CLI GLOBAL COMPENDIUM

THE GLOBAL VOICE OF CRITICAL LIMB ISCHEMIA

Correlation Between High-Volume CLI Specialists and Outcomes in Amputation Prevention Centers

Francesco Liistro, MD; Simone Grotti, MD
From the Cardiovascular Department, San Donato Hospital, Arezzo, Italy.

Francesco Liistro, MD

Critical limb ischemia (CLI) is considered one of the most complex and challenging scenarios in vascular medicine due to the high associated morbidity and mortality, poor long-term outcomes, and a relevant socio-economic impact.[1] Diabetes mellitus (DM) is the main cause of lower limb atherosclerotic disease, in particular for below-the-knee (BTK) artery disease.[2] A strong correlation exists between DM and peripheral arterial disease: diabetic patients show a four-fold increased risk of CLI,[1] with more frequent major amputation compared to nondiabetic individuals.[3] Among CLI patients, the disease generally affects distal segments,[4] with multivessel involvement[5] and long and calcified occlusions.[6,7]

CLI is considered a complex scenario in diabetic patients for several reasons. First, the pattern of BTK disease, characterized by long and heavily calcified occlusions, turns tibial intervention into a technical challenge that demands optimization of all aspects of lower-extremity intervention, from arterial access to lesion crossing to treatment to closure. Second, diabetic patients need a diabetic foot clinic with a dedicated program to pursue fast and complete ulcer healing to avoid major amputation and restore ambulation function. Third, high cardiovascular morbidity and mortality are associated with this condition, prompting an aggressive diagnosis and early treatment strategy. Thus, a multispecialty team is the ideal environment to deal with diabetic foot syndrome, providing angiosome-based limb revascularization, ulcer healing surveillance, and cardiovascular assessment and monitoring to reduce acute events.

In the last decade, the percutaneous approach to BTK disease has seen widespread adoption, replacing open surgical procedures as the primary modality of peripheral revascularization.[8] This observation is related to recent improvements in the technical success rate of chronic total occlusion (CTO) angioplasty, which appears to be more attributable to evolutionary improvement of conventional interventional equipment (e.g., guidewires, support catheters, drug-eluting devices) coupled with the introduction of

Continued on page 11

Valuable Real-World Data on CLI

By J.A. Mustapha
From Metro Health Hospital, Wyoming, Michigan.

As technology evolves, so do the severity and complexity of the disease state of critical limb ischemia (CLI). There is an aging global population that is more than ever in need of multiple peripheral interventions, which come at a high cost. Proper care and post-procedure follow-up seem to be weak at this time, with no clear pathway. Critical limb ischemia patients require intense pre and post peripheral vascular intervention (PVI) care, and the need is great for absolute care delivery for all CLI patients, regardless of their race or geographic location.

The PRIME CLI Registry was born because we recognized the lack of a formalized multidisciplinary pathway of care and saw the clearly unmet need for data. In March, the Critical Limb Ischemia Global Compendium

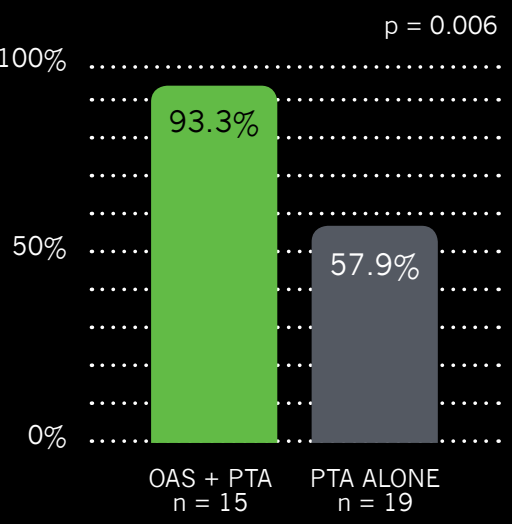
Continued on page 9

J.A. Mustapha, MD

HOW DO YOU OPTIMIZE PTA WHEN CALCIUM IS PRESENT?

SIMPLE.

STATISTICALLY SIGNIFICANT DIFFERENCE IN FREEDOM FROM MAJOR ADVERSE EVENTS (MAE) AT 12 MONTHS



Change Compliance First.

A randomized multi-center clinical study in PAD patients demonstrated that changing lesion compliance first with Orbital Atherectomy allowed for lower pressure PTA inflation and a significant reduction in major adverse events at one year compared to PTA alone. Make Diamondback 360 your first choice for treating PAD.

Think this is interesting?

Visit CSI360.com/thinkagain to find out more.

DIAMONDBACK 360®

PERIPHERAL ORBITAL ATHERECTOMY SYSTEM

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.

Major adverse events (MAE): All-cause mortality, device- or procedure related above-the-ankle amputation, and TLR/TVR.

Shammas NW, Lam R, Mustapha J, et al. Comparison of orbital atherectomy plus balloon angioplasty vs balloon angioplasty alone in patients with critical limb ischemia: results of the CALCIUM 360 randomized pilot trial. J Endovasc Ther. 2012;19(4):480–488.

CSI® CARDIOVASCULAR SYSTEMS, INC.

An Update on the PRIME Registry for Critical Limb Ischemia

J.A. Mustapha, MD[1]; Theresa McGoff, BSN[1]; Larry J. Diaz-Sandoval, MD[1]; George Adams, MD[2]; Robert Beasley, MD[3]; Fadi Saab, MD[1]
From [1]Metro Health Hospital, Wyoming, Michigan, [2]Rex Healthcare, Garner, North Carolina, and [3]Mount Sinai Medical Center, Miami Beach, Florida.

Larry J. Diaz-Sandoval, MD

In 2007, The Sage Group estimated that approximately 2 million people suffer from critical limb ischemia (CLI) in the United States (US). They also predicted that with the aging population and increased diabetes prevalence, this number may rise to between 2.8 million and 3.5 million CLI patients by 2020. Though this number equates to only 1% to 2% of the US population, it packs a huge financial punch to our health care system, with CLI treatment costing $10 billion to $20 billion annually. With a reduction in amputation, this cost could be significantly reduced.[1]

In the United States, CLI therapy has been considered a "pathway to amputation," as described by Allie et al in 2005, who found that of 67% of patients who received a major amputation, the major amputation was the first procedure for their critical limb.[2] With the current influx of endovascular techniques and devices, a need has grown to determine if endovascular revascularization can help to reduce amputation rates, mortality, and cost while increasing quality of life for CLI patients. Though peripheral arterial disease (PAD) registries do exist, the overall emphasis tends to be broad. For example, the focus of the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) registry was on both percutaneous coronary interventions (PCI) and peripheral vascular interventions (PVI). Additionally, the patients in this quality-focused registry were followed for only 6 months and the level of detail collected on each intervention is minimal. Trials studying CLI are also limited and exclude the most complicated CLI patients with serious comorbidities. The BEST-CLI trial is currently enrolling and will focus on comparing surgical revascularization to endovascular revascularization, which will provide extremely valuable information. Unfortunately, it will be several years before the results of this trial are available, and many patients will be excluded due to comorbidities limiting surgical eligibility.

No registry, thus far, has focused exclusively on the endovascular treatment of advanced lower extremity and CLI, until now. The Peripheral Registry of Endovascular Clinical Outcomes (PRIME Registry) was founded in January 2013 to prospectively collect comprehensive procedural and follow-up data for 3 years (1, 3, 6, 12, 24, and 36 months) following an index endovascular procedure. Eligible patients are over 18 years of age, able to consent, meet Rutherford Classification III-VI, and are scheduled to receive an endovascular intervention.

PRIME is a collaborative effort among 3 centers across the US with the goal of reaching 15 sites globally. To date, information has been collected on more than 500 patients and more than 800 endovascular procedures collectively. Follow-up data has been recorded on over 400 patients at 30 days and over 250 patients at 12 months. Variables collected include demographics, medical history, prior vascular procedures, presenting symptoms,

Continued on page 9

TABLE OF CONTENTS

Case Study: Securing Administration Support for a Successful Limb Salvage Program

Bryan T. Fisher, MD; Sharon Hannan
From The Surgical Clinic, PLLC, Nashville, Tennessee, and the TriStar Southern Hills Advanced Wound Care Center, Nashville, Tennessee.

Bryan T. Fisher, MD

Every endeavor by physicians to seek hospital administration support for a new initiative should begin with aligning the goals and mission of the hospital system. When done correctly, the results of these strategic alliances can be widely successful. Well-established and successful partnerships already exist in several fields of medical care. For example, stroke and STEMI alert systems are protocol-driven processes in multiple teams that result in evidence-based practices that vastly improve patient care and save lives.[1,2]

There are similarly well established partnerships in cancer care. To promote access to the same high-quality care for patients, regardless of residence, the National Cancer Institute (NCI), one of the 27 institutes of the National Institutes of Health, designed the Community Cancer Centers Program (NCCCP) pilot as a public-private partnership to accelerate the diffusion of the latest science to local communities.[3] Limb salvage programs are no different and have the potential to provide cutting-edge, high-quality care to the patients that are served, regardless of location. In 2013, we set out to secure TriStar Health's support in a much-needed limb preservation program by aligning our goal of decreasing major amputations with the goals of the hospital system and its commitment to the delivery of cost-effective, high-quality care.

According to Medicare, surgeons at hospitals in the Nashville metropolitan area amputated 3 per 1,000 diabetic patients diagnosed with PAD in 2010.[4] This rate exceeded all other major metropolitan cities in Tennessee, such as Knoxville and Memphis. Furthermore, Nashville physicians performed more open bypass procedures (4.8 per 1,000) and far fewer endovascular interventions (12.4 per 1,000).[4] These data were consistent with data we were collecting in our advanced wound care center in 2012-2013. We observed a low rate of endovascular procedures (especially for disease below the knee), a large number of open vascular procedures, and an alarmingly high rate of amputation. In fact, over 5% of patients that presented with lower-extremity wounds underwent a major amputation (below vs above the knee) despite the hospital being considered an advanced wound care center. This trend resulted in devastating outcomes for our patients and was consistent with national survival rates for patients post amputation (Figure 1).

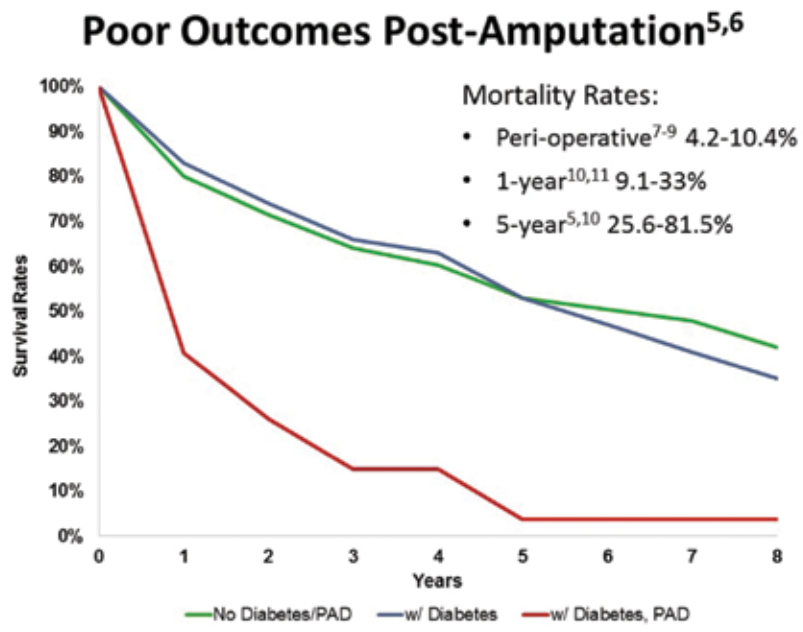


Figure 1. A summary table that illustrates yearly survival rates and the additive effect that PAD has on survival rates in patients with concomitant diabetes. Source: CSI Amputation Prevention Think Tank, September 21, 2015, Health Economics and Outcomes Research (HECOR) CTI Clinical Trial & Consulting Cincinnati, OH. Unpublished material; printed with permission.

Team Approach

Developing a multidisciplinary team was the first step we took in developing a successful limb salvage program. Our team began with an interventionalist, a wound care director and a device territory manager. Over time, we recruited additional clinician specialties and hospital administrators. Each member of this team brought a unique perspective and skill set to the initiative and a passion for improving outcomes for patients with critical limb ischemia. Our interventionalist is a fellowship-trained vascular surgeon with specialized knowledge of lower extremity disease processes and their natural progression. His skill set includes both advanced open (femoral-tibial and pop-pedal bypass) and endovascular techniques (tibiopedal access/pedal arch interventions). The director used her experience as a leader in the wound care center to better understand systems-based issues, such as patient access and hospital processes. Finally, the device territory manager had a wealth of resources, including market and national data as well as educational support materials. Similar to the Amputation Prevention Symposium model no hierarchy exists and each individual can freely contribute and critique unfavorable aspects of the program without the fear of reprisal from other members of the team (an observation of an intentional removal of titles like MD with only the attendee's first/last name on their badge). A passion for limb preservation is shared among all of the team members and likely represents the most important aspect of creating a successful program.

Engaging Administration and Achieving Buy-in

The components and processes mentioned above were absolutely necessary before the hospital was brought to the table. Prior to approaching administrative leadership about starting a limb salvage program, the vascular interventionalist was deliberate about educating physician leaders in the diverse fields that regularly encounter patients with peripheral vascular disease (hospitalists, emergency department, infectious disease). More specifically, he diligently worked to give feedback regarding the outcomes of patients that were referred due to a high risk of limb loss. This provided the foundation for conversations with administration by exemplifying a culture of collaboration where one previously did not exist.

Despite these efforts, beginning the process of a hospital physician partnership to decrease major amputations was disappointingly slow. Initially, the hospital was actively engaged in fostering a robust orthopedic surgery program. After a year of persistently pursuing a limb salvage program, the interventionalist engaged hospital leadership by inviting them to view live complex lower-extremity cases. Administrators soon realized that the key technical component (a competent interventionalist) of the program that was being proposed was already in place. Furthermore, the hospital realized that leveraging already established infrastructure (nurse navigators, cardiovascular marketing) would streamline and even accelerate the process of developing a robust program. General monthly meetings with the hospital chief operating officer and the interventionalist evolved into specific discussions about how to decrease the number of major amputations and thus improve outcomes in patients with critical limb ischemia.

Although our formal limb preservation program is still in its infancy, we have created a truly multidisciplinary evidence-based approach aimed at significantly reducing amputation rates and thus reducing patient mortality. Communication and teamwork provided the basis for establishing a successful partnership between hospital administration and physicians interested in limb preservation. Established paradigms helped all parties involved realize that a robust program was possible. Next, teamwork between medical specialties and industry helped start a conversation about the importance of preventing major amputations and the impact that a strong

An organized approach that explored the economic savings achieved by preventing major amputations created a strong argument for the hospital becoming a significant stakeholder.

Continued on page 10

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

Critical Limb Ischemia Case Study: My Most Challenging CLI Case 3 Years Post Fellowship Training

Maximiliano Arroyo, MD, FACC, FSCAI
From St. Bernards Heart and Vascular, Jonesboro, Arkansas.

Treatment of peripheral arterial disease ... is about skill, timing, and adequate follow-up, but mostly perseverance.

Maximiliano Arroyo, MD, FACC, FSCAI

I have been practicing interventional cardiology for 3 years. Peripheral endovascular interventions and critical limb ischemia (CLI) are a very important part of my practice. As I look back at my CLI cases from the past 3 years, I wondered if my most challenging case was the one that took the largest effort and time in the lab, or if it was the one with the best final angiographic or clinical result. Or was it the worst complication that was averted?

A "good" CLI case should bring out many attributes in a specialist: technical skills, ability to plan a revascularization strategy, outpatient follow-up, and, most importantly, perseverance.

Case Presentation

This is the case of a 64-year-old male with a history of heavy smoking, diabetes, and chronic kidney disease stage IV. He has a known history of coronary artery disease, with a coronary artery bypass graft in the past, as well as peripheral vascular disease, with bilateral resting pain in the legs on initial presentation. Initial evaluation with computed tomography angiography demonstrated a right external iliac artery severely calcified chronic total occlusion (CTO) with severe calcified contralateral iliac disease. He also had severe bilateral superficial femoral artery (SFA) disease. An aortofemoral bypass had been offered in the past, which he declined. He was previously not thought to be an endovascular candidate.

He was brought to the lab for bilateral stenting of the iliac territories using ipsilateral .035″ Glidewire Advantage (Terumo) and super stiff Glidewires (Terumo), introduced with a Navicross catheter (Terumo). We also attempted a contralateral approach, using the same Glidewires and a contralateral catheter. Despite these efforts, CTO crossing was not successful. A surgical approach was recommended, which he again declined. Months passed with close follow-up and, as expected, his symptoms progressively worsened. In hopes that my skill set had improved, I attempted another percutaneous intervention (Figure 1). This time, we used an Ocelot catheter (Avinger) with a Treasure wire (Asahi); fortunately, we were able to cross the CTO and stent the bilateral common and external iliac arteries with a combination of balloon expandable and self-expanding stents.

The patient had significant symptomatic improvement for months with a modest improvement of his resting ankle brachial index. After 10-12 months, he had recurrence of severe resting symptoms. This time his right SFA lesion had progressed and his left SFA was now a heavily calcified CTO. We treated the right SFA first, because the symptoms on the right were worse. We used CSI atherectomy and balloon percutaneous transluminal angioplasty, initially with a conventional .018″ balloon, then with a Lutonix balloon (Bard PV), with excellent angiographic and clinical results (Figure 2).

The left SFA was more challenging. The heavily calcified CTO proved very difficult to cross. We attempted using a Navicross catheter combined with Glidewires and .014″ wires. We also used .014″ catheters combined with different high-grain tip wires and hydrophilic wires. In addition, we had difficulty providing adequate sedation; it was not our day, so we terminated the procedure early. We monitored him for months until his symptoms were again severe and his left ankle brachial index was 0.3.

The second attempt at this lesion was successful (Figure 3). The lesion was crossed using an Ocelot catheter. After crossing, we ballooned and placed Supera stents (Abbott Vascular) in the entire segment. We achieved excellent angiographic and clinical results.

The final percutaneous intervention was performed in August 2015. At present, the patient's ankle brachial indices are around 0.7 bilaterally, and clinical results were fantastic.

Treatment of peripheral arterial disease, and CLI in particular, is about skill, timing, and adequate follow-up, but mostly perseverance. Many times, we are the last stop before our patients face limb amputation. We should always give our best effort before we throw in the towel. ■

Figure 1. Initial iliac anatomy and intervention. Chronic total occlusion (CTO) of the right external iliac artery, with severe lesions of bilateral common iliac arteries and the contralateral external iliac (A). Ocelot catheter (Avinger) with Treasure wire (Asahi) used to cross the CTO (B). Postinterventional results with balloon-expandable and self-expanding stents (C).

Figure 2. High-grade calcified disease of the right superficial femoral artery (A). After CSI atherectomy and balloon angioplasty, initially with a conventional .018-inch balloon, then with a Lutonix balloon (Bard PV) (B).

Many times, we are the last stop before our patients face limb amputation. We should always give our best effort before we throw in the towel.

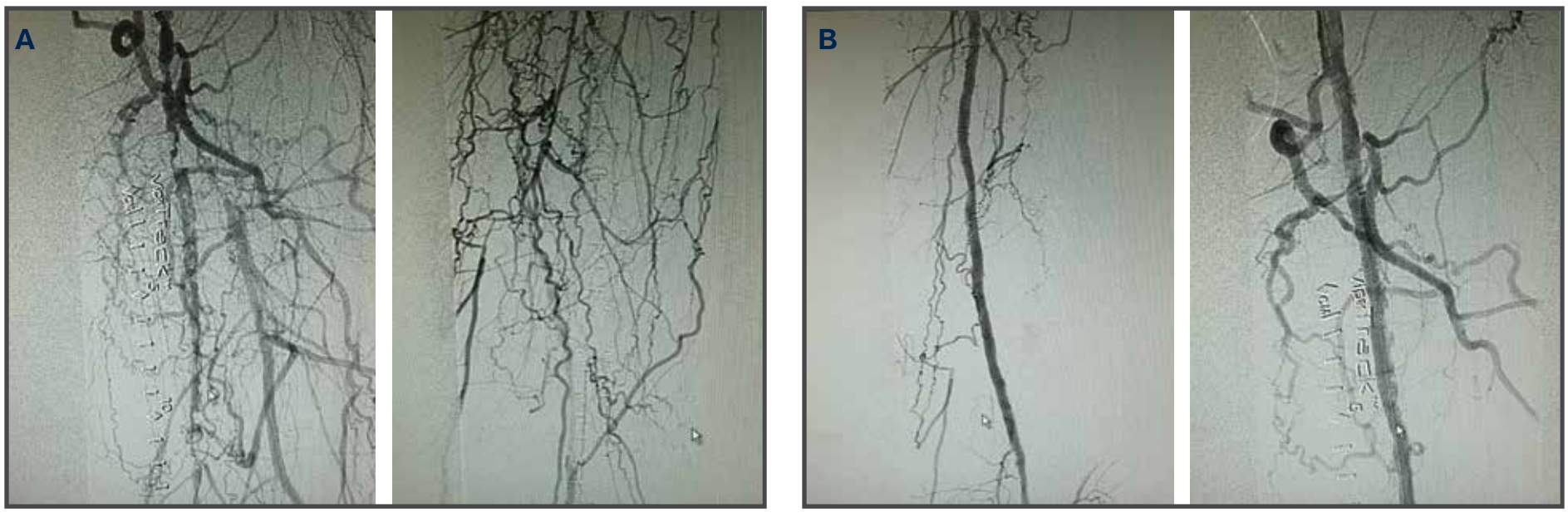


Figure 3. Severely calcified chronic total occlusion of proximal and mid left superficial femoral artery (A). The lesion was crossed using an Ocelot catheter (Avinger), then balloon angioplasty was performed followed by deployment of Supera stents (Abbott Vascular) through the diseased segment (B).

Economics of Limb Salvage and Racial Disparities in Treatment Patterns

Candace Gunnarsson, EdD; John Rizzo, PhD
From CTI Clinical Trial & Consulting, Cincinnati, Ohio.

Candace Gunnarsson, EdD

An estimated 160,000 to 180,000 major and minor limb amputations are performed annually in the United States.[1] Peripheral arterial disease (PAD) is responsible for the majority of foot and leg amputations.[2] The average amputation rate among PAD patients with critical limb ischemia (CLI) is estimated to be 25%.[3] Many patients with CLI are 65 years of age or older and have a history of smoking and serious comorbid conditions such as diabetes, hypertension, and heart and kidney disease.[4] Although severity of disease and a patient's risk profile each play an important role in the decision to revascularize or amputate, there appear to be other factors that contribute to CLI treatment variations observed across the United States. Utilizing the Healthcare Cost and Utilization Project (HCUP) nationwide inpatient sample, a heat map was constructed to visualize this variation by displaying amputation rates by hospitals for inpatient visits with a primary PAD diagnosis for the year 2011. As may be seen from Figure 1, amputation rates vary from as low as 2.5% to as high as 30% depending on hospital and region. Moreover, considerable variation persists even within narrowly defined geographic areas such as southern California. Why is there so much variation in care? A host of factors contribute to this variation in treatment patterns across the United States, including regional differences in patient mix and treatment norms, race, insurance, and a lack of consistent guidelines for the appropriate treatment of CLI.

The unfortunate fact is that following an initial [lower extremity] amputation, 27% of patients will have one or more re-amputations.

As Figure 2 indicates, whites have the lowest amputation rates, and markedly higher rates for blacks and Hispanics. Indeed, racial/ethnic disparities in the treatment and management of patients with PAD and CLI have been documented in several studies.[5-7] Compared to white patients, blacks were less likely to receive a revascularization, surgical or endovascular approach.[6,7] The probability of undergoing a revascularization was reduced by 34% to 65% among blacks relative to whites.[5,7,8] Furthermore, blacks were at a disproportionately high risk of lower extremity amputation.[5-8] In an analysis of acute-care hospitals in Florida, Huber et al found that, despite similar incidence rates of PAD-related surgical intervention, blacks were at a four-fold greater risk to undergo amputation than revascularization when compared with whites.[9]

A recent descriptive study demonstrated the low revascularization and high amputation rates in CLI patients among blacks and Hispanics compared to whites on a national level.[5] Building on that analysis, we examined revascularization and amputation rates over time in the HCUP nationwide inpatient sample. As Figure 3 indicates, amputation rates have been consistently highest among blacks followed by Hispanics compared to whites. In contrast, revascularization rates for whites are consistently higher than for Hispanics and blacks, the latter of which have the lowest revascularization rates (Figure 4). Notwithstanding the increased use of revascularization procedures, and endovascular interventions in particular, over the past 2 decades, significant racial and ethnic disparities persist for the treatment of patients with PAD and CLI.[5-8]

There is limited consensus on amputation vs limb salvage for target populations with no formal guidelines in place, leaving key decision-making up to a physician's discretion. For example, TASC II 2007 guidelines state that while limb preservation can be achieved through a multiarmed treatment involving antibiotics, revascularization, and/or staged wound closure, primary amputation is favored if it offers an expedient return to a useful quality of life vs a prolonged course of aggressive vascular reconstruction with little likelihood of healing.[4]

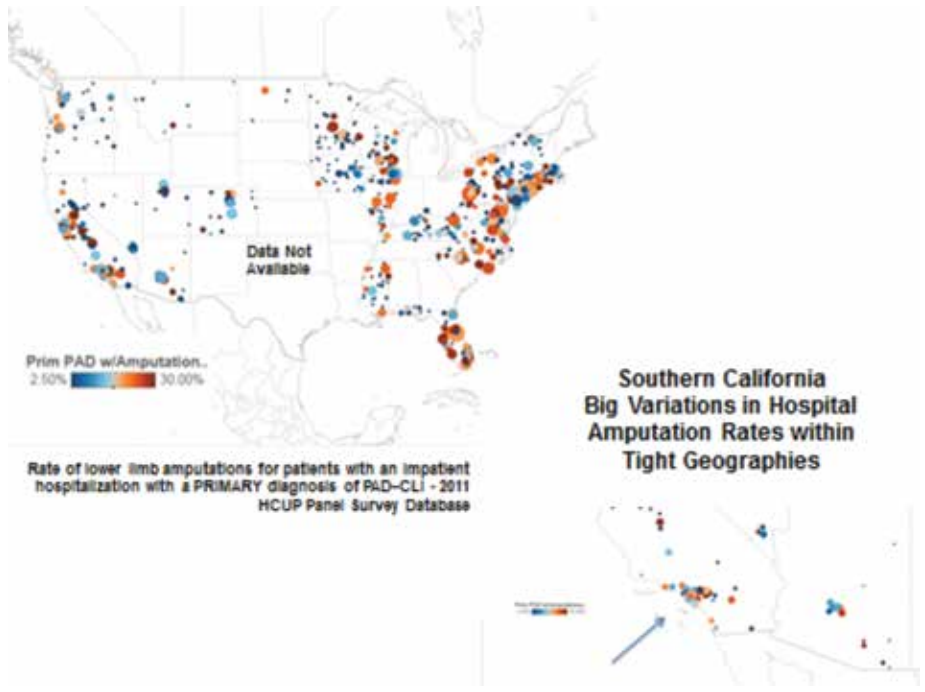


Figure 1. Variation in amputation rates across the United States.

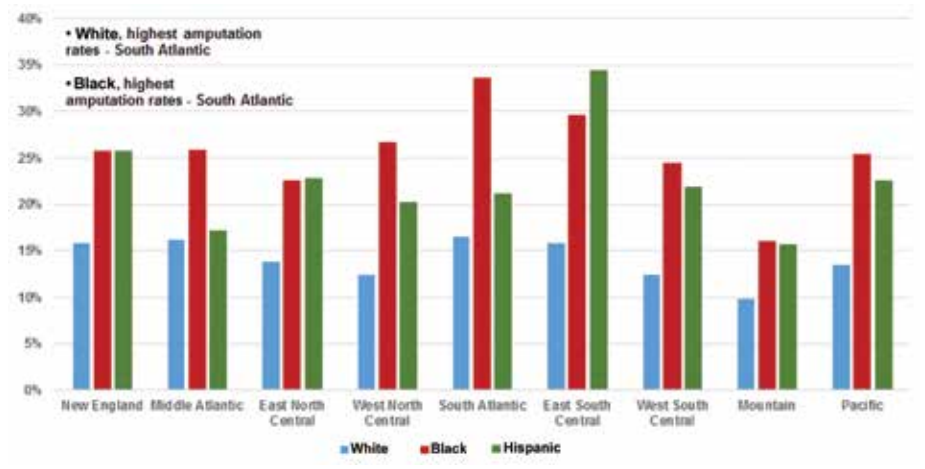


Figure 2. Amputation rate variation by region and race.

Amputation has a significant clinical, economic, and quality of life burden. In 2015, an estimated 1.3 million Americans are living with a lower extremity amputation (LEA).[2] Moreover, most amputees are not "one and done." The unfortunate fact is that following an initial LEA due to dysvascular causes, 27% of patients will have one or more re-amputations within a year.[9-10] For those patients that have a minor amputation, 40% progress to a higher level of limb loss within a year of an initial toe, foot, or ankle amputation.[10] Among diabetic patients, this rate rises to 62%.[10] And 55% of diabetics that are amputated get an opposite limb amputation within 2-3 years.[11] Post-amputation mortality rates are dismal, with perioperative mortality at 4.2% to 10.4%,[12-14] 1-year mortality at 9.1% to 33%,[9,10] and 5-year mortality at 25.6% to 81.5%.[9,15] This is a very costly condition as well, with lifetime post LEA per capita costs at $509,275.[16] The mean length of hospital stay for LEA is 9.8 days to 12.7 days[9,17] with diabetics having a >10% higher amputation-related cost than nondiabetics, primarily in office and outpatient care settings.[10] Quality of life suffers with an increase in anxiety and depression. People with amputations make significantly poorer psychosocial adjustments to their domestic and social environments, and report lower overall quality of life.[16,18-21]

What can be done? A multidisciplinary team-based approach to PAD management may lead to reduction in unnecessary amputation procedures. Given the large racial disparities in amputation rates, such an approach must pay particular attention to addressing unnecessary amputations among minority groups. A holistic amputation prevention program needs comprehensive pre- and post-revascularization procedure care. In addition to benefits to the patient, there are potential benefits to hospitals engaging in limb salvage programs including cost-effectiveness.[22] Substituting revascularization procedures for amputations may substantially reduce length of stay (LOS). Performing a revascularization procedure in place of an LEA reduces LOS by an average of 8.5 days (LOS reduction; amputation 11.3 vs revascularization 2.8 days).[9,17,23] Significant cost savings may be realized as well. Since average daily hospital ward expenses are $2,255,[24] moving a patient from LEA to revascularization may save the hospital $19,000 in ward expenses.

The rate of LEA has been relatively flat over time, but it remains markedly

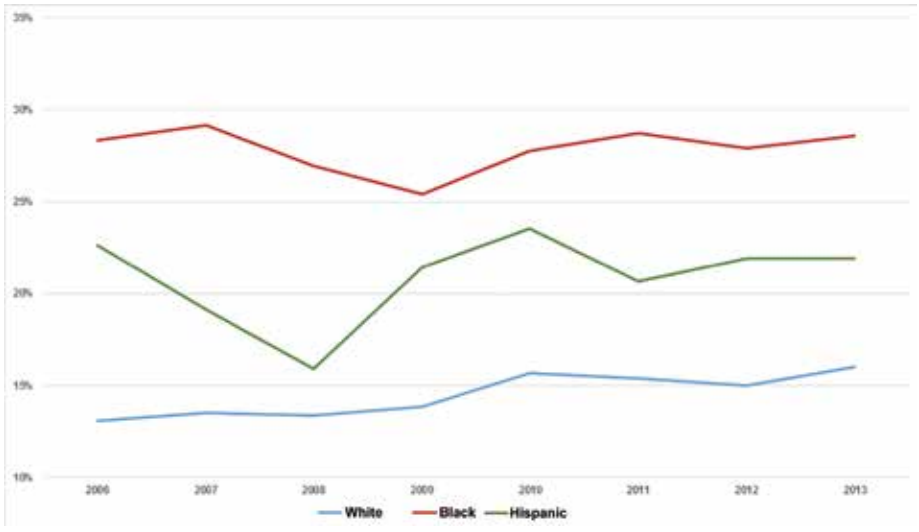


Figure 3. Amputation rates by race over time.

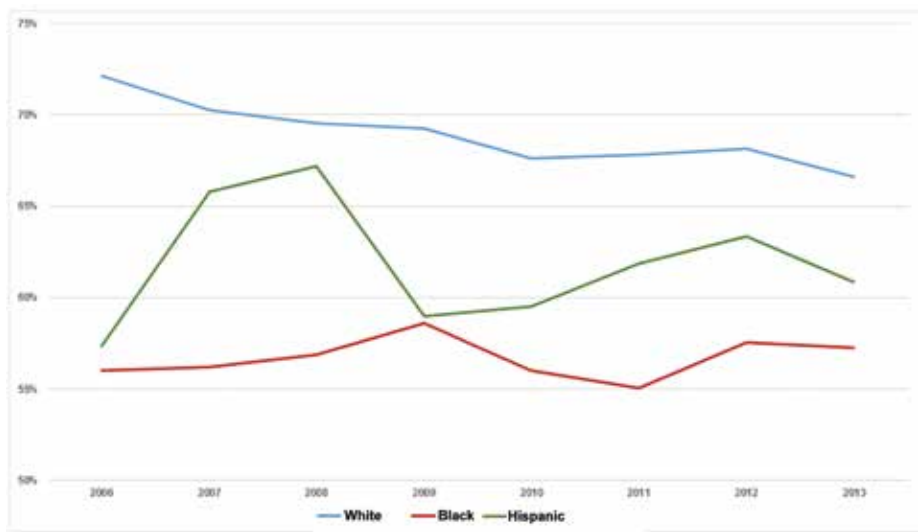


Figure 4. Revascularization rates by race over time.

higher for minorities than for whites. Policies aimed at limb-sparing treatments for PAD patients and research to better understand racial and ethnic disparities in amputation rates are essential to redress this issue. This holds the promise of providing treatment for PAD patients that is both higher quality and more cost effective than at present. ■

References

1. Allie DE, Hebert CJ, Ingraldi A, Patlola RR, Walker CM. 24-carat gold, 14-carat gold, or platinum standards in the treatment of critical limb ischemia: bypass surgery or endovascular intervention? *J Endovasc Ther.* 2009;16(Suppl I):I134-I146.
2. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil.* 2008;89(3):422-429.
3. Henry AJ, Hevelone ND, Belkin M, Nguyen LL. Socioeconomic and hospital-related predictors of amputation for critical limb ischemia. *J Vasc Surg.* 2011;53(2):330-339.
4. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg.* 2007;45 Suppl S:S5-S67.
5. Hughes K, Seetahal S, Oyetunji T, et al. Racial/ethnic disparities in amputation and revascularization: A nationwide inpatient sample study. *Vasc Endovascular Surg.* 2014;48(1):34-37.
6. Feinglass J, Kaushik S, Handel D, Kosifas A, Martin GJ, Pearce WH. Peripheral bypass surgery and amputation: Northern Illinois demographics, 1993 to 1997. *Arch Surg.* 2000;135(1):75-80.
7. Huber TS, Wang JG, Wheeler KG, et al. Impact of race on the treatment for peripheral arterial occlusive disease. *J Vasc Surg.* 1999;30(3):417-425.
8. Guadagnoli E, Ayanian JZ, Gibbons G, McNeil BJ, LoGerfo FW. The influence of race on the use of surgical procedures for treatment of peripheral vascular disease of the lower extremities. *Arch Surg.* 1995;130(4):381-386.
9. Jindeel A, Narahara KA. Nontraumatic amputation: incidence and cost analysis. *Int J Low Extrem Wounds.* 2012;11(3):177-179.
10. 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.
11. Pasquina PF, Miller M, Carvalho AJ, et al. Special considerations for multiple limb amputation. *Curr Phys Med Rehabil Rep.* 2014;2(4):273-289.
12. Davenport DL, Ritchie JD, Xenos ES. Incidence and risk factors for 30-day postdischarge mortality in patients with vascular disease undergoing major lower extremity amputation. *Ann Vasc Surg.* 2012;26(2):219-224.
13. Hasanadka R, McLafferty RB, Moore CJ, Hood DB, Ramsey DE, Hodgson KJ. Predictors of wound complications following major amputation for critical limb ischemia. *J Vasc Surg.* 2011;54(5):1374-1382.
14. Ghaferi AA, Birkmeyer JD, Dimick JB. Variation in hospital mortality associated with inpatient surgery. *N Engl J Med.* 2009;361(14):1368-1375.
15. Faglia E, Clerici G, Clerissi J, et al. Early and five-year amputation and survival rate of diabetic patients with critical limb ischemia: data of a cohort study of 564 patients. *Eur J Vasc Endovasc Surg.* 2006;32(5):484-490.
16. 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.
17. CDC. Diabetes Public Health Resource. http://www.cdc.gov/diabetes/statistics/lea/fig2.htm.
18. Vileikyte L. The psycho-social impact of diabetes foot damage. *Diab Voice.* 2005;50:11-13.
19. Amputee Coalition of America. Limb Loss Research & Statistics Program. http://www.amputee-coalition.org/wp-content/uploads/2014/09/lsp_people-speak-out_191214-012622.pdf.
20. Washington J. The Relations Among Psychological and Demographic Factors in Individuals With Lower Limb Amputation [senior thesis]. Hartford, Conn.: Trinity College; 2013. http://digitalrepository.trincoll.edu/cgi/viewcontent.cgi?article=1345&context=theses.
21. Remes L, Isoaho R, Vahlberg T, Viitanen M, Koskenvuo M, Rautava P. Quality of life three years after major lower extremity amputation due to peripheral arterial disease. *Aging Clin Exp Res.* 2010;22(5-6):395-405.
22. Barshes NR, Kougias P, Ozaki CK, et al. Cost-effectiveness of revascularization for limb preservation in patients with marginal functional status. *Ann Vasc Surg.* 2014;28(1):10-17.
23. Zafar AM, Dhangana R, Murphy TP, et al. Lower-extremity endovascular interventions for Medicare beneficiaries: comparative effectiveness as a function of provider specialty. *J Vasc Interv Radiol.* 2012;23(1):3-9.e1-14.
24. Kaiser Family Foundation. Hospital-Adjusted Expenses Per Inpatient Day. http://kff.org/other/state-indicator/expenses-per-inpatient-day/.

Real-World Data

Continued from page 1

describes this registry, which is the first CLI registry developed to collect valuable real-world data through which we will learn and adapt new methods of therapy with the goal of creating global evidence-based guidelines for physicians to follow. This issue also features global CLI experts who share their views and expertise. Successful multilevel, multivessel CLI therapy is not easy and definitely is not the same as treating only above-the-knee disease.

Critical limb ischemia kills more people that breast cancer, colon cancer, and prostate cancer, yet no formal program exists to raise awareness for patients and their families of CLI, a disease associated with severe outcomes if left untreated or if the presentation is late. The time has come for a call to action for more and better training of CLI specialists, more data on CLI therapy outcomes, and better public CLI awareness.

I recently returned from the Leipzig Interventional Course in Leipzig, Germany. This meeting is a good example of a conference where like minded individuals can discuss the above concerns and issues. It was an extremely educational conference with presentations on the latest cutting edge technologies and the latest updates on clinical trials. I encourage you to attend these meetings, meet with your colleagues, and stay abreast of the latest technologies in CLI therapy. ■

PRIME Registry

Continued from page 3

clinical characteristics, medications, endovascular procedure details, immediate and follow-up outcomes, and procedural information on subsequent endovascular revascularizations.

The registry has already yielded some interesting results, which were presented at the 2015 Amputation Prevention Symposium (AMP) in Chicago, IL. Ultrasound-guided access for 407 patients and 578 access sites were analyzed and revealed high access success and low complication rates for all arterial conduits (single femoral antegrade, single femoral retrograde, dual femoral retrograde, dual femoral/tibiopedal, and single tibiopedal [TAMI]).[3] Ankle-brachial and toe brachial indices (ABI, TBI) were found to be poor predictors of baseline disease severity and response to endovascular treatment for CLI patients, leading to the questions of whether these should be used as inclusion criteria for clinical trials.[4]

Currently, five new manuscripts are in development, led by site investigators. Through the collaboration of the PRIME team, a broad understanding of the complex nature and clinical outcomes of patients with advanced PAD and CLI is possible. Currently, randomized clinical trials represent the gold standard of high-quality data with which evidence-based medicine builds its foundation. However, it is of paramount importance to realize the complex nature of the disease process, along with regional variations in expertise and practice patterns, limit the ability of these trials to encompass a wide enough range of patients that are representative of "real-world" scenarios. By tracking patient history, clinical presentation, treatment modalities, and long-term follow-up, PRIME is creating a platform that can help clinicians understand the clinical course of CLI beyond revascularization. The PRIME registry will serve as a basis to define quality measures and guidelines that are focused on CLI care and improved outcomes. ■

References

1. Allie DE, Hebert CJ, Ingraldi A, Patlola RR, Walker CM. 24-carat gold, 14-carat gold, or platinum standards in the treatment of critical limb ischemia: bypass surgery or endovascular intervention? *J Endovasc Ther.* 2009;16 Suppl 1:I134-I146.
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. Mustapha JA, Saab F, Diaz-Sandoval LJ, et al. Abstract 18: Ultrasound-guided access in patients with critical limb ischemia: initial findings of the PRIME registry. In: Abstracts from the 2015 AMPutation Prevention Symposium. *Critical Limb Ischemia Global Compendium.* 2015;September:23-30.
4. Mustapha JA, Diaz-Sandoval LJ, Saab F, et al. Abstract 15: non-invasive hemodynamics poorly predict disease severity and response to endovascular therapy in patients with critical limb ischemia. In: Abstracts from the 2015 AMPutation Prevention Symposium. *Critical Limb Ischemia Global Compendium.* 2015;September:23-30.

Collaborative Critical Limb Ischemia Care: The CLI Program at Rex Hospital

George Adams, MD, MHS; James Zidar, MD; Ravish Sachar, MD; Robert Mendes, MD; Martyn Knowles, MD; Dorian deFreitas, MD; Wayne Smith, MD; Patrick Washko, RVT; Kelly Barbour, RVT; David Smith, MD; Daniel Vig, MD; Bruce Fawcett, DPM; Clarence Stewart, DPM; Vinayak Subramanian, BS; Diana Massa, MHA; Steve Burriss, MBA

Peripheral arterial disease (PAD) affects between 8 million and 12 million Americans and more than 202 million people worldwide, making it a significant public health burden. Characterized by the narrowing of arteries in the extremities, the presentation of PAD varies from patients who are asymptomatic to those with life-limiting rest pain and nonhealing ulcers. The latter is a typical feature seen in patients afflicted by critical limb ischemia (CLI). Historically, these patients have been underserved due to a lack of awareness and technological limitations. As our understanding of CLI has evolved, the paradigm for preventing amputation by revascularization and diligent wound care has become standard. Successful recognition and treatment of CLI requires dedicated clinicians and a supportive administrative structure that allows clinicians to treat patients optimally.

Rex Hospital, located in Raleigh, North Carolina, is recognized as one of the leading CLI programs in the United States. This past year, approximately 1,700 PAD patients underwent endovascular interventions at Rex Hospital, and of those cases 52% were CLI. We are the highest enrolling site for the peripheral vascular interventional registry supported by the National Cardiovascular Data Registry (NCDR). Rex is also one of currently 3 enrolling sites for the CLI-focused Peripheral RegIstry of Endovascular OutcoMEs (PRIME).

The success of our program stems from a collaborative work culture between our administrators and clinical team. Our multidisciplinary team is comprised of vascular interventionalists, which includes cardiologists, radiologists, and vascular surgeons supported by technicians and nurses; noninvasive vascular specialists; and wound care specialists, including podiatrists and surgeons. Recognizing the enormous public health burden of CLI, our program is committed to preventing amputation and enhancing quality of life as demonstrated in the following case study.

Case Presentation

A 68-year-old male with a past medical history of diabetes, hypertension, and hypercholesterolemia was referred to our CLI clinic because of a nonhealing left foot ulceration (Figure 1). His left lower extremity ankle brachial index was 0.52, and duplex ultrasound indicated a >70% stenosis of the left distal superficial femoral artery (SFA) and occlusion of the posterior tibial (PT) artery. Angiography confirmed these findings by accessing the right common femoral artery. The left SFA stenosis was crossed with a .014″ floppy tipped wire and balloon angioplasty was performed with a 5 mm x 20 mm cutting balloon taking the 70% stenosis to 20% residual. To prevent restenosis, a direct drug delivery device was used to deliver dexamethasone to the SFA site. Attention was then directed to the left occluded PT.

A series of wires including an .014″ coiled tip 18 gm wire, followed by a polymer coated 18 gm tipped .014″ wire, followed by a 30 gm tipped .018″ wire was attempted to cross the PT occlusion from an antegrade approach without success. Therefore, retrograde PT access was obtained and a 2.9 Fr sheath was placed. An 18 gm .014″ coiled-tip wire was advanced through the PT occlusion but could not reenter the proximal vessel.

A double-balloon technique utilizing a 2.5 mm x 40 mm balloon from above and a 2.5 mm x 80 mm pedal balloon from below was then utilized to fenestrate the lumen of the vessel, allowing the retrograde wire to reenter the proximal lumen. The retrograde wire was then inserted into an angled catheter and brought out the right femoral sheath in a flossing fashion. A 2.5 mm x 200 mm balloon was inserted from the groin and extended through the PT occlusion. The balloon was inflated to maximum pressure for 3 minutes, successfully taking the 100% PT occlusion to 20% residual, providing in-line flow to the ulcer.

The patient was then referred back to the podiatrist in the wound care clinic. Over the next 12 weeks, wound care with debridement, careful attention to signs of infection, and hyperbaric therapy were used to heal the wound (Figure 2).

As this case illustrates, successful patient outcomes are strongly dependent on the commitment of the clinicians and the dedication of a cohesive multidisciplinary team. Rex Hospital has become a center of excellence for the treatment of CLI by providing comprehensive clinical care and advancing the field through research (currently enrolling in 22 peripheral vascular trials). We participate in training and education of our national and international colleagues.

The Annual North Carolina Heart and Vascular conference held by Rex Hospital attracts experts in the CLI field from across the world. The opening of the NC Heart and Vascular Hospital in 2017 will mark a new chapter for our program. This new 8-story, 114-bed hospital will house 12 state-of-the-art procedure rooms. This facility will also house an education center that will enhance our ability to train both international and national audiences.

As we look to the future, our program will continue to evolve and contribute globally to the fight against CLI with the ultimate goal of eradicating unnecessary amputations. ■

Figure 1. Chronic nonhealing ulceration of the left foot.

Figure 2. The wound is successfully healed after revascularization followed by wound care.

Case Study

Continued from page 4

program would have on the community. Finally, an organized approach that explored the economic savings achieved by preventing major amputations created a strong argument for the hospital becoming a significant stakeholder in building a successful systems-based approach to preventing limb loss. Ultimately, each of these step-wise processes resulted in a multidisciplinary pilot program that will serve as the framework for nationwide scalability resulting in decreased costs to the medical system, improve patient care, and decrease long-term mortality in patients at high risk for limb loss. ■

References

1. Jacobs AK, Antman EM, Faxon DP, et al. Development of systems of care for ST-elevation myocardial infarction patients: executive summary. *Circulation*. 2007;116:217-230.
2. Alberts MJ, Latchaw RE, Selman WR, et al. Recommendations for comprehensive stroke centers: a consensus statement from the Brain Attack Coalition. *Stroke*. 2005;36:1597-1616.
3. Holden DJ, Reiter K, O'Brien D, et al. The strategic case for establishing public-private partnerships in cancer care. *Health Res Policy and Syst*. 2015;13:44.
4. The Sage Group LLC. Critical Limb Ischemia Vol 1 United States Epidemiology. 2010.
5. Faglia E, Clweici G, Clerissi J, et al. Early and five-year amputation and survival rate of diabetic patients with critical limb ischemia: data of a cohort study of 564 patients. *Eur J Vasc Endovasc Surg*. 2006;32:484-490.
6. Tentolouris N, Al-Sabbagh S, Walker MG, et al. Mortality in diabetic and nondiabetic patients after amputations performed from 1990 to 1995: a 5-year follow-up study. *Diabetes Care*. 2004;27(7):1598-1604.
7. Davenport DL, Ritchie JD, Xenos ES. Incidence and risk factors for 30-day postdischarge mortality in patients with vascular disease undergoing major lower extremity amputation. *Ann Vasc Surg*. 2012;26(2):219-224.
8. Hasanadka R, McLafferty RB, Moore CJ, et al. Predictors of wound complications following major amputation for critical limb ischemia. *J Vasc Surg*. 2011;54(5):1374-1382.
9. Ghaferi AA, Birkmeyer JD, Dimick JB. Variation in hospital mortality associated with inpatient surgery. *N Engl J Med*. 2009;361(14):1368-1375.
10. Jindeel A et al. Nontraumatic amputation: incidence and cost analysis. *Int J Low Extrem Wounds*. 2012;11(3):177-179.
11. 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.

Figure 1. A 69-year-old patient with diabetes, Rutherford class V claudication in the right limb, and a University of Texas Wound Classification System 3D lesion with gangrene of the second toe and the sole of the foot. Right-foot necrosis and dry gangrene (A, B); three months after revascularization and debridment the healing process stopped (C) as observed by fibrin deposition (arrows) and new necrosis. The healing process began again after target lesion revascularization and continued (D, E) until complete healing (F).

High-Volume CLI Practice

Continued from page 1

novel techniques such as the retrograde approach. Successful BTK recanalization requires high confidence with an antegrade approach, either intraluminal or subintimal with distal reentry, and all types of retrograde approaches (direct tibial puncture, transcollateral, navigation and pedal-plantar loop technique).

Direct tibial or digital puncture may increase the success rate in the case of antegrade failure. However, the puncture of a tibial artery is not always easy, particularly when dealing with a small, heavily calcified vessel, which in most cases is also the last remaining artery providing pedal perfusion. Complications of direct tibial artery puncture, such as dissection and acute occlusion, may further compromise distal flow to the wound, resulting in acute foot ischemia with catastrophic consequences. However, application of these novel techniques and availability of new devices allow an expert operator to achieve success in complex BTK occlusions without compromising patient safety. The adoption of this concept by low-volume operators and hospitals may lead to different procedural and clinical outcomes. As in coronary settings, several studies showed lower mortality, higher technical success, and lower amputation rates in high-volume compared to low-volume centers performing peripheral interventions. The difference in outcomes may be explained by the ability to complete a long learning curve in CTO recanalization and the possibility to build a dedicated logistic environment for patient and foot care in a large volume hospital. Figures 1-3 show an example of an early and aggressive treatment strategy by our multidisciplinary team.

Adhering to the following criteria will increase the chances of establishing a successful CLI program:

- Institutional volume of 400 peripheral vascular procedures yearly (minimum of 150 CLI procedures);
- Individual operator volume of at least 75 CLI cases per year;
- Creation of a CLI revascularization team that includes at least 2 operators to provide 24-hour coverage all year, as well as nurses and technicians with complete knowledge of the interventional armamentarium and vascular access management;
- On-site training with highly experienced operators in the early cases;
- Creation of an outpatient CLI team that includes a diabetic foot specialist and nurses who provide foot care management and healing surveillance. This unique group of individuals must be trained in CLI-related protocols, determine the timing of revascularization and minor amputations, drive the request for vessel patency testing (duplex ultrasound) and give indication for target lesion revascularization in a fast-track strategy fashion; and
- Serial planned cardiovascular evaluation in all patients to reduce the high morbidity and mortality observed in this specific population.

Figure 2. Angiography of the right infrapopliteal circulation showing occlusion of the anterior and posterior tibial arteries with peroneal artery filling the distal part of the posterior tibial artery with plantar arteries as the only remaining foot circulation (A). Retrograde recanalization of the PTA via peroneal collateral "surfing" (B) and reverse CART technique to cross the occlusion by retrograde wire (C, D). Angioplasty with 3 mm x 120 mm conventional balloon (E) and optimal final result (F).

Figure 3. Three months repeat angiography dictated by the evidence of no healing progression showing reocclusion of the right posterior tibial artery (A). Target lesion revascularization with 3 mm x 120 mm drug-eluting balloon (B) with optimal result (C, D).

Only in this way, with a dedicated team with extensive experience technical aspects of lower limb revascularization, will we see increased patency, lower target lesion revascularization, and reduced cardiovascular death. ■

Address for correspondence: Francesco Liistro, MD, Cardiovascular Department, San Donato Hospital, via Pietro Nenni 20, 52100, Arezzo, Italy. Email: francescoliistro@hotmail.com

References

1. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg.* 2007;45 Suppl S:S5-S67.
2. Faglia E, Favales F, Quarantiello A, et al. Angiographic evaluation of peripheral arterial occlusive disease and its role as a prognostic determinant for major amputation in diabetic subjects with foot ulcers. *Diabetes Care.* 1998;21(4):625-630.
3. Jude EB, Eleftheriadou I, Tentolouris N. Peripheral arterial disease in diabetes--a review. *Diabetic Med.* 2010;27(1):4-14.
4. van der Feen C, Neijens FS, Kanters SD, Mali WP, Stolk RP, Banga JD. Angiographic distribution of lower extremity atherosclerosis in patients with and without diabetes. *Diabetic Med.* 2002;19(5):366-370.
5. Diehm N, Shang A, Silvestro A, et al. Association of cardiovascular risk factors with pattern of lower limb atherosclerosis in 2659 patients undergoing angioplasty. *Eur J Vasc Endovasc Surg.* 2006;31(1):59-63.
6. Graziani L, Silvestro A, Bertone V, et al. Vascular involvement in diabetic subjects with ischemic foot ulcer: a new morphologic categorization of disease severity. *Eur J Vasc Endovasc Surg.* 2007;33(4):453-460.
7. Rueda CA, Nehler MR, Perry DJ, et al. Patterns of artery disease in 450 patients undergoing revascularization for critical limb ischemia: implications for clinical trial design. *J Vasc Surg.* 2008;47(5):995-999; discussion 999-1000.
8. Hong MS, Beck AW, Nelson PR. Emerging national trends in the management and outcomes of lower extremity peripheral arterial disease. *Ann Vasc Surg.* 2011;25(1):44-54.

Upcoming Clinical Events

Pan Arab Interventional Radiology Society (PAIRS) Scientific Meeting
Dubai, United Arab Emirates
March 10, 2016 to March 12, 2016
pairs2016.com/

Leipzig Interventional Course - LINC Middle East
Dubai, United Arab Emirates
APRIL 7, 2016 to April 8, 2016
www.linc-around-the-world.com/all-linc-congresses/linc-middle-east-2016/

The Symposium on Advanced Wound Care (SAWC) Spring Meeting
Atlanta, GA, United States
April 13, 2016 to April 17, 2016
www.sawc.net/spring/home

Outpatient Endovascular and Interventional Society
Miami Beach, FL, United States
April 15, 2016 to April 17, 2016
oeisociety.org/meeting/

The Society for Cardiovascular Angiography and Interventions (SCAI)
Orlando, FL, United States
May 4, 2016 to May 7, 2016
www.scai.org

New CardioVascular Horizons (NCVH) Fellows Course
New Orleans, LA, United States
May 31, 2016
www.ncvh.org/ncvh-fellows-course.html

New CardioVascular Horizons (NCVH) 17th Annual Conference
New Orleans, LA, United States
May 31, 2016 to June 4, 2016
www.ncvh.org/meetings/annual-conference-2016/overview.php

Multidisciplinary European Endovascular Therapy (MEET)
Nice, France
June 2, 2016 to June 3, 2015
www.meetcongress.com
International Congress of Polish Society of Vascular Surgery
Zakopane, Poland
June 23, 2016 to June 25, 2016
www.ptchn.pl/

Complex Cardiovascular Catheter Therapeutics (C3)
Orlando, FL, United States
June 28, 2016 to July 1, 2016
www.c3conference.net

Chicago Endovascular Conference (CVC)
Chicago, IL, United States
July 18, 2016 to July 21, 2016
www.cvcpvd.com

6th Annual Amputation Prevention Symposium (AMP)
Chicago, IL, United States
August 10, 2016 to August 13, 2016
www.amptheclimeeting.com

Vascular Interventional Advances (VIVA)
Las Vegas, NV, United States
September 18, 2016 to September 22, 2015
www.vivaphysicians.org

Endovascology International Congress
Shanghai, China
October 13, 2016 to October 15, 2016
endovascology.org/weben2016/

Transcatheter Cardiovascular Therapeutics (TCT)
San Francisco, CA, United States
October 29, 2016 to November 2, 2016
www.crf.org/tct

The Symposium on Advanced Wound Care (SAWC) Fall Meeting
Las Vegas, NV, United States
October 7, 2016 to October 9, 2016
www.sawc.net/fall/

VEITHsymposium 2016
New York, NY, United States
November 15, 2016 to November 19, 2016
www.veithsymposium.org

The VERVE Symposium in Conjunction With LINC Australia
Sydney, Australia
December 1, 2016 to December 3, 2016
www.vervesymposium.com

CLI GLOBAL

THE VOICE OF CRITICAL LIMB ISCHEMIA

Powerful Articles
Exclusive Interviews
In Depth Case Videos
Tips And Tricks
Hours of Content

Available On All Devices

WWW.CLIGLOBAL.COM

ACCESS TO MORE THAN

75 LEADING CLI EXPERTS

AMP™

THE AMPUTATION PREVENTION SYMPOSIUM

AUGUST 10—13, 2016

HILTON CHICAGO
CHICAGO, ILLINOIS

ATTEND THE LARGEST MEDICAL CONFERENCE
DEDICATED TO THE TREATMENT & PREVENTION
OF CRITICAL LIMB ISCHEMIA (CLI)

REGISTER TODAY

AMPTHECLIMEETING.COM

ASAHI
Peripheral Guide Wires

NEW Peripheral Guide Wires

Now available with ASAHI's unique guide wire technology

with ACTONE®

New Guide Wires

ASAHI **Gladius®** 0.014
Workhorse

ASAHI **Halberd®** 0.014
Complex Lesion

ASAHI **Gladius®** 0.018
Workhorse

ASAHI **Halberd®** 0.018
Complex Lesion

ASAHI **Gaia® PV** 0.018
Complex Lesion

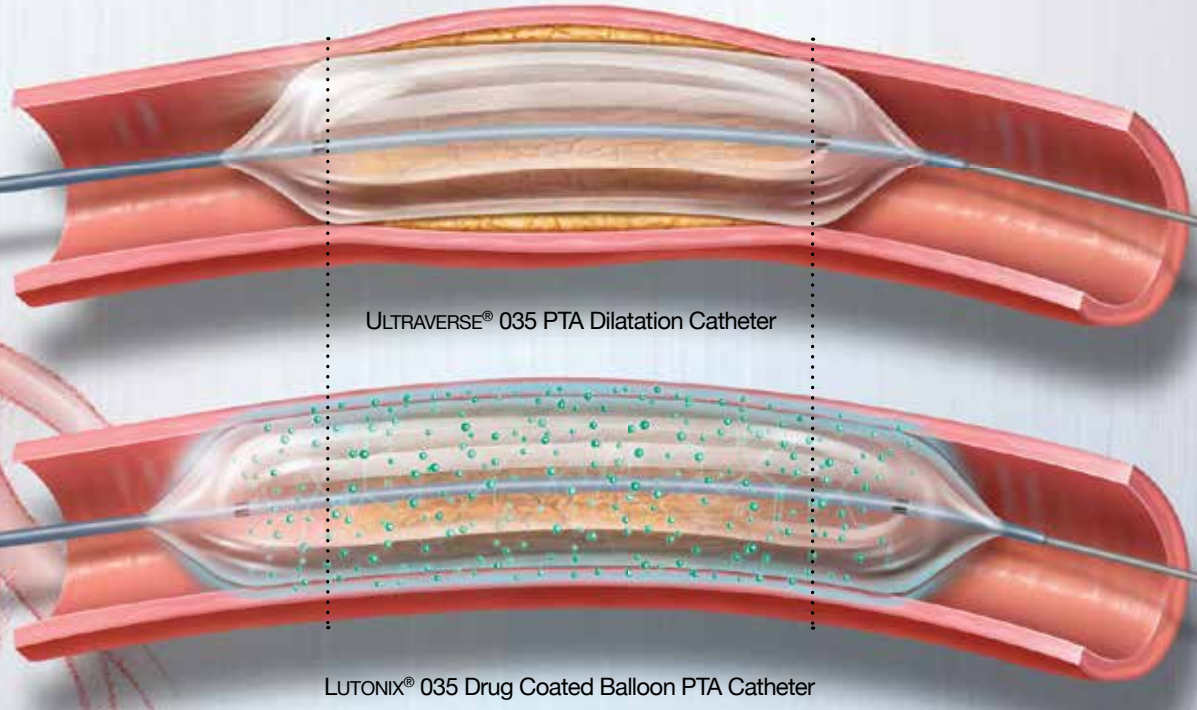
Your dreams. Woven together.
ASAHI INTECC

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

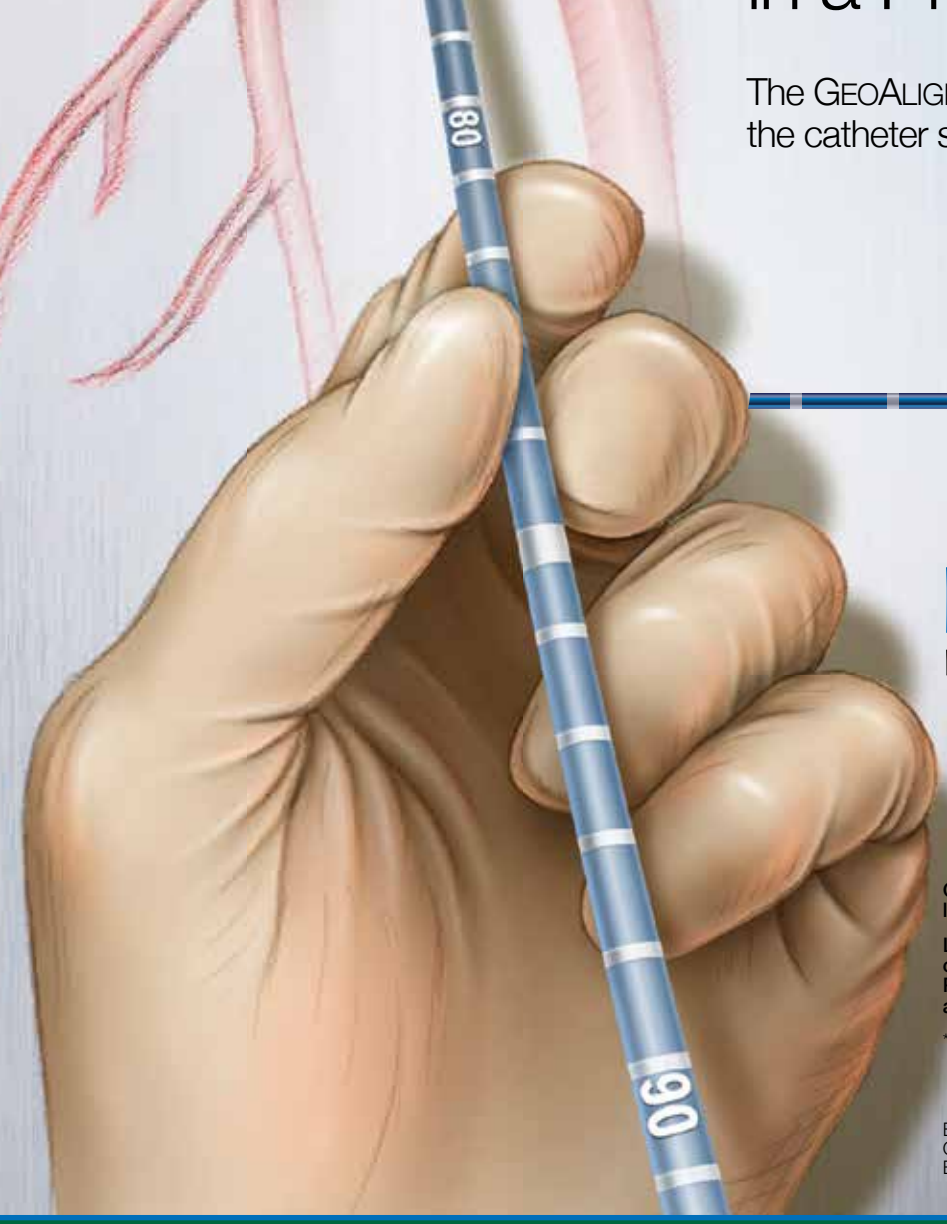
The ASAHI INTECC peripheral guide wires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. These devices are intended for peripheral vascular use only.

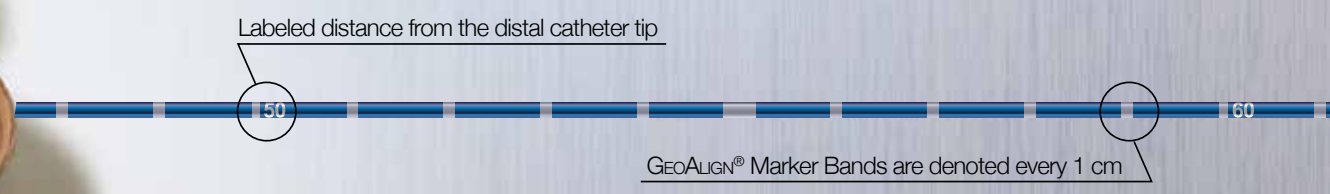
Featuring the **GeoAlign®** Marking System



27% Average Reduction in Fluoroscopy Time
in a Pre-Clinical Study*

The GeoAlign® Marking System is a simple-to-use, non-radiopaque ruler on the catheter shaft that is designed to facilitate repeatable catheter placement.





Lutonix® 035
Drug Coated Balloon PTA Catheter

Ultraverse® 035
PTA Dilatation Catheter

GeoAlign® Markers are not a replacement for fluoroscopy. When the catheter is exposed to the vascular system, the location of the balloon should be confirmed while under high quality fluoroscopic observation.

Lutonix® DCB should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds. The Lutonix® Catheter should always be manipulated under fluoroscopic observation when in the body. Please consult product labels and instructions for use for indications, contraindications, hazards, additional warnings and precautions. Rx_{Only}

* Animal study (repeat PTA in swine artery) was performed by 3 physicians who tested the Lutonix® 035 DCB (no drug) and the Ultraverse® 035 PTA Catheter, both with GeoAlign® Markers, to POBA with no GeoAlign® Markers (n=112, test n = 96 (with an average placement time of 66 seconds), control n = 16 (with an average placement time of 90 seconds)). Animal data on file. Bard. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.

Bard Peripheral Vascular, Inc. | 1 800 321 4254 | www.bardpv.com | 1625 W. 3rd Street Tempe, AZ 85281 **G71653R1**

BARD

Advancing Lives and the Delivery of Health Care™