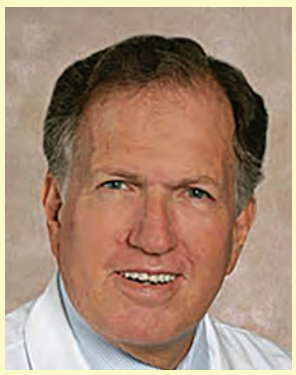
CLI GLOBAL
THE OFFICIAL PUBLICATION OF THE CRITICAL LIMB ISCHEMIA GLOBAL SOCIETY

A Call to Action From the CLI Global Society

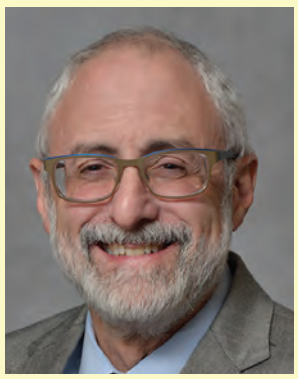
J.A. Mustapha, MD
Metro Health University of Michigan Health, Wyoming, Michigan

During his opening remarks at ISET 2017, Critical Limb Ischemia (CLI) Global Society President, Barry T. Katzen, MD, called attendees to action. The nonprofit, CLI Global Society was recently formed with a mission to improve quality of life by preventing amputations and death due to critical limb ischemia. CLI manifests in nearly 1 million Medicare patients per year,[1] resulting in a growing unmet need.

CLI GLOBAL SOCIETY LEADERSHIP



Barry T. Katzen, MD
President



Alan T. Hirsch, MD
Vice President

Jihad A. Mustapha, MD
Secretary/Treasurer

Robert Lookstein, MD
Board Member

Richard F. Neville, MD
Board Member

Dierk Scheinert, MD
Board Member

Frank J. Veith, MD
Board Member

CLI is a global problem due to many factors, including lack of consensus on definition and lack of awareness within the healthcare community and the general public. Despite the great burden CLI imposes, research remains limited. A lack of consensus exists on best methods to prevent, diagnose, treat and rehabilitate patients with CLI. Despite the great need, a limited number of CLI specialists are available to treat this complex multilevel, multi-vessel disease. Despite being a world-wide medical problem, no DRG exists for CLI. It is unacceptable that in 2017, amputation often remains a first line treatment for CLI.

How can we fix the problem? A concerted effort can create change. The Society will provide unique services to members that are not duplicated by other societies. The CLI Global Society initiatives include:

- Create a facilitated new definition of CLI.
- Amplify public and health professional awareness of CLI.
- Create a public and professional effort to prevent CLI.
- Increase clinical cooperation and information sharing in the management of CLI.
- Improve the CLI standard of care for prevention, diagnosis, treatment, and rehabilitation.
- Reduce time from symptom onset to provision of definitive care for CLI.
- Reduce variability in delivery of care that promotes preventable amputations.
- Identify disparities in access and treatment to quality CLI care. Identify strategies to correct these disparities.
- Advocate for team-based programs that simultaneously address awareness, management, and treatment of CLI.

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 Global*, 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. ■

REFERENCES

1. Goodney PP, Holman K, Henke PK, et al. Regional intensity of vascular care and lower extremity amputation rates. *J Vasc Surg.* 2013 June;57(6):1471-1480.

I Find Myself Overwhelmed With CLI Therapy and With No Time for Proactive Awareness

George A. Pliagas, MD, FACS, FRCSC
Premier Surgical Associates, Vascular Division, Knoxville, Tennessee

It's Monday morning and the beginning of a new work week, and I am about to start my office. The phone rings and it is a referring physician's office, and they need me to urgently see a patient with a non-healing ulcer of the lower extremity. I do what every one of us would do and accept to see the patient that day. This type of scenario repeats itself several times a week throughout the year. As vascular specialists, we are experiencing firsthand the acute influx of the growing numbers of patients with peripheral arterial disease (PAD).[1]

It is estimated that 1.3-1.7% of patients age 40-49 and 24-29% over the age of 80

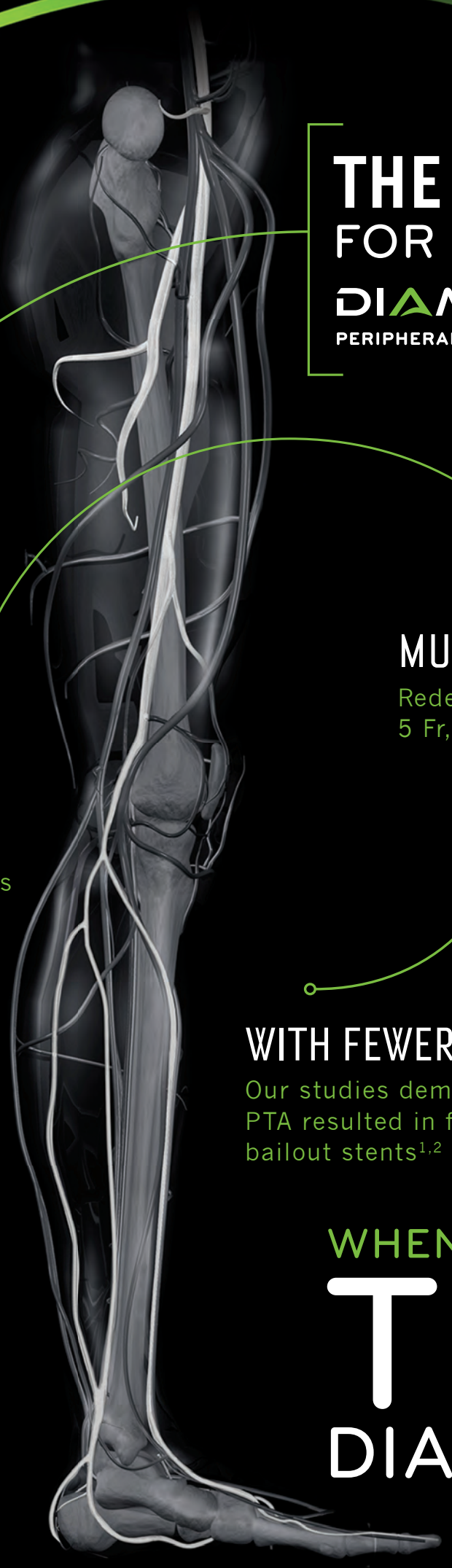
Continued on page 13

George A. Pliagas, MD, FACS, FRCSC

THE SMART SOLUTION
FOR ARTERIAL CALCIUM

DIAMONDBACK 360®

PERIPHERAL ORBITAL ATHERECTOMY SYSTEM



TREAT MORE PATIENTS

Treat PAD via tibiopedal access with 4 Fr sheath compatibility

MULTIPLE ACCESS OPTIONS

Redefining minimally invasive with 4 Fr, 5 Fr, and 6 Fr sheath compatibility

WITH FEWER COMPLICATIONS

Our studies demonstrated OAS+ low pressure PTA resulted in fewer complications and fewer bailout stents[1,2]

WHEN YOU SEE CALCIUM,
THINK
DIAMONDBACK.

The CSI Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. Contraindications for the system include use in coronary arteries, bypass grafts, stents, or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm.

Caution: Federal law (USA) restricts this device to sale by, or on the order of, a physician.

1. Shammas NW, et al. J Endovasc Ther. 2012;19(4):480-8. 2. Dattilo R, et al. J Invasive Cardiol. 2014;26(8):355-60.

To see our case studies, visit WhyOrbital.com

CSI® | CARDIOVASCULAR SYSTEMS, INC.

Based on the Past, What Does the Future Hold for CLI? Is There Hope for Change?

Philip P. Goodney, MD, MS
Associate Professor and Vice Chair for Research
Dartmouth Hitchcock Medical Center
The Dartmouth Institute, Lebanon, New Hampshire
Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire

Philip P. Goodney, MD, MS

The treatment of patients with critical limb ischemia (CLI) has been a constant source of challenge and change in recent years. This challenging disease — which threatens the independent living status of our oldest patients, and presents morbidity and mortality risks akin to the most aggressive cancer diagnoses — has been an ever-present clinical battle for cardiovascular physicians. However, for three important reasons, there is good news on the horizon, both for patients with CLI and the physicians who provide their invasive and non-invasive cardiovascular care.

First, while financial analysts often debate how much past performance will dictate future results, recent trends can be useful in predicting future outcomes for patients with critical limb ischemia. And if the last two decades can help us to learn about what lies ahead for CLI, then the news on the horizon is good. The number of major amputations in Medicare patients has fallen by 60% between 1996 and 2011 (Figure 1), and recent trends suggest this good news will continue.[1] Why have these improvements occurred? This is likely a multidisciplinary "success story," with improvements in vascular care, medical therapies, and podiatric care — each contributing to the success in avoiding limb loss.[2]

Second, in addition to better results, cardiovascular physicians will have better information to guide treatment for patients with CLI. The Best Endovascular versus Surgical Therapy for CLI (BEST-CLI, www.bestcli.org) trial, funded by the National Heart, Lung, and Blood Institute in 2014, will compare open and endovascular treatments for patients with CLI to provide the highest quality information for patients and their physicians.[3] The BEST-CLI trial, open in more than 140 sites across the United States, recently randomized its 500th patient (Figure 2). This study, which will evaluate limb preservation, cost effectiveness, and quality of life, will use lessons learned in more than 2,000 patients to help guide the decisions made for treating CLI in its most advanced forms.

Third, new evidence will emerge in the context of high quality clinical trials, and we will continue to study the care that is provided to patients with CLI in real-world practice. Large registries — from institutions such as the Society for Vascular Surgery's Vascular Quality Initiative (www.vascularqualityinitiative.org)[4,5], as well as the American College of Cardiology's National Cardiovascular Data Registry

Continued on page 20

Despite an improvement in vascular care, disparities in the care of patients with advanced PAD remain significant. Who better to address these challenges than our own specialty?

TABLE OF CONTENTS

Published in collaboration with

HMP Communications LLC™
an HMP Communications Holdings Company

Editor's note: Articles in this supplement to Cath Lab Digest did not undergo peer review.

Retrograde Transpedal Access for Treatment of CLI

Andrew M. Galmer, DO, Ido Weinberg, MD, and Mitchell D. Weinberg, MD, Department of Cardiology, Division of Vascular Medicine, Northshore University Hospital, Manhasset, NY

Andrew M. Galmer, DO

CASE DESCRIPTION

A 71-year-old male presented with critical limb ischemia (CLI). His history is significant for coronary artery disease, ischemic cardiomyopathy with a severely reduced left ventricular ejection fraction (estimated left ventricular ejection fraction of 15%), stage 4 severe chronic kidney disease (CKD) (GFR= 23 mL/min, creatinine clearance = 24.85 mL/min), and heavy tobacco use.

This was his second hospitalization over a four-month period. On his initial presentation he underwent a 1st and 3rd digit amputation. However, revascularization was deferred by numerous practitioners due to limited endovascular options and excessive cardiac risk associated with open surgical bypass. Poor healing at the prior amputation site and constant pain at rest prompted him to seek treatment.

Physical examination revealed a diffusely cool foot with infected, macerated, purulent amputation sites at the first and third digits, and a gangrenous second digit (Figure 1). Vascular examination revealed a palpable common femoral artery pulse. The popliteal artery was not palpable. Also noted were non-palpable and non-Dopplerable anterior tibial and posterior tibial pulses.

Non-invasive testing was performed. Pulse volume recording revealed severely diseased waveforms at the calf and flat tracings at the ankle, metatarsal, and toe levels. An arterial duplex demonstrated femoro-popliteal occlusive disease. A long occlusion involving the entire extent of the superficial femoral and popliteal arteries was apparent, along with faint reconstitution in the posterior tibial and anterior tibial arteries (Figure 2). Venous duplex was also performed and failed to identify an available bypass conduit.

In addition to surrounding cellulitis, there was radiographic evidence of osteomyelitis of the second metatarsal and phalangeal joints. The patient was started on broad spectrum antibiotics upon admission.

On hospital day 4, diagnostic angiography confirmed that the aorta, iliac arteries, the common femoral artery, and profunda femoral arteries were without significant disease. The ostial superficial femoral artery occlusion was long and moderately calcific. The proximal cap was concave in contour. The popliteal artery was totally occluded (Figure 3). The posterior tibial artery reconstituted in the mid-calf and provided straight line flow to the foot. The anterior tibial artery also reconstituted in its mid-portion and was patent to at least the ankle. The pedal arch was not well visualized.

INTEGRATING LIMB PRESENTATION WITH PATIENT CLINICAL CHARACTERISTICS

Choosing the appropriate therapeutic approach to CLI can be complicated. While some patients should be offered open surgical revascularization, others will do better with an endovascular-first approach. Sometimes primary amputation is in the best interest of the patient. Decisions on the most appropriate patient-centered approach should incorporate patient, lesion and anatomical characteristics.

WIFI SCORING FOR PROGNOSTICATION AND CLINICAL DECISION MAKING

The SVS-WIfI score incorporates three major elements: the wound characteristics, the presence and extent of ischemia, and the presence and extent of infection. The score may be predictive of the yearly amputation risk and highlight patients with either very favorable or, conversely, dismal prognoses. The current patient presented with deep ulceration and digital gangrene (wound grade 2), toe pressures of <30 mmHg (ischemia grade 3) and local infection without systemic signs (infection grade 2) — translating to an absolute WIfI score of 232 and a WIfI composite score of 7 (Table 1). The patient was estimated to have a 33% risk of major amputation, 57% risk of re-intervention, major amputation, or stenosis (RAS), and a 22% chance of mortality at 1 year based on the composite score.[1]

INTEGRATED RISK ASSESSMENT

While the presenting characteristics of the limb described above offer some insight, complete decision-making requires integration of relevant patient clinical characteristics. Such characteristics not only provide an overall sense of morbidity and mortality, but help guide the selection of various revascularization strategies. Cardiac risk and contrast nephropathy risk both help elucidate the preferred revascularization method. While the Revised Cardiac Risk Index (RCRI) was commonly used, the recently published VQICRI assesses the risk of postoperative myocardial infarction after infrainguinal bypass. It was estimated that our patient would have a 7.8% risk of in-hospital postoperative MI if a surgical route was taken (Table 2).

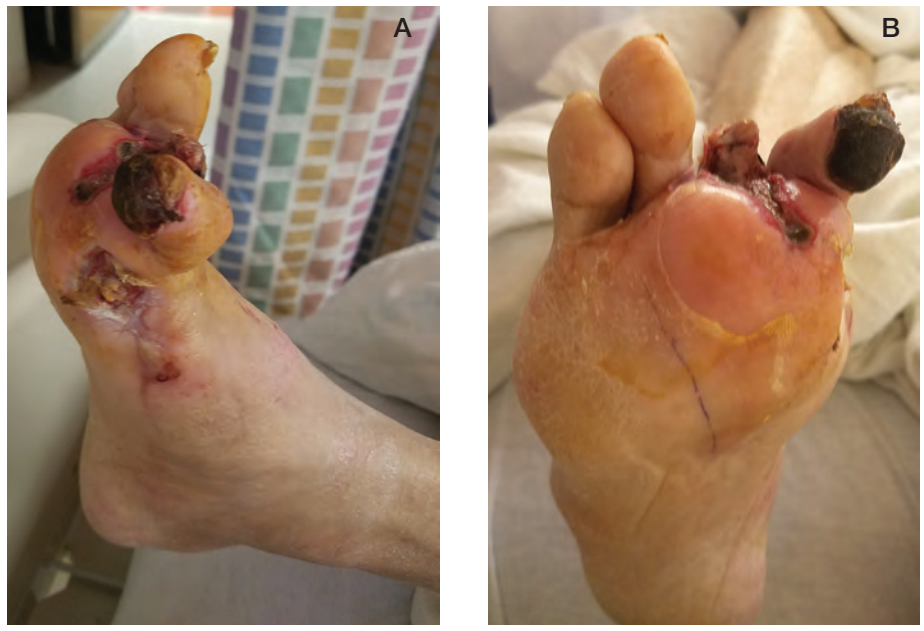
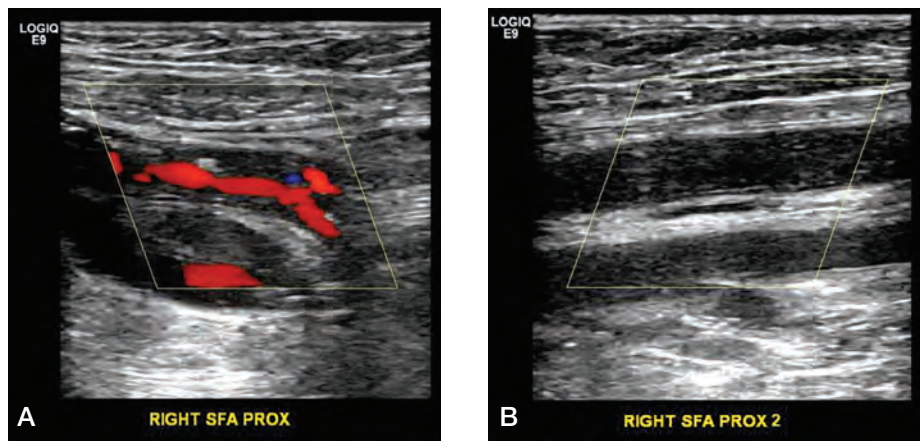


Figure 1. Right foot. Purulent infected, macerated, amputation sites at the first and third digits was visible, along with a gangrenous second digit with associated edema.



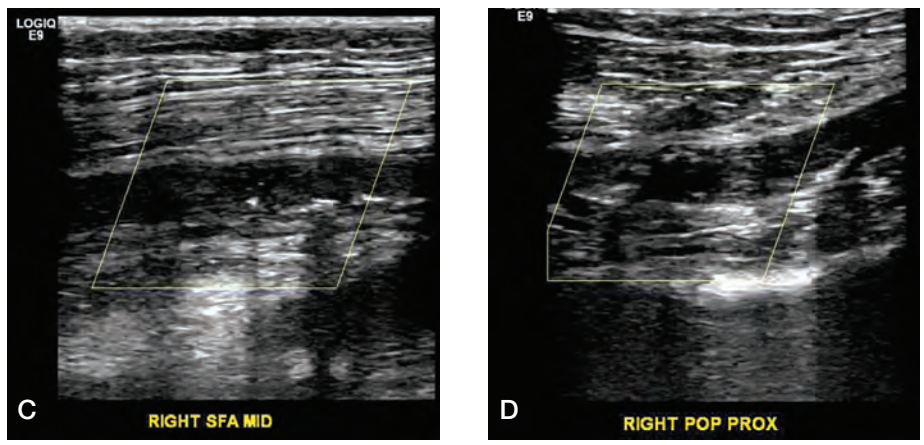


Figure 2. Arterial duplex. Arterial duplex demonstrated femoro-popliteal occlusive disease, with a long occlusion involving the entire extent of the superficial femoral and popliteal arteries, and with faint reconstitution in the posterior tibial and anterior tibial arteries.

NEPHROPATHY AND DIALYSIS RISK ASSESSMENT

The benefits of endovascular revascularization are tempered by the risk of contrast-induced nephropathy (CIN). Quantification of risk for CIN after percutaneous intervention can be calculated using an online calculator. Employing an endovascular strategy on this patient was estimated to confer a 26.1% risk of CIN and a 1.09% risk for dialysis (Table 2).

LESION CHARACTERISTICS

Naturally, lesion characteristics must be taken into account when choosing

Continued on page 16

TERUMO
INTERVENTIONAL
SYSTEMS

ACHIEVE MORE TOGETHER

The perfect combination for crossing complex lesions

Glidewire Advantage®
Peripheral Guidewires

Navicross®
Support Catheters

Pinnacle® Destination®
Guiding Sheath

Committed to helping you do more

Learn about our hands-on training and expert clinical support.

Phone: 800.862.4143 terumois.com/together

For Rx only. Before using refer to **Instructions for Use** for indications, contraindications as well as warnings and precautions @ terumois.com

A Case-Based Definition of Critical Limb Ischemia

Bret Wiechmann, MD
Vascular & Interventional Physicians, Gainesville, Florida

Bret Wiechmann, MD

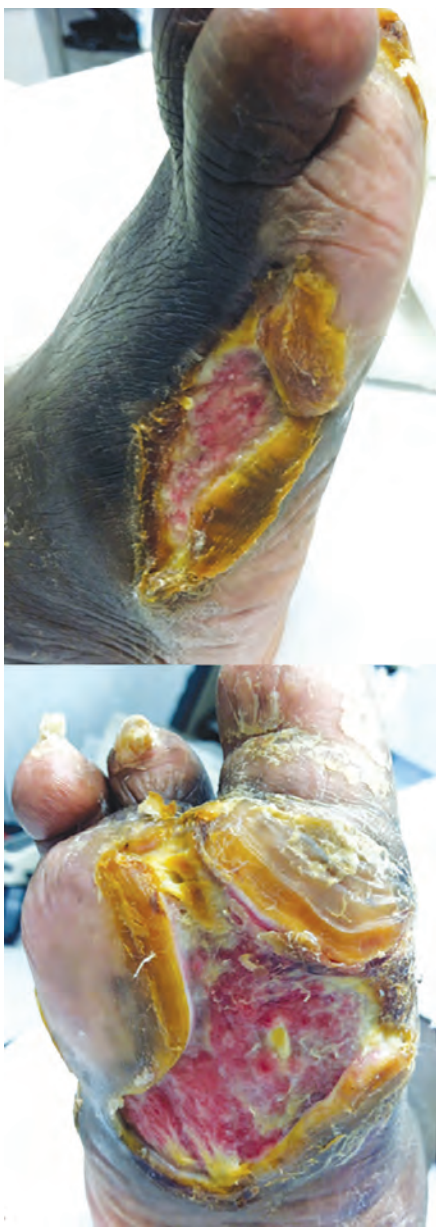


Figure 1. Photograph of right lateral and plantar foot wound, at presentation, with devascularized, hyperkeratotic rim and pink granulation tissue at base.

Wound healing and relief of ischemic rest pain are treatment goals in patients with lower extremity amputation (LEA). The long term effects of LEA are well known, including physical, economic, and quality of life issues. The increased energy expenditure required to walk with a limb prosthesis results in fewer than two-thirds of patients with a below-knee amputation and fewer than one-half of patients with an above knee amputation ever achieving successful rehabilitation. Economically, per capita lifetime costs of LEA can exceed $500,000.[1] Twenty-five percent of CLI patients will have some form of amputation within the first year simply by carrying the diagnosis of CLI.[2] Of these, 27% will require another amputation and/or revision within twelve months. Diabetic patients with CLI fare even worse.[3,4] Fifty-five percent of diabetic patients with an amputation will have a contralateral amputation within 3-5 years.[3] Quality of life scores in patients with any amputation are very low, with reports of anxiety, depression, poor psychosocial life adjustments and lower overall quality of life. Finally, life expectancy in the CLI population is low, with an approximately 50% mortality rate at 3 years.

These sobering statistics tell a most unfortunate but all too familiar tale. Better awareness of peripheral arterial disease (PAD) in general is needed. It is paramount to promptly identify those patients with CLI in order to initiate immediate treatment. All aspects of vascular care have to be addressed, from optimal medical management and risk factor modification to intervention and follow-up. As limb salvage is the ultimate measure of success in the treatment of the CLI patient, I'd like to describe a recent case to highlight the need for limb preservation in patients who have already had an amputation on one leg. These patients are even less likely to ambulate than those discussed above if the remaining leg needs to be amputated. [5]

CASE HISTORY

A 59-year-old black female with a history of insulin-dependent diabetes mellitus, hypertension, and dyslipidemia contacted the office while still an inpatient at an outside hospital. She had been admitted there for progression of two non-healing right foot wounds, and a primary amputation had been recommended based on the appearance of the wound and non-invasive vascular studies. Approximately two years prior, she had undergone a left below-knee amputation for progressive critical limb ischemia of the left foot. She remained somewhat active and ambulated with a prosthesis, but was adamantly opposed to any amputation on her right. She was discharged from the outside hospital and was evaluated as an outpatient in our office. Pre-procedural laboratory evaluation revealed elevated hemoglobin A1C of 7.5 and serum glucose of 212. She admitted to noncompliance with her insulin and in routine home monitoring of her blood sugar. Initial wound evaluation was performed (Figure 1) and she was sent for urgent assessment by our wound care specialist. Shortly thereafter, she underwent lower extremity angiography (Figure 2) that demonstrated diffuse infrapopliteal disease with segmental occlusions of all three tibial vessels and moderate popliteal artery stenosis with calcification.

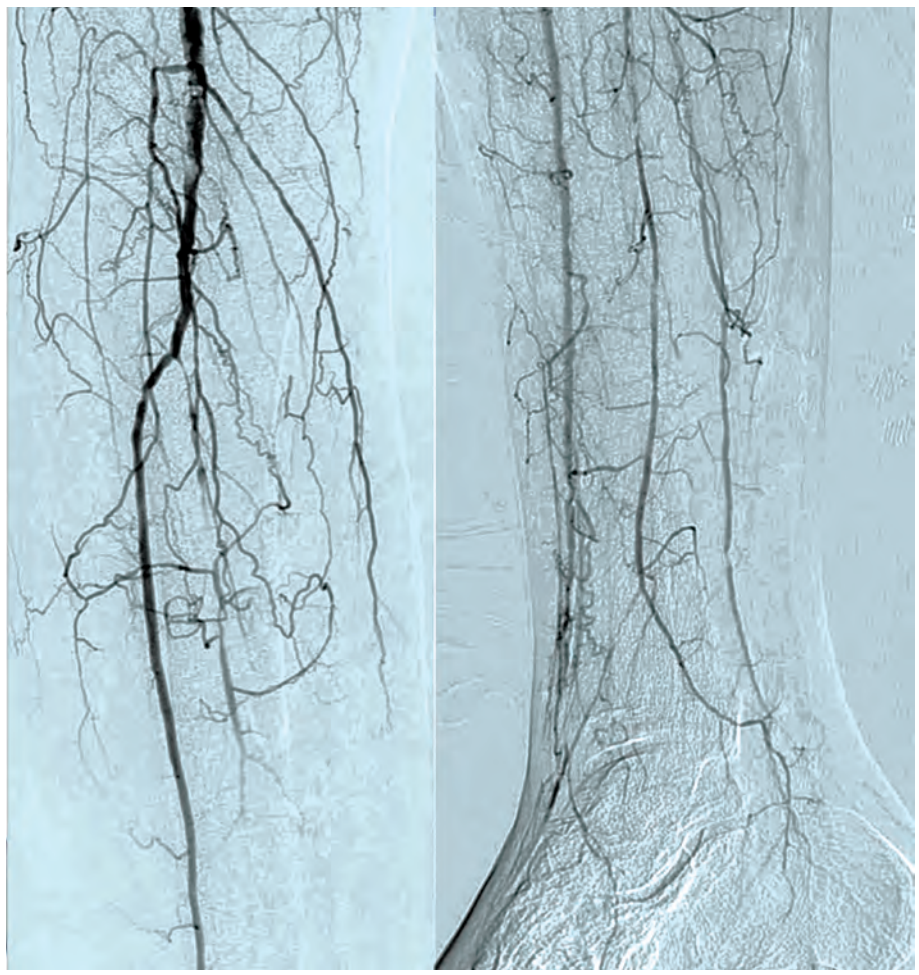


Figure 2. Lower extremity angiogram images demonstrate diffuse infrapopliteal disease with segmental occlusions of all three tibial vessels and moderate popliteal artery stenosis with calcification.

Successful angioplasty was performed on the anterior tibial, tibio-peronal trunk/peroneal, and posterior tibial arteries with markedly improved flow (Figure 3). At 10 weeks post intervention and wound care, the patient demonstrated a wound healing trajectory with nearly complete healing of the lateral and plantar wound (Figure 4).

Treating patients with CLI is challenging in several ways. In general, these patients have multiple vascular risk factors including diabetes, hypertension, dyslipidemia, tobacco abuse, and end-stage renal disease. The systemic manifestations of these diseases lead to high overall mortality, and also contribute to the extent and severity of the atherosclerotic lesions that lead to a threatened limb. Multi-segment and multi-vessel disease is common in CLI patients with tissue loss. Diffuse and often aggressive calcification adds to the lesion complexity frequently seen in below-knee disease.[6] The overall small size of the tibial arteries is a factor as well, especially in dealing with total occlusions. Acute procedural success has been enhanced with better tools and techniques. And while short-term wound healing and limb salvage improvements have been impressive, long-term patency is poor and the need for repeat intervention is still substantial. This is particularly true in Rutherford 6 patients.

In addition to revascularization, attention to total medical management is key to avoiding amputation. The OLIVE study has shown the various indicators that dictate limb prognosis in CLI patients, including body-mass index (BMI), nutritional status, cardiac function, and wound status, among others.[7] Improving as many as possible of these factors individually is known to increase the chance of amputation-free survival. This highlights the need for multiple specialties with different areas of expertise to provide total care for the patient.

SUMMARY

This case summarizes some of the frustrations faced by physicians who treat CLI. The patient described in this report was destined for a below-knee amputation based solely on the appearance of the wound without any consideration of her vascular status. It was presumed that there was no prospect of limb salvage! It is hard to imagine for those of us in the vascular

Continued on page 8

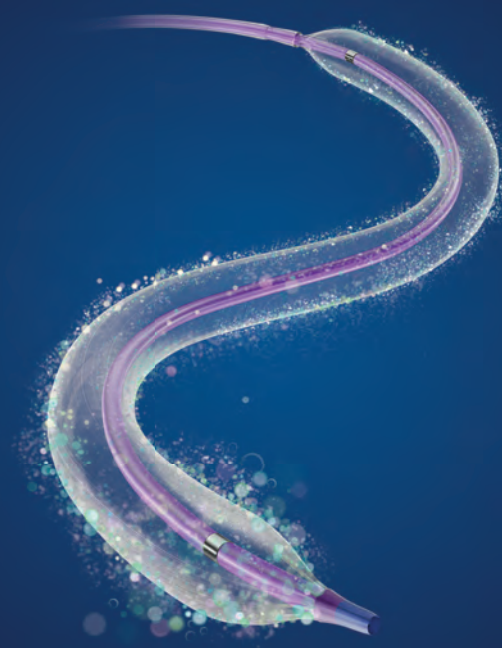
GAIN.

HawkOne™
Directional Atherectomy System

GAIN vessel lumen

MAINTAIN.

IN.PACT™ Admiral™
Drug-Coated Balloon



MAINTAIN vessel patency

BEST-IN-CLASS TECHNOLOGIES

Directional atherectomy[1] and DCB[2] are supported by peer-reviewed published data.

[1]McKinsey JF, Zeller T, Rocha-Singh KJ, , et al. Investigators DL. Lower Extremity Revascularization Using DA: 12-Month Prospective Results of the DEFINITIVE LE Study. JACC. Cardiovascular Interventions. Aug 2014;7(8):923-933.

[2]Tepe G, Laird J, Schneider P, et al. DCB Versus Standard PTA for the Treatment of Superficial Femoral and Popliteal PAD: 12-Month Results From the IN.PACT SFA Randomized Trial. Circulation. Feb 3 2015;131(5):495-502.

Medtronic
Further, Together

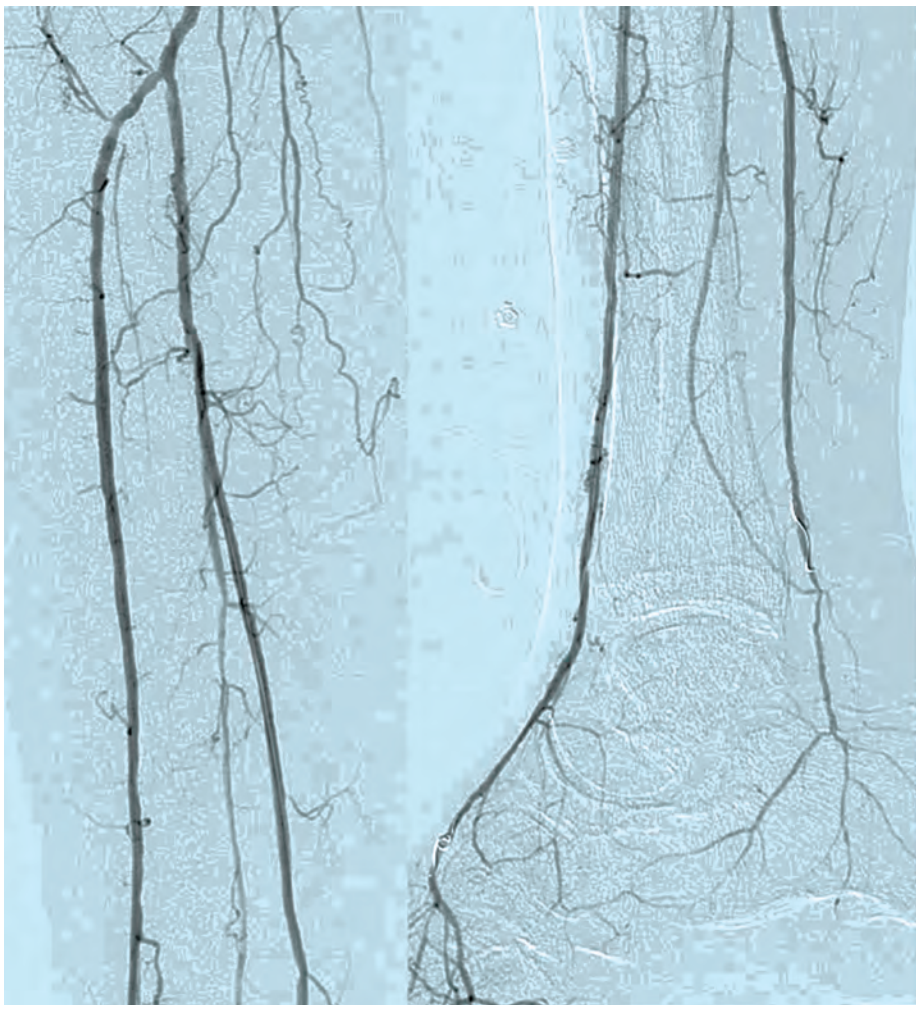


Figure 3. Angiographic images demonstrate markedly improved post anterior tibial, TP trunk/peroneal, and posterior tibial artery angioplasty.

WIECHMANN from page 6

space, but that mentality is still out there in some parts of the medical community. Fortunately, the patient was able to advocate for herself and made the bold call to try to find someone willing to at least provide another opinion or option. Part of our responsibility as vascular specialists is to educate other physicians and patients about PAD and the current status of CLI treatment. We have made tremendous strides in this endeavor, but much work still remains. ■

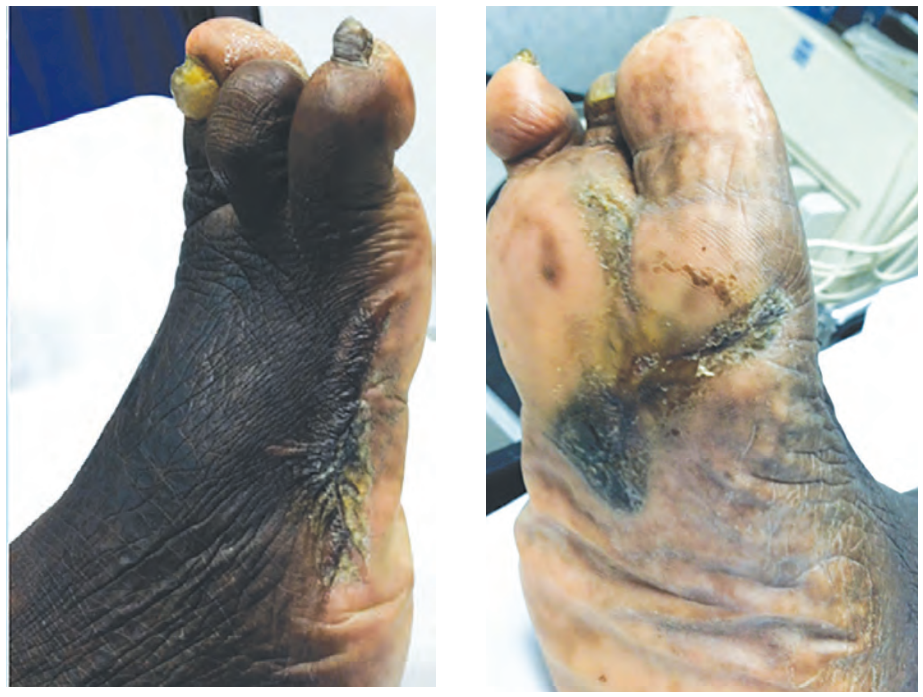


Figure 4. Photograph taken at 10 weeks post-intervention and wound care shows near complete healing of lateral and plantar wound.

REFERENCES

1 MacKenzie EJ, Jones AS, Bosse MJ, et al. Health-care costs associated with amputation or reconstruction of a limb-threatening injury. *J Bone Joint Surg Am*. 2007;89(8):1685-1692.

2 Allie DE, Hebert CJ, Lirtzman MD, et al. Critical limb ischemia: a global epidemic. A critical analysis of current treatment unmasks the clinical and economic costs of CLI. *EuroIntervention*. 2005;1(1):75-84.

3 Jindeel A, Narahara KA. Nontraumatic amputation: incidence and cost analysis. *Int J Low Extrem Wounds*. 2012;11(3):177-179.

4 Dillingham TR, Pezzin LE, Shore AD. Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations. *Arch Phys Med Rehabil*. 2005;86(3):480-486.

5 Pasquina PF, Miller M, Carvalho AJ, et al. Special considerations for multiple limb amputation. *Curr Phys Med Rehabil Rep*. 2014;2(4):273-289.

6 Al-Ameri H, Clavijo L, Matthews RV, Kloner RA, Shavelle DM. (2012). Devices to treat peripheral chronic total occlusions. *J Interv Cardiol*. 2012;25(4):395-403.

7 Iida O, Nakamura M,Yamauchi Y, et al. Endovascular treatment for infrainguinal vessels in patients with critical limb ischemia: OLIVE registry, a prospective, multicenter study in Japan with 12-month follow-up. *Circ Cardiovasc Interv*. 2013;6(1):68-76.

ASAHI®

PRECISION ENGINEERED for *Tough Peripheral Cases*

NEW Peripheral GuideWires

Now available with ASAHI's unique guide wire technology

ACT ONE

New GuideWires

ASAHI **Gladius®** 0.014/0.018
Workhorse

ASAHI® **Halberd®** 0.014/0.018
Complex Lesion

ASAHI **Gaia® PV** 0.018
Complex Lesion

New Microcatheter

ASAHI® Corsair® **Armet®**

Durable metal tip

Super SHINKA-Shaft

Low profile, supportive catheter body, excellent torque

Your dreams. Woven together.

ASAHI INTECC

Learn more at

asahi-inteccusa-medical.com

ASAHI INTECC USA, INC.

2500 Red Hill Avenue, Suite 210, Santa Ana, CA 92705
Toll-Free 855-286-9473
customersupport@asahi-intecc.com

The ASAHI INTECC peripheral guide wires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. These devices are intended for peripheral vascular use only.

The ASAHI® Corsair® Armet® is intended to provide support to facilitate the placement of guide wires in the peripheral vasculature, and can be used to exchange one guide wire for another. The ASAHI Corsair Armet is also intended to assist in the delivery of contrast media into the peripheral vasculature. This device should not be used in coronary vasculature or neurovasculature.

6-Month Data from Landmark Clinical Trial Demonstrates Sustained Benefit of Endovascular Intervention in Patients with Lower Extremity Peripheral Arterial Disease

A roundtable interview discussing the significance of the LIBERTY 360° 6-month results

Tom P. Davis, MD
Director of the Cardiac Catheterization Lab, Peripheral Interventions and Disease
St. John Hospital and Medical Center
Detroit, Michigan
Disclosure: Consultant to Cardiovascular Systems, Inc.

Jihad A. Mustapha, MD
Director of Cardiovascular Research
Metro Health Hospital
University of Michigan Health
Wyoming, Michigan
Clinical Associate Professor of Medicine
Michigan State University, College of Osteopathic Medicine
East Lansing, Michigan
Disclosure: Consultant to Cardiovascular Systems, Inc.

George A. Pliagas, MD
Vascular Surgeon
Premier Surgical Associates, Vascular Division
Tennova Physician's Regional Medical Center
Knoxville, Tennessee
Disclosure: Consultant to Cardiovascular Systems, Inc.

Mahmood K. Razavi, MD
Medical Director, Comprehensive Aortic Center
Director, Dept. of Clinical Trials
St. Joseph Heart & Vascular Center
Orange, California
Disclosure: Consultant to Cardiovascular Systems, Inc.

The LIBERTY 360° study is a prospective, observational, multicenter trial sponsored by Cardiovascular Systems, Inc. to evaluate procedural and long-term clinical and economic outcomes of endovascular device interventions in patients with symptomatic lower extremity peripheral artery disease (PAD), including critical limb ischemia (CLI).[1] The design of this study is truly unique, with liberal inclusion criteria and few exclusion criteria, so that the study encompasses a broad range of patients and treatment modalities. Additionally, any U.S. Food and Drug Administration–approved device could be utilized for endovascular treatment of the target lesion(s). LIBERTY includes quantitative and qualitative data collection, with patient follow-up at 30 days, 6, 12, 18, and 24 months, and then annually up to 5 years. Clinical evaluations include physical examination, wound assessment, ankle-brachial index (ABI), toe-brachial index, duplex ultrasound (DUS) testing, 6-minute walk test, and EQ-5D-5L and VascuQoL questionnaires. In addition, health care resource utilization and hospital billing data from all index and subsequent PAD-related evaluations, office visits, treatment procedures, and hospitalizations will be collected to provide a thorough acute and long-term economic analysis. LIBERTY study enrollment was completed in February, 2016 with 1,204 subjects enrolled across 51 sites in the U.S.

STUDY OUTCOMES

Study outcomes include procedural and lesion success, major adverse events (MAEs), patency (DUS), quality of life (QoL), 6-minute walk test, and economic analysis.

STUDY RIGOR

Four core laboratories were utilized for independent analysis of procedural and lesion success (SynvaCor, Springfield, Ill.); rate of target vessel revascularization (TVR); DUS interpretations (VasCore, Boston, Mass.); 6-minute walk test (CPC

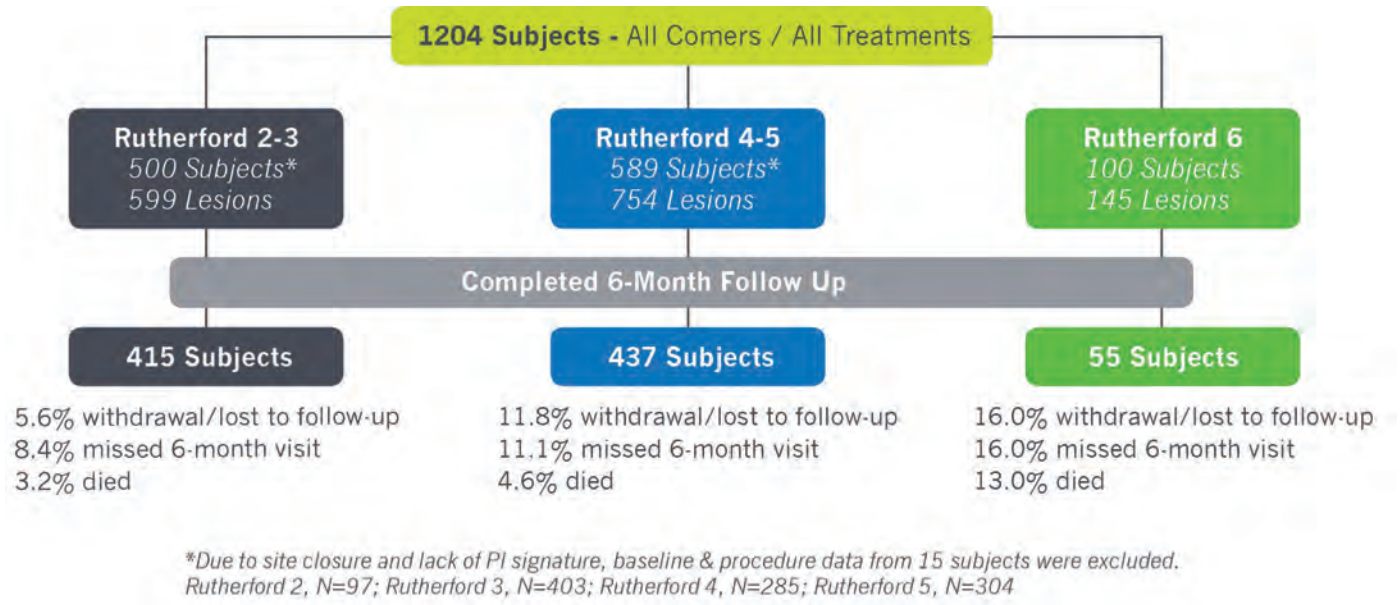


Figure 1. Enrollment and 6-month follow-up. The LIBERTY 360° study included 51 sites and 131 operators, with 37 individual operators treating Rutherford 6 patients.

Clinical Research, Aurora, Co.); and economic analysis (Mid America Heart Institute, Kansas City, Mo.).

ROUNDTABLE DISCUSSION

Four national key opinion leaders were asked to discuss the significance of the LIBERTY study design and findings from the 6-month data set, which was recently presented as a late-breaking clinical trial at the International Society of Endovascular Therapy (ISET) conference in February 2017.

1. What is unique or novel regarding the overall design of the LIBERTY study?

Dr. Mustapha: The LIBERTY study is unique in that it represents as close to a real-world experience as possible with various endovascular strategies across Rutherford Classes 2 to 6. Many of the subjects enrolled in LIBERTY would not have met the enrollment criteria for other clinical trials; in particular, those classified as Rutherford 6. The LIBERTY study also includes any FDA-approved technology to treat claudication and CLI to give us a more representative landscape of endovascular treatment than what has been previously studied.

Dr. Razavi: Many industry-sponsored studies focus on a narrow group of patients to satisfy stringent inclusion/exclusion criteria. These are not always applicable to our daily practice and it is hard to know how many of these devices perform in our everyday patients. The strength of LIBERTY is that it collected core-lab adjudicated data on an "all-comers" basis, meaning various endovascular devices are included. Hence, this data is more relevant to daily practice.

Dr. Pliagas: I found it surprising but also reassuring that LIBERTY did not exclude any patient in the symptomatic Rutherford classes. We see and evaluate each and every patient in the office, regardless of Rutherford classification. To me, this reinforces the fact that LIBERTY has real-world significance. LIBERTY is also unique in that it will track patient-centric outcomes using two different quality-of-life (QoL) questionnaires and a walking assessment (required for Rutherford 2-5 subjects only) at follow-up visits.

Dr. Davis: Being able to utilize any FDA-approved technology for this broad patient set provides the medical community a unique lens through a more contemporary landscape and treatment algorithm than previous studies that have been published in the peripheral space. The addition of an economic core lab to analyze procedural costs will also bring tremendous value to the medical community.

2. What is the primary takeaway from the 6-month results and how do these results build off of the existing 30-day data?

	RUTHERFORD CLASS		
	2-3	4-5	6
Freedom from (FF) MAE (6-Month)	92.6%	81.2%	73.7%
FF Major Amputation	99.8%	96.8%	87.1%
FF Target Vessel Revascularization (TVR)	93.0%	83.1%	85.1%
FF Death	97.1%	95.3%	85.1%

Table 1. High freedom from MAEs at 6 months across all Rutherford Classes. Kaplan-Meier method used to estimate event-free rates. MAE defined as death (≤30 days after the procedure), major amputation of the target limb, and TVR.

Dr. Razavi: We need to emphasize and share the 6-month LIBERTY data, including the very low rate of major adverse events in CLI patients in this study. This is of particular importance in Rutherford 6 patients. Existing literature, mostly based on surgical series, seem to indicate that as many as 40% of Rutherford 4-6 patients end up with an amputation within 6 months.[2] Although only 100 Rutherford 6 patients were enrolled, this is one of the first Rutherford 6 data sets that exists which captures procedural and long-term outcomes. Also, the 87.1% freedom from major amputation of the target limb at 6 months is very encouraging.

Dr. Mustapha: Marked improvement in Rutherford classification was seen at 6 months. The Rutherford 4-5 and Rutherford 6 groups demonstrated continued improvement from 30 days to 6 months, while Rutherford 2-3 maintained improvement at 6 months. Patients also completed two QoL questionnaires at 6 months, and results demonstrated improved quality of life from baseline across all Rutherford Classes.

Dr. Davis: Rutherford 6 patients continued to demonstrate a low incidence of major adverse events out to 6 months. This tracks well with the originally reported low rates of significant angiographic complications in this patient cohort. Interestingly, the "severe" complications that did occur with this group required zero bail-out stent utilization.

Dr. Pliagas: The 6-month data reveals that the endovascular intervention shows beneficial and sustainable results; however, as surveillance continues, it will also help us understand when and where we may need to re-intervene.

3. What struck you as interesting or surprising in the 6-month results?

Dr. Mustapha: The results of this novel all-comers PAD study continue to suggest that "watchful waiting" in Rutherford 2-3 patients and "primary amputation" in Rutherford 6 patients may not be necessary — peripheral vascular interventions (PVI) can be successful in those patient populations as well. In addition, these data demonstrate that on average, PVI can restore Rutherford 4-5 patients with CLI status to moderate claudicant status. Therefore, LIBERTY provides further evidence to support PVI treatment in Rutherford 4-5 patients, with continued improvement of Rutherford classification and sustained quality-of-life results out to 6 months.

Dr. Pliagas: It was excellent to see that even at 6 months, the freedom from major amputation was 96.8% in Rutherford 4-5 patients. This reinforces the fact that our dedication to endovascular revascularization, and the time and effort we put forth to revascularize these ischemic limbs, plays a meaningful role in changing our patients' lives for the better.

Dr. Davis: It was interesting to see Rutherford 6 patients continue to do very well 6 months after their procedure. This study demonstrated excellent procedural results in this difficult patient set, including low rates of significant angiographic complications and a remarkable 78% of Rutherford 6 patients discharged to home rate. Combined with a positive trend in major adverse events at 6 months, the LIBERTY data pushes the envelope that we really do need to treat these patients in need.

Dr. Razavi: A lower prevalence of hyperlipidemia in Rutherford 6 patients was a surprise to me. Perhaps these patients receive more aggressive medical management as compared to claudicants, which unfortunately, is often seen as a benign condition.

4. What is your interpretation of the significance of the more patient-centric data points such as change in Rutherford class and Quality of life (QoL)? **Dr. Davis:** At 6 months, it's impressive to see that all Rutherford Class patients maintained the improvement in QoL scores from baseline to 30 days. This speaks to the clinical significance from the patient's perspective in terms of what revascularization can do for decreasing symptoms of PAD, while improving important physical and emotional aspects of their lives.

Dr. Pliagas: Analysis of Rutherford 2-6 patients indicates that their QoL scores improved across the board in all domains, again reinforcing the benefits of endovascular intervention. We can honestly say that we are making a difference in these patients' lives.

Dr. Razavi: Many prospective multicenter studies in "real world" patients lack QoL data. These data are not only important to us and our patients but also to payors. However, anatomic and physiologic endpoints such as patency and ankle brachial index are important metrics for comparative analyses and assessment of technologies and devices producing incremental improvements. Hence it is crucial that studies report both types of data moving forward.

Dr. Mustapha: The significance of change in the Rutherford Class is the value associated with it. For the patients that saw improvement from Rutherford 4-6 to Rutherford 3 or less, the primary value that comes to mind is the reduction in mortality, which tends to correlate with long-standing advanced Rutherford classification. Also, the reduction in Rutherford Class means an improvement in the clinical status of the patient. It appears that the improved QoL, across the board, is directly proportional to the improved clinical status and reduced Rutherford Class.

5. What impact will these data have on the current treatment guidelines, especially in regards to treatment of patients with claudication and CLI?

Dr. Mustapha: Two important updates were recently published with the 2016 AHA/ACC Guidelines[3] on the Management of Patients with PAD. The updated guidelines state, "Revascularization is a reasonable treatment option for patients with lifestyle-limiting claudication and an inadequate response to medical management and exercise" (Class IIa). Additionally, "an evaluation for revascularization options should be performed by an interdisciplinary care team before amputation in the patient

Continued on page 12

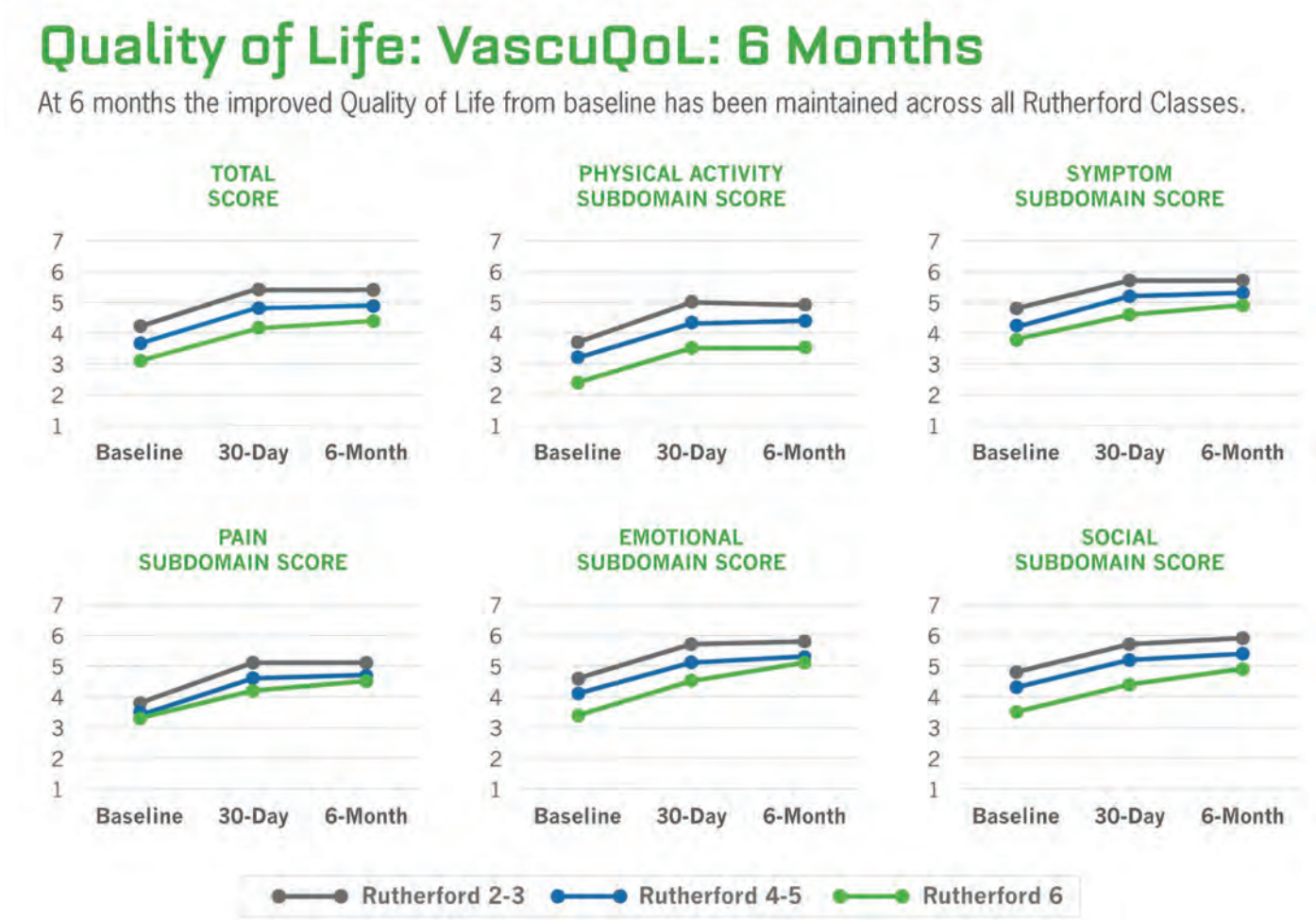


Figure 2. All Rutherford Classes demonstrated improvement in VascuQoL scores at 30 days, and either continued to improve or maintained improvement through 6 months.

ROUNDTABLE from page 11

with CLI" (Class I). We practice in a world with limited guidance on the benefit of endovascular treatment over surgical bypass in these difficult patients. This is probably best exemplified by the ongoing BEST-CLI trial designed to address that very question. Progress is most certainly being made and it is encouraging to see real-world clinical data from studies like LIBERTY to support the 2016 AHA/ACC Guidelines.

Dr. Pliagas: The data continue to reinforce the notion that a high level of commitment to treating CLI patients adds benefit to this population, and may result in limb salvage and overall improvement in their daily lives. Specifically, the LIBERTY data have shown us that skilled operators can safely intervene on all symptomatic PAD patients with low rates of significant angiographic complications and high rates of procedural success. Hopefully this will prompt other vascular societies to take the LIBERTY data into consideration, and help them develop new strategies and algorithms for treatment of PAD and CLI.

Dr. Razavi: Professional society guidelines are usually behind practice, especially in fields such as endovascular treatment, where rapid change is a rule rather than the exception. The impact of this type of robust real-world observational study is more on our daily practice than on guidelines. Having said that, however, quality data are always influential in changing guidelines.

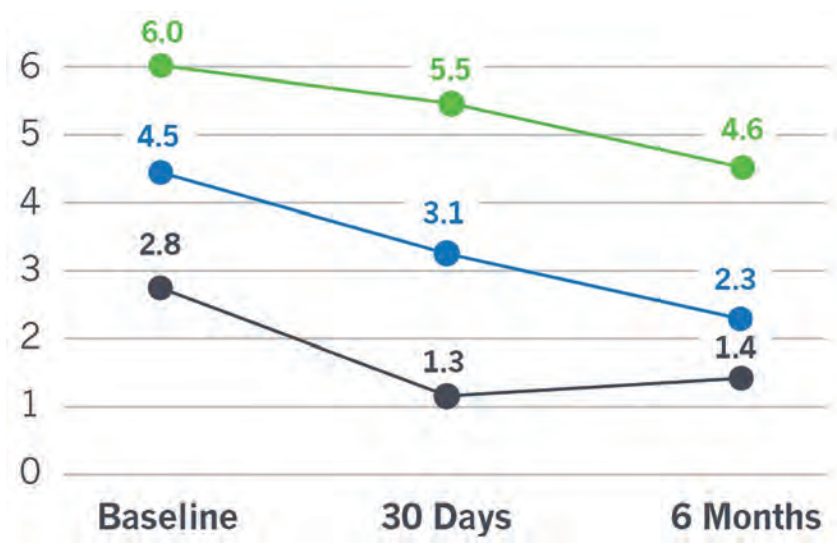
Dr. Davis: Endovascular intervention of claudicant patients can be done with low risk and sustained benefits. We continue to hear fear of "making matters worse" and "shutting down already patent run-off vessels" as a reason for not treating claudicant patients, opting instead for medical management and monitoring. LIBERTY demonstrated that endovascular treatment led to worsened runoff status in only 5.9% of Rutherford 2-3 patients. At 6 months, the freedom from MAE rate was 92.6% in Rutherford 2-3 patients and these patients had a mean improvement of 1.4 ± 1.2 in Rutherford class from baseline.

6. What are you most excited about and what do we hope to learn regarding the future data releases for LIBERTY?

Dr. Razavi: I was pleased to see the sustained improvement of patients from 30 days to 6 months, especially in regards to the CLI patients with multiple comorbidities. I am particularly interested in seeing if these favorable 6-month outcomes continue to show durability through 12 months and beyond. The long-term economic analysis will also be interesting and will shed much-needed light on the cost-effectiveness of different treatment strategies.

Dr. Davis: I think one of the most exciting aspects of LIBERTY are the limb salvage and wound status sub-analyses. Seventeen percent (17%) of Rutherford 6 patients enrolled in LIBERTY had a previous major amputation of the non-target limb, demonstrating the advanced disease state captured in this trial and the potential opportunity for earlier intervention. We already see freedom from major amputation in 99.8% of Rutherford 2-3 patients, 96.8% of Rutherford 4-5 patients, and 87.1% of Rutherford 6 patients at 6 months, so it will be interesting to see if this limb salvage is sustained and if we see a corresponding improvement in wound status.

Dr. Pliagas: I truly liked that the LIBERTY study not only included all symptomatic PAD patients, but also included various sites of care such as large teaching hospitals, small community hospitals, VA centers, and outpatient clinics. With 15 of the 51 LIBERTY sites being office-based



Rutherford Classification *(Mean ± SD)*	RC2–3	RC4–5	RC6
Baseline	2.8 ± 0.4	4.5 ± 0.5	6.0 ± 0.0
Change to 30 days	-1.6 ± 1.2	-1.4 ± 1.8	-0.5 ± 1.3
Change to 6 months	-1.4 ± 1.2	-2.2 ± 1.9	-1.4 ± 2.3

Figure 3. Patients in all Rutherford classes showed improvement in Rutherford class from baseline to 30 days. Rutherford 4-5 and Rutherford 6 patients showed continued improvement from 30 days to 6 months, while Rutherford 2-3 patients maintained improvement at 6 months.

labs, I am excited for additional analysis regarding the type of patients and procedures, as well as the safety of endovascular procedures, at this particular site of care.

Dr. Mustapha: For the first time, we were able to look at a trial involving Rutherford 6 patients with scientific optimism. It is hard not to be hopeful, and here is some insight as to why. Rutherford Class 6 and some rare cases of complex Rutherford 5 patients have been forever labeled as "no option" patients. Today I can say with confidence that the "no option" label can be removed. This is primarily based on the data we have seen thus far from LIBERTY, especially from the Rutherford 6 arm. The fact that 78% of Rutherford 6 patients were discharged home post-revascularization reinforces new hope for patients with advanced CLI. LIBERTY shows us that at 6 months, the rates of death, major amputation, and TVR/TLR in Rutherford 6 patients were numerically similar to Rutherford 4-5 patients, yet there would be no debate on the benefit of treating a Rutherford 4 or 5 patient. We should therefore think hard and look deep into every Rutherford 6 patient before scheduling a life-changing amputation. The data are clear. Endovascular revascularization is the new hope for amputation-free survival for the Rutherford 6 patient.

7. How will you personally utilize these findings (i.e. Will you share these with diagnosing physicians in your area? Will this change your treatment strategy? Will this inform the design of new trials moving forward, etc.)?

Dr. Pliagas: The data collected by LIBERTY allow us to share with our colleagues our passion and commitment to limb salvage and the treatment of CLI. It reinforces the fundamental idea proposed all along by CLI experts that no one should undergo an amputation without a selective angiogram and intervention. Finally, we see the guidelines starting to follow suit and stipulate the need for endovascular assessment prior to an amputation. With the advent of new technology, LIBERTY data can serve as a baseline standard of current endovascular treatment options when evaluating future technologies.

Dr. Davis: I will communicate this with the local diagnosing physician community, including podiatrists at various upcoming meetings, to share the benefits of treating an under-studied and under-diagnosed patient population. We need to ensure that the diagnosing community is aware that we have come a long way in treating CLI patients, and that a limb salvage focus and partnership can lead to fewer amputations. We know that the disease is prevalent and the patients are out there, but we need to educate those upstream diagnosing physicians as to the benefit of endovascular treatment in order to more broadly affect this at-risk population.

Dr. Mustapha: The LIBERTY trial changes everything for CLI patients. It will absolutely change my practice to become more aggressive in treating severe and complex patients. I will definitely share this finding with all specialties to increase awareness about the benefit of treating Rutherford 5-6 patients who do receive benefit from revascularization. Transmetatarsal amputation is not associated with mortality, but major amputation is. It is the responsibility of everyone that is aware of the positive findings of the LIBERTY trial to raise awareness so patients receive what might end up being a lifesaving procedure.

Dr. Razavi: All of the above. While LIBERTY may not be randomized data powered to show a significant advantage of one treatment over another, it adds substantial insight in to a much needed data gap in real-world, advanced PAD and CLI patients. This is a significant milestone in the medical community, because it provides both procedural and long-term economic, qualitative, and clinical outcomes for a wide variety of PAD patients. These aspects will continue to guide our decision making and help inform the study design of future endovascular device trials. ■

REFERENCES

1. Adams GL, Mustapha J, Gray W, et al. The LIBERTY study: Design of a prospective, observational, multicenter trial to evaluate the acute and long-term clinical and economic outcomes of real-world endovascular device interventions in treating peripheral artery disease. *Am Heart J.* 2016;174:14–21. Epub 2015 Dec 30.
2. Dormandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). TransAtlantic Inter-Society Consensus (TASC) Working Group. TASC document. *J Vasc Surg.* 2000;31SI-S296.
3. Gerhard-Herman M,D, Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2016 Nov 8. pii: S0735-1097(16)36902-9. doi: 10.1016/j.jacc.2016.11.007 [Epub ahead of print].

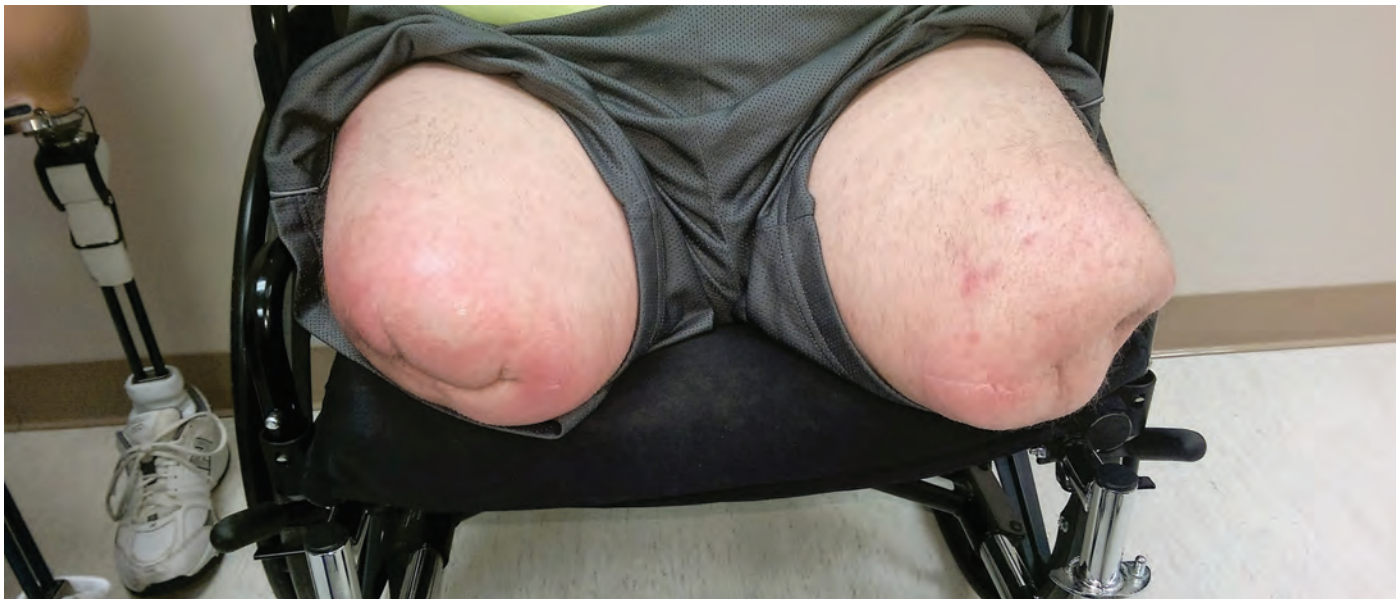


Figure 1. Within two years following their first amputation, 36-50% of patients will undergo a contralateral amputation.

PLIAGAS from page 1

have PAD.[2] Critical limb ischemia (CLI) as diagnosed by various methods has an incidence of 500-1000 cases per million population, but these are acknowledged as old statistics.[2,3] It is estimated that 1% of Americans over the age of 50 will manifest some presentation of CLI.[4,5] According to the United States Census Bureau, the population aged 65 and over, by 2020, is projected to be 83.7 million. That is double the population that was accounted for just five years ago in 2012.[6] Recent analysis and projections by The Sage Group indicate that patients with CLI could grow to 2.8-3.5 million patients by the year 2020.[7] *The Journal of Vascular Surgery*, in October 2009, predicted a 6.1% shortage of vascular surgeons by the year 2020.[8] Additionally, there are reports of cardiology workforce shortages of as much as 33%, resulting in longer wait times for appointments and treatment.[9,10] Let us be cognizant of the fact that not every vascular surgeon and every cardiologist treats critical limb ischemia. This will strain our existing and future work force even more.

In the interventional suite or operating room, we all have noticed that CLI patients have multilevel and multivessel disease. The skill level required to treat complex, calcified, long chronic total occlusions is significant. Not only are advanced techniques required to revascularize the affected limb, but the process is lengthy and time-consuming. At times, treatment requires a staged approach and even hybrid procedures. There are many who believe that the diagnosis of CLI should carry a modifier indicating the complexity of the case. Centers of excellence for CLI and advanced PAD are emerging. These usually require a minimum of 100 CLI procedures per year.[4] Several studies are ongoing to determine which approaches are best suited for patients and their presentation.[11-13] The scope of all these individual studies is too extensive to present here, but there are conclusions indicating that a well performed, adequately sized venous bypass with satisfactory proximal and distal landing zones is the current gold standard.[1] Concurrently, we have studies indicating that when physicians are free to individualize therapy to CLI patients, the endovascular-first approach achieved a noninferior amputation-free survival compared with bypass surgery.[2] The debates will certainly continue and in this era of complex interventions, hybrid techniques, and advanced endovascular techniques, we may eventually realize that no single trial can proclaim one technique to be the superior approach.[1] Perhaps one day, as we change our endpoints and study objectives, we will learn from each other and realize that we had more options than we anticipated.

As we consider best treatment algorithm, we also have to take into account the reality that 36-50% of patients undergo contralateral amputation within two years following their first amputation (Figure 1).[14] I follow our amputees in our vascular clinic so that we can be aware of any progression of atherosclerotic disease in the contralateral limb (Figure 2). Prior angiograms are available and the findings are documented in the operative notes. Future thoughts and recommendations are usually included in my concluding paragraph.

The Vascular Group of New England published a study in 2012 showing that patients with contralateral amputations who presented with CLI in the intact limb had increased rates of adverse events, increased rates of one-year graft occlusions, and increased rates of limb loss.[15] Taking this into account, the Vascular and Endovascular Divisions at Beth Israel Deaconess and Harvard concluded that

Continued on page 15

CLI Center of Excellence – Interview With Dr. Siddhartha Rao

With J.A. Mustapha, MD

Siddhartha Rao, MD

Siddhartha Rao, MD, is an interventional cardiologist who practices at WakeMed Health and Hospitals in Raleigh, North Carolina. He completed his residency in internal medicine, along with his chief medical residency, at Wayne State University in Detroit, Michigan. He completed cardiovascular and interventional cardiology fellowships at the University of North Carolina at Chapel Hill. He pursued further formal interventional training in peripheral vascular and structural heart interventions at Ochsner Medical Center, New Orleans, Louisiana, and Prairie Cardiovascular, Springfield, Illinois.

Dr. Rao is board certified in Internal Medicine, Cardiovascular Disease and Interventional Cardiology. He is a Registered Physician in Vascular Interpretation (RPVI) and an American Board of Vascular Medicine diplomate in Vascular Medicine and Endovascular Medicine.

Dr. Rao shares with Dr. Mustapha his experiences developing a multidisciplinary CLI Center of Excellence at his institution.

What drove you to pursue the creation of a CLI Center?

In North Carolina, we have a large population of patients with critical limb ischemia for whom amputation has, historically, been the most common option. Lower limb amputation often has ramifications beyond the patient's immediate physical health, namely, the patient's mental health, loss of mobility, loss of productivity, and increased long-term mortality. Most physicians are unaware of the fact that patients with CLI often have 1-year prognoses worse than that of some cancers.

In this context, the concept of a multidisciplinary CLI Center of Excellence to prevent amputations in patients with critical limb ischemia not only becomes an urgent societal need, but also, in my opinion, a moral imperative.

What factors led to your decision to focus on CLI?

As somebody who immigrated to the United States many years ago from a developing country with few resources, I feel incredibly grateful to the people of this wonderful state, who have provided me much personal and professional happiness. Much like others, I have my own personal experience that was a strong motivating factor. My own grandmother, who was a very vibrant and productive member of society, unfortunately became a CLI statistic. She died within 8 months of a below-knee amputation. These life experiences have certainly steered me to focus my efforts on CLI care.

What outside factors have influenced you in your path to become a CLI specialist and develop a CLI Center?

My personal experiences aside, I have to say the strongest motivating factor has been the constant motivating presence of you, my friend, and someone I feel fortunate to call my mentor. Your pioneering efforts in advancing CLI care in our country are second to none. Your passion has certainly rubbed off on me.

Thank you. I am humbled by your words and would be remiss if I didn't mention that the success of the program I am fortunate enough to be involved in is definitely due to a team effort.
You have developed a multispecialty CLI Center. What are the different specialties representing the members of your CLI team?

At WakeMed Health and Hospitals, we truly believe in the concept of a multidisciplinary approach to amputation prevention. Our team includes vascular interventionalists, hospitalists, vascular surgeons, podiatrists, wound care therapists, infectious disease physicians, and primary care physicians, who have the difficult task of managing the patients' many comorbidities.

How were you able to bring the different specialties together?

This is often the most challenging part of starting a CLI program. Multidisciplinary CLI care is such a new concept that educating your colleagues and convincing them to change their practice patterns is the most challenging part of putting together a team. However, polite persistence with data supporting your efforts and sharing good patient outcomes can often change the most resistant mind sets. Conducting lunch or dinner presentations with the goal of educating your peers on the latest data for CLI therapy is one way to start off your efforts.

Identify partners in your ultrasound lab — RVTs, cath lab nurses, and technologists that share your passion for CLI care —and invest time in their training.

Are there similar centers you hope to emulate?

There are several hospitals across the nation where great CLI work is being done, but I think the gold standard is definitely your program at Metro Health University of Michigan Health in Wyoming, Michigan.

Again, thank you, Dr. Rao. The combined efforts of a multidisciplinary team can truly make a difference. How do the members of the differing specialty areas work together?

We utilize EPIC, an integrated electronic medical record system across WakeMed, that makes communication between the various arms of the CLI program quite easy and efficient. We also have identified a coordinator who watches over the entire process to make sure that things don't fall through the cracks.

For more urgent needs, there is, of course, the old-fashioned way of contacting each other directly by telephone about the patient's care. Our goal, over the next several months, is to have a formal CLI clinic that is staffed by an endovascular specialist and a wound care therapist, and with immediate imaging ability so that it can truly be a "one-stop shop" for patients and referring physicians.

How is wound care provided to your CLI patients?

We have a formal wound clinic in which trained therapists, under the supervision of a vascular surgeon or the referring podiatrist, provide wound care. For minor dressing changes, our clinics are staffed with medical assistants with the necessary resources and training.

Was the development of a CLI Center a major paradigm shift in care for your institution?

As I mentioned, this is often the most difficult part of setting up a CLI Center — changing established practice patterns. It took multiple meetings with the administration to share the data and need for a CLI program, allocate resources, and formalize our efforts. From the initial shock of listening to a physician say that the only treatment for CLI is "Fem-Pop Chop," we have come a long way in providing data-driven, state-of-the art care for these sick patients.

Can you share lessons learned during this endeavor?

Setting up a CLI program is the most difficult professional task I have ever undertaken. Convincing the administration of the need for an amputation prevention program and then bringing the various specialties to the table to build a program is a much more difficult task then one would think. One needs physicians with the requisite endovascular skills, mountains of patience, well-trained cath lab technologists, and a true "team building" mindset and approach to building a CLI program.

Continued on page 15

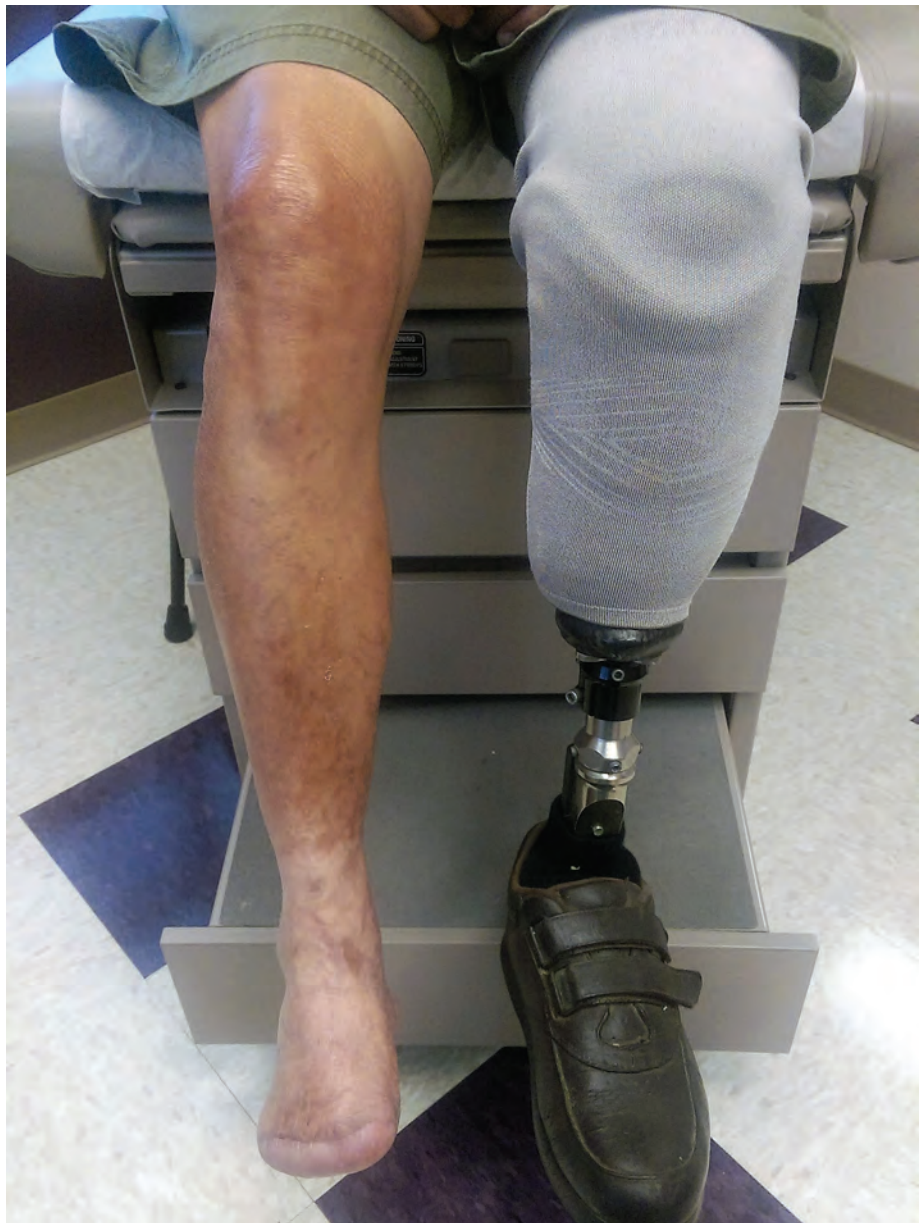


Figure 2. This patient's contralateral limb will undergo close surveillance and early intervention if a hemodynamic lesion is identified.

PLIAGAS from page 13

all patients should undergo close surveillance and counseling to help prevent subsequent amputations in their contralateral limb.[16] With this in mind, when hemodynamic lesions threaten the contralateral limb, my treatment protocol is to take these patients to the endosuite, where I intervene early in hopes of salvaging the remaining limb. In a similar scenario, because of the known progression of disease in the opposite limb, if, after initial salvage, a hemodynamic lesion is found in the contralateral limb, I then offer a separate staging procedure whereby the lesion is addressed. This is consistent with the finding that more than half of patients with CLI who end up with amputations usually do not have any intervention or workup the prior year.[17]

So, my philosophy is simple and leads me to the following algorithm: I saved one limb from CLI and I will now proceed to intervene on the contralateral limb which is in what I consider to be in a "pre-CLI state." Amputations cost the system significantly and bilateral amputations cost even more, imposing both financial and psychosocial strain on the family and our medical system.

Awareness and prevention have to be continuous and ongoing while we carry out our daily limb salvage procedures. Our role as vascular specialists who treat CLI is to prevent unnecessary amputations and improve quality of life.[4] A team approach must be put in place that will contribute to patient, general public, and physician awareness. This helps with patient identification, coordination of care, providing clinical outpatient testing and evaluation, and long-term follow up. This streamlined approach allows the patient with critical limb ischemia to enter the system. The referral process must be effortless to accommodate the busy referring physician. This approach also requires educating the community you serve. The program you help set up will require your oversight and input.

Lower extremity ulcerations are a vascular emergency and should undergo prompt evaluation. Up to 50% of CLI patients undergo amputation without a previous diagnostic or therapeutic endovascular intervention.[18] Most of the world-wide health systems, including England, Australia, Sweden, and Italy, have instituted this multidisciplinary team algorithm with great success and have noticed a decrease in their amputation rates of up to 51%.[19]

Going forward, the multidisciplinary team helps build awareness and promotes widespread prevention throughout the community. Physicians with a passion for CLI and limb salvage will lead the way to improve the quality of life of our patients. CLI will continue to rise annually over the next 10-14 years. New techniques and devices will emerge to assist us in the daily challenge that we face. In the past we had underestimated the impact of CLI on our health system, but with new studies, observations, and patient demographics, we are now ready to take on the CLI revolution.

It is now Friday morning, and the phone rings with another referral for a patient with Rutherford 5 ischemic lesions. I do what we all do; work the patient into an already full office schedule and start the workup in order to salvage his limb. ■

BIBLIOGRAPHY

1. Conte MS. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) and the (hoped for) dawn of evidence-based treatment for advanced limb ischemia. *J Vasc Surg* 2010;51:69s-75s.
2. Nehler MR, Duval S, Diao L, et al. Epidemiology of peripheral arterial disease and critical limb ischemia in an insured national population. *J Vasc Surg* 2014;60:686-695.
3. Katzen BT. Defining CLI and the scope of the problem. The Miami Critical Limb Ischemia Symposium, June 7-8, 2014.
4. Saab F, Mustapha JA. The nuts and bolts of building a critical limb ischemia program. American College of Cardiology, September 8, 2015.
5. Weitz JL. Diagnosis and treatment of chronic arterial insufficiencyof the lower extremities: a critical review. *Circulation*. 1996;94:3026-3049.
6. Ortman JM, et al. An aging nation: the older population in the United States. United States Census, May 2014. U.S. Department of Commerce.
7. Sage Group. The SAGE Group predicts that in 2007 approximately 2.8 million people in Western Europe suffered from critical limb ischemia. Oct. 20, 2008, Atlanta, GA.
8. Satiani B. Predicted shortage of vascular surgeons in the United States: population and workload analysis. *J Vasc Surg*. Oct 2009;50(4):946-952.
9. Pepine CJ. Who will treat the aging population in 2020? *Cardiology Today*. November 2006.
10. Williams JL. Projecting the general cardiology workforce shortage. *Am Heart Hosp J*. 2007 Fall;5(4):203-209.
11. Bisdas T, Borowski M, Stavroulakis K, Torsello G; CRITISCH Collaborators. Endovascular therapy versus bypass surgery as first-line treatment strategies for critical limb ischemia: Results of the interim analysis of the CRITISCH Registry. *JACC Cardiovasc Interv*. 2016;9(24):2557-2565.
12. Jaff MR, White CJ, Hiatt WR, et al. An update on methods for revascularization and expansion of the TASC lesion classification to include below-the-knee arteries: a supplement to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *Ann Vasc Dis*. 2015; 8(4):343-357.
13. Farber A, et al. The Best-CLI trial: a multidisciplinary effort to assess which therapy is best for patients with critical limb ischemia. *Tech Vasc Interv Radiol*. 2014;17(3): 221-224.
14. Yost ML. Cost-benefit analysis of critical limb ischemia in the era of the Affordable Care Act. *Endovascular Today*. 2014 May: 29-36.
15. Baril DT, Goodney PP, Robinson WP, Nolan BW, Stone DH, Li Y, et al; Vascular Study Group of New England. Prior contralateral amputation predicts worse outcomes for lower extremity bypasses performed in the intact limb. *J Vasc Surg*. 2012 Aug;56(2):353-360.
16. Glaser JD, Bensley RP, Hurks R, et al. Fate of the contralateral limb after lower extremity amputation. *J Vasc Surg*. 2013;58(6):1571-1577.
17. Goodney PP, et al. Variation in the use of lower extremity vascular procedures for critical limb ischemia. *Circ Cardivasc Qual Outcomes*. 2012 Jan;5(1):94-102.
18. Sanguilly J III, et al. Reducing amputation rates in critical limb ischemia patients via a limb salvage program: a retrospective analysis. *Vascular Disease Management*. 2016 May; 112-119.
19. Varcoe RL. The treatment of critical limb ischemia in Australia: advancing toward an independent discipline. *CLIC*. June 2015.

RAO from page 14

Has the institution of a multi-specialty approach to CLI care changed outcomes for your patients?

Our preliminary data certainly suggests markedly improved outcomes for patients. We have had recanalization rates of exceeding 80% in complex chronic total occlusions involving the arteries above and below the knee, thereby providing the first step in improving patient outcomes. Close follow-up with podiatrists and wound care therapists, along with robust risk factor modification, have certainly led to dramatically improved outcomes in the last year since we have formalized our program.

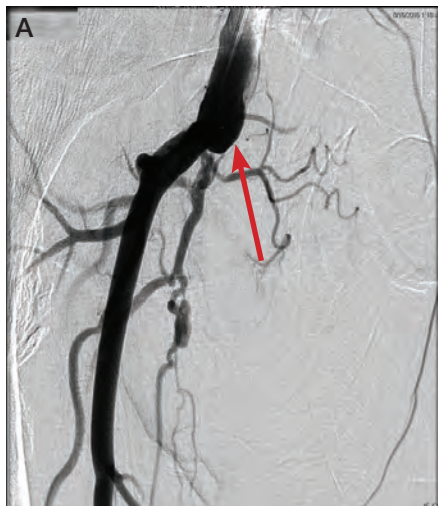
What are your next steps?

From a personal perspective, I hope to continue to learn new skills that will help me improve patient outcomes. From an institutional perspective, our immediate focus, over the next several months, is to set up a formal CLI clinic so that the entire process, starting from initial patient contact with the referring physician to revascularization and wound healing, becomes a smooth and streamlined process.

What advice can you give to a physician and/or institution planning to initiate a CLI Center?

Be patient. Pay your dues. The first thing you need to do, as a physician, is to hone your endovascular skills. This will take a lot of effort. It is my firm belief that you cannot be a CLI endovascular expert without being comfortable with ultrasound-guided antegrade femoral artery access and pedal access. Familiarize yourself with the necessary equipment, tips, and tricks that will increase your chances of success when performing these complicated procedures. Identify partners in your ultrasound lab — RVTs, cath lab nurses and technologists — that share your passion for CLI care and invest time in their training. Reach out to your colleagues from other specialties and share your data and outcomes so that you have support within your institution. You cannot have a CLI Center of Excellence without a "team" approach. ■

Dr. Rao can be reached at Rao.Siddhartha@gmail.com



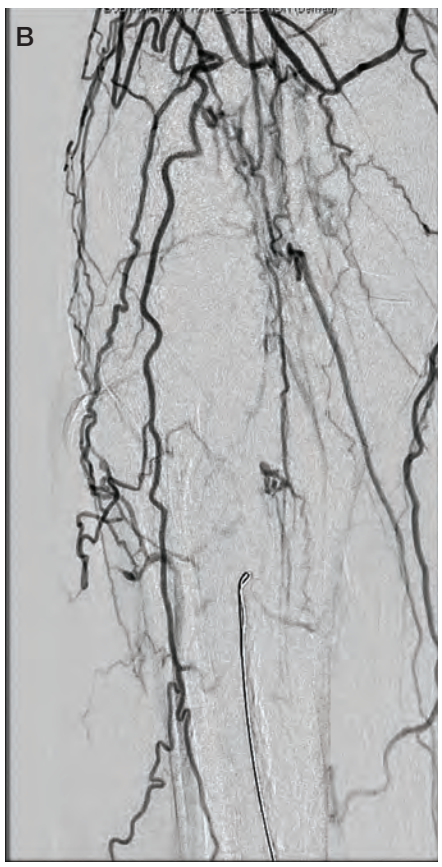


Figure 3. Diagnostic angiogram. The ostial superficial femoral artery occlusion was flush at the ostium (Panel A, arrow). The proximal cap was concave in contour. Note the complete occlusion of the superficial femoral and popliteal artery demonstrated by the absence of distal reconstitution at the level of the knee (Panel B).

Table 1. Wound characteristics

WOUND CHARACTERISTICS				
WIfI Score	**Wound** 2*	**Ischemia** 3**	**Infection** 2***	**Composite Score** 7
Risk Interpretation				
Rate of Major Amputation				**33%**
Rate of RAS				**57%**
Mortality				**22%**

Using WIfI score to assess risk of major amputation, RAS, and mortality.[2] Recent work has sub-stratified patients' composite scoring into three larger groups.[1-3, 4-6, 7-9] The discussed patient's score places him in the highest risk category.
** Deep ulceration and digital gangrene (Wound grade 2)*
*** Toe pressures of <30 mmhg (Ischemia grade 3)*
**** Local infection without systemic signs (Infection grade 2)*

Table 2. Patient Characteristics

PATIENT CHARACTERISTICS		Surgery	Endovascular
MI risk with infrainguinal surgical bypass	7.8%		✔
CIN risk	26.1%	✔	
Hemodialysis risk	1.09%		✔
Autologous venous conduit available	No		✔

Patient characteristics valuable to the selection of various revascularization strategies. Integrating quantitative risk scores such as the above must be performed on a case-by-case basis.
MI = myocardial infarction; CIN = contrast-induced nephropathy.

Table 3. Lesion characteristics

LESION CHARACTERISTICS		Surgery	Endovascular
TASC II D lesion*	Yes		✔*
Antegrade access possible	No	✔	
Proximal and/or distal cap favorable (concave)	Yes		✔
Lesion length	>30cm	✔	
Heavily calcific**	Yes	✔	
2 or more vessel runoff ***	Yes		✔
Pedal artery amenable for access	Yes		✔
2 year patency of infra-popliteal PTFE graft[5]	32%		✔

Shown is a list of easily assessed lesion characteristics using non-invasive vascular imaging and diagnostic angiography.
** Advances in technique and technology have rendered almost all lesions amenable to percutaneous revascularization.*
***Favors surgical if spares potential anastomoses.*
****Diminishes harms of theoretical pedal vessel compromise associated with pedal access.*

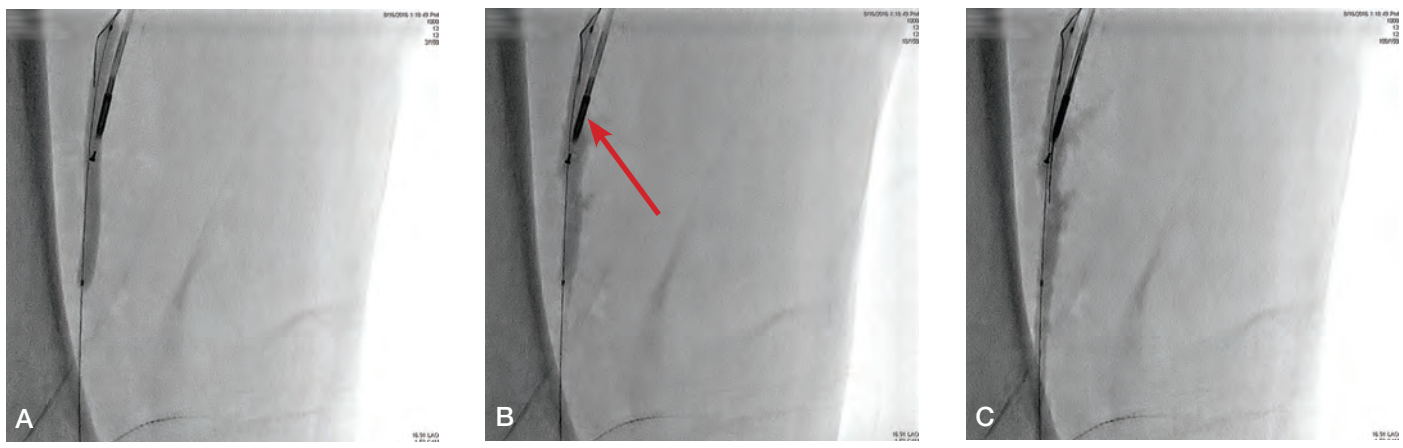


Figure 4. Virtual true lumen creation. "Virtual true lumen" creation was performed using the 4.0 x 80 mm balloon passed from the pedal sheath and the Outback (Cordis) reentry catheter passed via the femoral artery sheath. The needle punctured the balloon (arrow) and the wire was passed into the ruptured balloon lumen where it was trapped. The wire was then externalized via the pedal sheath, facilitating balloon and stent placement from the femoral artery sheath.

GALMER from page 4

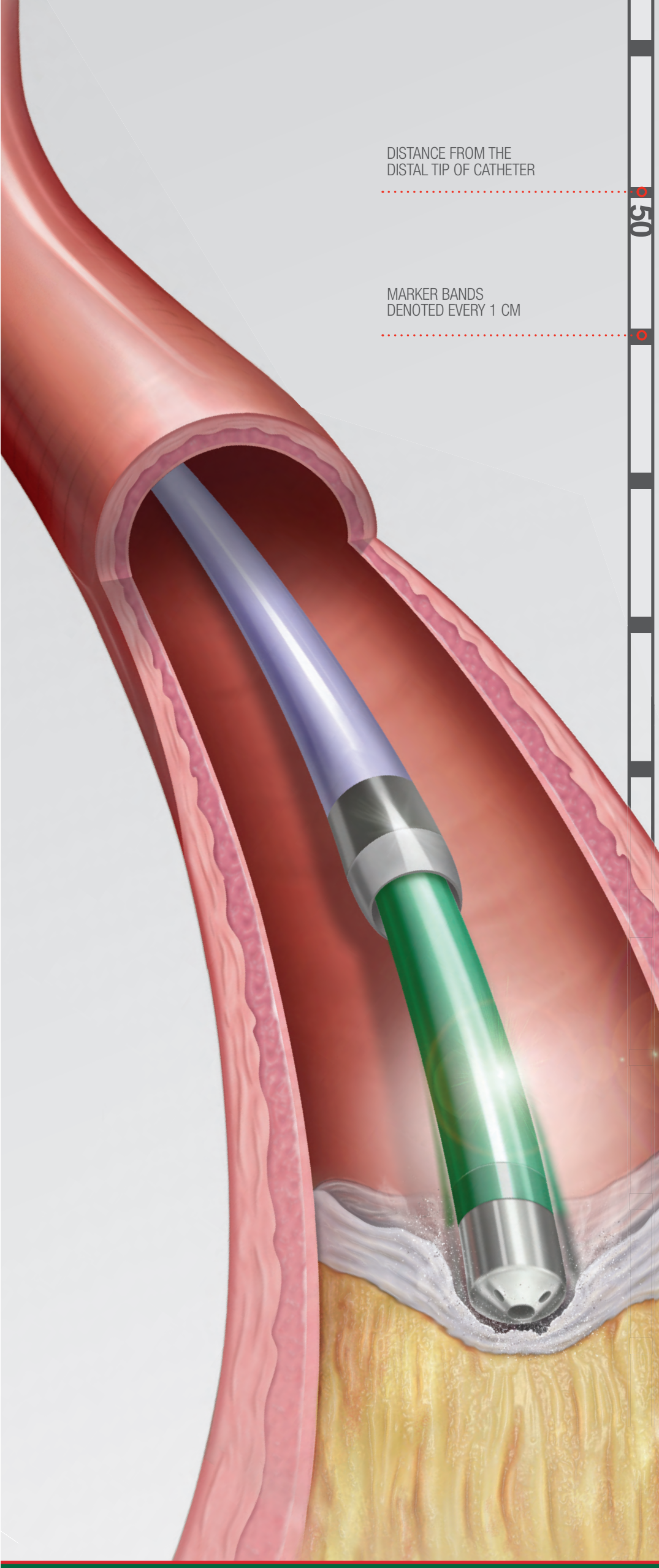
a revascularization approach. Inadequate saphenous vein conduits limited the surgical revascularization options to non-autologous conduit such as homografts and prosthetic grafts. As a general rule, the patency of bypass grafts declines with the incorporation of non-autologous graft and with the need for more distal infrapopliteal anastamosis sites. A meta-analysis of a pooled series showed that the 2-year patency of an infrapopliteal PTFE graft is 32% compared to 76% for an in-situ vein bypass. The frequently referenced BASIL trial demonstrated that overall survival and limb salvage was inferior with prosthetic material compared to a venous conduit. Novel graft materials have yet to bridge this gap.

Advances in endovascular techniques and technologies have rendered the vast majority of lesions amenable to percutaneous revascularization. The technical success of endovascular intervention for even the longest femoropopliteal lesions has been reported to be as high as 95%. However, despite these advances, the correlation between technical success and patency, and the correlation between patency and limb salvage, is numerically less compelling. Yet the primary patency rates of very long femoropopliteal occlusive disease at 1 year was reported to be 63% in one study, a number that has been reproduced in a number of other works. Despite the apparent differences in primary patency between endovascular and surgical therapies, the limb salvage rates of the two therapies appear to be statistically comparable. The two most common explanations for this are: (1) only a short period of enhanced perfusion is needed to achieve limb salvage; or (2) while endovascular patency rates are lower, secondary interventions help achieve comparable rates of limb. Whatever the reason, at the current time, revascularization strategy should be based upon an integrated patient, wound, and anatomic assessment (Table 3).

BACK TO THE CASE: TREATMENT

After the above assessment, the decision was made to attempt percutaneous revascularization. Contralateral femoral access was obtained with a 6 Fr, 45 cm sheath. The posterior tibial artery was accessed proximal to the medial malleolus using ultrasound guidance and a 4 Fr pedal sheath was placed (Cook). A 260 cm, .035-inch, straight stiff Glidewire (Terumo) and an angled 135 cm, .035-inch support catheter (Navicross, Terumo) were used to traverse the proximal superficial femoral artery cap. As the wire became immediately extraluminal, the catheter and wire were used to blunt dissect to the level of the popliteal artery. A 260 cm, .18-inch V18 wire (Boston Scientific) was advanced from the posterior tibial sheath with the support of a 90 cm, 0.18-inch CXI catheter (Cook).

Continued on page 18



Enhance Your CTO Procedures with the GeoAlign® Marking System*

The CROSSER® CTO Recanalization Catheter is now part of the GeoAlign® Marking System family of peripheral products.

The GeoAlign® Marking System is a **non-radiopaque ruler** on the catheter shaft measured from the distal tip. These markings are designed for **simplified length measurement** between two intravascular points. During repeat catheter placement, the GeoAlign® Marking System is designed to help **increase procedure efficiency** and **reduce radiation exposure** by minimizing fluoroscopy time.

To find out more, please visit **www.BardPV.com**.

CROSSER®
CTO Recanalization Catheter

*The GeoAlign® Marking System provides an approximation that may not be an exact representation of the distance traveled intravascularly and should be confirmed under fluoroscopy.

Please consult product labels and instructions for indications, contraindications, hazards, warning and precautions.

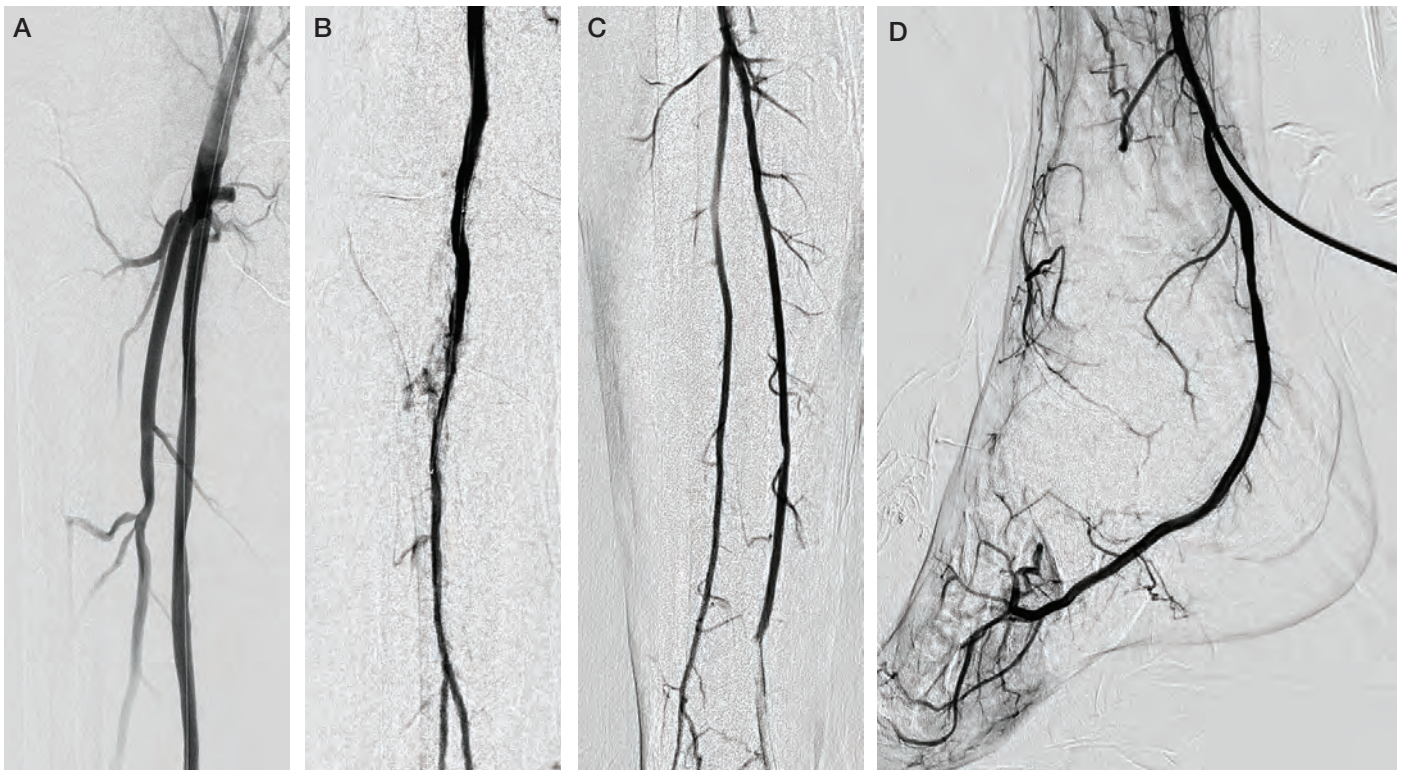


Figure 5. Flow after intervention. The superficial femoral artery status post self-expanding stent placement (Panel A). The popliteal artery after self-expanding stent placement (Panel B). Patent posterior tibial and peroneal arteries after robust straight-line flow was successfully established into the tibioperoneal trunk (Panel C). Patent posterior tibial artery and plantar arteries at the ankle and foot with a non-diseased pedal arch filled via the lateral plantar artery (Panel D).

GALMER from page 16

This wire too became extraluminal. The wire and catheter were passed to the level of the popliteal artery. Despite numerous "flossing" attempts with various wires, the two subintimal planes could not be unified. Double balloon disruption was performed with a 4.0 mm x 80 mm balloon (Sterling, Boston Scientific) passed over the .018-inch wire via the pedal sheath, and a 4.0 mm x 100 mm balloon passed over the .035-inch wire from the contralateral femoral sheath. However, despite this, the wires could not be unified. Then, "virtual true lumen" creation was performed using the 4.0 x 80 mm balloon passed from the pedal sheath and the Outback (Cordis) reentry catheter passed via the femoral artery sheath. The needle punctured the balloon (Figure 4) and the wire was passed into the ruptured balloon lumen, where it was trapped. Then the wire was externalized via the pedal sheath. A 5.0 mm x 120 mm self-expanding nitinol stent was placed in the popliteal artery, followed by three additional 6.0 mm x 120 mm stents that were deployed in the SFA. The final angiography result is demonstrated below (Figure 5).

POST-PROCEDURAL COURSE

Upon completion of the case, dual antiplatelet therapy with aspirin and clopidogrel was prescribed. The patient underwent transmetatarsal amputation 1 day after revascularization and was discharged the following day. Physiologic testing was performed 2 weeks after surgery with marked improvement in PVR waveforms and ABI (Figure 6). He successfully healed his post-operative amputation wound within 4 weeks (Figure 7). ■

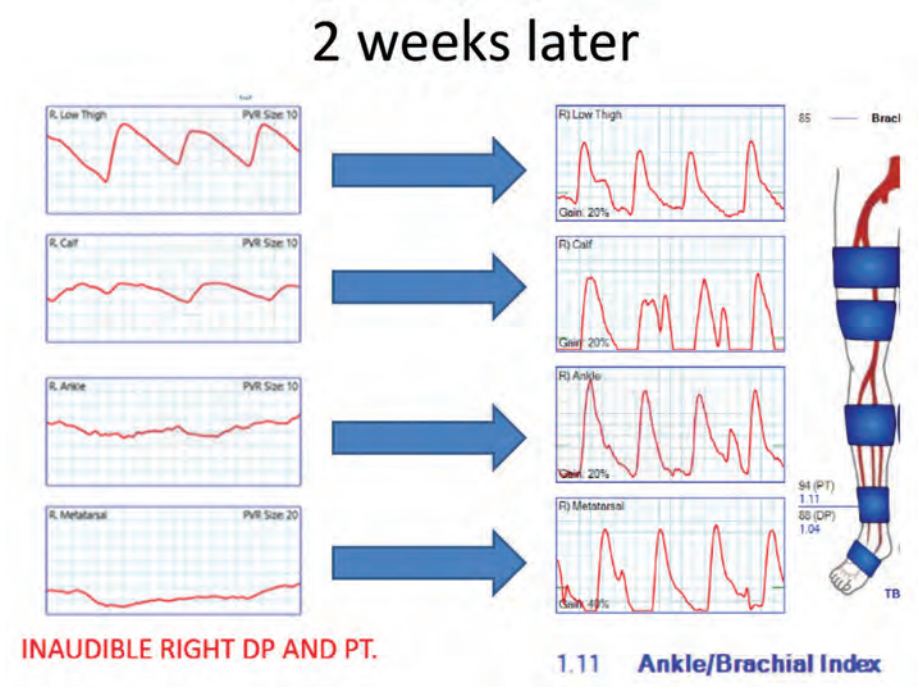


Figure 6. Comparison of ABI/PVR pre and post procedure. Single-level ankle-brachial index and pulse volume recordings performed 24 hours post procedure. A dramatic improvement in perfusion is demonstrated at the thigh, calf, ankle, and metatarsal levels.

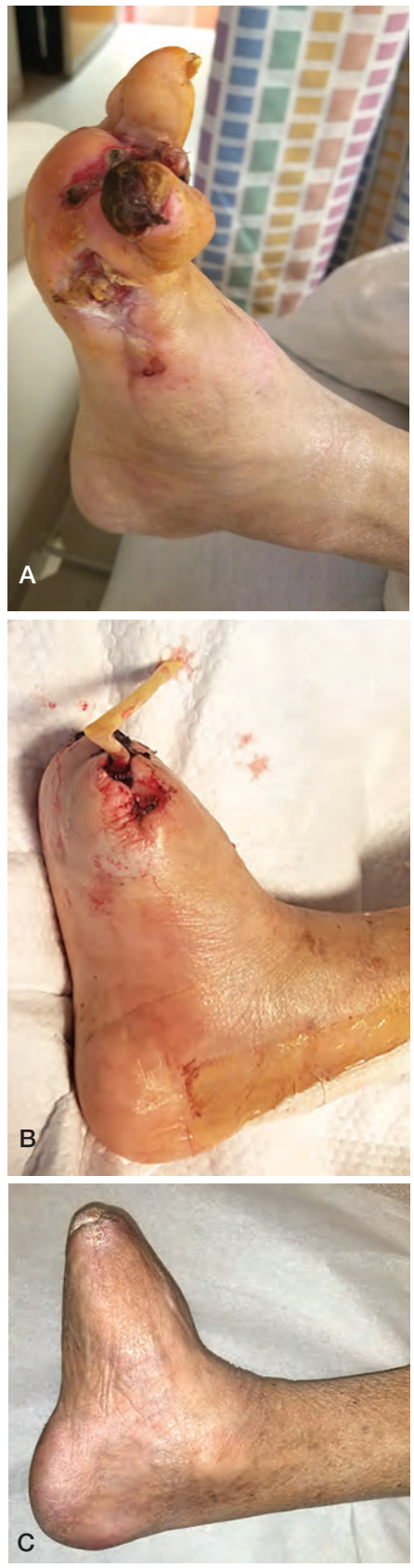


Figure 7. Progression of wound healing. Initial photograph of the right foot prior to revascularization and transmetatarsal amputation (Panel A). Post-operative day 0 status post transmetatarsal amputation with drain in place, which healed completely within four weeks (Panel B). At 6 months follow-up, completely intact right lower extremity noted without ulceration or gangrene after revascularization and transmetatarsal amputation (Panel C).

REFERENCES

1. Mills JL Sr, Conte MS, Armstrong DG, et al, The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI). *J Vasc Surg.* 2014;59(1):220–234.e2.
2. Darling JD, McCallum JC, Soden PA, et al. Predictive ability of the Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIfI) classification system after first-time lower extremity revascularizations. *J Vasc Surg.* Jan 7. pii: S0741-5214(16)31507-5. doi: 10.1016/j.jvs.2016.09.055. [Epub ahead of print].
3. Bertges DJ, Neal D, Schanzer A, et al, The Vascular Quality Initiative Cardiac Risk Index for prediction of myocardial infarction after vascular surgery. *J Vasc Surg.* 2016;64(5):1411-1421.e4.
4. Mehran R, Aymong ED, Nikolsky E, et al. A simple risk score for prediction of contrast-induced nephropathy after percutaneous coronary intervention. *J Am Coll Cardiol* 2004;44(7):1393-1399.
5. El-Sayed HF. Bypass surgery for lower extremity limb salvage: vein bypass. *Methodist Debakey Cardiovascular J.* 2012;Oct-Dec;8(4):37-42.
6. Bradbury AW, Adam DJ, Bell J, et al; BASIL trial Participants. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: Analysis of amputation free and overall survival by treatment received. *J Vasc Surg.* 2010 May;51(5 Suppl):32S-42S.
7. Kapfer X, Meichelboeck W, Groegler FM. Comparison of carbon-impregnated and standard ePTFE prostheses in extra-anatomical anterior tibial artery bypass: a prospective randomized multicenter study. *Eur J Vasc Endovasc Surg.* 2006;32(2):155-168. Epub 2006 Apr 17.
8. Guo X, Xue G, Huang X, et al. Outcomes of endovascular treatment for patients with TASC II D femoropopliteal occlusive disease: a single center study. *BMC Cardiovasc Disord.* 2015; May 29;15:44.
9. Richards C and Schneider PA. Explaining the discrepancy between lower patency and higher limb salvage rates after revascularization for critical limb ischemia. *Vasc Disease Management.* 2016;13(11):E245-E251.

THE CLI REVOLUTION NEEDS YOU

- It causes approximately **65,000 to 75,000** major amputations per year.
- It costs **$25 billion** in healthcare expenditures annually.
- It has a **5-year mortality rate** exceeding that of coronary artery disease and breast cancer.

It's time to **STOP** critical limb ischemia (CLI) in its tracks.

AMP™

THE AMPUTATION PREVENTION SYMPOSIUM

AUGUST 9—12, 2017

HILTON CHICAGO
CHICAGO, ILLINOIS

AMP FEATURES

Access to the foremost experts in interventional cardiology, vascular surgery, interventional radiology, podiatry and wound care

Live case presentations highlighting the latest advances in revascularization

Hands-on workshops to help you hone techniques and test new devices

REGISTER TODAY WITH CODE **CLI100**
& **SAVE $100** ON YOUR REGISTRATION!

AMPTHECLIMEETING.COM

facebook.com/amptheclimeeting @AMPSymposium

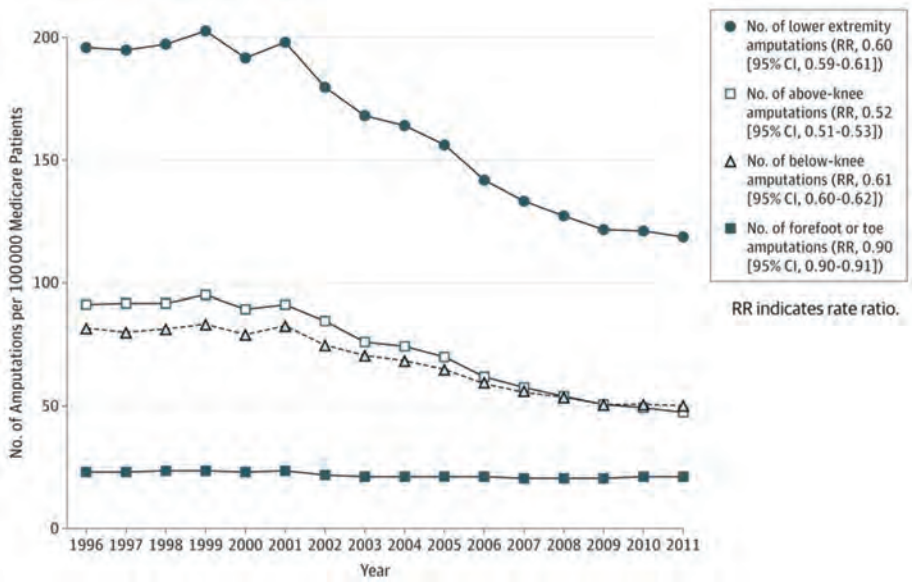


Figure 1. Fifteen-year trends in major lower limb amputation in Medicare patients.

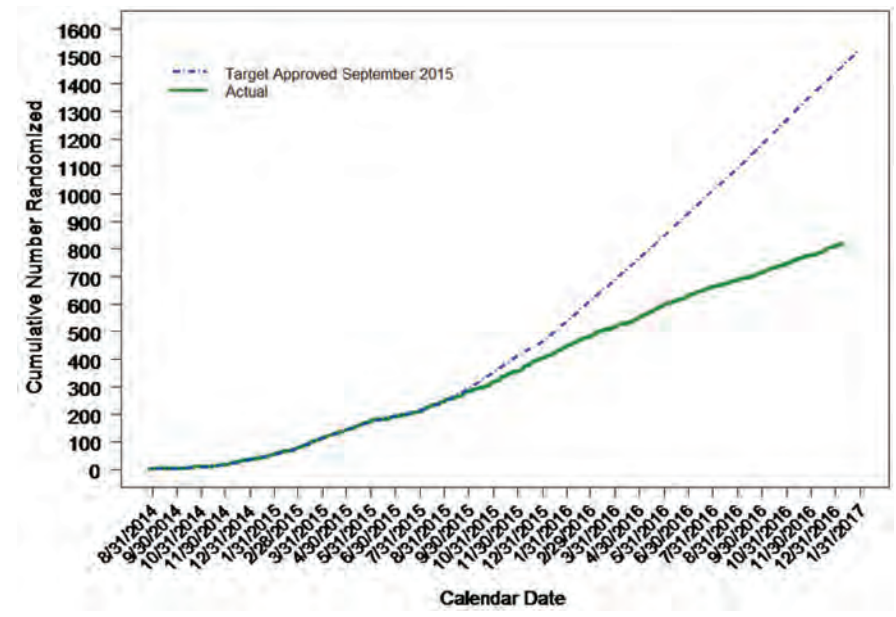


Figure 2. Enrollment trends in the BEST-CLI trial in 2016.

GOODNEY from page 3

(https://cvquality.acc.org/NCDR-Home.aspx) — provide a forum for better understanding how treatments are used in everyday cardiovascular clinical practice and offer the best way to understand how to guide quality improvement.[6] Further, participation in registries and quality improvement has become a common lever for payers to use to drive patients and interventionalists toward the highest quality care, delivered to the right patients, at the lowest cost. And while physicians focus on target lesion revascularization or patency, registries will begin to study patient-centered outcomes, such as independent living status, ambulatory ability, and quality of life — the outcomes that really matter most.

These structural evolutions — trials, registries, and outcomes assessments — have helped us to better understand the treatments we use to care for patients with CLI. These treatments continue to evolve as well. Novel drug delivery mechanisms, new atherectomy options, and innovative access techniques have made the long list of treatment options grow at an even faster rate for patients with CLI.

Where will we go from here? New stent platforms, new local and systemic medical regimens, and new, less invasive approaches are likely to be the tools we will use to advance the care of patients with CLI in coming years.

While these are certainly laudable goals, cardiovascular physicians should also not lose sight of two additional challenges — making these treatments less expensive and delivering them to the patients who need them the most. Costs for the treatment of CLI are among the greatest health care expenditures challenging the United States today, and prioritizing treatments and treatment goals to better align with patient and societal goals is an achievable target. Should every patient with claudication be treated with an expensive atherectomy procedure, while others with advanced diabetes and CLI suffer limb loss at a rate several times higher than the national average? Should we focus our attention on a new bioabsorable stent platform, or find better ways to reach indigent, rural patients with foot ulceration and PAD, where simple treatments are likely to make a dramatic impact?

Variation in the amputation risk has long been studied across the United States.[7-10] And despite an improvement in vascular care, disparities in the care of patients with advanced PAD remain significant. Who better to address these challenges than our own specialty? If we can reduce amputation risk by more than 60% — as we have done in the last 15 years — then certainly we can determine how to deliver our life and limb-saving interventions where they are desperately needed most. Cardiovascular physicians have met many challenges before, and the challenge of disseminating vascular care more widely, more effectively, and with greater impact, lies ahead. While these woods are lovely, dark, and deep, we have miles to go before we sleep. ■

Acknowledgment. Dr Goodney was supported by U01 FD005478 (Sedrakyan, PI) from the US Food and Drug Administration for creation of the Vascular Implant Surveillance and Interventional Outcomes Network (VISION).

REFERENCES

1. Goodney PP, Tarulli M, Faerber AE, Schanzer A, Zwolak RM. Fifteen-year trends in lower limb amputation, revascularization, and preventive measures among Medicare patients. *JAMA Surg*. 2015;150:84-86.
2. Vemulapalli S, Greiner MA, Jones WS, Patel MR, Hernandez AF, Curtis LH. Peripheral arterial testing before lower extremity amputation among Medicare beneficiaries, 2000 to 2010. Circulation. *Cardiovascular Quality and Outcomes*. 2014;7:142-150.
3. Menard MT, Farber A, Assmann SF, et al. Design and rationale of the best endovascular versus best surgical therapy for patients with critical limb ischemia (best-CLI) trial. *J Am Heart Assoc*. 2016;5.
4. Cronenwett JL, Likosky DS, Russell MT, et al. A regional registry for quality assurance and improvement: The vascular study group of northern New England (vsgnne). *J Vasc Surg*. 2007;46:1093-1101; discussion 1101-1092.
5. Bensley RP, Beck AW. Using the vascular quality initiative to improve quality of care and patient outcomes for vascular surgery patients. *Semin Vasc Surg*. 2015;28:97-102.
6. Subherwal S, Patel MR, Tang F, et al. Socioeconomic disparities in the use of cardioprotective medications among patients with peripheral artery disease: An analysis of the American College of Cardiology's NCDR pinnacle registry. *J Am Coll Cardiol*. 2013;62:51-57.
7. Jindeel A, Gessert C, Johnson BP. Variation and trends in lower extremity amputation rates in Los Angeles county hospitals 2000-2010. *Int J Low Extrem Wounds*. 2016;15:232-240.
8. Jones WS, Patel MR, Dai D, Subherwal S, Stafford J, Calhoun S, Peterson ED. Temporal trends and geographic variation of lower-extremity amputation in patients with peripheral artery disease: Results from u.S. Medicare 2000-2008. *J Am Coll Cardiol*. 2012;60:2230-2236.
9. Wrobel JS, Mayfield JA, Reiber GE. Geographic variation of lower-extremity major amputation in individuals with and without diabetes in the medicare population. *Diabetes Care*. 2001;24:860-864.
10. Goodney PP, Travis LL, Nallamothu BK, et al. Variation in the use of lower extremity vascular procedures for critical limb ischemia. *Circ Cardiovasc Qual Outcomes*. 2012;5:94-102.

CLI GLOBAL SOCIETY

Critical Limb Ischemia Global Society

Become a member of an organization focused on transforming the lives of those with CLI and PAD.

You can make a difference.

Join us today.

Membership

- We are the only professional membership-based medical society focused on advanced PAD and CLI.
- Members contribute to the scientific study, research, literature and education of CLI.
- Alliance and advocacy for the prevention of unnecessary amputation.

Resources

- Subscription to CLI Global, the official publication of CLI Global Society.
- $150 discount toward registration at AMP, ISET, NCVH, SAWC and VERVE meetings.
- Invitations to CLI Global Society networking opportunities and member events.

Advocacy

- Opportunities to get involved with a strong unified community of physician, healthcare and industry leaders with a focused goal of CLI education.
- Commitment to raise public, patient and health professional awareness of CLI treatments to prevent unnecessary amputations.

(888) 254-2541 | info@cliglobalsociety.org | cliglobalsociety.org

Future Events

Find your next learning opportunity here.

April 5-9, 2017
SAWC - The Symposium on Advanced Wound Care
Location: San Diego, CA
Website: www.sawc.net

April 25-28, 2017
Charing Cross (CX)
Location: London, United Kingdom
Website: www.cxsymposium.com

May 10-13, 2017
SCAI 2017 – Society of Cardiovascular Angiography & Intervention
Location: New Orleans, LA
Website: www.SCAI.org

May 16-19,2017
EuroPCR
Location: Paris, France
Website: www.europcr.com

May 31-June 2, 2017
New Cardiovascular Horizons (NCVH)
Location: New Orleans, Louisiana
Website: www.ncvh.org

May 31-June 3, 2017
2017 Vascular Annual Meeting
Location: San Diego, Calif.
https://vascular.org/meetings/2017-vascular-annual-meeting

June 1-2, 2017
MEET - Multidisciplinary European Endovascular Therapy
Location: Nice, France
Website: www.meetcongress.com

June 13-14, 2017
LINC New York @ Mount Sinai
Location: Mount Sinai Hospital, New York, NY
Website: www.leipzig-interventional-course.com

June 14-17, 2017
Society for Vascular Medicine - 28th Annual Scientific Sessions
Location: New Orleans, LA
Website: www.vascularmed.org

June 29-July 2, 2017
(C3) Complex Cardiovascular Catheter Therapeutics
Location: Orlando, Florida
Website: www.c3conference.net

July 24-27, 2017
Chicago Endovascular Conference (CVC)
Location: Chicago, Illinois
Website: www.cvcpvd.com

August 9-12, 2017
Amputation Prevention Symposium (AMP)
Location: Chicago, IL
Venue: Hilton Chicago
www.amptheclimeeting.com

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

September 11-15, 2017
Vascular InterVentional Advances (VIVA 17)
Location: Las Vegas, Nevada
Website: www.vivapvd.com

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

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

November 14-18, 2017
VEITHSymposium
Location: New York, New York
Website: www.veithsymposium.org

December 7-9, 2017
VERVE Symposium
Location: Sydney, Australia
www.vervesymposium.com

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

In Memory of JO DIRTADIAN

JoAnn Dirtadian, a special friend and supporter of the CLI Global Society, passed away unexpectedly on Tuesday, January 3, 2017, with her loving family by her side.

Jo was born on October 10, 1964, in Utica, New York, the daughter of Donald and H. Suzanne Dirtadian. She was a 1982 graduate of UFA and received her Associate's Degree in Business from MVCC. Since 2003, Jo was a valued member of Bard Peripheral Vascular, most recently as Convention Manager for the organization. In charge of over 250 meetings of all sizes, she took pride in her job and was passionate about events running smoothly. Jo's enthusiastic contribution to the advancement of medical education will be greatly missed by the physicians and industry friends who have come to know her over the years.

Jo was a devoted daughter, sister, and loyal friend to many. Her generous spirit helped many charities, especially those focused on underprivileged or sick children. Her work included spearheading the annual Angel Tree initiative that benefitted the Phoenix area Child Crisis Center, HopeKids, and Ronald McDonald House. Jo was instrumental in leading the annual Amanda Hope Rainbow Angels fundraising event. Jo was a friend to all who knew her. She will be greatly missed. ■

Boston Scientific
Advancing science for life™

JETSTREAM™ Atherectomy System

CALCIUM. PLAQUE. THROMBUS.
TREAT IT ALL.

Jetstream is engineered to predictably treat multiple morphologies, such as calcium, plaque or thrombus, commonly found in total occlusions. As reported in the Calcium Study, Jetstream's front-cutting, expandable blades created statistically significant luminal gain in severe and moderate calcium (post versus baseline IVUS measurements)[1]. As the only atherectomy system with active aspiration, Jetstream removes debris, helping minimize the risk of distal embolization.

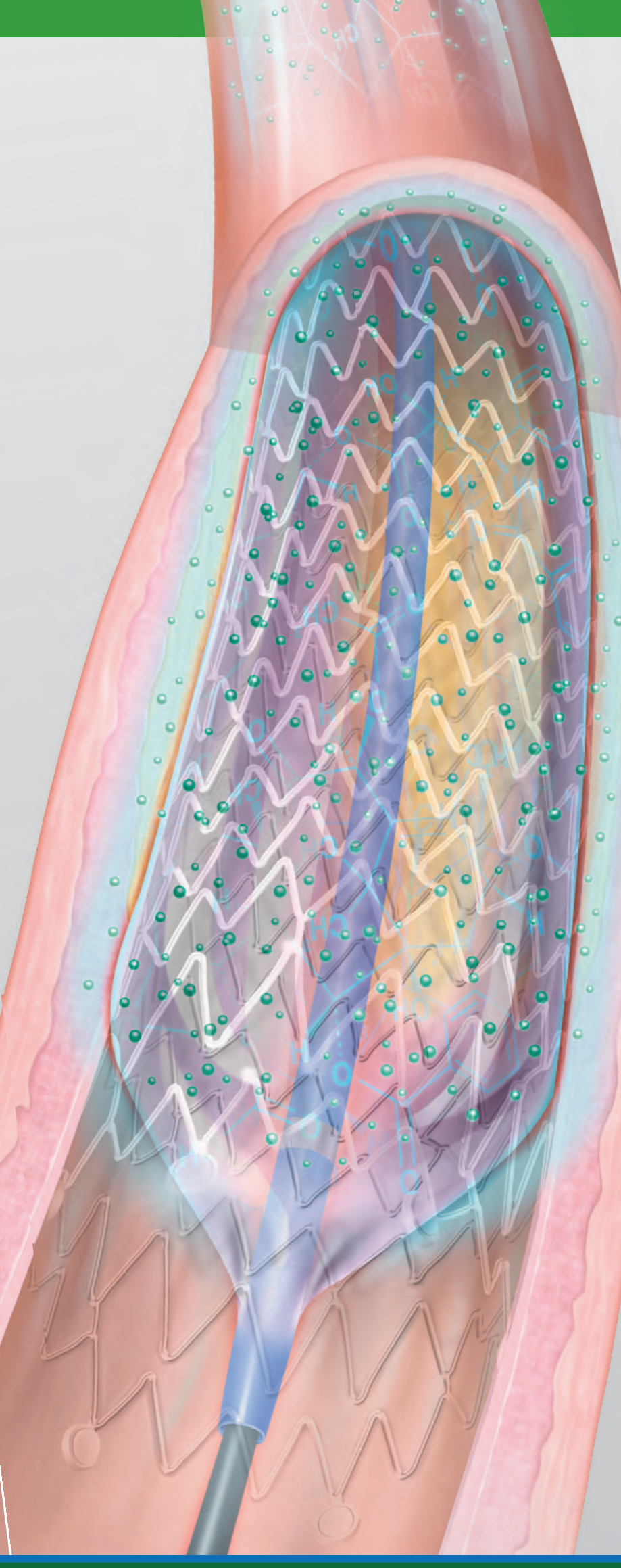
See Jetstream in action: **bostonscientific.com/jetstream**

1. Jetstream Calcium Study

Now Indicated for **ISR**

Only U.S. DCB Indicated for **Long Lesions**

(up to 300 mm)



LUTONIX® 035

Drug Coated Balloon PTA Catheter

Advancing Lives and the Delivery of Health Care™

BARD

The LUTONIX® 035 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 300mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7mm. **Please consult product labels and instructions for indications, contraindications, hazards, warnings, and precautions.** $R_{x\ Only}$

 BPV/LTNX/0117/0104