, (D) retrograde PTA crossed into proximal ATA. PT = posterior tibial; PTA = posterior tibial artery; ATA = anterior tibial artery.

Figure 4. Oval (A) antegrade and retrograde wires in ATA and arrow (B) externalization of antegrade wire through the retrograde ATA access. ATA = anterior tibial artery.

Figure 5. Atherectomy of ATA through PTA access with 1.5 Classic CSI catheter. ATA = anterior tibial artery; PTA = posterior tibial artery; CSI = Cardiovascular Systems, Inc.
To reduce the risk of access-related complications, we usually perform balloon tamponade with 2.5- or 3.0-mm Advance Micro 14 2.5-Fr balloon through a distal 2.9-Fr sheath which can safely be closed with minimal manual pressure.

DCB (BD Bard) with an excellent result (Figure 6).

A 3.0- x 80-mm Advance Micro 14 2.5-Fr (Cook Medical) balloon was inserted through the retrograde ATA 2.9-Fr sheath over the ViperWire guidewire which was exchanged for a 0.014-inch Fielder XT (Asahi Intecc) and advanced distally to the 4- to 5-Fr GSS PTA access for intraarterial balloon tamponade to obtain hemostasis (Figure 7). Finally, the retrograde 2.9 Fr ATA sheath was removed, and hemostasis was achieved with manual pressure (Figure 8). He tolerated the procedure well and ambulated an hour later. He underwent additional debridement and placement of a wound vac.

The TAMI approach has been well documented. It can be utilized as an alternative in patients with high risk of complications related to transfemoral access. In other cases, we used up to 5 to 6 and 6 to 7 GSS sheaths. To reduce the risk of access-related complications, we usually perform balloon tamponade with 2.5- or 3.0-mm Advance Micro 14 2.5-Fr (Cook) balloon through a distal 2.9-Fr sheath which can safely be closed with minimal manual pressure (Figure 9). We always utilize a hockey stick ultrasound probe to obtain access. We maintain an ACT greater than 250 seconds during the case. We inject between 200 or 400 mcg of intra-arterial nitroglycerin for vasodilation and repeat the same process every thirty minutes.

**REFERENCES**

The STAND Trial: How the MicroStent® Attempts to Break Through Barriers in Below the Knee CLI

Omosalewa Adenikinju, MD; Michael Patel, MD; Adam Zybulewski, MD; Brandon Olivieri, MD; and Robert E. Beasley, MD

The goal of CLI treatment is direct: relieve pain, augment wound healing, improve quality of life, and prevent amputation and mortality. Unfortunately, comorbidities such as diabetes, renal failure, tobacco smoking, heart failure, and infection tend to accompany CLI, leading to major amputation and subsequently, increased mortality.

In order to understand the intent behind the pivotal STAND (Clinical Evaluation of the MicroStent PeripheralArterial Vascular SteNt in Subjects with Arterial Disease Below the Knee) trial, it is important to comprehend the barriers of clinical success in below-the-knee (BTK) revascularization.

BARRIERS TO SUCCESSFUL BTK TREATMENT

BTK disease is commonly composed of complex tandem, long-segmented lesions that require complicated revascularization techniques. Currently, there is no U.S. Food and Drug Administration (FDA)-approved stent for primary treatment of BTK disease. Thus, treatment of these complex, diseased vessels has been limited to angioplasty, recent atherectomy, and off-label use of drug-eluting coronary stents in the setting of matched luminal diameter and previously revered drug-coated technology. These treatment modalities, which are sometimes used as bailout options in limb salvage cases, do present challenges.

Despite angioplasty after optimal nominal balloon diameter selection, Baumann et al. state that up to 97% of cases have a significant amount of vessel recoil in complex BTK lesions, thus only temporarily improving the luminal gain and inline flow achieved shortly after procedure completion. It is also well established that the microtrauma exhibited by plaque during angioplasty can lead to non-flow and flow-limiting dissections in approximately 20% to 30% of cases.5-7 Dissections often go untreated as many are underreported or missed, especially in the absence of intravascular ultrasound (IVUS). These tend to become a nidus for restenosis or occlusion.5-7

Atherectomy devices, including laser and orbital atherectomy, can decrease plaque burden in tibial vessels. However, their utility can be limited to vessel size compatibility and true lumen use depending upon the debulking method chosen. Even then, these therapies may need adjunctive therapy from percutaneous transluminal angioplasty (PTA) or stenting.

The use of off-label drug-eluting coronary stents BTK has been employed in complex limb salvage cases for years. Historically, size compatibility and drug-eluting technology made this a viable option to improve and maintain inflow in the BTK vessels, with favorable outcomes as demonstrated in the ACHILLES trial, which showed high patency rates at 1 year with balloon-expandable drug-eluting stents in BTK vessels compared to PTA.8 However, in lieu of the recent paclitaxel conundrum set forth in 2018, application of the once-prized chemotherapy agent in the treatment of PAD/CLI must now be evaluated on a case-by-case basis due to the possible increased mortality signal. In addition, due to their intended use, coronary stents are typically short (<4 cm in length) and are typically applied only to the proximal tibial vessels when feasible. Since they are balloon-expandable, these stents tend to have limited flexibility and have less radial strength than self-expanding stents, thus bringing a higher risk of extrinsic compression.

With the present challenges, it is imperative to use evidence-based medicine when forming a treatment algorithm for BTK revascularization. Historically, the BASIL trial simulated equal amputation-free survival at 6 months between patients undergoing PTA versus infragenual saphenous vein bypass to an above-the-knee or BTK arterial segment. The BASIL trial proved that an endovascular approach is as efficacious and less expensive than a surgery-first strategy for the treatment of infragenual disease in CLI.9

Subsequent studies, such as the meta-analysis by Caruca et al., demonstrated no significant advantage in off-label use of balloon-expandable bare metal stents versus PTA in patency or wound healing, but highlighted good results with self-expanding stents for PTA bailout. However, no direct comparison was made to PTA in that analysis.

The randomized YUKON-BTX and DESTINY trials have demonstrated higher rates of freedom from target lesion revascularization (TLR) when comparing bare metal and drug-eluting stents BTK, but a clear clinical benefit has yet to be shown.10 There are conflicting conclusions on improvement in Rutherford class, a query on the economic benefit of drug-eluting stents, and no significant difference in major amputations or survival has yet to be demonstrated between bare metal and drug-eluting stents.10-12

Thus, in the U.S., use of BTK stenting has traditionally been reserved to combat recoil and dissections in complex CLI cases, especially in patients that are poor surgical candidates.13 Although some of the trials that have led to such employment may have been limited by statistical power and short-term assessments, their findings may also be reflective of the existing technology and comprehension of CLI (from vessel histology to the pathological implications of this systemic disease) at that time, both of which have vastly evolved.

The current BTK revascularization outcomes thus far, in addition to the paclitaxel conundrum, suggests that the challenges in treating BTK disease in CLI have yet to be met. The meta-analysis of Romiti et al. demonstrated more than 90% of patency failures and amputations occurred within 6 months after endovascular infrapopliteal treatment. This timeline parallels the average wound healing time seen after complex BTK revascularization.10-12 Keeping ‘20/50’ in mind, along with the poor outcomes described throughout this article, the efficacy that can flatten CLI mortality is apparent by 6 months. By establishing primary effectiveness and safety endpoints at 6 months, the STAND trial seeks to break down the barriers that have held us back from successful BTK treatment.

THE MICROMEDICAL SOLUTIONS MICROSTENT

The MicroMedical Solutions MicroStent® is a self-expanding nitinol stent designed with the intent to treat BTK vessels in CLI and combat the alarming amputation...
and death rates. With the goal of limb salvage, the stent has been tailored to meet the challenges that come with diseased tibial vessels. The woven nitinol composition makes the scaffold highly conformable without excessive outward force. This is advantageous as it allows for the following:

(1) Precise deployment. The lesion length is matched to the predicted stent length upon deployment based on vessel diameter. With help from the 3 French (Fr) MicroGuide® catheter, this ensures reliable and accurate stent selection by the operator and precise delivery.

(2) Optimal stent opposition. The stent adheres to varying eccentric plaque morphologies as seen on IVUS, permitting luminal gain. Precise deployment.

(3) “Gentle” luminal gain. As excessive chronic outward force between the inner and stent can propagate inflammation and promote in-stent restenosis (ISR), especially in small-caliber arteries, this stent’s self-expanding scaffold negates elastic recoil and allows for the 30-day follow-up, which is pending at the time of authorship.

HEAL REGISTRY

As our globe battles the challenges brought forth by COVID-19, enrollment in the STAND trial has been temporarily paused to ensure the safety of physicians and patients. The MicroStent® is also under investigation in Europe through the HEAL registry, which began enrollment in October of 2019. The HEAL registry is an open-label, all-comers registry in Italy, Belgium, Germany, Netherlands, and Austria, seeking to characterize the real-world use of the MicroStent®, with open inclusion and exclusion criteria. Furthermore, as regards real-world experience, the registry places no parameters on adjunctive therapy, permitting evaluation of the MicroStent® in conjunction with additional treatments. The primary effectiveness endpoint is primary patency at 6 months post procedure, as defined by freedom of target lesion occlusion and clinically driven TLR. The safety endpoint is freedom from major adverse limb events. Additional enrollment and analysis are forthcoming.

CONCLUSION

As our world heals from the impacts of the COVID-19 pandemic and research continues, we remain enthusiastic in our view of how the MicroStent® will contribute to the dynamic limb salvage treatment landscape, with its goal of clinically effective change by 6 months.

Reprinted from Vascular Disease Management 2020;7(5):E100-E103.

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REFERENCES

The lower limb arterio-venous vasculature has a gradually tapering distribution, with around 91% of cases showing typical patterns of vasculature and 9% with anatomical variations, and is closely related to the muscular components of the leg. Arterial vasculature of the calf and foot gathers three main vascular bundles: the anterior, the posterior, and the peroneal arteries. These arteries correlate with four distinct anatomical compartments in the calf, and nine others in the foot, and are associated with roughly sixteen corresponding inframalleolar bundles. In addition to this balanced compartmental distribution, the lower limb arterial tree unfolds specific areas of transmural vessels, known as “angiosomes.” Similar to genuine muscular compartmental orientation, the angiosome partition expresses topographic reproducibility in humans. The angiosomal branches are not indivisible, or “terminal” ramifications of the entire arterial tree. They are millimetric branches that further divide in smaller divisions (“fetal ramifications”), before reaching the arteriolar level with specific, topographically oriented zones of tissues. From the main ilio-femoral flow sources, throughout the angiosomal branches, and down to the capillaries, a harmonious “pyramid of gradual limb flow distribution” is created. This vascular system is structured in several levels of tapering vessels (Levels I to VI) toward specific angiosomes. Each of these levels continuously provides coordinated and dynamic adaptations in regional perfusion, in accordance with various endogenous and exogenous factors.

Every bifurcation becomes progressively thinner than its parent trunk. Each arterial path progressively branches into inferior degrees of segmentation that ultimately creates a wider cross-sectional area toward peripheral tissues and increases the amount of perfusion to the tissue. It is important to note that even in the presence of sparse arterial anatomical variants (0-12%), the limb maintains steady vascular distribution among all compartments, angiosomes, and their collateral networks. No random flow is observed among the calf perfusion sectors, or between the dorsal and the plantar territories of the foot. Appropriately knowledge anatomical features of the lower limb is beneficial for the interventionist. Such knowledge facilitates diagnostic solutions in various presentations of ischemic limbs, as well as a better perspective of outcomes when planning revascularization for optimal tissue regeneration.

**MAIN TIBIAL TRUNKS**

The anterior tibial artery (AT) originates at the interosseous membrane of the calf as the first principal infragenicular arterial branch. At this level, it reveals a constant anastomosis (of changing degrees in individuals), “the hook.” Calcifications may commonly be encountered at this anterior crossing point between distinct leg compartments. This calcification is thought to be due additional stiffness and turbulences that are induced by the surrounding fibro-tendinous structures. The AT artery courses along the deep posterior calf as the first principal infragenicular arterial branch. At this level, it reveals a constant anastomosis (of changing degrees in individuals), “the hook.” Calcifications may commonly be encountered at this anterior crossing point between distinct leg compartments. This calcification is thought to be due additional stiffness and turbulences that are induced by the surrounding fibro-tendinous structures.

**Anatomical Variations.** According to a recent meta-analysis by Kropman and colleagues that included 7671 cases, atypical calf and foot arteries were observed in approximately 7% to 10% of individuals. High origins (at the popliteal level) of AT, or atypical Tibial trifurcations, were reported in 5.6% to 6.2% of individuals, while abnormal DP origins were found in 4.3% to 6.3% of cases. An anomalous first dorsal metatarsal artery origin, associated with atypical first toe collateral perfusion, was described in 8.1% of individuals, concomitant abnormalities of the arcuate artery in 5%, and variants of plantar arches and plantar arteries in 5%. The presence of one atypical tibial or pedal presentation on one leg should alert the interventionalist to a 21% risk of encountering similar abnormalities on the contralateral extremity. Although it is useful to acknowledge these abnormalities, these anatomical variants may prompt a more detailed local angiosomal flow evaluation, yet only lead to small changes in wound-targeted revascularization. This strategy follows and adapts to every available local collateral network, with or without uncharacteristic anatomical features.

**Practical Issues.** Large DP collaterals (≥1 mm diameter) on the lateral side of the foot (the “lateral tarsal” or “diagonal arteries”) connect the AT territory to the lateral plantar branches that belong to the posterior tibial artery (PT), in an effective regulatory system. In cases of DP thrombosis in patients with unaffected vessels, healing of dorsal foot and anterolateral ischemic wounds can be observed as a result of these collateral branches. Conversely, with thinner (<1 mm) and less available collaterals on the medial aspect of the foot (medial tarsal arteries), the same DP dysfunction seldom allows recovery of dorsomedial CLI ulcers, and wounds improve only via indirect, medial plantar collateral support.

The posterior tibial artery (PT) bifurcates the tibi-peroneal trunk (TPT), 1 cm distally from the AT emergence. The PT courses along the deep posterior compartment of the calf where current surgical, or endovascular approaches for revascularization procedures can be initiated. A higher frequency of long (>15 cm) calcific obstructions in the segment of the PT appears to be more prevalent in diabetic and renal patients. At the ankle level, in the retro-malleolar zone, the PT crosses the retinaculum of the flexor muscles of the foot, a transition zone towards the fixed plantar circulation. This high shear-stress zone (similar to the adductor ring for the superficial femoral artery, or the extensor retinaculum for the AT) equally inflicts local turbulence of flow and chronic endothelial injuries that may lead to a higher prevalence of atherto-occlusive disease. After releasing its medial calcaneal branch, the PT bifurcates at the plantar aspect of the foot, into the medial and the lateral plantar arteries. The lateral plantar vessel represents an important, large caliber (1-1.5 mm) terminal PT bifurcation that further creates the deep plantar arch. Both foot branches share vital compensatory flow via the deep plantar artery, an important trifurcation branch from the DP. The PT, via its medial calcaneal branch, and through the medial and lateral plantar source arteries, provides angiosomal topographic flow for the plantar portion of the foot and toes, in addition to providing 70% of perfusion in the heel. Anatomical variations. According to the meta-analysis by Kropman and colleagues, PT native variants can be found in about 6.8% of individuals. Among these variations, PT artery hypoplastic, aplastic, or high emergences were observed in 3.3% of cases. TP dominance (absence of the AT artery) was documented in 1.5% of cases, whereas atypical plantar arch and plantar arteries were seen in 5% of cases.

In atypical cases, the vast majority of the plantar vessels have a peroneal origin. As mentioned for the dorsal foot and the arcuate artery (DP/AT), the lateral plantar artery (PT) hosts a parallel and key role for the plantar side of the foot. Probably among the most difficult ischemic foot lesions to treat by purely hemodynamic means are those located at the hallux level. The hallux and the first interdigital space territories are an important collateral hub of the forefoot. This zone is a watershed area from at least two or three neighboring angiosomal “source arteries.” These watershed arteries.
are the first dorsal metatarsal artery (DP/AT), and the media and lateral plantar arteries (PT). Critical ischemic wounds/necroses confined to this level are often expressions of a wide and multilevel occlusive disease, located upstream of the pedal vessels. Necrotic lesions detected in this foot territory frequently indicate severe disease of the plantar and forefoot collateral and web, and critical injury of more than half of all native compartmental hallux interdigital collaterals.1,14,15

In the anterior and posterior tibial-plantar arch vascular territory, specific “high shear-stress” flow zones have been described. These zones seem preferentially exposed to severe atherosclerous, chronic occlusions, and heavy calcifications. Therefore, the “flexor retinaculum” passage (concerning the PT), the interosseous membrane transition point (the AT), and also the “extensor retinaculum” (the AT), all represent constant challenging zones for endovascular techniques, via either antegrade or retrograde approaches and interventions.1,13,14

The peroneal artery (PA) supplies the lateral compartment of the leg. The PA is often seen as a “rescue” revascularization trunk, as it shows less significant atherosclerotic occlusive disease in the common CLTI context. Accordingly, it can support current surgical1,15 or more demanding endovascular transcutaneous approaches1,13 for reperfusion. Despite traveling in the deep posterior compartment of the calf, the PA ends superficially by its lateral calcaneal artery, to the plantar arch and also to the anteromedial ankle via its anterior perforating branch and source artery.14,15

Anatomical variations. The peroneal artery shares fewer independent normal distributions than those described among all tibial trunks. Most cited variants are associated with a high peroneal origin from a dominant calf peroneal trunk in hypoplastic or aplastic PT presentations (2%).1,15,16

Practical issues. In the CLI context, the peroneal trunk currently has fewer calcifications than the AT or PT, with a higher technical accessibility for surgical or endovascular techniques for limb salvage.1,17,18 Large-caliber anterior and posterior communicants may provide good filling in the foot arches, although only in isolated collateral patterns.1,15,18,19 Accordingly, some authors have labeled the PA as “the best artery to treat,” particularly in the multifaceted diabetic foot context.1,15,16 Although the PA can provide an effective rescue supply for most CLI Rutherford 4 presentations, it useful in healing Rutherford 1-2 forefoot or hindfoot complex tissue lesions by unspecified indirect revascularization remains questionable. Metabolic reparative angiographic assessment may enable us to identify and utilize every individual peroneal flow distribution and collateral partition when planning wound-targeted revascularization.1,12

For further discussion, including pedal arches, angiosomes of the lower leg, and variations of the ischemic foot, see VASCULAR DISEASE MANAGEMENT 2019;16(7):E179-E182.

Practical issues. Specific footroot and hindfoot ischemic wounds or multiple CLI ulcers often reveal severe neighboring collateral deprivation that originates from two or three affected neighboring angiosomes. In such cases, routine angiosomal evaluation can be arduous to perform. Advanced macro and microcirculatory CLTI conditions perpetuate the destruction of collateral and cutaneous perforators.10,16 These patterns are frequently encountered in diabetic or renal patients, via severely distorted ankle landmarks.1,7,12,15 Clinical presentation of the most impressive ischemic ulcer or necrosis zone may not always relate to the lowest perfusion area in CLI feet. Irregular decay of collaterals, the patchy distribution of remnant choke vessels and cutaneous perforators,1,17,20,21 local capillary shunting by severe neopraxy,22,23 superficial triggering edema, and deep compartment hypertension, may all lead to substantial variations in “real-life” CLI presentations. Parallel risk factors for tissue recovery such as chronic inflammation, fibrotic scars, remote-intercurrent extensive infections, and regional hyper-pressure syndromes, may lead to acute thrombosis of small collaterals, particularly the highly vulnerable interdigital and cutaneous perforator branches.1,17,20,21 Understanding these elements may help clinicians to better deduce the real ischemic burden of each ulcer presentation and more completely assess eventual wound-directed revascularization.

CONCLUSIONS

From main ilio-femoral vascular sources, throughout the angiosome branches, and up to the arterial and the capillary vascular territory, there is a harmonious pyramid of global arterial arch system. CLI is associated with specific infrageneric patterns of arterial atherosclerotic decay. Compensatory flow pathways are useful for intervalist undertakers to understand for eventual topographic foot reperfusion. Regardless of irregular collateral availability, efficient limb revascularization must involve an arterial arterial rerouting from the level of the diac down to the foot arches to achieve limb salvage and adequate wound healing.

Disclosure: All authors have completed ICMJE disclosure forms and have reported no conflicts of interest regarding the content herein.

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• Role of health care system funding mechanism
• Average difference in favor of tax-based vs. insurance-based systems is equal to 4.5 per 100,000 diabetic amputations

CLI SITUATION IN EUROPE

The Organization for Economic Cooperation and Development (OECD) studied lower-extremity amputation (LEA) rates in people with diabetes from 26 European countries from 2000 to 2011. The study showed a decline in amputation rates of more than 50% from a mean of 13.2 (median, 9.4; range, 4.1–28.1) to 7.8 amputations per 100,000 in the general population. Despite the decline, still in 2011 an amputation attributed to diabetes occurred every 7 minutes (216 amputations per day). Variability between countries exists and is difficult to explain. For example, Germany has a rate of amputation more than 18 times higher than Hungary (18.4 vs 1.1 per 100,000). The result for Germany may be biased by a higher number of minor amputations in the numerator or lack of accurate data, given that there is no national register to verify the precision of these estimates. The data from these 26 countries show lower amputation rates in health systems financed by public taxation. The average difference in favor of tax-based versus insurance-based systems is equal to 4.5 per 100,000 diabetic amputations (Figure 1).

In a similar study that examined a time period between 2000 and 2013, Carinci et al reported a mean reduction of major amputations in the general population from 10.8 to 7.5 per 100,000 (~30.6%). Additionally, a mean reduction of major amputations in people with diabetes from 182.9 to 128.3 per 100,000 (~29.8%) was seen. Interestingly, minor amputations remained stable over the study period. The implementation of standardized definitions, necessary to increase the comparability of multinational data, highlighted remarkable differences between countries. Therefore, these results can help identify and share best practices effectively on a global scale (Figures 2 and 3).

CLI SITUATION IN BELGIUM

In a nationwide study of 5,438 individuals provided by the Belgian national health insurance funds, covering more than 99% of the Belgian population (approximately 11 million people), the risk of undergoing a major lower extremity amputation in Belgium gradually declined for individuals between 2009 and 2013. Many reports have demonstrated that a substantial decrease in the incidence of major amputations, as well as a decrease in the total incidence of amputations in people with diabetes, is feasible after the implementation of multidisciplinary and trans-sectoral programs for diabetic foot ulcer care and prevention. A new finding of this was the strong decline in the major amputation rate in people with diabetes, but not in people without diabetes. The relative risk comparing people with and without diabetes decreased but remained high. The decline in the amputation rate in those with diabetes was particularly prominent for major amputations above the knee. A weaker, but still significant decrease in the amputation rate for minor lower extremity amputations with and without diabetes was also observed.
A study by Heyer et al showed that the amputation rates per patient in Germany have remained stable in the overall population, while a slight decline in patients with both diabetes mellitus and with arterial occlusive disease between 2006 and 2012 was seen. The authors recommend the implementation of intensified preventive measures that are considered crucial to the permanent reduction in the number of amputations.

In a retrospective analysis of the database of the largest public health insurance in Germany, which included all in-and outpatient diagnoses and procedural data obtained from a cohort of 418,882 patients hospitalized due to PAD during 2009 to 2011, including a follow-up until 2013, it was shown that 44% of amputees with CLI did not undergo a diagnostic angiogram in the hospital prior to their amputation. When taking into account a 24-month time frame prior to the amputation, the number of patients who underwent lower extremity amputations decreased over the years from 55.0 to 36.3 per 10,000 patients with diabetes (P<.05). This rising population with diabetes combined with a decline in major amputations reflects an increased attention toward the diabetic foot. The number of hospitals in the Netherlands with access to podiatrists increased from 32% in 1995 to 72% in 2000. The number of multidisciplinary foot clinics increased from 16% to 40% in the same time frame.

The first striking observation in the study was the decrease in the number of diabetes-related lower extremity amputations in the Netherlands over a period of 10 years. The incidence decreased by 26% in men and 38% in women with diabetes. A clear explanation for the difference in growth in the numbers of individuals with diabetes between men and women is lacking. The prevalence of diabetes diagnoses in the U.S. also showed a greater increase in men than women.

The increase in the prevalence of diabetes in the Netherlands was marked and reflects an increased attention toward the diabetic foot. The incidence of diabetes in the Netherlands was marked and showed an increase of 22.4% and those without diabetes increased 20.7% and without diabetes (12.5%). The rates of minor amputations for those with diabetes a decrease of 83% for men and 79.1% for women (P<.001). No significant change in cadence of minor amputations was noted. Due to improvements in metabolic risk factor and lifestyle factor management, increased emphasis on early and aggressive treatment of foot ulcer and better patient education may have contributed to these results.

A study conducted using the National Hospital Discharge Record database for the period 2001 to 2010 looked at lower extremity amputations in persons with and without diabetes in Italy. The study showed a reduction of major amputations during the study period of patients with diabetes (20.7%) and without diabetes (12.5%). The rates of minor amputations for those without diabetes increased 22.4% and those without diabetes remained stable. These data reflect an improvement in the quality of diabetes therapy as well as in the overall approach to diabetic foot care such as the inclusion of peripheral vascular revascularizations, for example.

CLI SITUATION IN ITALY

A study by Jorgensen et al of a Danish diabetic specialist center from 2000 to 2011 showed an incidence of all lower-extremity amputations in Type 1 diabetes of 87.5% for men and 47.4% for women. It showed in incidence of all lower-extremity amputations in Type 2 diabetes a decrease of 83% for men and 79.1% for women (P<.001). A clear explanation for the difference in growth in the numbers of individuals with diabetes between men and women is lacking. The prevalence of diabetes diagnoses in the U.S. also showed a greater increase in men than women.

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CLI SITUATION IN DENMARK

A study by van Houtum et al, including data from 1991 to 2000 from the Dutch National Medical Register, showed that in 1991, a total of 1,687 patients with diabetes had been admitted 1,865 times for 2,409 amputations. In 2000, a total of 1,673 patients with diabetes were admitted 1,932 times for 2,448 amputations. The overall incidence rates of the number of patients who underwent lower extremity amputations decreased over the years from 55.0 to 36.3 per 10,000 patients with diabetes (P<.05). This rising population with diabetes combined with a decline in major amputations reflects an increased attention toward the diabetic foot. The number of hospitals in the Netherlands with access to podiatrists increased from 32% in 1995 to 72% in 2000. The number of multidisciplinary foot clinics increased from 16% to 40% in the same time frame.

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Figure 3. Lower extremity amputation rates in diabetes according to different definitions, year 2013, or last year available, OECD data collection 2013.12 Used with permission from Springer Nature.
COVID-19 from cover

test immediately upon admission to the emergency room and likely wait to treat until results were known. In the interim, the patient would be started on anticoagulation and antiplatelet therapy. “We have seen an anecdotal change in the last several weeks to a less liberal stance to intubate COVID-19 patients due to the dismal prognosis for those who are intubated. We have adopted an almost never intubate approach to these patients. I think this approach is being replicated around the New York area. Intubation is not considered benign and is really viewed as a high-risk intervention, even for emergent cases.”

Dr. Richard Neville, from Virginia, stated that just a couple of weeks ago his institution may not have even intervened on this patient who would have been considered a Tier 2 patient. These patients would instead get treatment after 48 hours. However, over the past couple of weeks, the window has been expanded, and now Tier 2, or urgent, cases are being intervened upon immediately. If the patient has any symptoms, they would be tested. Without symptoms, standard precautions would be followed.

Q AND A

Q: What are your thoughts on testing for everybody?
A: Dr. Michael Jaff responded, “From a staff standpoint, it is reassuring and shows empathy and concern. Anything we can do to reassure staff is of great value. We need to keep in mind the facts regarding acute diagnosis: active viral shedding tests were designed to diagnose sick patients and not designed to screen populations of asymptomatic patients. The false negative rates, in my view, are unacceptable and give people a false sense of security.” Dr. Jaff underscored the fact that staff should know you care and are trying to protect them as best you can.

Q: Are patients comfortable being treated in an outpatient setting versus a hospital and what type of protection are you providing?
A: Dr. Jihad Mustapha, who performs CLI revascularization in a busy outpatient CLI center in Michigan, described seeing an increase in patients being referred from the hospital systems to the outpatient center for treatment. “Hospitals are performing fewer non-COVID procedures and patients fear going to a hospital setting. We provide screening of patients and staff and provide adequate PPE for our staff. Patients are comforted by being treated in an environment where they believe their risk of exposure is less.”

Q: What are you seeing in the United States regarding urgent versus emergent treatment for patients with CLI needing podiatric surgery?
A: Dr. Driver reports that her experience now on the west coast and her communication with the east coast confirms that CLI patients are being seen in the clinic setting as much as possible and being kept out of the ER. Minor procedures needing to be done urgently are being done in the outpatient setting as much as possible.

Q: There has been a lot of talk of arterial and venous thrombosis in the COVID environment.
What is your opinion of the risk of COVID to patients with CLI and vice versa?
A: Dr. Lookstein reports anecdotally seeing a massive uptick in large vessel strokes in a unique population much younger than typically seen. We are seeing patients who underwent endovascular therapy in the last 6 months coming in with a complete thrombosis of the infragenual circulation, where the typical presentation would be a focal restenosis. This is mostly not a chronic CLI population, however, but rather a more ALI population.

Q: Who in hospital administration in the United States came up with the theory that procedures like CLI are not important and urgent procedures to be done? What is the CLI Global Society’s statement on this matter?
A: Dr. Katzen responded on behalf of the Board with assurance that they believe CLI is an urgent, life threatening disease that needs to be addressed in that manner. The goal is to prevent loss of life and loss of limb. The CLI Global Society supports this type of therapy as needed urgent and emergent attention. Dr. Neville’s experience is not necessarily that the administration thinks CLI is any less important, but rather they were dealing with a utilization problem. “We saw what was happening in New York and it scared the heck out of everybody. The response was to shut down at first to reserve resources. We’ve now backed off on that after having secured resources. However, I do think we potentially are going to see an increase in amputations during this COVID period due to this.” Dr. Jaff, as a former hospital administrator, stated that the hospital administrators were not the decision makers. “The truth of the matter is that Medicare, American College of Surgeons, and American College of Cardiology came out with guidelines. Quite frankly, our voice wasn’t loud enough.”

Q: Do you feel that treating CLI in the COVID era conveys a higher risk for the CLI patient?
A: Dr. Mustapha responded, “CLI patients are fragile. Treating them now in the era to keep them out of the hospital is more important than ever before.”

Q: Is COVID less disruptive in New Zealand?
A: Dr. Holden responded, “One of the advantages of living on a couple of islands in the South Pacific may have afforded some protection. However, the New Zealand government went hard and went early on a complete isolation and lockdown that I believe helped us. One of the things we did right from the beginning was to state that any CLI patient presenting acutely would be treated acutely in our hospital system with the kind of protection mentioned earlier. As we open up more of our clinics, we have assumed a much more liberal stance with late-presenting CLI patients who have been battling on at home despite huge advertising campaigns urging patients not to wait to seek needed therapy.”

Q: As we are starting to look at recovery in various parts of the world, will we see a deliberate attempt to push things more into the ambulatory space than they were before?
A: Dr. Mustapha stated, “Actually, I see the future to be right for CLI centers like ours because the patients can be isolated, you can control who comes in and out, you can deliver the majority of care you need to deliver, and the safety is extremely good. I look forward to a future with more CLI centers. For me, it’s been a great experience.”

Q: Germany has had the lowest mortality rate of almost any place in the world. Does this translate into a population less fearful of hospitals?
A: Dr. Zeller stated, “This differs from region to region in Germany. In my area we have an infection rate of less than 2% at the moment. In our institution and our area, patients do not seem to fear coming to the hospital. So, we did not have the experience of patients coming in with delayed treatment. We did inform our physicians right from the beginning to refer CLI patients for therapy. We are not experiencing an increase in amputation; I believe due to this.

Q: What is happening in wound centers? How far can telehealth go for this population?
A: Dr. Driver responded, “These are very important questions because patients are being left behind. Programs with good telehealth are critically important. If you have a patient with a CLI diabetic foot with potential sepsis, it is critical to get them in front of a provider. Many wound care centers are completely closed down. Centers of excellence, particularly with combined vascular and podiatric specialists, that are separate from the hospital are being allowed to stay open. But there are not many of them.”

Dr. Neville reports that his organization has four wound centers. Their volume is down about 50%. “As we proceed with our standard technique and procedural steps to take care of patients and staff.”

Dr. Mustapha: This pandemic forced us to become more flexible and nimble to address the urgent needs of CLI patients while adapting to the changing environment.

Dr. van den Berg: I think what we have learned from this pandemic is that in addition to all the damage that was done by the virus, there is a lot of collateral damage due to delayed treatment affecting patients with CLI, but also patients who need to postpone oncology treatment among other things. We are bracing for the impact when we can fully reopen our activity. We need to be prepared for longer working days.

Dr. Driver: The bottom line is that we are still fighting for our patients. In the middle of a pandemic, if not treated, these patients are going to lose their limb or their life. We have to keep fighting for them and help them understand the best way to get care from us. We can’t back down.

Dr. Holden: Planning and preparation is important. There is a large, silent group of patients who are going to turn up in the next few weeks. I believe there is always a positive and there are opportunities that will come from this, opportunities to be more efficient and improve the way we communicate with patients and educate our colleagues. Take this webinar for example. We should embrace the good things that come out of it.

Dr. Neville: I think the importance of the CLI Global Society is now more important than ever in terms of raising awareness and advocating for our patients.

Dr. Lookstein: I am very proud to say that at our institution none of the staff have become symptomatic despite having done hundreds of cases over the past weeks, with close to 150 of those being COVID positive. I think that is because we’ve all come together as a dedicated team motivated to do the right thing. This is a testament to how you can be successful and understand you can overcome the challenges we are all facing.

Dr. Jaff: I am heartened by how the scientific community around the world has banded together to share data. As we come out of this, the voice of the physician is going to be even more important. This is particularly new to us because the US is going to have to figure out how to rebuild healthcare again and we need to have a loud and upfront voice.
Lee from page 3

at the inguinal ligament, as it may lead to stent fracture. An interwoven nitinol stent like the Supera stent (Abbott) is flexible and may lower the risk of stent fracture compared to other nitinol stents. However, the Supera stent strut design is not very conducive to ballooning the side branch. This may pose a challenge in the setting of distal bifurcation involvement of the CFA, which could lead to compromise of the deep femoral artery (DFA). Bifurcation lesions are also associated with increased risk of procedural failure and a trend toward higher 1-year rates of restenosis and target lesion revascularization. The presence of a stent in the CFA could make arterial access and the use of a vascular closure device to achieve hemostasis more difficult. Stenting of the CFA may hinder the option of CFE. The rates of restenosis and target lesion revascularization are higher after PVI of calcified lesions.

Strategies to improve procedural success rates in heavily calcified CFA include the use of atheroablative devices and intravascular lithotripsy (Figures 1–4). We reported that orbital atherectomy appeared to be safe and effective for the treatment of severely calcified CFA. The primary endpoint of angiographic complication, defined as the composite of flow-limiting dissection, perforation, slow flow, vessel closure, spasm, embolism, or thrombosis. However, the number of patients in our study was low and limited to short-term follow-up.

In summary, controversy surrounds the ideal revascularization strategy for CFA disease. Surgery has long been considered the gold standard. However, despite the technical success of surgery, it is associated with complication rates. PVI of the CFA is associated with less procedural mortality and morbidity compared with surgery. PVI may represent a paradigm shift for the treatment of CFA disease. Disclosure: None.

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REFERENCES


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It is possible that increased use of minor amputations may result in a lower incidence of major amputations, with their impact on patients’ quality of life.
The Critical Limb Ischemia (CLI) Global Society’s mission is to improve quality of life by preventing amputations and death due to CLI.

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