CLI GLOBAL
THE OFFICIAL PUBLICATION OF THE CRITICAL LIMB ISCHEMIA GLOBAL SOCIETY

CLI Global Society at ISET 2019: Spreading Awareness Among Physicians of All Disciplines

Jihad A. Mustapha, MD, FACC, FSCAI, Advanced Cardiac and Vascular Amputation Prevention Centers, Grand Rapids, Michigan

Jihad A. Mustapha, MD, FACC, FSCAI

Figure 1. The CLI Global Society sessions, co-developed with ISET, were moderated by Drs. Constantino Peña, Jihad Mustapha, Richard Neville, and Alex Powell.

Figure 2. Custom scrub caps supporting #CLIfighters were distributed during the meeting.

The CLI Global Society, led by President Dr. Barry T. Katzen, was proud to have a presence at the 2019 International Symposium on Endovascular Therapy held in January in Hollywood, Florida. They joined the more than 1,000 members of the endovascular community who came together for an ISET experience like never before, featuring expanded live cases, a greater focus on cutting-edge research, a thought-provoking town hall session on paclitaxel, and a dedicated track on CLI that was co-developed by leadership from the CLI Global Society.

The co-developed CLI Sessions experienced a fantastic turnout. These sessions were moderated by ISET course co-directors and CLI Global Society members, Drs. Constantino Peña, Jihad Mustapha, Richard Neville, and Alex Powell. The sessions provided a wide-ranging examination of CLI and covered treatment techniques, management, data, controversies, complications, and new horizons.

The global faculty presented on topics such as "Drug Elution in the Femoral Popliteal Segment" by Dr. Thomas Zeller, CLI Global Society board member from Bad Krozingen, Germany and "Vessel

Continued on page 15

Endovascular vs. Open Common Femoral Artery Treatment: The Surgeon's Perspective

Konstantinos Stavroulakis, MD,[1] and Theodosios Bisdas, MD[2]

Konstantinos Stavroulakis, MD

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The continuous development of minimally invasive techniques during recent years has led to a paradigm shift in the treatment of femoral and popliteal atherosclerotic disease, and the endovascular approach is now the favored first-line treatment option in this territory. Common femoral artery (CFA) disease is, however, a notable exception, because open repair is still considered the 'gold-standard' approach. Several studies reported the durability of open repair with primary patency rates up to 96% at 7 years.[1-4]

Nevertheless, surgical endarterectomy is not always a straightforward procedure, as it is generally considered to be associated with increased perioperative morbidity including both local and cardiovascular complications.[5-7] Obesity, diabetes, and chronic steroid use have been identified as risk factors for postoperative morbidity.[5,6]

Angioplasty, atherectomy with or without anti-restenotic treatment, as well as primary bare-metal or stent graft therapy, have been described as minimally invasive alternatives to surgery for the treatment of CFA disease.[8-12] Interestingly, in The Endovascular Versus Open Repair of the

Continued on page 20

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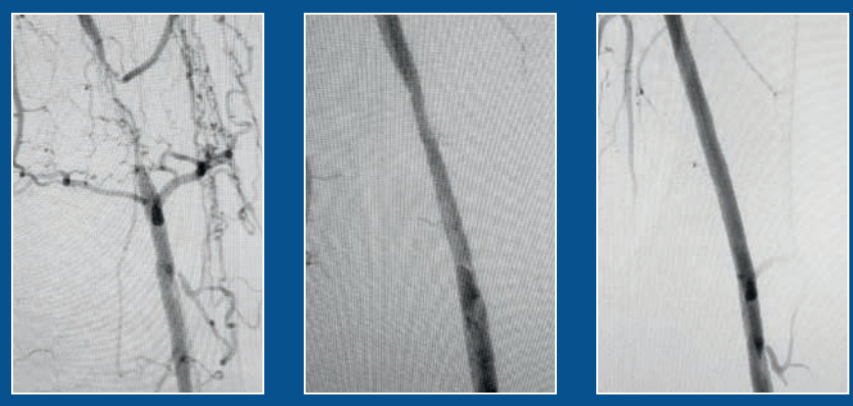

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Chronic Total Occlusion Crossing With Dual Access Approach: A Single-Center Experience

Joji J. Varghese, MD, and Bailey Ann Estes, BSN, RN-BC, RCIS, Hendrick Medical Center, Abilene, Texas

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Bailey Ann Estes, BSN, RN-BC, RCIS

"The greatest challenge in successful endovascular revascularization is chronic total occlusions (CTO)."

Endovascular revascularization for the treatment of peripheral arterial disease (PAD) has grown remarkably over the past decade and led to breakthroughs in technology and treatment techniques. When PAD progresses and patients develop critical limb ischemia (CLI), revascularization is imperative for limb salvage.

The greatest challenge in successful endovascular revascularization is chronic total occlusions (CTO). Their complex morphology and variability in length contribute to the high (20%–40%) crossing failure rate.[1,2] To combat this problem, advanced techniques such as a dual-access approach have been adopted from our coronary counterparts to increase the likelihood of crossing and allowing for more techniques to be utilized. By adopting this approach for our peripheral cases, success rates have increased significantly from utilizing a single-access only approach.

Using single access in complex CTO cases can significantly limit your options for treatment. The contralateral "up and over" approach is traditionally the most common approach, however it carries a 20% failure rate, even in the hands of skilled operators.[3] The major limitations of this approach include decreased torquability, pushability, and reach of equipment, which are all vital elements for treating CTOs.

We conducted a retrospective evaluation of our experience with crossing success utilizing dual access to evaluate safety and efficacy versus single access. A total of 141 patients with lower extremity CTOs were evaluated who demonstrated a high percentage of CLI,

Continued on page 18

TABLE OF CONTENTS

Critical Limb Ischemia: A Deadly Disease Requiring a Dynamic Approach to Revascularization

Moving Beyond Alternative Access: The Assisted TAMI Technique

Fadi Saab, MD, Advanced Cardiac and Vascular Amputation Prevention Centers, Grand Rapids, Michigan

Fadi Saab, MD

Critical limb ischemia (CLI) therapy is a constantly moving and evolving target. This deadly disease has been eluding physicians for decades. Unfortunately, it's the only disease where getting rid of the limb affected (ie, major amputation) is considered to be an accepted and, in many instances, the first line of therapy. Lack of data and constant focus on unrelated outcomes distracted a lot of healthcare providers and led to amputation becoming an accepted modality of treatment. In recent years, however, an explosion in new revascularization technologies has made limb salvage a reality in a growing number of advanced CLI cases. A recent analysis evaluating CLI patients with Rutherford Class 6 showed amazing results in a patient population that is currently deemed non-salvageable.[1] The success rate of chronic total occlusion (CTO) crossing, the improvement in revascularization techniques, and paired with an equally aggressive multidisciplinary wound care approach, created a movement within the medical community to champion limb salvage. Pedal access has been hailed as a great tool to improve the success rate of crossing in complex CTOs.[2] Furthermore, pedal-based revascularization via the tibio-pedal arterial minimally invasive retrograde revascularization technique (known as the TAMI technique) has propelled the field forward.

Traditionally, with the TAMI technique, single pedal access is obtained. The case presented here includes a variation—a relatively new concept described as an assisted TAMI procedure. In the past, whenever femoral access was involved, the operator would deliver therapy via traditional common femoral artery (CFA) access. However, groin access remains the biggest source of access complications. The term "assisted TAMI" refers to obtaining radial, brachial, or femoral access in combination with pedal access. The goal of upper body access is to assist in crossing the CTO while delivering therapy via pedal access. This case demonstrates this concept and describes the technical steps necessary to achieve a successful result.

CASE PRESENTATION

A 69-year-old male presented with intermittent rest pain in the right lower extremity and life limiting claudication of the left lower extremity. His past medical history was significant for an aorto-iliac bifemoral bypass 7 years prior. At the time, there was a right CFA complication that required percutaneous placement of a self-expanding stent. Surgical revascularization was deemed high risk secondary to prior surgery and stenting of the CFA. The patient comorbidities included diabetes, hypertension, and a remote history of smoking. The patient work-up included an extremely depressed ankle brachial index (ABI) of 0.3 on the right and 0.5 on the left. A detailed diagnostic angiogram showed the anatomy of the right and left lower extremities. Revascularization of the right lower extremity was performed in stages. Treatment of the right profunda was performed via atherectomy and drug-coated balloon angioplasty. The decision was then made to revascularize the left lower extremity (Figure 1A).

EVALUATION

The treatment modality decision for the left lower extremity was somewhat of a challenge. While the revascularization modality was easy to choose, the fibrotic left groin posed a challenge. Clearly an up-and-over approach was not feasible. An upper body approach is limited in this patient due to the patient's height of 6 feet 2 inches. Device selection here is limited and if faced with a complication, treatment options can be further limited. This complex CTO appeared to be a type II CTO based on CTOP classification. In theory, we would require both antegrade and retrograde modalities to cross the CTO. Traditionally, we would cross the CTO and deliver therapy via the CFA approach. For reasons described previously, having a large sheath in an antegrade fashion would increase the risk of complications. An assisted TAMI approach was determined to be the best option. An antegrade approach is needed to help cross the CTO while delivering therapy via a pedal sheath.

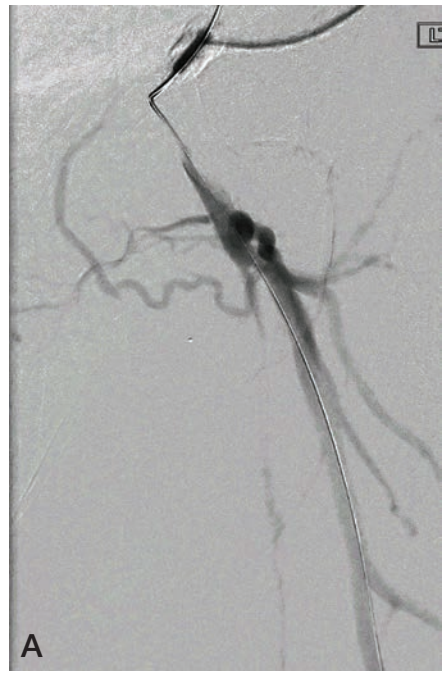

Figure 1. (A) Antegrade angiogram showing an occluded left superficial femoral artery. (B) A 2.9-French sheath is inserted into the left common femoral artery.

ACCESS

The case was started by placing a CFA antegrade 2.9-Fr Cook Medical sheath with a very small outer diameter (Figure 1B). The access was obtained under ultrasound guidance. The small arteriotomy site decreased the risk of access complications. Through this sheath, a 0.018-inch CXI angled catheter (Cook Medical) was advanced. Then, an 0.018-inch V18 wire (Boston Scientific) was used to help break the antegrade concave CTO cap. The next step entailed obtaining retrograde pedal access via the posterior tibial artery. A 4/5-Fr Slender sheath (Terumo Medical) was then placed in the vessel (Figures 2 and 3).

Figure 2. Slender 5/5-French sheath is inserted into the left posterior tibial artery.

Figure 3. Angiogram showing retrograde access through the Slender sheath.

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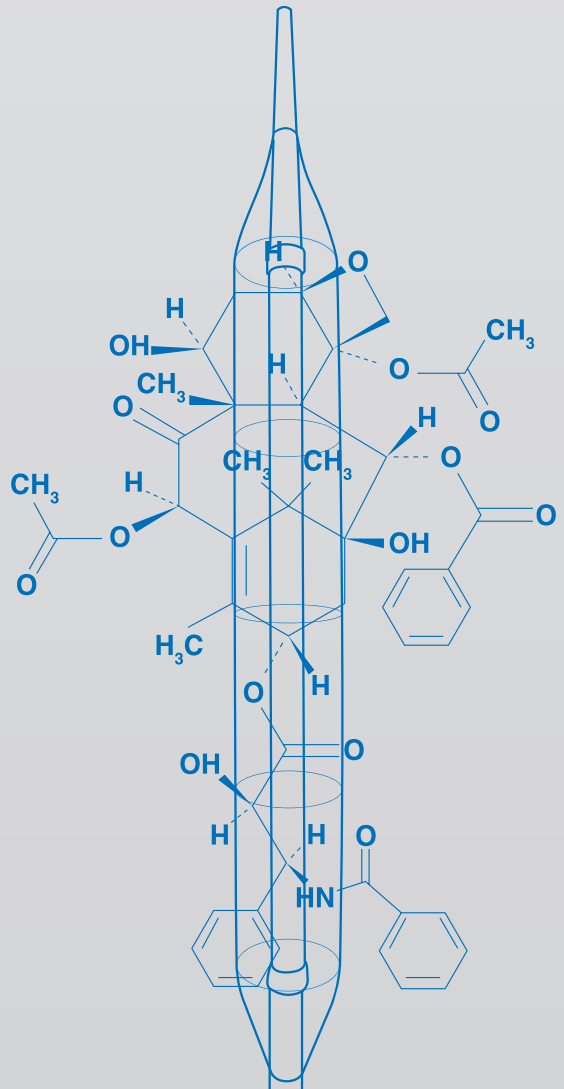

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** PK1400100 Rev. 2 04/18

† Virmani et al. Comparison of Particulate Embolization after Femoral Artery Treatment with In.Pact Admiral versus Lutonix 035 Paclitaxel-Coated Balloons in Healthy Swine. J Vasc Interv Radiol. 2016 Nov;27(11):1676-1685.e2. doi: 10.1016/j.jvir.2016.06.036.

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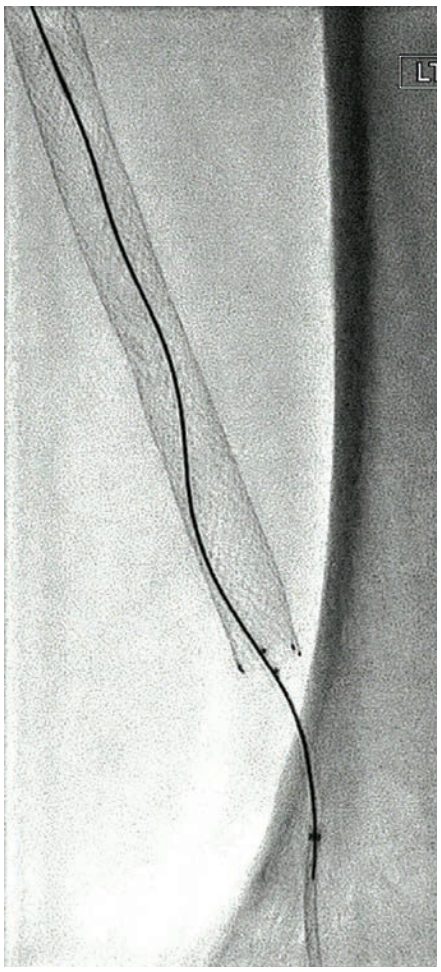

Figure 4. Angiogram showing tunneling of the CXI catheter into the Navicross catheter.

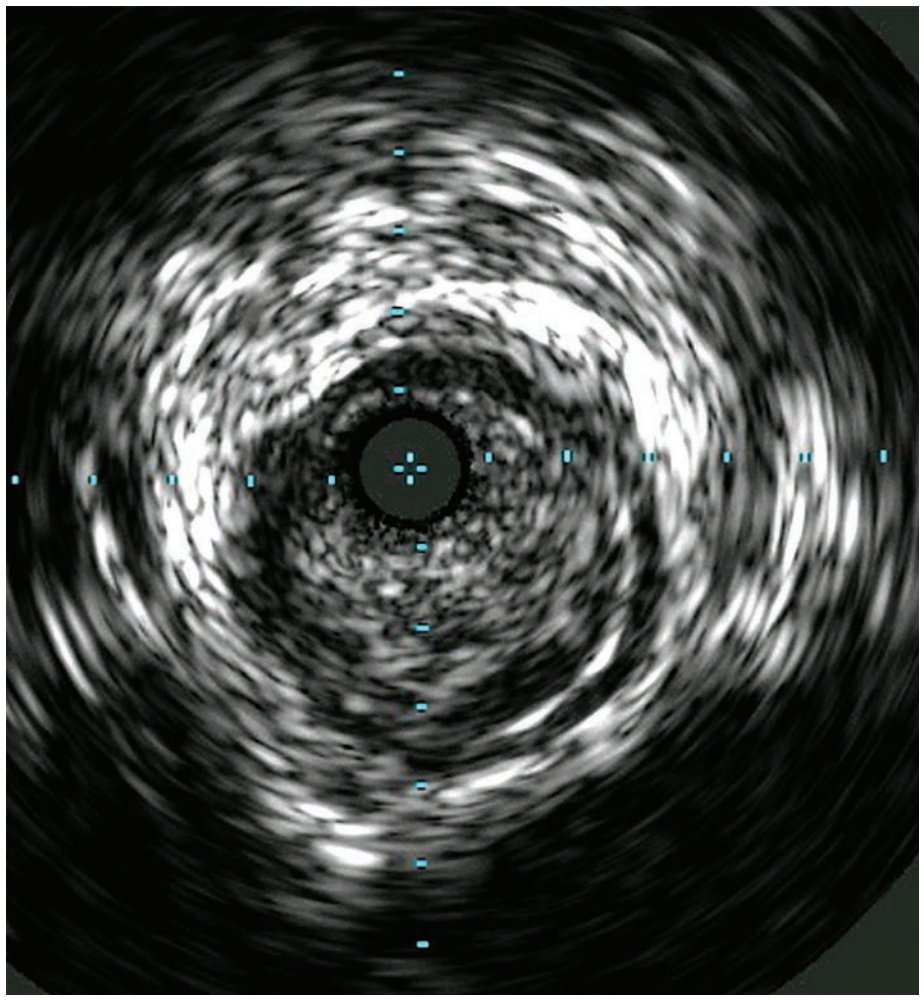

Figure 5. Intravascular ultrasound image confirming intraluminal superficial femoral artery positioning.

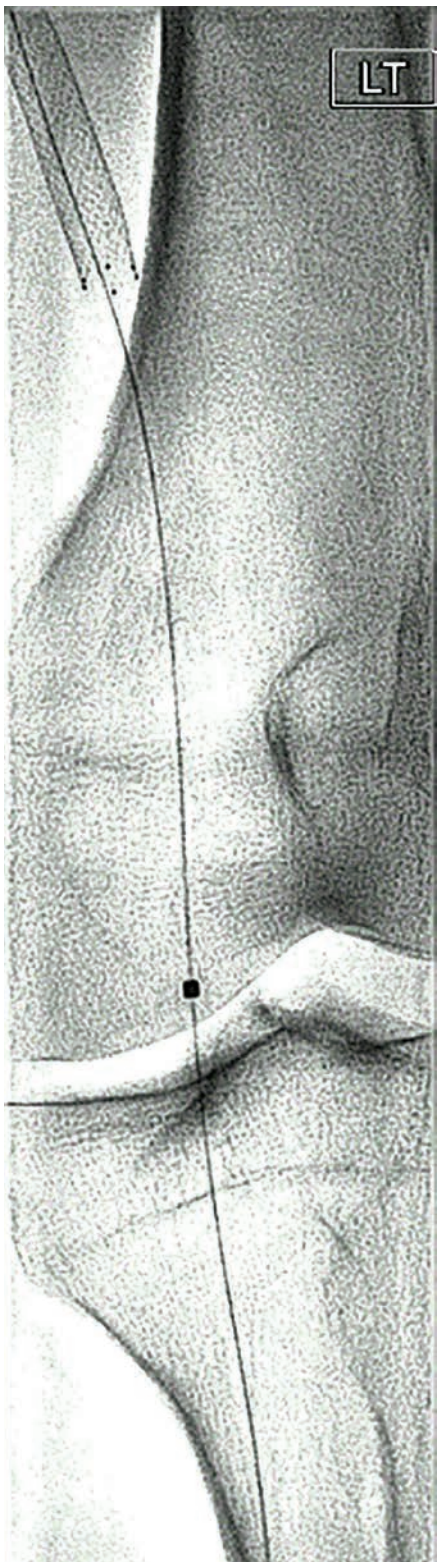

Figure 6. A 1.7-mm Turbo Elite catheter.

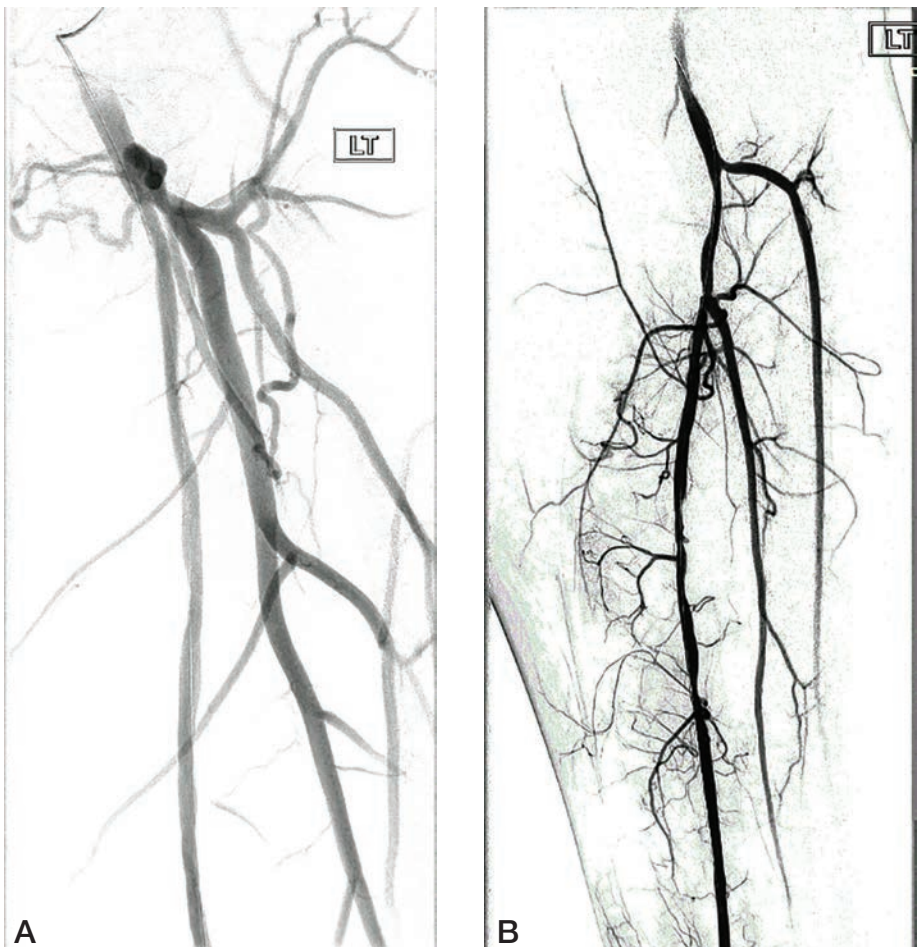

Figure 7. Final angiogram showing patent superficial femoral artery and popliteal artery (A) into the tibial vessels (B) with resulting 30% residual stenosis.

"An explosion in new revascularization technologies has made limb salvage a reality in a growing number of advanced CLI cases."

SAAB *from page 4*

CTO CROSSING AND REVASCULARIZATION

The distal CTO cap was then crossed in a retrograde fashion via an 0.035-inch Navicross catheter (Terumo Medical) and an 0.018-inch V18 wire. After tunneling the CSI catheter into the Navicross catheter (Figure 4), flossing occurred with a 0.014-inch Savion delivery wire (Boston Scientific). Prior to delivering therapy, positioning was evaluated with the aid of intravascular ultrasound (IVUS), which confirmed the intra-luminal position (Figure 5).

Revascularization strategy for this instent restenosis involved excimer laser atherectomy with a 1.7-mm Turbo Elite catheter (Spectranetics) followed by balloon angioplasty (Figure 6). Final angiographic images revealed restoration of normal flow with reduction of stenosis to 30% (Figures 7A and 7B). Hemostasis was achieved via manual compression of the left CFA access site where a 2.9-Fr sheath was utilized. Manual compression of the pedal sheath access site was also performed to achieve hemostasis. The patient recovery time was ideal as the patient was able to sit up in 30 minutes and ambulate in 60 minutes.

CONCLUSION

The assisted TAMI technique is a novel new concept that expands on the pedal-based revascularization concept. The antegrade crossing of a CTO cap is a well validated approach. The need for a large CFA access sheath is replaced with low-profile sheaths. As technology advances, and device profiles continue to decrease, the ability to deliver therapy will only improve. ■

REFERENCES

1. Mustapha JA, Martinsen BJ, Igyarto Z. LIBERTY 360 Study presentation at AMP 2016 reveals hope for Rutherford-6 CLI patients. *Cath Lab Digest*. October 2016: 24(10).
2. Saab F, Jaff MR, Diaz-Sandoval LJ, et al. Chronic total occlusion crossing approach based on plaque cap morphology; The CTOP Classification. *J Endovasc Ther.* 2018 Feb 1:1526602818759333.

Disclosures: Consulting and Physician Trainer agreements with Boston Scientific and Terumo Medical.
Dr. Saab can be reached at fsaab@acvcenters.com or on Twitter @fadisaab17.

Please follow #CLIfighters and #stopthechop on Twitter and add to the discussion of relevant CLI treatment issues and strategies.

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CLI GLOBAL SOCIETY

2018 EXECUTIVE SUMMARY

FINDINGS FROM RECENT STUDY:

- CLI is a serious problem that threatens both life and limb. Patients with CLI suffer poor long-term prognosis and generate high healthcare costs.
- Revascularization and attempts to salvage the limb are effective in saving both limbs and reducing mortality.
- Considerable efforts are needed to raise disease awareness and implement coding to better define and identify the disease.

Full article and editorial at www.cliglobalsociety.org/study

The Critical Limb Ischemia (CLI) Global Society was formed by passionate leaders to address the unmet need of CLI. It was incorporated on January 11, 2016 and received 501(c)(6) status on June 20, 2016.

The CLI Global Society is the only organization that is solely dedicated to patients and the public health aspect of CLI.

The intent of the Society is to work toward a coalition of multiple organizations that share an interest in CLI to facilitate implementation of goals that would lead to ideal management of this impactful problem. The best way to improve awareness and enhance the way CLI is treated is through a coalition of like-minded organizations that can address clinical, coding, and reimbursement points of view. The Society will also work with like-minded organizations around the world to globally improve treatment and outcomes in patients with CLI.

SUMMARY OF CLAIMS DATA

The CLI Global Society-sponsored study "Determinants of Long-Term Outcomes and Costs in the Management of Critical Limb Ischemia: A Population-Based Cohort Study" was published this year in the Journal of the American Heart Association. Administrative claims were obtained on Medicare beneficiaries with initial critical limb ischemia diagnosis in 2011. Clinical outcomes and healthcare costs over 4 years were estimated among all patients and by first treatment (endovascular, revascularization, surgical revascularization, or major amputation) in unmatched and propensity-score-matched samples. Among 72,199 patients with initial primary CLI in 2011, survival was 46% and freedom from major amputation was 87%. Among 9,942 propensity-score-matched patients, survival was 38% with endovascular revascularization, 40% with surgical revascularization, and 23% with major amputation. Corresponding major amputation rates were 6.5%, 9.6%, and 10.6% respectively ($p<0.001$ for all pair-wise comparisons). The cost per patient year during follow-up was $49,700, $49,200, and $44,700, respectively ($p<0.001$ for each revascularization procedure versus major amputation).[1]

Long-term survival and cost in CLI management is comparable between revascularization techniques, with lower major amputation rates following endovascular revascularization. Primary major amputation results in shorter survival, higher risk of subsequent major amputation, and higher healthcare costs versus revascularization.[1]

Full article and editorial at www.cliglobalsociety.org/study.

CLI GLOBAL SOCIETY COMMITTEE STRUCTURE

The Society has developed committees 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.

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#CLIFighters

CLI GLOBAL SOCIETY

CMS STRATEGY

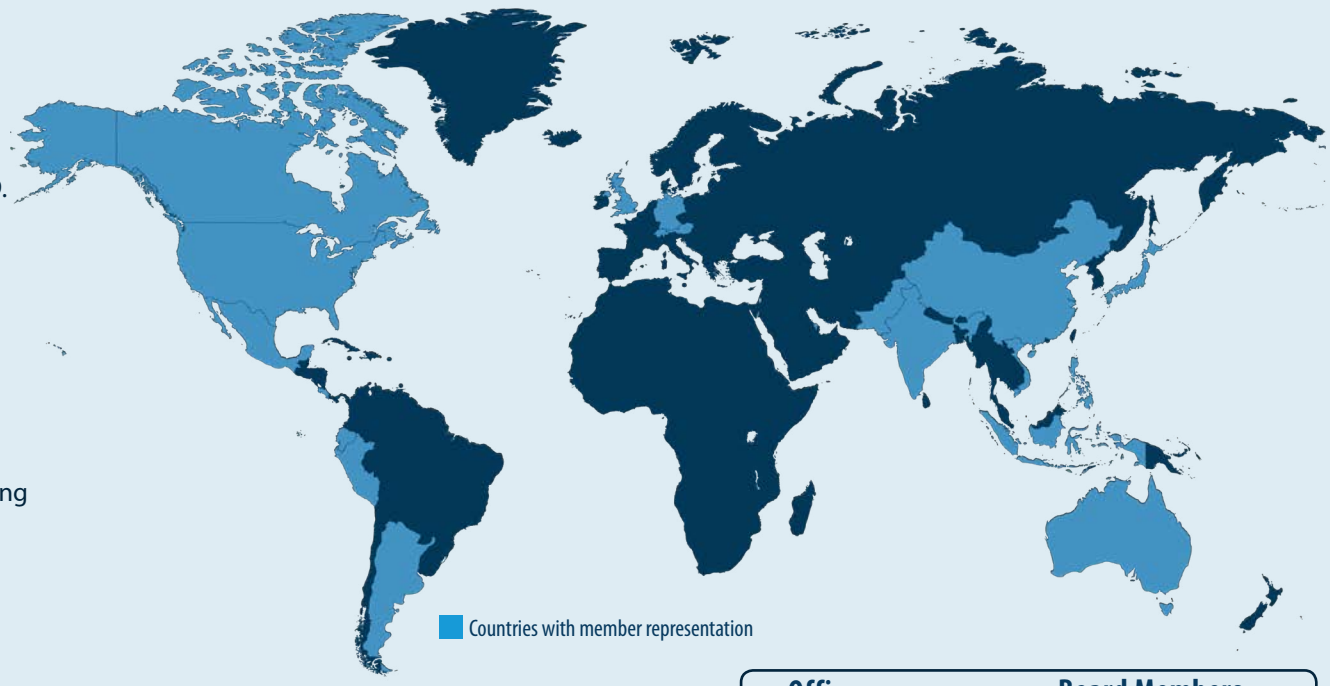
The CLI Global Society has done expansive work leading up to this publication and recognizes the many challenges that CLI places upon patients, healthcare providers, and payers. In an effort to address these challenges, the Society is working on strategies to engage the government payer system to enact reform to improve care of patients suffering from this devastating disease.

Issue	Strategy
CLI is not sufficiently recognized as the growing public health concern that it is.	Improve clinical outcomes and economic impact of CLI for Medicare beneficiaries via policy and payment strategies.
No diagnosis codes exists for CLI	Create a definitive set of diagnosis codes that define CLI in acceptable granularity (by stage, disease severity, etc.) already recognized in clinical practice.
Costs for the treatment of CLI are among the greatest health care expenditure challenges today.	Develop consensus on critical costs for tracking and analysis purposes to inform potential care improvement/ economic value propositions of new care models.
Amputation often remains a first line treatment and results in major disability, loss of work productivity and burdens to family and colleagues.	Develop cost models that include disability, loss of work productivity, caregiver costs, etc., to highlight the magnitude and impact of CLI as a vehicle for awareness and change.

The Society is working to tactically implement strategies by seeking CMS' proactive engagement to define, identify CLI clinical consequences, patient outcomes and economic impact. The Society has intent to pursue ICD-10 codes within the prescribed CMS/NCHS process. Engagement with CMS will be sought to evaluate possible payment models to align payment with CLI care that follows best clinical practices. Leveraging existing research and publications and the engagement of health economists, data analytic experts, employer, and actuarial health data analytics experts is essential to model non-CMS-related costs of CLI.

CURRENT SOCIETY ACTIVITIES

Membership has grown significantly with a firm benchmark in place to exceed 500 members in 2019. Global presence continues to excel with member representation in 21 countries:



An active advisory board has begun the process of creating alliances to achieve goals. The Society has been actively involved in supporting educational content focused on CLI in support of the mission. A priority is to create the data to support establishing public health goals that will fulfill the mission. The growing membership of the Society will be enhanced by collaboration and support of the CLI components of educational meetings.

Consensus activities with partnering organizations now include society educational sessions and/or member discounts at:
Amputation Prevention Symposium (AMP)
Amputation Prevention Symposium Europe (AMP Europe)
Cardiovascular and Interventional Radiological Society of Europe (CIRSE)
Charing Cross International Symposium (CX Symposium)
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National Interdisciplinary Congress on Critical Limb Ischemia
New Cardiovascular Horizons (NCVH)
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> We must address the unmet need of **critical limb ischemia**. 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.[2] One in 190 Americans (1.6 million) are living with loss of a limb. Unchecked, this number may more than double by 2050 to 3.6 million.[3]
>
> Barry T. Katzen, MD
> President, CLI Global Society

REFERENCES

1. Jihad A. Mustapha MD, Barry T. Katzen MD, Richard F. Neville MD, Robert A. Lookstein MD, Thomas Zeller MD, Larry E. Miller PhD, Michael R. Jaff DO. Determinants of Long-Term Outcomes and Costs in the Management of Critical Limb Ischemia: A Population-Based Cohort Study. J Am Heart Assoc. 2018;7:e009724. DOI: 10.1161/JAHA.118.009724.
2. J Vasc Surg. 2013 June ; 57(6): 1471–1480.e3. doi:10.1016/j.jvs.2012.11.068. The incidence and health economic burden of critical limb ischemia and ischemic amputation in Minnesota: 2005–2007. Circulation. 2009; 120:S1148.
3. Ziegler-Graham K, MacKenzi EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the Prevalence of Limb Loss in the United States: 2005 to 2015. Arch Phys Med Rehabil Vol 89, March 2008.

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#CLIFighters

#CLIFighters: Podiatry Residents Collaborate to Create Dedicated CLI Rotation to Say "No" to Amputation

Robby Caballes, DPM PGY-II,[1] and Paul Michael, MD, FSCAI[2]

Robby Caballes, DPM PGY-II

The future of critical limb ischemia (CLI) therapy will be determined by, among many factors, how well our training programs address the need for advanced options for amputation prevention. The interdisciplinary collaboration required for wound healing, foot and ankle reconstruction, and CLI therapy should be taught at the training level in order to have the future #CLIFighters ready to hit the ground running when confronted by the challenges of limb salvage early in their careers. By eliminating the borders of competition and raising the bridges of collaboration, amputation-free survival becomes a reality for many more patients. Prompted by the social media awareness campaign #CLIFighters, many of our residents became more involved with advancing CLI care and learning opportunities for limb salvage training. Due to the #CLIFighters campaign, our residents then became members of the CLI Global Society and became aware of increased learning and career opportunities such as the Amputation Prevention Symposium (AMP) meeting, which is held in Chicago every year.

Following the enthusiasm for CLI and limb salvage care within the Bethesda Health Podiatric Medicine and Surgery Residency Program in Boynton Beach, Florida, a dedicated endovascular and CLI rotation was created by residency director Dr. Kyle Kinmon, DPM, to ensure that foot and ankle surgeons were properly trained throughout their podiatry residency on evaluating CLI patients and better equipped for their future careers. A core curriculum dedicated to CLI, in addition to their vascular surgery and wound care rotations, was created. The curriculum includes didactic CLI training, hands-on endovascular procedural time, obtaining pedal access, understanding the complex peripheral anatomy associated with CLI that contributes to the inaccuracy of non-invasive findings, and understanding the importance of wound-directed therapy. After initiating this CLI rotation, immediate benefits were noted with a marked reduction in wound healing time and a reduction in major amputation.

CASE DESCRIPTION

The following case is a great example of the results of this new program. A 66-year-old professional truck driver presented to a podiatry office complaining of a non-healing wound to his left heel. He had a past medical history significant for Type II diabetes, coronary artery disease, coronary artery bypass graft surgery, hypertension, and well-known peripheral artery disease with multiple vascular procedures performed in the past. He was working full time as a truck driver yet diligent with his wound care. Despite compliance with his vascular, podiatric, and medical care for more than a year, he could not get his heel wound to close, making his work life difficult. None of his therapy was leading to a healing rate close to 50% post-intervention.

At this point, the patient was evaluated by a resident of the Bethesda Health Podiatric Medicine and Surgery Program, Dr. Robby Caballes, DPM, along with teaching attending Dr. Ashley Bowles, DPM, FACFAS. Following multiple previous revascularization attempts, the wound presentation was as follows: a 4.0 cm x 5.2 cm left heel wound (Figure 1) surrounded by necrotic tissue. After 8 months of battling his wound including IV antibiotics, strict offloading, and debridement, his imaging (Figure 2) work-up revealed bone marrow edema within the inferior aspect of the calcaneus at the attachment of the plantar fascia without T1 marrow replacement compatible with reactive osteitis and no evidence of osteomyelitis. Non-invasive imaging done by the podiatry team revealed a toe brachial index (TBI) of the affected foot to be 0.27. At this point, the patient was admitted to the hospital where angioplasty was performed again without wound directed therapy to the ankle, followed by excisional debridement and application of a wound vacuum. The patient was brought back for additional debridement (Figure 3) and application of a porcine liver graft (Figure 4) to the left heel wound. Despite attempted revascularization, sharp excisional debridement, wound vacuum therapy, and graft application, there was failure of the wound to respond with much less than 50% closure at 4 weeks' time.

Subsequently, the patient's case was presented at the interdisciplinary foot, wound, and vascular academics meeting and the decision was made to refer him to a CLI specialist. After initial evaluation by the CLI team, the patient was promptly studied with a digital subtraction angiography, low-contrast technique, selective angiogram via the radial approach (Figure 5) revealing total occlusions of the left posterior tibial artery, left peroneal artery, and left anterior tibial artery. The distal

Figure 1. Presenting non-healing 4.0 cm x 5.2 cm left heel wound.

Figure 2. Eight months post-initiation of IV antibiotics, strict offloading, and debridement, imaging showed bone morrow edema within the inferior aspect of the calcaneus at the attachment of the plantar fascia without T1 marrow replacement compatible with reactive osteitis and no evidence of osteomyelitis.

Figure 3. Post-angioplasty without wound directed therapy to the ankle, followed by excisional debridement and application of a wound vacuum, the patient was brought back for additional debridement.

Figure 4. Porcine liver graft applied to the left heel wound.

Continued on page 12

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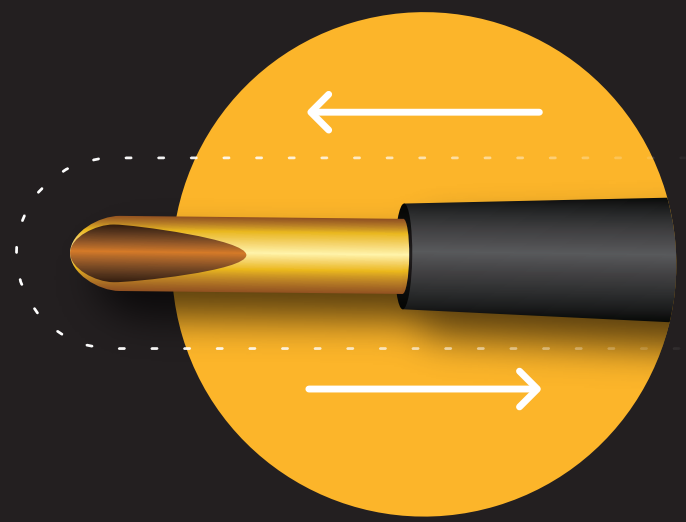

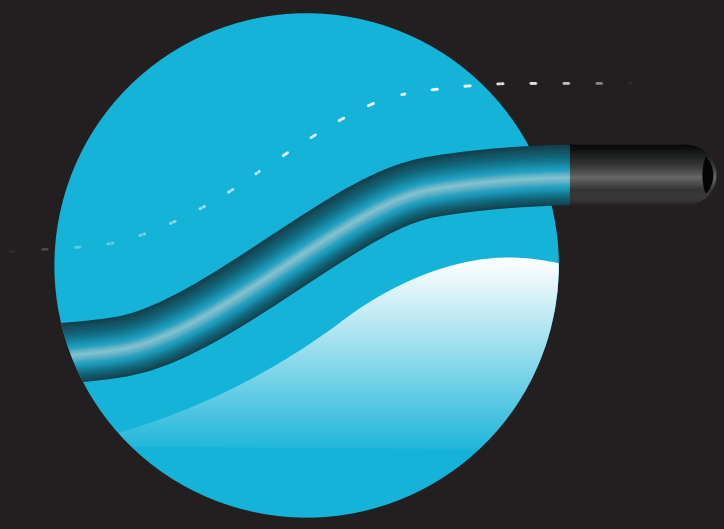

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Figure 5. (A-C) Baseline digital substraction angiography low-contrast technique selective angiogram via the radial approach revealing total occlusions of the left posterior tibial artery, left peroneal artery, and left anterior tibial artery. The distal anterior tibial artery reconstituted via collaterals and the plantar circulation does not have sufficient collateralization from any source explaining the lack of vascularity following any previous debridement.

Figure 6. Angiogram demonstrating intraluminal crossing of the posterior tibial artery chronic total occlusion.

Figure 8. Photograph showing complete wound healing 4 weeks after wound directed revascularization.

Figure 7. (A, B) Post-procedure angiography showing posterior and anterior communicating artery antegrade flow in the pedal circulation with a now complete pedal loop with brisk antegrade flow and a very generous wound blush of the heel.

CABALLES *from page 10*

anterior tibial artery reconstituted via collaterals and the plantar circulation did not have sufficient collateralization from any source explaining the lack of vascularity following any previous debridement. Soon after, revascularization with wound directed therapy was performed. After the standard CLI patient prep, with exposure of the entire leg available for the operator, antegrade left common femoral artery access was obtained and a 6-Fr, 45-cm Destination sheath (Terumo) was positioned in the popliteal artery. A combination of a Corsair 150-cm catheter (Asahi) and 0.014-inch Command wire (Abbott Vascular) were used to initially cross the posterior tibial artery chronic total occlusion. After the catheter was positioned in the distal lateral plantar artery confirmatory angiography revealed intraluminal placement (Figure 6). This was followed by angioplasty of the plantar and posterior tibial artery circulation beginning with a 2.0-mm x 200-mm Armada balloon (Abbott Vascular) and finishing with a 4.0-mm x 120-mm Armada balloon proximally. Given the amount of time the patient had spent attempting to close his wound and the multiple previous attempts at revascularization, it was decided to complete his tibio-pedal circulation to best ensure a complete pedal loop for optimal results and improved wound healing time. The anterior tibial artery total occlusion was crossed with the same Corsair and Command wire combination followed by angioplasty from the dorsalis pedis artery beginning again with a 2.0-mm x 200-mm balloon and finishing proximally with a 4.0-mm x 120-mm balloon. Intravascular ultrasound was used throughout the case for proper tibial sizing. After successful angioplasty of the anterior tibial artery was performed, the Corsair catheter and 0.014-inch Command wire were used once again, this time to cross the peroneal artery total occlusion. Successful angioplasty of the peroneal artery now provided posterior and anterior communicating artery antegrade flow in the pedal circulation. At this point, there was a complete pedal loop with brisk antegrade flow and a very generous wound blush of the heel (Figure 7). A Perclose vascular closure device (Abbott Vascular) was used for hemostasis of the antegrade access at the termination of the case.

After CLI intervention with tibio-pedal reconstruction, the patient underwent debridement and presented back to the CLI clinic just 4 weeks later with a completely closed heel wound (Figure 8). This case highlights the importance of interdisciplinary collaboration to achieve the best wound healing results in CLI therapy. This case is only one example of many amputation prevention cases in our residency program which have benefited from the podiatry CLI rotation and educational experience. This experience has been jumpstarted by the social media #CLIFighters movement, prompting our residency program to become members of the CLI Global Society. By creating better awareness of advanced CLI therapy and integrating with CLI-focused disciplines, our foot and ankle patients reap the rewards and can say "no" to amputation. ■

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Disclosures: Dr. Caballes has no disclosures to report. Dr. Michael reports consulting agreements with Asahi and Abbott Vascular.
Dr. Michael can be reached at drpaulmichael@gmail.com or on Twitter @drsavealimb.

Please follow #CLIfighters on Twitter and add to the discussion of CLI treatment issues and strategies.

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The Genesis of #CLIFighters and Our Mission

Timothy E. Yates, MD[1]; Kumar Madassery, MD[2]; Bailey Estes, BSN RN-BC, RCIS[3]

Timothy E. Yates, MD

Kumar Madassery, MD

Critical limb ischemia (CLI) is an under-recognized and under-treated disease across the globe. In the US, there are approximately 2 million patients suffering from this deadly disease annually. Approximately 40% receive major amputations within the first 6 months of diagnosis and there is a mortality rate of 25% at 1 year.[1-3] Alarmingly, CLI has a higher mortality rate than most cancers, yet providers and the public remain largely unaware of this disease. And even though lower extremity angiography prior to surgery has been demonstrated to significantly improve limb preservation, fewer than 50% of major amputation patients undergo this procedure. This disparity in education and awareness is not only rampant in the general public, but also within the healthcare community at large.

The CLI Global Society was established with the mission of raising awareness and establishing resources for CLI and amputation prevention. The CLI Global Society is not a physician-centric society, but rather a patient-centric society with an initiative to identify, define, and alter this critical disease state. In fact, the CLI Global Society is the only international body solely devoted to CLI. The founding members have espoused a multidisciplinary operational approach for this model, incorporating new scientific discovery with technology and appropriate application to healthcare problems. As the CLI Global Society has grown, so has the need for professional, patient, and public outreach. Traditionally, publications, business relationships, and medical meetings have served as the stage for this outreach. However, in the exponentially expanding information age, we are constantly presented with a barrage of often largely unfiltered information. Thus, another real-time mode of communication is needed.

Social media such as Twitter, Facebook, Instagram, LinkedIn, etc, is in widespread societal use; traditionally as a communication tool for friends and family and increasingly in professional networking. In healthcare, this platform has become an increasingly vital means of disseminating information and evaluating clinical scenarios. Academic institutions and industry alike have seen a flurry of social media growth; it has become a virtual loudspeaker. But this platform has no absolute rules or structure. Conceptually, this usage operates in a similar way to the online dictionary Wikipedia, whose goal is to allow the public knowledge worldwide to determine the most appropriate definitions and information on given topics. Over time, experts and novices alike have the same opportunity to chime in and shape human knowledge. However, this approach has led to myriad questions. Can information in SoMe be used for real-time decision-making? Is it peer-reviewed and trustworthy? Who has the right to make claims or to pose questions? No one has the "answer" to these questions, but it is imperative we attempt to do just that. The scientific method provides an objective means of posing and answering them. This will become increasingly important because the future of healthcare involves significantly more technology integration. SoMe's digital arms can impact the delivery of optimized care to patients.

Figure 1. After regular wound care and tibiopedal revascularization, Francisca Perez is shown with her healed foot and fellow #CLIFighters.

Figure 3. #CLIFighters represented at AMP Symposium 2018, with #CLIFighters neckties.

#CLIFighters started as a grass-roots movement among physician members of the CLI Global Society from different specialties, nurses, techs, and wound care professionals to create and share information. What began as a virtual "angio club" to display techniques and variations in management strategy, has led to a vibrant dialogue for education and new collaboration. The #CLIFighters method is a great way to share case reports, live educational cases, research, and

"Through increased member support and coordinated planning, the CLI Global Society and #CLIFighters movement can become the most all-inclusive limb preservation society in existence."

Figure 2. Twitter account for #CLIFighters.

Figure 4. Example of social media case discussion by #CLIFighters.

Figure 5. Gathering of #CLIFighters to discuss needs and goals, 2018.

Figure 6. Results from Instagram search of #CliFighters.

conference updates regarding CLI. Use of social media in healthcare has also created conundrums amongst different specialties, forcing members to closely review controversies and dogmas. The virtual educational discourse that we have witnessed amongst varying specialties has even led to increased dialogue and friendships offline, which has become an additional interesting aspect. Increasing patient stories (with patient permission) have been noted, which creates true humanistic and emotional connection to the digital content.

The CLI Global Society Founding Board realized that the #CLIFighters movement is a fantastic multidisciplinary CLI specialist networking strategy, with the end goal of improving outcomes for providers and patients. Representatives of the #CLIFighters were invited to establish an initiative for membership growth and social media outreach, to enhance the conventional missions of the CLI Global Society with a planned and organized approach.

Through increased member support and coordinated planning, the CLI Global Society and #CLIFighters movement can become the most all-inclusive limb preservation society in existence. This will require improved education for all providers, further development in advertising and marketing, as well as more scientific evidence. The collaborative potential of a vast body of specialists and regions can translate into powerful data collection, study initiation, and rapid dissemination of new findings. The end result will foster the next generation of CLI specialty centers with decreased major amputations and improved limb salvage in this population of sick patients.

CASE STUDY

Francisca Perez (name changed for privacy, but permission given for use of case information and photography in this publication) is a 61-year-old female widow with a long-time history of tobacco use and uncontrolled diabetes. She initially presented from about 4 hours away with debilitating ischemic rest pain of the right foot and gangrenous 2nd and 3rd toes. She underwent tibiopedal reconstruction and digital amputation. During this time, she continued smoking. One month later, she presented with chest pain and wound dehiscence. She underwent percutaneous coronary intervention and subsequent transmetatarsal amputation.

It was at this time she became aware of social media through the vascular and limb salvage program. Through social media, she was able to understand her disease process, other patients' dilemmas, and how they overcame their personal obstacles. Through direct messaging and interaction with "tweets," she was motivated to quit smoking. Additionally, input through social media allowed involved providers to track her care and algorithmically discuss optimization. From angiogram to wound-care and transmetatarsal amputation, both patient and providers had a quick and easy method to "own the wound." Thanks to the tremendous efforts of a #CLIFighter colleague, John Houseworth, DPM, regular wound care after tibiopedal revascularization healed her wound. Today, she is ambulatory and able to chase her grandchildren around the dock at her Florida home. This is the essence of the #CLIFighters mission.

We are Bailey Estes, RN, Kumar Madassery, MD, and Timothy Yates, MD; we are #CLIFighters. Stand on both feet with the CLI Global Society and help us change medicine today. ■

"Through social media, she was able to understand her disease process, other patients' dilemmas, and how they overcame their personal obstacles. Through direct messaging and interaction with "tweets," she was motivated to quit smoking. Additionally, input through social media allowed involved providers to track her care and algorithmically discuss optimization."

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Disclosures: None.

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MUSTAPHA *from cover*

Figure 3. The #CLIFighters enjoyed the night away with cocktails, dessert, and games. Of course, no party would be complete without selfies sporting custom scrub caps in support of the CLI Global Society!

Continued on page 16

Figure 4. During the CLI Global Society co-developed CLI track, key opinion leaders covered a wide array of topics, including treatment techniques, management, controversies, complications, data, new horizons, and future directions.

MUSTAPHA *from page 15*

Prep: The Use of Atherectomy, Scoring and Lithotripsy" by Dr. Andrew Holden from Auckland, New Zealand.

Although more CLI data are still desired, more information than ever before was presented::

- Original research from the PRIME Registry on "the CTOP Trial: Should Plaque Morphology Change Your Crossing Approach?" by CLI Global Society board member Dr. Jihad Mustapha
- "What to Do When the Data Do Not Support the Guidelines and the Guidelines Do Not Represent Real-World CLI Patients?" by CLI Global Society board member Dr. Robert Lookstein
- "PADDIII Study Experience" by Dr. Gunnar Tepe from Rosenheim, Germany
- "Efficacy of XTRACT on Atrial Fibrillation Patients With Peripheral Arterial Disease: Subset Analysis from PRISM" by Dr. James Benenati
- "2-Year Experience Using Flex Catheter as a Preparatory Device for Drug-Coated Balloon and/or Balloon Angioplasty" by Dr. Fedor Lurie
- "SAVAL Trial: Next Steps in DES for BTK Intervention" by Dr. Jihad Mustapha
- "Phoenix Registry Update: Hybrid Atherectomy" by Dr. Micheal Ayad
- "Data-Driven Treatment of Restenosis and Re-Occlusion" by Dr. Bret Wiechmann

The CLI Global Society Board held a retreat pre-ISET. The focus was on the development of a multi-society coalition approach to petition CMS for the creation of a definitive set of diagnosis codes that define CLI in sufficient granularity (eg, by stage, severity, etc) already recognized in clinical practice.

Please join Dr. Katzen and the other CLI Global Society Board Members today at www.cliglobalsociety.org. Society members will receive discounted registration rates at medical meetings that include education on critical limb ischemia; a subscription to *CLI Globa*l, the official publication of the CLI Global Society; and the opportunity to get involved with a strong unified community of physician, healthcare, and industry leaders with a focused goal. Working together we can prevent amputation and death due to critical limb ischemia. ■

Disclosures: None.

CLI GLOBAL SOCIETY

The Critical Limb Ischemia (CLI) Global Society's mission is to improve quality of life by preventing amputations and death due to CLI.

FINDINGS FROM RECENT STUDY:

- CLI is a serious problem that threatens both life and limb. Patients with CLI suffer poor long-term prognosis and generate high healthcare costs.
- Revascularization and attempts to salvage the limb are effective in saving both limbs and reducing mortality.
- Considerable efforts are needed to raise disease awareness and implement coding to better define and identify the disease.

Full article and editorial at www.cliglobalsociety.org/study

BECOME A MEMBER OF AN ORGANIZATION FOCUSED ON TRANSFORMING THE LIVES OF THOSE WITH CLI AND PAD.

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#CLIFighters

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Charing Cross International Symposium (CX Symposium)
April 15-18, 2019 | Olympia, London, United Kingdom

Symposium on Advanced Wound Care Spring (SAWC)
May 07-11, 2019 | San Antonio, TX

New Cardiovascular Horizons (NCVH)
May 29-31, 2019 | New Orleans, LA

National Interdisciplinary Congress on Critical Limb Ischemia
June 13-14, 2019 | Düesseldorf, Germany

Amputation Prevention Symposium (AMP)
August 14-17, 2019 | Chicago, IL

Cardiovascular and Interventional Radiological Society of Europe (CIRSE)
September 07-11, 2019 | Barcelona, Spain

Amputation Prevention Symposium Europe (AMP Europe)
October 02-04, 2019 | Lugano, Switzerland

Symposium on Advanced Wound Care Fall (SAWC)
October 12-14, 2019 | Las Vegas, NV

Visionary Endovascular & Vascular Education (VERVE)
December 05-07, 2019 | Sydney, New South Whales, Australia

International Symposium on Endovascular Therapy (ISET)
January 22-25, 2020 | Hollywood, FL

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VARGHESE *from page 3*

smoking, diabetes, and hypertension. The patients were divided into two groups with 88 in the single-access cohort and 53 in the dual-access cohort.

When utilizing dual access, the crossing success rate was 92.5% versus 73.6% using single access. CTOs from every vascular level (iliac, femoral/popliteal, and infrapop-liteal) were included in the study and the mean CTO length was 14.5 cm. The most common access site combination was common femoral and infrapopliteal and the most common crossing direction was retrograde. In a multivariable analysis, dual access was a positive predictor for successful CTO crossing.

The access sites were decided by the interventionalist prior to the procedure based on a combination of physical exam, prior arterial Doppler studies, computed tomography angiography, and prior invasive angiogram if available. The dual access patients were prepped for both probable access sites before the start of the procedure. Upon initial angiography, the proximal and distal cap morphology was studied and a decision for antegrade or retrograde approach was made from that assessment.

Dual access could help approach a CTO from both directions, and it increases the success when there is more than one CTO. In cases involving long lesions, dual access can provide the option of treating the lesions from both the antegrade and retrograde route after crossing, which could potentially decrease procedural time and radiation exposure.

Most interventionalists do not attempt retrograde access unless a traditional antegrade attempt fails. This could stem from the fear of compromising the last patent outflow vessel and doubling vascular complications. A recent study published by Saab et al characterized CTO cap morphology and proposed an algorithm for crossing CTOs.[4] Dual access is recommended for Type II (concave proximal cap and convex distal cap) and Type III (convex proximal cap and concave distal cap) caps. Taking this into account, traditional single access would be insufficient to cross a significant portion of CTOs. Severely calcified and long fibrotic lesions need the incorporation of dual access and advanced crossing techniques for successful crossing.

Our study indicates that utilizing dual antegrade and retrograde access for the treatment of CTOs has a higher chance of crossing success and revascularization compared to single access in a real-world, all-comer, patient population.

We present several short case examples utilizing a dual access approach for CTO crossing in different vascular levels:

Case 1 (Figure 1). This case demonstrates a long CTO of the distal superficial femoral artery extending through the entire popliteal artery into the tibio-peroneal trunk. There is a large

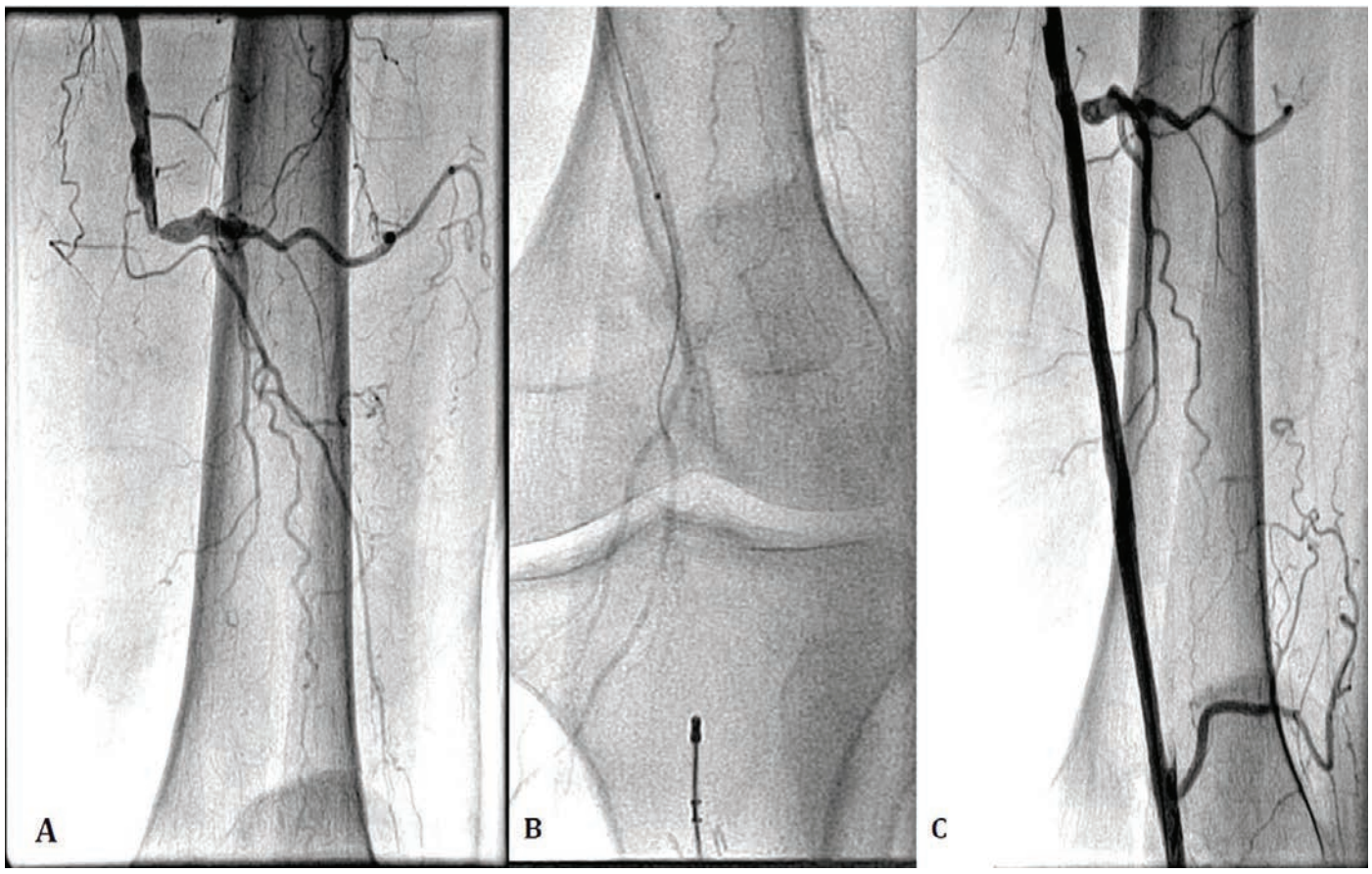

Figure 1. (A) Long CTO of the left distal superficial femoral artery (SFA) and popliteal. (B) Crossing of CTO from antegrade and retrograde access. (C) Final angiography of open SFA and popliteal artery.

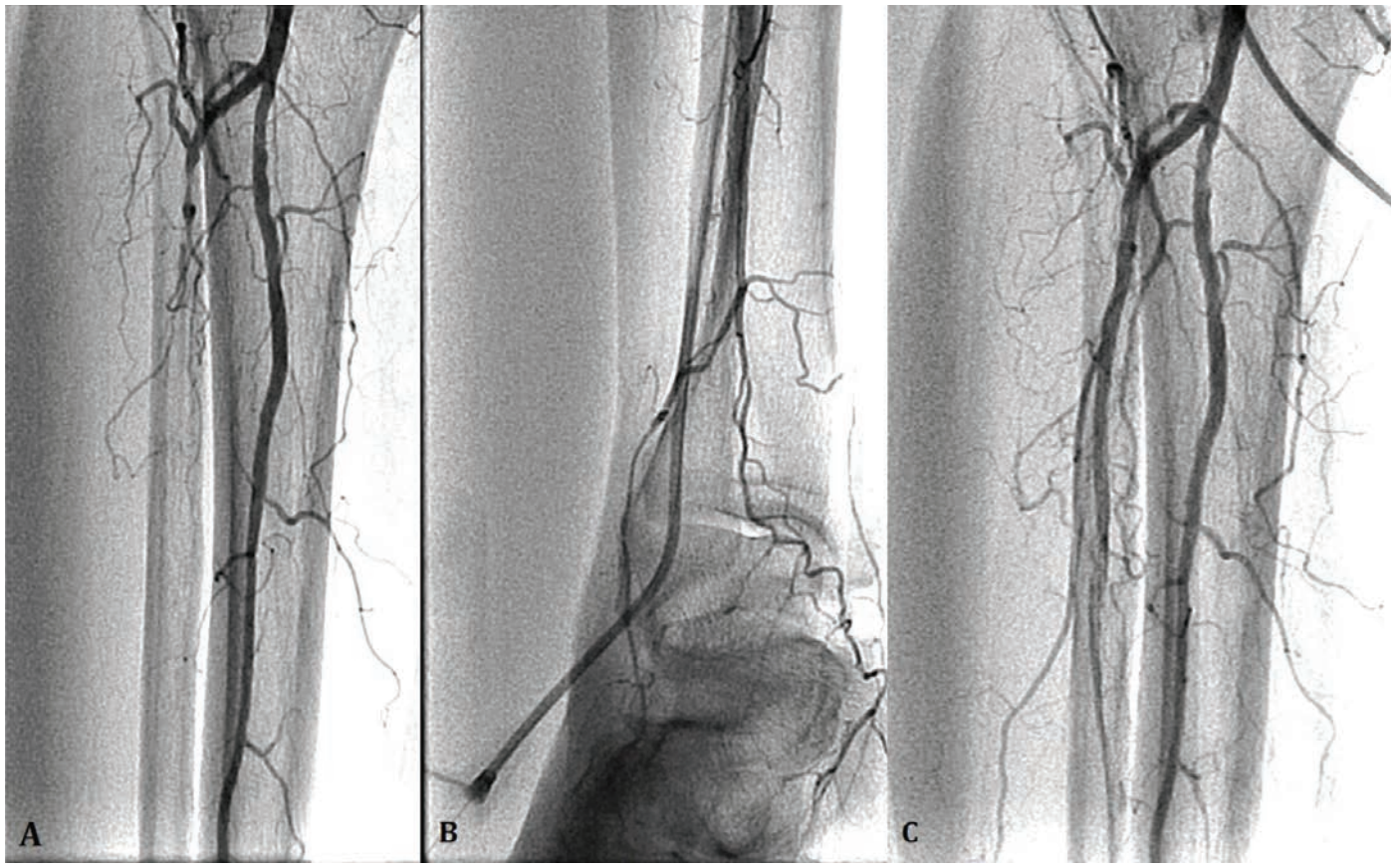

Figure 2. (A) CTO of the right anterior tibal artery. (B) Retrograde access of the anterior tibial artery. (C) Final angiogram of open anterior tibial artery.

"Our study indicates that utilizing dual antegrade and retrograde access for the treatment of CTOs has a higher chance of crossing success and revascularization compared to single access in a real-world, all-comer, patient population."

"In cases involving long lesions, dual access can provide the option of treating the lesions from both the antegrade and retrograde route after crossing, which could potentially decrease procedural time and radiation exposure."

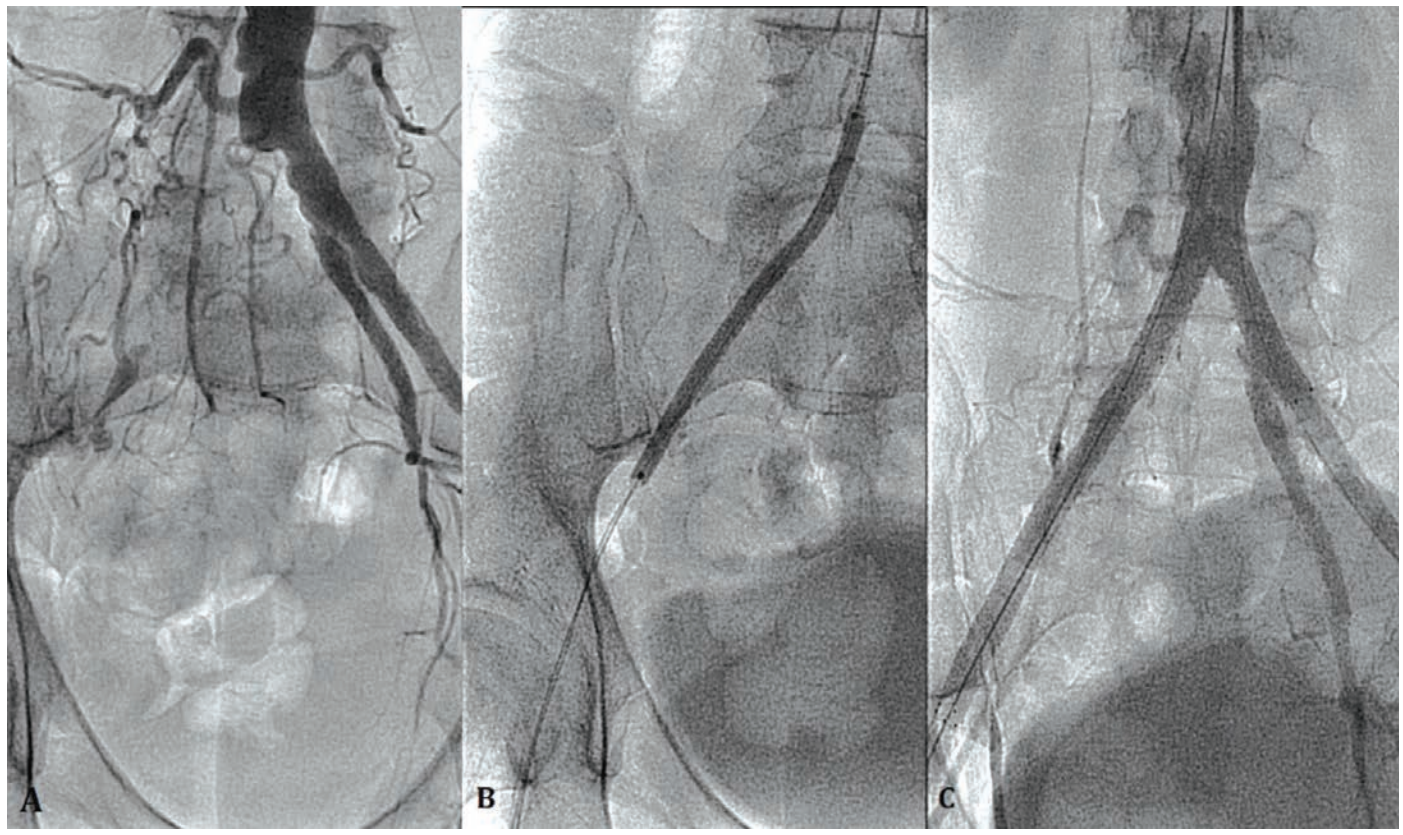

Figure 3. (A) CTO of the right common iliac artery. (B) Crossing and angioplasty of common iliac artery from access in the right brachial and right common femoral artery. (C) Final angiography of open common iliac artery.

collateral extending from the proximal cap. Because of this, the antegrade approach proved to be unfavorable as wires and catheters were inadvertently directed into the collateral instead of the vessel lumen. Retrograde access was achieved in the posterior tibial artery and the entirety of the lesion was crossed. Successful treatment with atherectomy along with use of a drug-coated balloon demonstrated excellent results with rapid inflow.

Case 2 (Figure 2). The patient had a long CTO of the anterior tibial artery with collaterals coming from the proximal cap. Antegrade common femoral and retrograde anterior tibial access was obtained. A wire and support catheter crossed the lesion through the retrograde sheath and the wire was externalized for subsequent treatment. Atherectomy, angioplasty, and a drug-eluting stent demonstrated excellent outflow.

Case 3 (Figure 3). The patient had a flush occlusion of the right common and external iliac artery. Antegrade access was achieved in the left brachial and retrograde access in the right common femoral artery. A 90-cm sheath was placed from the brachial for support. The lesion was partially crossed from the antegrade direction and the remainder of the lesion from the retrograde direction. Subsequent angioplasty and stents demonstrated excellent flow.

Case 4 (Figures 4 and 5). The patient had a CTO in the P2 segment of the popliteal. The tibio-peroneal trunk was indiscernible and the posterior tibial artery reconstituted mid-calf with flow down to the dorsalis pedis. Analyzing the cap morphology, there were multiple collaterals coming off of the proximal cap, which appeared to be unfavorable for an antegrade approach. Left common femoral antegrade access and posterior tibial access were utilized. Ultimately, a retrograde wire and support catheter crossed the CTO. Atherectomy, balloon angioplasty, and one stent resulted in excellent inline flow from the superficial femoral artery to the posterior tibial artery. ■

REFERENCES

1. Hamur H, Onk OA, Vuruskan E, et al. Determinants of chronic total occlusion in patients with peripheral arterial occlusive disease. *Angiology*. 2017;68(2):151-158.
2. Mustapha JA, Saab F, McGoff T, et al. Tibiopedal arterial minimally invasive retrograde revascularization in patients with advanced peripheral vascular disease: the TAMI technique, original case series. *Catheter Cardiovasc Interv*. 2014;83(6):987-994.
3. Montero-Baker M, Schmidt A, Braunlich S, et al. Retrograde approach for complex popliteal and tibioperoneal occlusions. *J Endovasc Ther*. 2008;15(5):594-604.
4. Saab F, Jaff MR, Diaz-Sandoval LJ, et al. Chronic total occlusion crossing approach based on plaque cap morphology: The CTOP classification. *Eur J Vasc Endovasc Surg*. 2018;25(3):284-291.

Disclosure: None.

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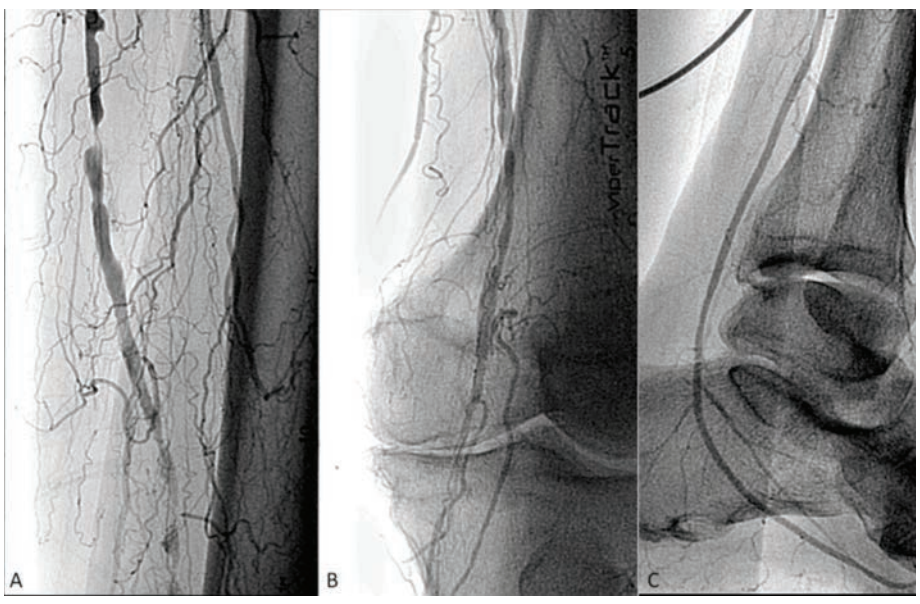

Figure 4. (A) Diffusely diseased SFA. (B) CTO of the P2 segment of the popliteal artery. (C) One vessel run-off of the posterior tibial artery.

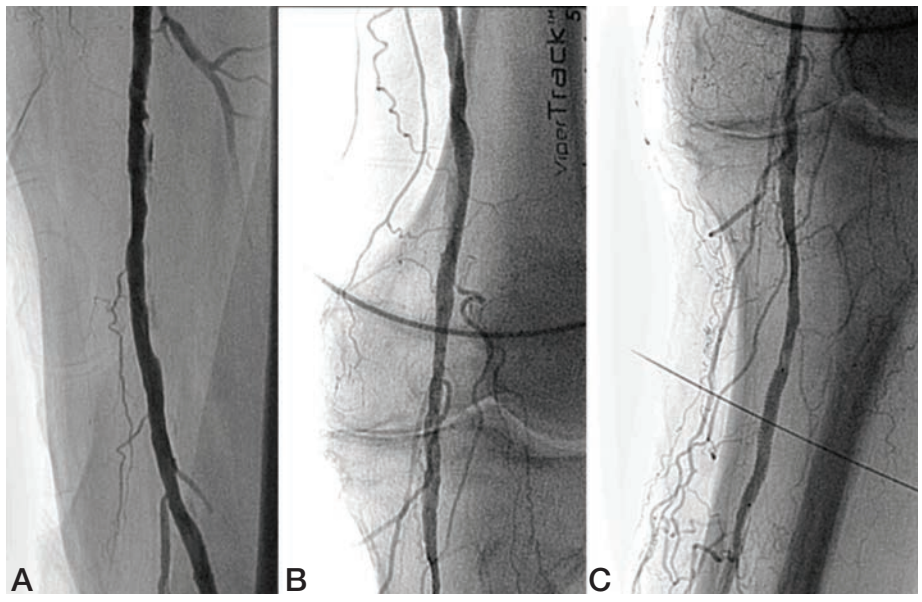

Figure 5. Final angiography of the (A) SFA, (B) popliteal, and (C) posterior tibial artery after atherectomy, balloon angioplasty, and stenting.

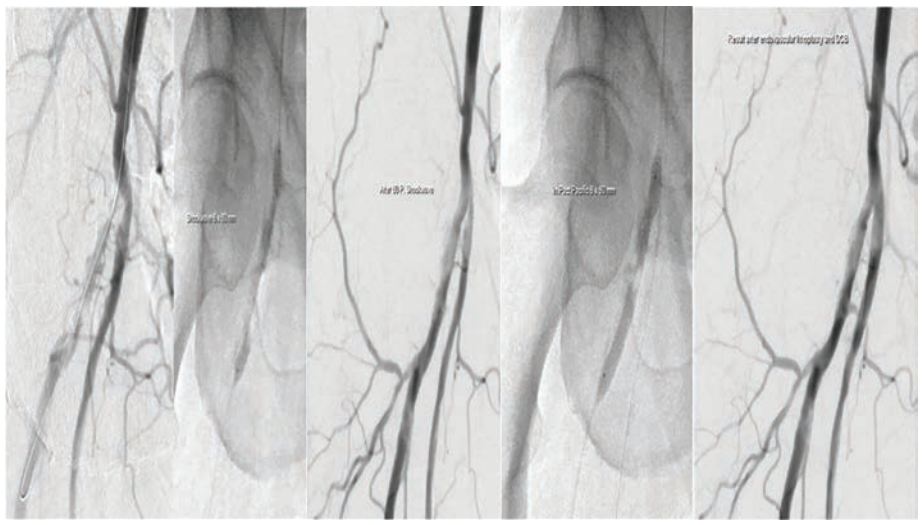

Figure 1. Endovascular lithoplasty (Shockwave) with anti-restenotic therapy (using In.Pact DCB, Medtronic) for a severely calcified deep femoral artery lesion.

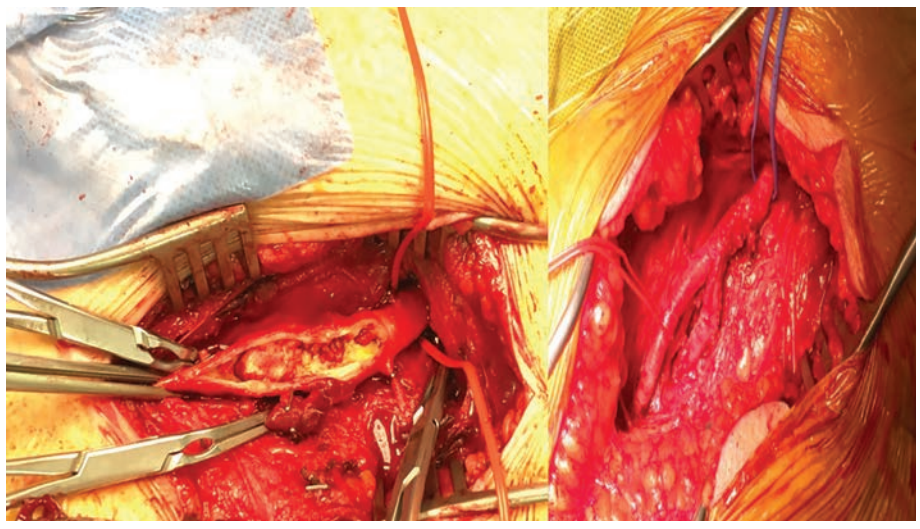

Figure 3. Surgical endarterectomy of common femoral artery disease.

STAVROULAKIS *from cover*

Common Femoral Artery (TECCO) trial, primary stent deployment was associated with comparable clinical and hemodynamic outcomes at 2 years compared to surgery.[11]

There are several issues that should be taken into consideration regarding the treatment of CFA disease and its branches. First, severe calcification due to the osteoid metaplasia of the atherosclerotic plaque is usually observed in this anatomical region.[13] Although surgery enables the removal of the calcified plaque, this can limit the use of endovascular therapy. Sufficient vessel preparation with debulking devices or endovascular lithoplasty might be crucial for both acute and long-term outcomes (Figure 1). Moreover, the high mechanical stress exerted on the artery during the flexion of the hip joint might undermine the results of traditional endovascular modalities and especially stent therapy. However, stent therapy with new-generation devices with increased flexibility and radial force may be a treatment option in highly selected patients. Finally, the potential loss of femoral access for future percutaneous interventions and the risk of jailing the deep femoral artery are additional drawbacks of stent deployment.

In our practice, surgery remains the treatment of choice for the majority of patients with CFA disease, not only because of the excellent long-term patency rates but also for lower risk for periprocedural occlusion of the deep femoral artery due to plaque shift. Furthermore, in cases of concomitant iliac or tibial disease, we favor a hybrid approach with surgery for the CFA and proximal or distal endovascular revascularization. Additionally, in the event of a flush SFA occlusion, we perform an endarterectomy of the proximal SFA in order to simplify the future endovascular treatment of the vessel.

Nonetheless, we consider endovascular therapy to be a very valuable tool in patients with restenosis after open repair, and in patients with multiple co-morbid conditions or high-risk for local complications (uncontrolled diabetes, obesity, previous radiation, lymphedema stage 2 and 3, steroid or methotrexate therapy). Given the importance of the CFA as the access vessel and of the deep femoral for the salvage of the affected limb, a "leave-nothing-behind" approach with debulking and drug-coated balloon angioplasty is usually preferred over stent therapy

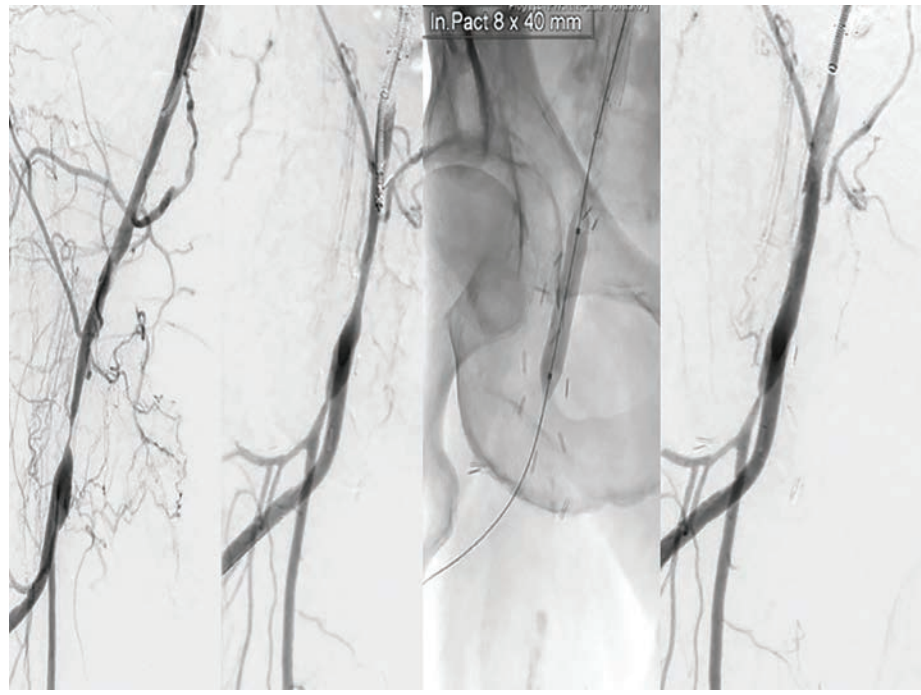

Figure 2. Hybrid atherectomy (Phoenix, Phillips) with anti-restenotic therapy (In. Pact DCB, Medtronic) for a proximal anastomosis stenosis of a PTFE bypass graft.

(Figure 2). The ongoing Percutaneous Intervention Versus Surgery in the Treatment of Common Femoral Artery Lesions (PESTO-AFC) trial (www.clinicaltrials.org, NCT02517827), which will compare the performance of directional atherectomy with drug-coated balloon angioplasty over open repair, will provide further evidence concerning the efficacy of a "leave-nothing-behind" approach for the treatment of CFA disease. ■

REFERENCES

1. Ballotta E, Gruppo M, Mazzalai F, et al. Common femoral artery endarterectomy for occlusive disease: an 8-year single-center prospective study. *Surgery*. 2010;147(2):268-274.
2. Malgor RD, Ricotta JJ 2nd, Bower TC, et al. Common femoral artery endarterectomy for lower-extremity ischemia: evaluating the need for additional distal limb revascularization. *Ann Vasc Surg*. 2012;26(7):946-956.
3. Kang JL, Patel VI, Conrad MF, et al. Common femoral artery occlusive disease: contemporary results following surgical endarterectomy. *J Vasc Surg*. 2008;48(4):872-877.
4. Nishibe T, Maruno K, Iwahori A, et al. The role of common femoral artery endarterectomy in the endovascular era. *Ann Vasc Surg*. 2015;29(8):1501-1507.
5. Siracuse JJ, Gill HL, Schneider DB, et al. Assessing the perioperative safety of common femoral endarterectomy in the endovascular era. *Vasc Endovasc Surg*. 2014;48(1):27-33.
6. Nguyen BN, Amdur RL, Abugideiri M, et al. Postoperative complications after common femoral endarterectomy. *J Vasc Surg*. 2015;61(6):1489-1494.
7. Wieker CM, Schönefeld E, Osada N, et al. Results of common femoral artery thromboendarterectomy evaluation of a traditional surgical management in the endovascular era. *J Vasc Surg*. 2016;64(4):995-1001.
8. Bonvini RF, Rastan A, Sixt S, et al. Endovascular treatment of common femoral artery disease: medium-term outcomes of 360 consecutive procedures. *J Am Coll Cardiol*. 2011;58(8):792-798.
9. Bath J, Avgerinos E. A pooled analysis of common femoral and profunda femoris endovascular interventions. *Vascular*. 2016;24(4):404-413.
10. Baumann F, Ruch M, Willenberg T, et al. Endovascular treatment of common femoral artery obstructions. *J Vasc Surg*. 2011;53(4):1000-1006.
11. Gouëffic Y, Della Schiava N, Thaveau F, et al. Stenting or surgery for de novo common femoral artery stenosis. *J Am Coll Cardiol Intv*. 2017;10:1344-1354.
12. Stavroulakis K, Schwindt A, Torsello G, et al. Directional atherectomy with antirestenotic therapy vs drug-coated balloon angioplasty alone for common femoral artery atherosclerotic disease. *J Endovasc Ther*. 2018;25(1):92-99.
13. Herisson F, Heymann MF, Chétiveaux M, et al. Carotid and femoral atherosclerotic plaques show different morphology. *Atherosclerosis*. 2011;216(2):348-354.

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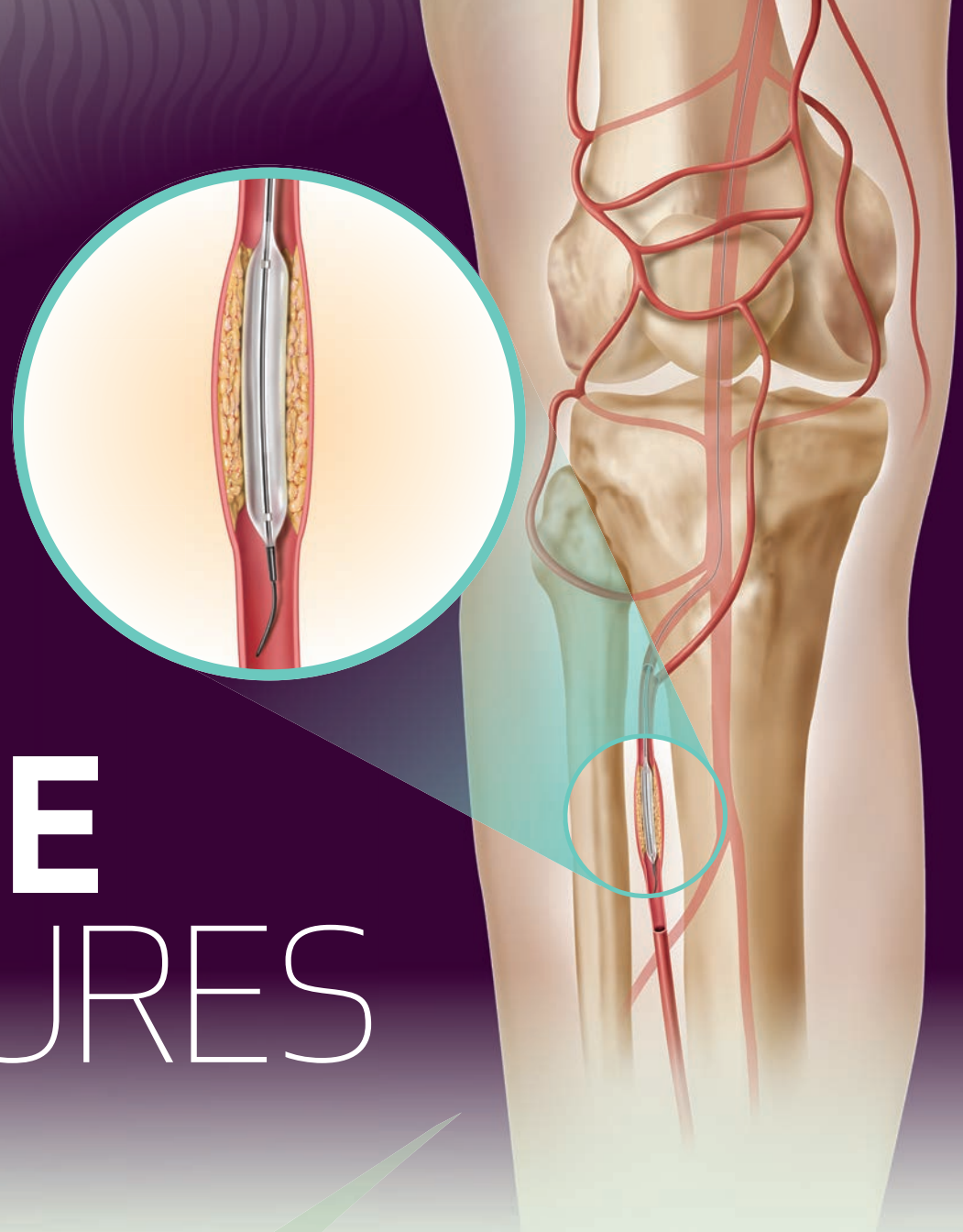

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