CLI GLOBAL COMPENDIUM

THE GLOBAL VOICE OF CRITICAL LIMB ISCHEMIA

Critical Limb Ischemia Centers of Excellence: Toward Global Standardization of Therapy

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As we continue to build the armament in our battle against critical limb ischemia, we find new tools, techniques, and approaches that enhance our ability to achieve better outcomes through revascularization. Historically, revascularization was achieved exclusively through surgical means, however endovascular interventions are gaining momentum as they offer a less invasive alternative to treat patients who tend to present with a multitude of comorbid conditions that make their surgical risk unacceptable. These comorbidities further enhance the complex microvascular and macrovascular disease process that presents itself as a multivessel and multilevel affliction, which spans from the origin of the aortoiliac junction to the tibial and pedal circulation.

While revascularization remains the main pillar of treatment for CLI patients, the contemporary management of this condition requires a multifaceted approach that encompasses the simultaneous expertise of members of a multidisciplinary team. Current studies looking at cutting-edge technologies for the endovascular management of infrapopliteal disease have revealed ambiguous results, partially due to the apparently invisible fractures of current practice workflows, whereby different specialists treat the CLI patient in an isolated fashion (taking care of one aspect of the patient), without a cohesive approach.

Despite the social, economic, cultural, and regional differences among patients, it is clear that CLI knows no boundaries. It is becoming a worldwide epidemic and its prevalence is only expected to rise.

Here, the Critical Limb Ischemia Global Compendium presents the unique insights of expert CLI therapists from around the world on the universal need for the creation of CLI centers of excellence, in an effort to promote expert multidisciplinary care for our CLI patients and hence improve outcomes. These contributions identify the challenges to be met and the recommendations point to a common goal that transcends barriers and calls for the creation of standardized protocols that can be tailored to the specifics of each region while maintaining the essence represented by the benefits provided by a simultaneous, transitionless, passionate, and dedicated multidisciplinary approach.

Creating a Comprehensive CLI Program

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Over the last decade the treatment of critical limb ischemia (CLI) has matured and developed due to a number of factors. It was not too long ago when there were no acceptable endovascular treatments for infrapopliteal disease. The lucky few patients were treated with a distal bypass while, unfortunately, most patients received an amputation. Today, the awareness in the medical community of potential successful treatment options for CLI has fueled early referrals for the treatment of these patients. Additionally, technology has become a driver in this growth by allowing significant improvement in the endovascular as well surgical treatment of these patients. However, this technology and the treatment of these patients can be expensive. In the future, it will be important to study and clearly demonstrate the benefit and value associated with quality and complete treatment of patients with CLI.

What is the best way to deliver care to patients with critical limb ischemia? We should likely reword the question: What is the best way to deliver complete wound care? Centers

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Thomas Zeller, MD
Guest Editor

Critical limb ischemia is an increasing global health care burden due to the epidemic increase in obesity, and, as a consequence of diabetes mellitus, obesity is one of the major drivers of CLI development. Because treatment resources, both financial and provider-related, are and will remain limited, global standardization of diagnostic and treatment strategies, including revascularization procedures and wound care, is crucial to provide as many affected people as possible with high-quality medical care and prevent major limb amputation. Utilizing "centers of excellence" is one option for bundling those resources. This Critical Limb Ischemia Global Compendium (CLIC) focuses on the various international approaches to CLI therapy and the need for a global consensus for therapy. Internationally renowned authors like Dr. Varcoe, Dr. Iida, Dr. Kamal, and Dr. Jaffer represent medical knowledge from different continents and will discuss the current best practice of CLI care. Moreover, the issue includes a piece from the Latin American REAL group on international centers of excellence for CLI.

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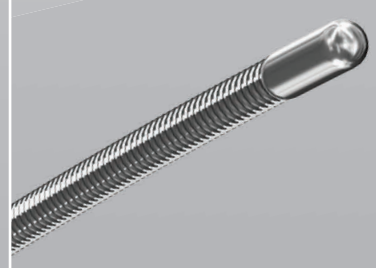

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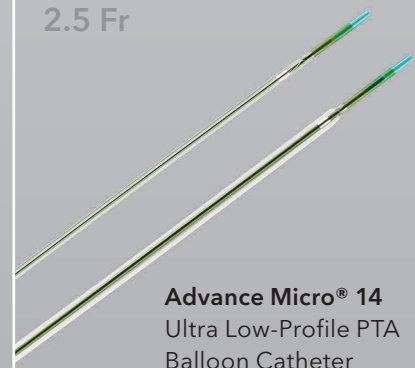

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Current Status of CLI Treatment and Results of the OLIVE Study

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Osamu Iida MD, FACC

The first-line therapy for patients with critical limb ischemia (CLI) is revascularization. Although to date bypass surgery (BSX) has been considered the standard therapy, there are several categories of CLI patients for whom BSX under general anesthesia is poorly indicated:

1) Elderly patients (octogenarian patients are commonly found in the clinical setting).
2) Patients with impaired activities of daily living (ADL) at the onset of CLI. Some patients present with severely compromised ADL (requiring a wheelchair or bedridden).
3) Patients whose autologous vein is inadequate as a conduit due to history of coronary artery bypass and cachexia.
4) Patients with multiple comorbidities including cardiovascular disease and history of neoplasia.

Recent enhancements on devices for endovascular therapy have translated into improved therapeutic outcomes. The multicenter, prospective OLIVE registry for endovascular treatment of infrainguinal vessels in patients with critical limb ischemia study in Japan evaluated outcomes following endovascular therapy for CLI patients with culprit infrainguinal arteriosclerotic lesions.[1] Among patients in the OLIVE registry, notable comorbidities included regular dialysis (52%), diabetes mellitus (71%), and coronary artery disease (46%). In terms of pretreatment ADL, 88% of patients had non-ambulatory status.

Diseased limbs were assessed as Rutherford V in 73% of all registered patients, and 15% had complications of infection at the ischemic limb wound site. Culprit arteriosclerotic lesions in below-the-knee (BTK) arteries were complicated by calcification in 81% of patients and 42% of patients had an isolated BTK lesion. In 93.5% of patients, early endovascular therapy successfully restored blood flow in at least one opened BTK artery to the site below the foot joint level. Amputation-free survival (AFS) after 12 months was 74%. According to multivariate analysis, body mass index of <18.5 kg/m^2, heart failure, and wound infection were independent risk factors for AFS.

The OLIVE study highlighted the important influence of various factors on prognosis of CLI patients, in particular those related to general status, including nutritional status (malnutrition) and cardiac function and to wound status, including wound size and presence of wound infection. Although current progress on endovascular therapy improves blood flow, much attention has to be paid to improving nutritional status and cardiac function; wound infection also is usually treated with antibiotics. A multidisciplinary approach by a CLI medical care team is extremely important and considered best practice by bringing together specialists from several specialties including dermatology, plastic surgery, endocrinology (in particular diabetes specialists), cardiovascular medicine, and vascular surgery.

Three-year results of the OLIVE registry were reported this year,

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The Treatment of Critical Limb Ischemia in Australia: Advancing Toward an Independent Discipline

Ramon L. Varcoe, MBBS, MS, FRACS
From the Department of Surgery of the Prince of Wales Hospital, the University of New South Wales, and The Vascular Institute of Prince of Wales Hospital, Sydney, Australia.

Peripheral arterial disease (PAD) is characterized by atherosclerotic plaque creating stenoses in the arteries outside of the heart.[1] It is most commonly found in the lower limbs but may also be present in upper limbs, carotid arteries, or any of the other arteries that supply major organs of the body.[2,3] It is extremely prevalent in our society and results in a significant burden of patient-related and economic costs.[3] Critical limb ischemia (CLI) occurs when that atherosclerotic plaque accumulation causes sufficient lower limb ischemia that rest pain, tissue loss, or gangrene develop.[4] Critical limb ischemia is a limb-threatening condition, and even today many patients lose limbs unnecessarily due to inadequate treatment in centers where subspecialist treatment for the condition does not exist.[3]

The Multidisciplinary Team

The cornerstone of the treatment of CLI is the multidisciplinary team (see figure). This is because of the multifactorial nature of end-stage tissue ischemia, which is often associated with neuropathy, foot osteopathy, pressure loading, infection, and poor diabetic control. A team of specialists is required to address these factors and work together to ensure that the patient completes the journey from limb threat to salvage and subsequently better health with prevention measures put in place. The vascular specialist is very often the leader of this team as perfusion evaluation and revascularization plays such an important role. That person must have expertise in both surgical revascularization and catheter-based intervention or be in a position to manage other specialists who do. There are usually multiple specialists in internal medicine who will take responsibility for the management of diabetic control, renal impairment, coronary artery disease, and the treatment of infectious disease. Wound care specialists implement and oversee all of the local dressing therapies that may play a local debridement and antibacterial role as well as optimize the aqueous environment for wound healing. Alterations in foot architecture are a common predisposing factor in CLI, particularly in diabetes.

An orthopedic specialist with expertise and interest in foot reconstructive surgery plays an integral role in the CLI team, usually once the immediate threat is under control. They work in close collaboration with podiatrists, whose role is to manage the day-to-day foot care that is so important for these patients. Finally, hyperbaric oxygen therapy is used in cases where a patient's microcirculatory impairment has resulted in regional perfusion deficits that respond to hyperbaric oxygen challenge. Hyperbaric physicians may also give insight into these locally malperfused regions through the use of transcutaneous oxygen manometry.

Ramon L. Varcoe, MBBS, MS, FRACS

The Endovascular Revolution

It is evident to all clinicians with lengthy experience in the treatment of CLI patients that the ability of the

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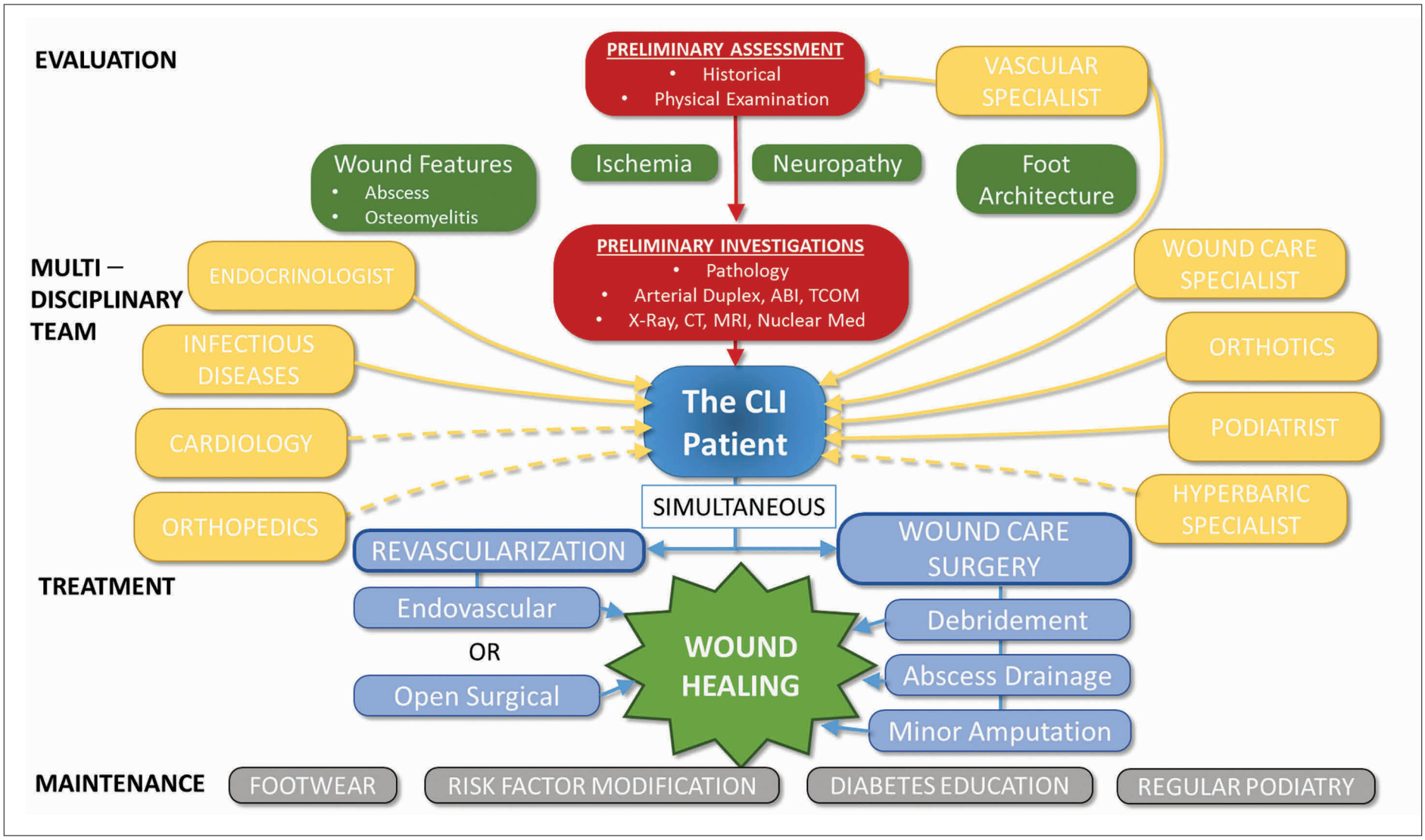

Figure 1. The multidisciplinary model of care for critical limb ischemia.

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vascular specialist to revascularize the ischemic limb has taken a great leap forward over the past 10 years. Certainly the technology behind the tools that we use to achieve revascularization has expanded exponentially thanks to industry research and development. Moreover, there has been extensive technique development led by CLI pioneers that has enabled technical success rates, which now approach 100% in most CLI centers.

In Australia there remains a gulf between those centers of excellence and other institutions that have a less passionate, learned, and structured approach to the treatment of these complex patients. However, this is slowly changing with patient awareness being one of the main driving forces that now sees a number of vascular specialists seeking additional overseas and local training for the treatment of CLI.

The Prince of Wales Hospital Vascular Institute Approach

In our own institution we examined our approach to the treatment of these patients with CLI over an 8-year period leading up to 2012. Throughout that time, we moved from a unit that predominantly utilized open surgical techniques for revascularization to one that had a preference for an endovascular-first approach in the majority of cases. This modification in approach resulted in a 51% reduction in major lower limb amputations when the second half of that period was compared to the first (from 25.6% to 12.6%, $P<.01$), which was accompanied by a 10-day reduction in mean length of stay ($P=.003$) and 80% reduction in intensive care utilization ($P=.02$) with a significant decrease in the number of admissions per ischemic limb.[5]

Through utilizing a larger proportion of minimally invasive techniques, we found we were able to treat more patients with a broader array of medical comorbidities. This was achieved without an increase in the number of repeat admissions for vascular care, which you might expect from a treatment approach that some criticize for inferior durability. Upon reflection and discussion we have realized that an effective revascularization strategy is as much about persistence and dedication to the cause of limb salvage as it is to advanced procedural skills, which have also clearly come a long way during this endovascular revolution.

Following revascularization we have adopted a minimalistic approach to foot debridement and amputation whereby we target only infected tissue and bone, removing as little as we must while maintaining a low threshold for multiple surgical treatments as required. We have found that preserving the architecture of the foot where possible leads to fewer pressure-related injuries once the patient returns to mobilizing after recovery from the index injury. We work closely with our endocrinologists, infectious diseases team, and hyperbaric physicians in the recovery period to optimize the environment for wound healing, and we seek to cover the wound defect early using skin grafting and flap reconstruction techniques. Orthotics and pressure offloading complete the recovery phase and help to prevent future limb threatening insults with custom-made orthotic footwear.

Conclusion

It is our view that the treatment of critical limb ischemia has evolved into a complex and highly specialized discipline, very much akin to interventional cardiology and interventional neuroradiology. Whereas it may have been acceptable in the past for vascular specialists working in isolation to perform surgical bypass and local amputations, the discipline has certainly evolved to become considerably more complex. At our institution we seek regular consultation and collaboration with international centers of excellence to ensure that our methodology remains well aligned at a global level and our treatment methods state-of-the-art, so that our local patients continue to receive the very best care equivalent to that seen anywhere in the world. A global initiative of working toward clear, evidence-based, protocol-driven CLI treatment and established centers-of-excellence is a much-needed advancement in the management of this complex disease and one that we would welcome enthusiastically.

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Pena

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of excellence and centers with comprehensive wound care programs are essential in properly evaluating and treating patients with critical limb ischemia.

Unfortunately patients with CLI usually have a number of comorbidities. These patients require much more than a simple revascularization. Firstly, the patients require proper cardiovascular optimization. The patient's glucose level, blood pressure, renal function, and lipid levels require evaluation and subsequent management. Furthermore, the high rate of cardiovascular morbidity and mortality in this patient population warrants careful risk assessment. The patient's ambulatory requirements and baseline mobility prior to their CLI presentation requires discussion in order to establish reasonable expectations and goals after treatment. Secondly, the wound may require evaluation for the extent of infection. This may vary from a small dry ulceration to an infected wet gangrenous ulcer with associated osteomyelitis. The wound may require appropriate debridement, offloading and wound care. Thirdly, an assessment of the arterial blood flow to the extremity may require a detailed pulse examination, noninvasive pressure and waveform evaluation, Doppler assessment, computed tomographic angiography, or magnetic resonance angiography. These results are then combined to determine the need for revascularization. Furthermore, the continued evaluation and care of the patient after the revascularization, in order to ensure wound healing, proper rehabilitation, and prevention of other ulcerations become paramount for a successful therapy.

The successful management of these patients requires an extensive team potentially involving a large number of team members with training in podiatry, wound care, endocrinology, cardiology, vascular medicine, vascular surgery, nephrology, and vascular interventions. The ability of these providers to communicate and coordinate proper and timely care is essential to the quality benefit associated with centers of excellence.

Presently, the endovascular treatment of critical limb ischemia is still in its infancy. There are still multiple questions in the endovascular arena that need to be answered. We understand that increasing blood flow is helpful and likely crucial in the setting of CLI; however, we have barely scratched the surface in understanding what actually occurs on a cellular level before and after revascularization. This understanding may help us better determine when and how to revascularize patients as well as provide a better understanding as to how to deliver more durable and successful results from our treatments. The role of both endovascular and open surgical revascularization strategies will likely be important in the future. The opportunity to have a randomized clinical trial (BEST-CLI) to evaluate medical management along with either open surgical or endovascular revascularization in a CLI population that was deemed candidates for both options will allow the evaluation of the benefit of both therapies. This study should help characterize which patients may perform best with each of the treatment alternatives.

As new technology becomes available, treatment protocols will need to adapt to maximize patient benefit while balancing the cost of treatment. Specifically, the role of novel technologies such as drug-eluting stents, absorbable scaffolds, and drug-eluting balloons in long and calcified lesions will need to be studied and applied to the patients that will most demonstrate their benefit. In the future treatment teams will realize that it may not be sufficient to simply tip the balance toward wound healing with revascularization. The role of paclitaxel-eluting balloons in the setting of distal wounds will need to be carefully assessed. While the potential role of atherectomy or controlled angioplasty as a vehicle to increase eluting drug delivery will need to be evaluated and incorporated into future treatment options.

We face an exciting time in the future of critical limb ischemia and wound treatment. I have little doubt that comprehensive CLI programs featuring multiple specialties all working as a unit will become the model treatment delivery system for these complex patients with CLI. Centers of excellence will allow for the development of treatment algorithms and guidelines to increase efficiency and ultimately quality care as defined by both success and value in treatment. More importantly, treatment groups will be able to properly adjust the treatment to the complexity of the patient as well as to the availability of new technology.

As health care begins to focus on processes, guidelines and treatment algorithms in the setting of experienced centers of excellence should demonstrate improved and repeatable outcomes. Multidisciplinary teams will be necessary in order for these centers of excellence to be successful on the local and national level.

Editor's note: Disclosure: The author has completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr. Pena reports consultancy to Boston Scientific, C.R. Bard, and Penumbra, as well as honoraria from Cook Medical.

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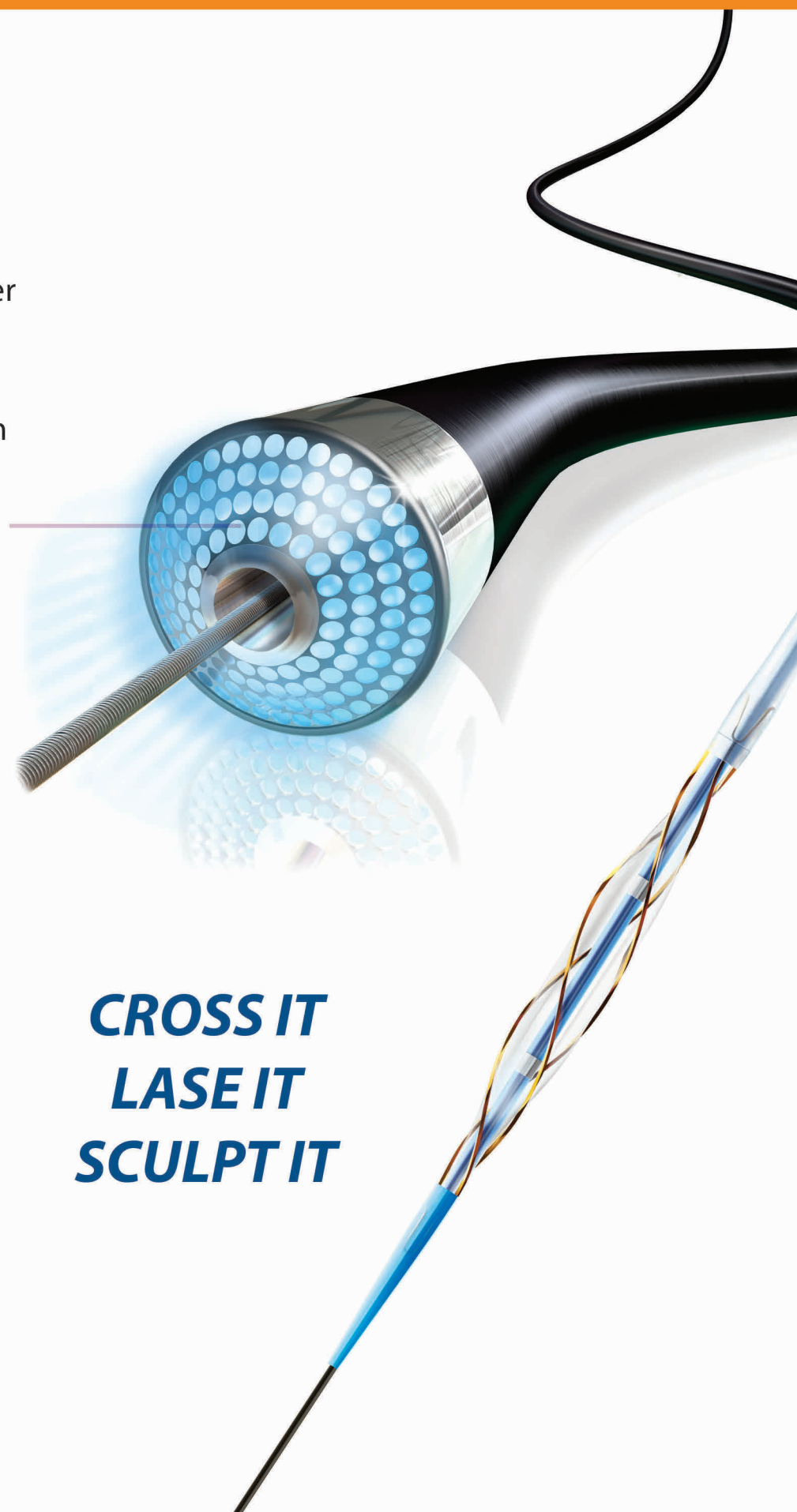

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Establishing a Center of Excellence for Critical Limb Ischemia: A UK-Based NHS Model

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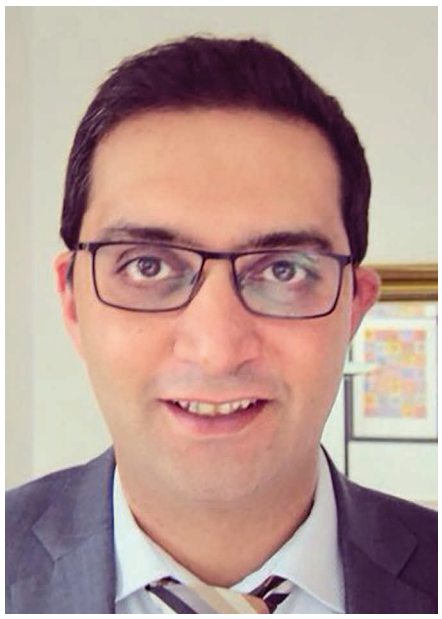

Ounali S. Jaffer, MBBS, MRCP, FRCR

The successful management of patients with critical limb ischemia (CLI) is often complex, but it is imperative from a socioeconomic standpoint. Primary amputation should always be considered the last resort, especially because we know revascularization is associated with lower perioperative mortality, is more cost-effective, and allows the patient a better quality of life. A key component of fulfilling this goal is the establishment of a multidisciplinary model (see figure) in which each subspecialty must have invested stakeholders who can facilitate an integrated care pathway. Within this, each member should have an understanding about the optimum treatments available, both interventional and noninterventional, to deliver a seamless continuum of care. We describe our experiences in establishing such a pathway and the distinct advantages and challenges found within the UK health care system in managing patients with CLI.

In our institution, we have clear access points to consultation from relevant specialties, such as podiatry and endocrinology, so that patients requiring more complex and specialist treatment can be identified early. Our NHS trust (the largest in the United Kingdom) serves an underprivileged population in excess of 2 million people in which diabetes is endemic and life expectancy is lower than the national average.[1] To facilitate clear coordination in an institution so extensive, we have centralized our vascular and endovascular services into a central hub hospital. As a result, we now have an established high-volume center which has better overall outcomes and a robust system for data collection to allow audit and quality improvement, as well as education and research across the catchment region.

As part of our model, we offer formal seminars to those within the multidisciplinary team (MDT) of our peripheral feeder hospitals. This enables our referrers to be informed about evolving treatment options and provides a point of reference to encourage appropriate and timely referral. The breadth of topics discussed extends from simple primary prevention, to the most complex secondary interventions. This approach is supplemented by site presence of our vascular specialists, which in combination, ensures a patient pathway that is fully integrated across primary, secondary, and tertiary care.

Within the tertiary hospital environment, each complex case is discussed at an MDT meeting, which is attended by interventional radiologists, vascular surgeons, anesthesiologists, and vascular sonographers. The collaborative decision making is based on the individual needs of the patient and is guided by the best available evidence, including guidance from the National Institute for Clinical Excellence (NICE). If appropriate, some patients may then be placed into an ongoing clinical trial (i.e. BASIL II).

The vascular MDT meeting is supplemented by a CLI diabetic MDT ward round in which the key elements of diabetes control, sepsis control, vascular insufficiency, pressure offloading, and patient education are targeted. Unlike the vascular MDT, this group will often consist of a single specialist representing each specialty, with emphasis on clear (often binary) decisions and prompt execution. This approach is particularly necessary due to the severity of disease encountered and is arguably critical to ensuring successful outcomes for the most complex endovascular procedures.

Once the patient is discharged from the hospital, continuity of care is maintained through strong links with the community and primary care team and is supplemented by an open-access clinic.

Perhaps a recognized advantage of the NHS model is that there is no financial loss to an individual clinician when offering a treatment that is not within their armamentarium. This negates a potential conflict of interest and allows a truly patient-centered approach. Also, resources in a public institution need to be carefully managed, especially as the basic rules of consumer economics do not apply. Patients with CLI often have multiple comorbidities and disjointed management can have deleterious health cost implications. Through careful negotiation with the budget holders, we have maximized the

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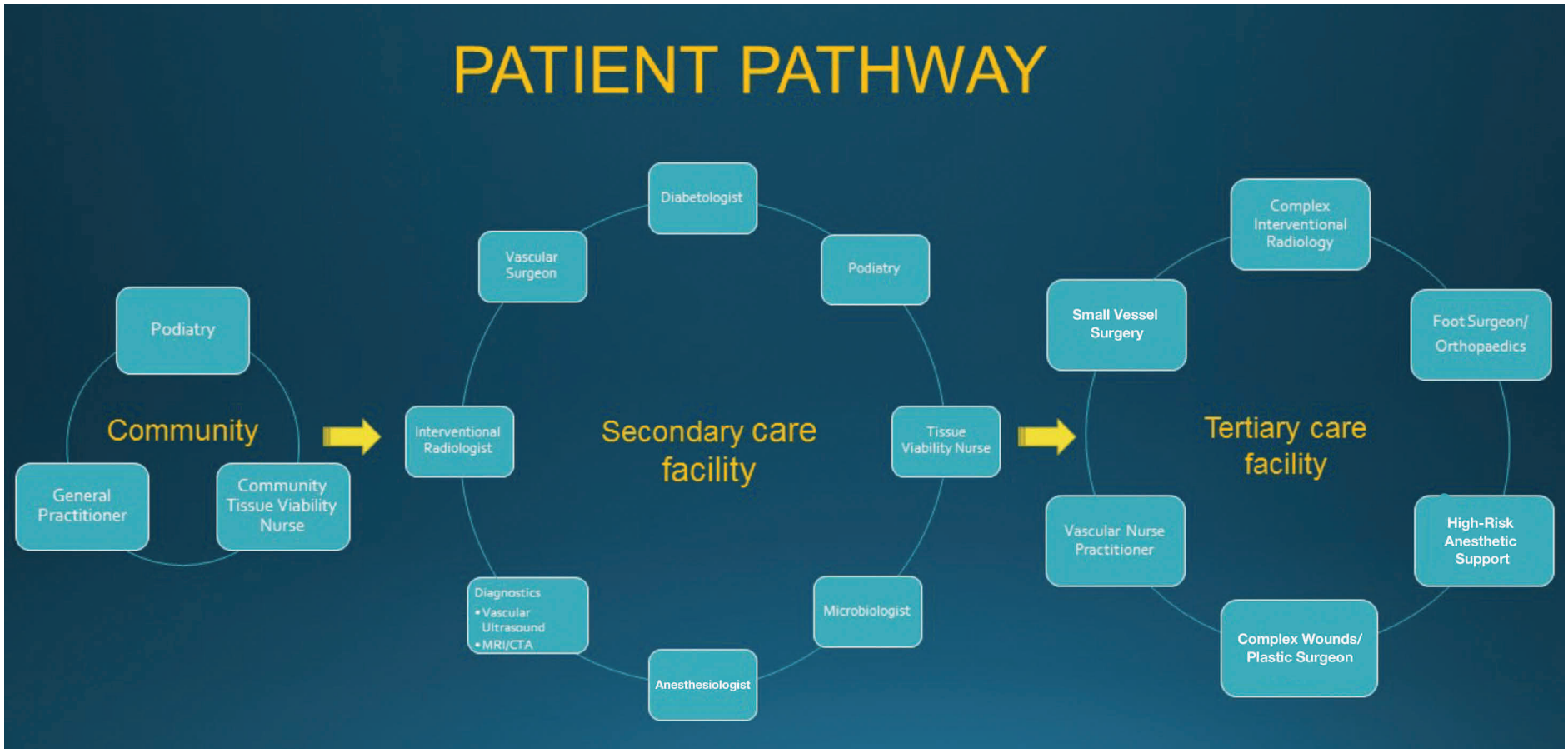

Figure. Multidisciplinary model for critical limb ischema care.

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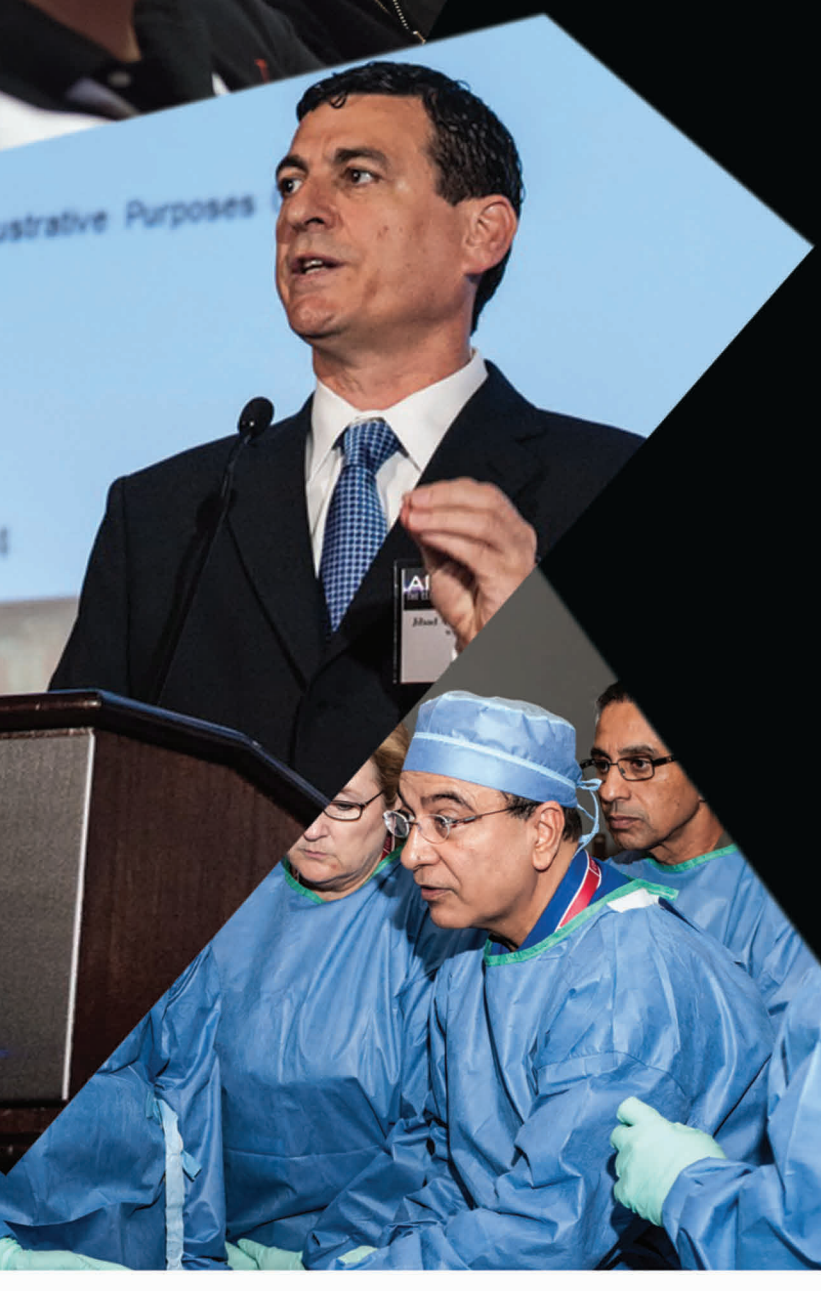

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- Apply comprehensive, multidisciplinary best practice approach for patients with advanced peripheral arterial disease (PAD) and critical limb ischemia (CLI) at risk for major amputation.
- Describe various treatment options (surgery, atherectomy, endovascular therapy) and their application in amputation prevention.
- Treat complex chronic total occlusions in tibial and pedal arterial vessels in the CLI patient.
- Describe arterial angiosome anatomy in conjunction with cutaneous and ultrasonic angiosome mapping in patients with advanced tibiopedal arterial disease at risk for major amputation.
- Implement procedural and technological advances in wound care practices for patients facing major amputation due to PAD and advanced non-healing wounds and gangrene.
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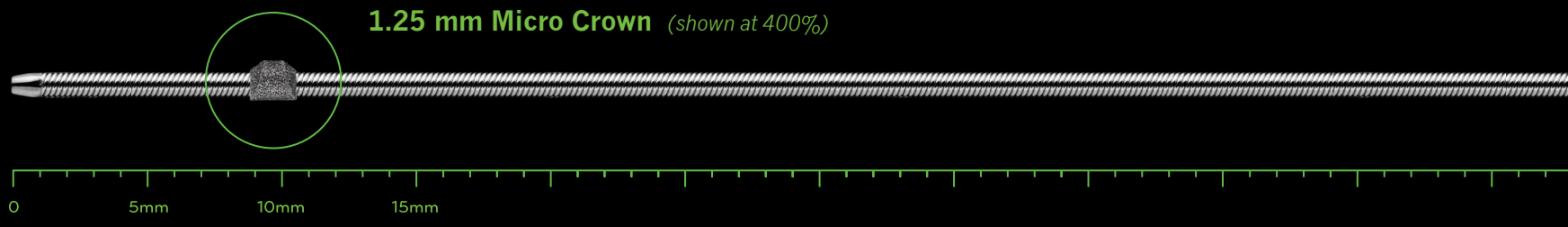

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Case Study*

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lesion in the SFA and popliteal

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Case study courtesy of Jihad Mustapha, MD, Metro Health Hospital-Metro Heart and Vascular in Wyoming, MI. Case study results may vary. Dr. Mustapha is a paid consultant for Cardiovascular Systems, Inc.

UK-Based NHS

Continued from page 8

efficiency of our treatment pathway and cut unnecessary costs.

This has enabled a cohesive model of care that far outperforms those that operate in silos. The key to this might be the engagement of like-minded individuals who have a specialist interest in the management of CLI and are willing to invest the initial time and resources required to set up a working model. The maximization of individual components, be it through procurement, job planning, operating room/cath lab/clinic availability, or team building, can be a somewhat arduous process but ultimately defining in the establishment of a robust working model that is not hampered by a particular deficiency.

Over the last 10 years, there has been a paradigm shift in the treatment of CLI that has been supported by an ever-increasing product portfolio. Since the BASIL trial,[2] we have seen a marked evolution in balloon and stent technology, especially with the advent of drug-eluting formats of both. The need to revisit the most appropriate treatment for patients with advanced Rutherford scores is apparent. A criticism that is often cited is the paucity of high-level evidence for the practices undertaken for CLI. It would seem that prospective randomized multicenter trials (RMT) comparing current surgical and endovascular treatments, inclusive of the newer technologies, would be the only true measure of clinical effectiveness. With a view to this, 2 recently instigated RMTs (BEST-CLI and BASIL II) have begun recruiting to look at the efficacy, functional outcomes, and cost of endovascular therapy vs open surgical bypass in CLI patients. As has been emphasized in the study design for BEST-CLI, it is important to incorporate centers where there is a multidisciplinary approach and the "best treatment" (after randomization) is dictated by the investigator.[3] Given this, it would be most appropriate to include centers in which there is a high degree of familiarity with the latest and more challenging endovascular and surgical techniques.

The need for clear, integrated pathways at national and international levels is arguably more necessary than ever before. A global aim of amputation reduction and improved quality of life can only be met with more succinct coordination between the specialties, which addresses best practice in all stages of diagnosis, treatment, and follow-up.

In the UK, the pooled experience of high-volume tertiary centers with specialty leads would seem the ideal model. These would operate as de facto "centers of excellence" in which the facilities to enable exemplary care can be built into the infrastructure of the departmental workings. These leading centers could then collaborate to help shape national guidelines and algorithms and therefore ensure that patients are within the correct stage of care, be that primary, secondary or tertiary (see figure).

As with many evolving vascular practices, the management of complex CLI, much like complex aortic work, can then be filtered seamlessly into high-volume tertiary centers. This would then enable a more informed contribution to an international standardization of management (in all its aspects), based on unequivocal evidence and learned experience of centers of excellence.

Editor's note: Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no disclosures related to the content herein.

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OLIVE Study

Continued from page 3

highlighting the clinical challenge of wound recurrence.[2] The 3-year recurrence rate after wound healing was 43.9%, and its predictor was CLI due to isolated tibial arterial lesions. This high rate of wound recurrence is considered to be associated with a high incidence of restenosis in the tibial artery after angioplasty.

Three-month angiographic follow-up in the Japanese BElow-the-knee Artery Treatment trial for critical limb ischemia (the J-BEAT angio study) revealed a restenosis rate after plain old balloon angioplasty as high as 73%, which led to recommendations for drug-coated balloons (DCB) for the to initially treat CLI.[3] However, the randomized study of the IN.PACT Amphirion drug-eluting balloon vs standard PTA for the treatment of below-the-knee critical limb ischemia (IN.PACT DEEP), whose results were reported last year, failed to show superiority of DCB compared to percutaneous transluminal angioplasty.[4] Although the reason for this result remains unclear, it might be secondary to heterogeneity in the CLI patient population studied, further underscoring the importance of whole-body control, infection control, wound management, and revascularization treatment by a multidisciplinary medical care team in this case to appropriately test a treatment modality.

Endovascular therapy devices, therapeutic revascularization strategies, and wound treatment after revascularization have been rapidly improving; however, the treatment for CLI has not been standardized as has been the case for other vascular diseases, and here again, the concerted effort of the multidisciplinary medical care team is of paramount importance.

Editor's note: Disclosure: The author has completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The author reports no disclosures related to the content herein.

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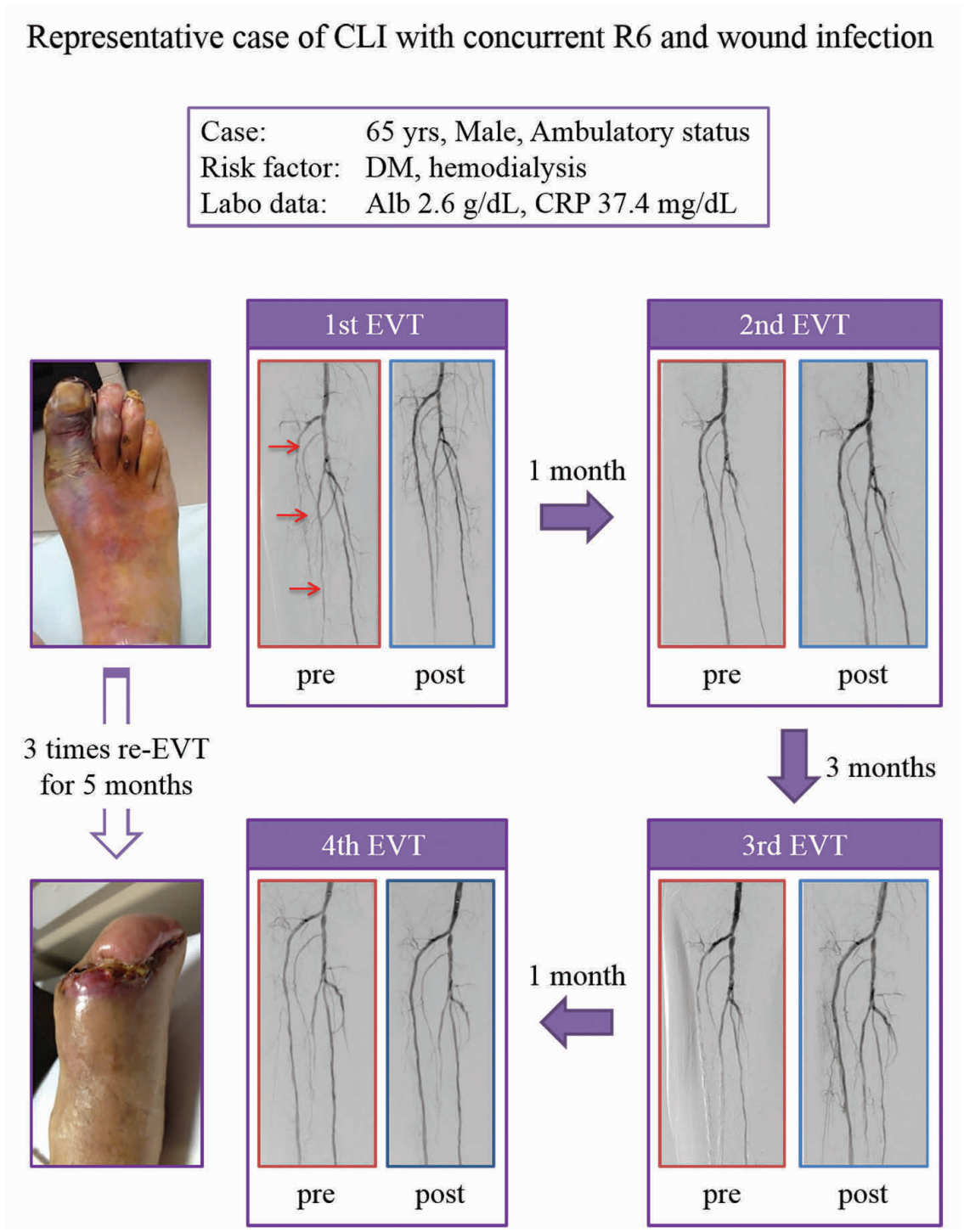

Figure. Critical limb ischemia case with concurrent Rutherford VI status and wound infection.

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Moving to an Outpatient Model for Vascular Procedures

Interview With Arthur Chang Young Lee, MD, FACC

Arthur Chang Young Lee, MD, FACC

Outpatient surgery has long been considered the future of surgical care.

Over the past 3 decades, outpatient surgery has made great strides. From 1981 to 2011, the number of all US surgeries done as outpatient procedures steadily increased from 19% to 60%.[1] Credit for such growth can be spread over serveral areas, including refinements in anesthesia and pain medication, advancements in diagnostic imaging and surgical technique, and changes to insurance reimbursement policies.

But, it seems the future of surgical care is now. Over 30 million nonelderly Americans will be eligible for health insurance over the next 2 years on the strength of the Affordable Care Act, followed by an additional 25 million each year from 2017 through 2024.[2] As a result, steeper inclines in outpatient procedures are not just expected – they're practically required.

The growing number of ambulatory surgical centers (ASCs) should help the healthcare system meet the demands of the upcoming influx. Obviously, ASCs should create more options for patients, but even better, ACSs could offer more efficient, patient-friendly care at lower costs.

Munnich and Parente recently found that ASCs perform more efficient surgeries than hospitals.[1] Using 4 years of CDC data from 52,000 surgical visits, the researchers determined that procedures performed in ASCs take 31.8 fewer minutes than those performed in hospitals, which equates to about 25% less time relative to the mean.

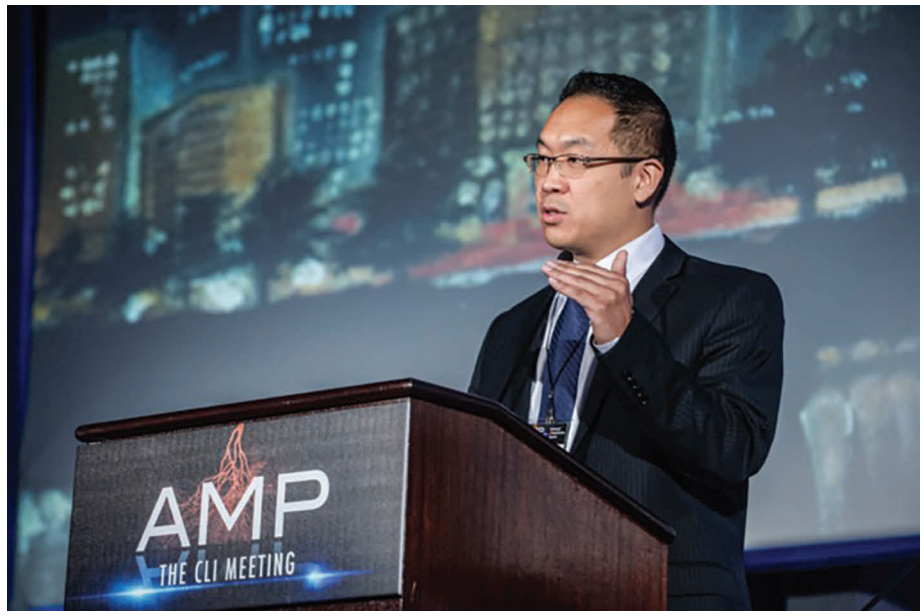
Less time in surgery means an enhanced ability to meet growing demands, but it also means lower costs. Earlier this year, the US Department of Health and Human Services Office of the Inspector General estimated ASCs have saved Medicare more than $1 billion in each of the last few years, and even greater savings are expected.[3] It is estimated that ASCs have the potential to save Medicare and its beneficiaries up to $57.6 billion over the next decade.[4]

Vascular Applications

It wasn't long ago that this news would have meant little to vascular specialists. Arthroscopies, endoscopies, cataract removals – these are the types of procedures that are normally viewed as outpatient. But now, with the incredible innovations in minimally invasive tools, not to mention bailout devices like coverage stents and aspiration catheters, outpatient surgery is becoming an increasingly common part of the vascular landscape, especially since atherectomy codes were approved on an outpatient basis 3 years ago.

"Up to that point, we were doing most of our interventions in the hospital, but we've had an outpatient lab since 2003 doing diagnostic, coronaries and peripherals, and occasional peripheral interventions," said Arthur Chang Young Lee, MD, FACC, of The Cardiac & Vascular Institute in Gainesville, Fl. "2011 was a big transition year, and since then, we've been doing most of our procedures in the outpatient lab."

Lee estimates that his center performed artherectomies on 200 patients in 2012 and 300 patients in 2013, but that those numbers have begun to taper this year due to improved access to new technologies like drug-coated balloons and drug-coated stents. And although it's natural to assume doing these procedures in an outpatient setting would be more challenging, Lee has found the opposite to be true. His thoughts illuminate the findings of Munnich and Parente related to efficiency of care in ASCs.



"Really, we find it a lot easier to do procedures in our office from every aspect in terms of scheduling, control, getting the equipment we want to get, and getting the staff that is well trained to do peripheral work vs at the hospital," he said. "Not that they are not trained well in the hospital, but they're doing mostly cardiac procedures, so when we do a peripheral procedure, they're not familiar with the atherectomy devices and how to activate them … Here, they are much easier to do, and the staff is more proficient with the devices."

Satisfaction, Safety, and Success

Unsurprisingly, ASCs can lead to greater patient satisfaction and safety. ASCs offer seamless and timely "one-stop-shop" care – patients aren't being carted all over a hospital and they will never be pushed back or bumped due to an emergency as can often happen in a hospital setting. And then there's the ability to recover at home, increasing comfort and avoiding the risks of a nosocomial infection, which is a risk at even the best of hospitals.

"Patients love avoiding the hospital – avoiding anything to do with the hospital, really," said Lee. "The office lab is service oriented, so it's just more user-friendly for them all the way around."

For any vascular specialist considering adding an outpatient lab to their facility, Lee recommends being prepared for the task both in terms of staffing, expertise, and equipment.

"Definitely gain familiarity with the procedures and the devices in the hospital setting with other operators around you so that you're not dealing with learning-curve complications in the outpatient setting," he said. "Make sure you have the right equipment to get out of trouble, even if it's rare. Having the right equipment, the right staff, the right imaging equipment, good quality equipment – those are all the tips."

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"Pre CLI": Aberrant Point in the Time Continuum or Oversight of the True Beginning Stage of Critical Limb Ischemia?

J.A. Mustapha, MD; Larry J. Diaz-Sandoval, MD; Fadi Saab, MD

Critical limb ischemia (CLI) is a complex entity, best described as the chaotic expression of the atherosclerotic process affecting the arterial circulation of the lower limbs. We have long been taught that atherosclerosis behaves in a deterministic fashion, and therefore can be predicted and modulated with adequate risk factor modification, early detection and early treatment. However, according to the theory of chaos, these behaviors are only predictable for a while and then appear to become random. According to this theory, a small change in the initial condition of the system can cause a chain of events that lead to large-scale phenomena (the "butterfly effect").

Despite the fact that well described risk factors are known to eventually determine the future outcome of peripheral artery disease, small individual variations or factors (i.e. trauma, infection, embolism, noncompliance, etc.) can widely alter the time line of disease progression through the different stages of severity, affecting different patients in different ways, in a non-predictable pattern. Some patients present with acute limb ischemia without any previous complaint of claudication. Some patients have progression of their claudication symptoms until they develop pain at rest. There is no clear way to predict which patient will have which presentation.

As endovascular therapies for peripheral arterial disease (PAD) continue to evolve, so does our diagnostic approach, leading to the not uncommon identification of patients whose anatomy appears to be incoherent with their clinical presentation and Rutherford classification. These patients tend to present with waxing and waning atypical symptoms, which do not allow the clinician to make a confident determination as to whether they have "advanced PAD" (Rutherford III), with short distance claudication, or early CLI (Rutherford IV), when they describe "occasional" episodes of rest pain or "leg fatigue."

This description of the reigning landscape serves to pose the question that clearly depicts the conundrum faced by the vascular specialist in 2015:

Is it time to define the "pre-CLI" stage, its features, and an algorithmic approach to diagnosis and treatment, or should these patients continue to be haphazardly categorized as early Rutherford IV or advanced Rutherford III? It would appear that in the modern era, with the currently available knowledge and tools for noninvasive & invasive evaluation, the time has come for us to call a spade a spade.

Bringing this diagnosis to the forefront would add significant value for those patients who are currently hovering in the black hole typified by the poorly defined space between "advanced Rutherford III" and "early Rutherford IV." It is time to conquer this uncharted territory and to provide these patients with a more accurate classification.

Patients with pre-CLI tend to present with multilevel and multivessel chronic total occlusions (CTO; typical anatomical hallmark of CLI), yet with clinical features that intermittently resemble symptoms consistent with both Rutherford III and IV classifications (see figure). Analysis of the vascular anatomy in such patients reveals the presence of occlusions and collateral clusters that appear to predominate in 3 major areas of the infrainguinal arterial tree:

1. The first collateral cluster originates from the profunda, as the descending branch from the lateral femoral circumflex weaving a network with the lateral superior genicular artery. This cluster is most commonly seen in patients with severe stenotic/occlusive disease in the femoropopliteal segment.
2. The second collateral cluster is formed by the anastomoses of the superior and inferior medial and lateral genicular arteries around the knee joint, most commonly feeding the proximal third of the anterior tibial via the circumflex fibular and the recurrent tibial arteries. Occasionally these genicular collaterals extend through the entire length of the leg to the level of the tibial-pedal junction, reconstituting the distal third of the tibial arteries above the ankle joint.
3. The third cluster develops from branches that arise from the proximal tibial vessels and reconstitute in a variety of arrays both above and below the ankle.

Vascular specialists caring for CLI patients are familiar with the aforementioned inconsistent presentations that characterize the pre-CLI stage, as well as patients with similar vascular anatomy who present instead with advanced tissue loss and gangrene. This seemingly antagonistic dichotomy is the driving force behind this article; we struggle with the current passive approach, which (in the majority of cases) leads to delay in appropriate care.

Patients with pre-CLI features should be thoroughly evaluated and treated with aggressive current optimal medical therapy, exercise and walking regimes and close clinical follow-up. For patients who fail to improve clearly, expeditious attempts at revascularization (through surgical or endovascular means) are recommended.

Our common goal is to raise awareness among vascular specialists and health care teams in general of this increasingly common presentation of patients with the typical risk factor profile, who have intermittent claudication symptoms that wax and wane in severity (therefore intermittently corresponding to Rutherford III and IV categories), fail to improve with aggressive non-invasive therapies, and are shown to have multilevel and multivessel CTOs. For these patients we propose the recognition of the pre-CLI stage, which should give the same urgency that we give to the patient who presents with declared Rutherford V and VI class features.

With regard to the underlying mechanisms responsible for the seemingly chaotic transition of patients from one stage to the next, several hypotheses have been proposed, including embolization of tibial and pedal vessels, as well as the last standing collaterals. The common denominator through all these stages is the fragile equilibrium in which the limb resides at any given point, which is constantly threatened and can be easily broken with potentially catastrophic outcomes.

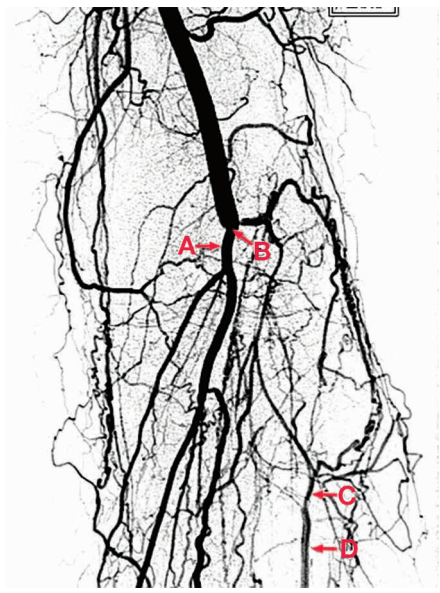

Figure. Large genicular collateral (A), P2 segment of the popliteal (occluded) (B), genicular branch (recurrent anterior tibial branch) (C), anterior tibial artery (D).

Understanding of this paradigm is essential for the health care community to become proactive in the management of these patients with the goal of avoiding minor and major amputations.

In summary, pre-CLI constitutes an increasingly frequent presentation of patients with advanced PAD. It is currently underdiagnosed, as it does not fit in any of the one-size-fits-all categories that vascular specialists and their teams are used to, and hence the condition is undertreated. Clear algorithms for the diagnosis and management of this group of patients are needed, and therefore clinical data is warranted. The clinical recognition and adequate contemporary management of the CLI spectrum must continue to move forward in an engaged and proactive fashion to meaningfully improve patient outcomes.

"Global standards for critical limb ischemia care will provide the foundation for recognition and treatment, thus unifying a multidisciplinary group focused on amputation prevention."

—George Adams, MD, MHS
Rex Healthcare, Garner, North Carolina

George Adams, MD, MHS

A Unique Amputation Prevention Clinic

Interview With Raymond Dattilo, MD, FACC

Raymond Dattilo, MD, FACC

Outpatient clinics can have an array of benefits, but if you talk to enough vascular specialists who are experienced in their operation, one perk you'll hear over and over is the opportunity for enhanced control.

Usually, that refers to scheduling, availability of equipment, and the ability to offer timely, streamlined care, because the pre-op room, the lab and the recovery area are in close proximity to one other. But Raymond Dattilo, MD, owner of the Flint Hills Heart, Vascular and Vein Clinic in Manhattan, Kansas, has taken the concept of control to a whole new level by integrating a wound care clinic into his vascular practice.

"The objective was to have complete control over the patient with critical limb ischemia, both on the wound site — the topical therapy — and also on the vascular side," Dattilo says. "I think that makes my clinic somewhat unique, but I feel like it is a more cohesive experience for the patient."

It also may be safer for them as well, because it helps ensure proper management of complications.

"Often we treat the vascular side, and we leave it up to the patient and the wound clinic to take care of treating wounds," Dattilo says. "I have found that it was not always done efficiently, and then patients would come back to me and I would have to do additional vascular interventions."

Having a wound center within his clinic allows Dattilo to interact more with his patients when they come in for follow-up treatments and dressing changes, meaning he's quick to catch regressions in the healing process. As a result, he can promptly correct any issues, resulting in better patient outcomes and less drastic measures like amputation.

"I can quickly address that and order a vascular ultrasound, which I'll do at my clinic, and then do an arterial intervention if there's been a closure of the vessel," he said. "When patients go to other centers for their wound care, the communication is not quite as good and as immediate, so a lot of times the wound healing will stagnate and I won't know about it until a month or two later."

Dattilo's wound clinic is more than an additional service populated by his previous vascular patients. It's a comprehensive endeavor that includes a hyperbaric chamber, debridement devices, and a certified wound care nurse. In fact, many of his new patients first come to Flint Hills Heart, Vascular, and Vein Clinic for wound treatment, which has resulted in

patients getting help for vascular issues much earlier than they normally would.

"For years I've had to spend time educating physicians about the connection between vascular disease and wounds, particularly in the case of diabetics," says Dattilo. He explains that typically, patients with diabetes have a wound and are sent often to a general surgeon and end up with amputations.

"Having the wound center in my clinic … takes a little bit out of the equation. There's no necessity for all the referring doctors to really understand the relationship between the ulcers that they see and the vascular disease, because they just send them to my wound clinic.

"They're not referring them to me for vascular evaluation, but I see them in the wound clinic because I run the wound clinic. So I get the vascular evaluation, and, of course, the majority of them have arterial disease that ends up needing intervention."

Dattilo has experience with other benefits to working in an outpatient setting as well. Although he initially feared he might not be able to work with complex patients, Dattilo says he has not turned any patients away and that they have all gone home the same day. He credits this success to a reduction in complications related to his lack of limitation when it comes to closure devices.

"The goals between the physician like myself and the hospital do not always align 100 percent," Dattilo says. He explains that due to costs, hospitals may prefer not to use closure devices on every patient, but in his clinic he uses closure devices on each patient.

"I use suture-based and non suture-based closure devices, and I think that's critical to making sure they get home and we don't have any late bleeds at any of the puncture sites."

As Dattilo sees it, no matter which process improvements you consider, the bottom line is that all of them lead to improved patient satisfaction.

"Patient satisfaction has been enormous compared to their experience with similar procedures in a hospital-based setting," he said. "I think it's possible to deliver a higher quality product when you do it through a clinic of this nature, and that's been something I've enjoyed very much."

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www.cvcpvd.com

5th Annual Amputation Prevention Symposium
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Transcatheter Cardiovascular Therapeutics (TCT)
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www.crf.org/tct

VIVA 2015: Vascular Interventional Advances
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Critical Limb Ischemia Centers of Excellence: The Latin American Perspective on Global Standardization of Therapy

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Critical Limb Ischemia (CLI) represents the terminal stage of peripheral arterial disease (PAD), and is best described as the chaotic expression of the atherosclerotic process affecting the arterial circulation of the lower limbs. Despite the fact that well described risk factors are known to eventually determine the future outcome of PAD, small individual and regional variations (personal, social, cultural, political) can widely alter the timeline of disease progression through the different stages of severity, affecting different patients in different ways, in an unpredictable pattern. Patients with CLI typically present with multivessel and multilevel disease spanning from the origin of the aortoiliac junction to the tibial and pedal circulation. If we consider the plethora of data to be interpreted when simply describing the vascular tree, one cannot help but wonder about the overwhelming magnitude and depth of clinical evaluation (risk factor management), noninvasive and invasive testing (diagnostic and surveillance), revascularization strategies (endovascular & surgical), wound care, and ancillary management (coordination with infectious disease, plastic surgery, orthopedists, orthotic specialists, podiatrists, nutritionists), that should be done or implemented when treating a CLI patient.

The contemporary treatment of patients with CLI is complex due to the multifaceted disease and the fractures in our current practice workflow, whereby different specialists treat the CLI patient in an isolated fashion, taking care of only one aspect of the patient's disease. However, it is becoming clear that this approach misses the big picture represented by the need of a simultaneous, multidisciplinary approach.

In Latin America, this problem is further compounded by the difficult access to health care, which is a rather vast and heterogeneous issue that varies widely among countries but shares some common deficiencies. In these countries, CLI continues to be seen by most physicians as the result of the classical progression of poorly controlled diabetes, and until recent years it was accepted that amputation was the best strategy to manage these patients. Over the last few years, a proliferation of talented physicians have pursued training and acquired experience in the management of complex CLI patients and are leading national and regional initiatives to bring CLI to the forefront and create significant changes in outcomes. This movement is based on the understanding that, as of 2015, the management of CLI should include revascularization as the mainstay of therapy, complemented by a host of non-interventional therapies delivered simultaneously by an experienced team with seamless communication and patient transitions in order to maximize efficacy and outcomes.

We believe that this treatment can only be provided efficiently through the creation of state-of-the-art CLI Centers of Excellence (CLI COE), which should provide a comprehensive program that focuses on the clinical outpatient evaluation and its integration with noninvasive and invasive testing, revascularization procedures, and appropriate follow-up, including rehabilitation services.

A critical part of the process is to continuously deliver education to all potential members of the health care community that are likely to see patients with CLI, such as primary care providers, podiatrists, endocrinologists, nephrologists, orthopedists, infectious disease, orthotics specialists, as well as nurse practitioners and physician assistants to expedite the process of referral to the vascular specialist and the CLI COE team. Once a patient is referred, a series of tests should be performed in order to diagnose the extent of disease, plan the therapeutic revascularization strategy, and to serve as baseline for future surveillance studies. After complete revascularization, the patient should continue to be followed by all members of the team to ensure complete healing and post-healing surveillance. A high index of suspicion with a low threshold to repeat revascularization should be considered to minimize potential complications and increase the likelihood of permanent positive outcomes. Unfortunately, in the United States (and Latin America as well) current protocols in clinical practice are not designed to function in this manner, and display several weaknesses:

1. Generally, patients only are referred to the vascular specialist after months of failed wound therapy or repetitive visits to the podiatrist for serial debridements without improvement.
2. There are ingrained referral patterns to specialists who are not trained in the latest revascularization techniques, leading to frequent amputations without even an angiographic evaluation.
3. Among patients properly referred to well-trained vascular specialists, only a very small fraction returns for follow-up after revascularization. At best, they follow up with only the local wound clinic, which is not affiliated with the system where the intervention was performed, and therefore the providers are not familiar with the latest techniques and advances.

Due to this lack of communication and coordination, when the patient finally comes back, often the situation is worse than it was at the first encounter. Overall, there is a widespread lack of knowledge and attachment to old ways that need to be overcome. Unfortunately, data-driven clinical studies to evaluate strategies for surveillance; use and duration of antiplatelet therapy, anticoagulants, and other risk-factor-modifying agents; noninvasive testing; and indications for repeat revascularization in these patients do not exist. Current data have been derived from retrospective studies with inconsistent reporting standards, which has led to a paucity of evidence regarding endovascular revascularization in CLI. The creation of CLI COE would enable data collection from high-volume centers, which would aid in the creation of guidelines and protocols that are evidence based, because the collection of randomized, multicenter data to answer these questions is unlikely to happen in the near future.

CLI Centers of Excellence: Should Every Hospital Have One?

Although the idealistic answer to this question is yes, one must stop and consider all the real challenges that are involved in treating the CLI patient. As previously mentioned, these patients typically have multilevel and multivessel disease and will require the performance of multiple procedures in both lower extremities to establish direct in-line blood flow to the feet in patients with tissue loss.[1] They also tend to present with multiple and complex comorbidities such as poorly controlled diabetes, end-stage renal disease, and advanced congestive heart failure, which require the availability of multiple specialists and infrastructure to address all of the patient's needs. The revascularization procedures to treat complex, severely calcified, and long chronic total occlusions (CTOs) still tend to be time consuming. Operators and the team must be proficient and posses a highly refined set of skills in order to achieve technical success, which is the first step on the long ladder that leads to the successful treatment of the CLI patient and ultimately to amputation prevention. The other steps are represented by the input from each of the other members of the team, including the program coordinator, who should be responsible for design workflow protocols that allow the seamless transition of care between specialists, to provide the patient the best care and likelihood of a successful and permanent positive outcome.

As can be seen from this complex algorithm, the CLI therapist must almost exclusively be dedicated to treating these patients, which raises the question as to whether this should be a new subspecialty. To be able to efficiently perform all these tasks, this physician must develop the needed expertise, which is unlikely to occur while performing only 1-2 procedures per month. The future CLI therapist must constantly be driven to learn new technologies and techniques, maintaining abreast of the wealth of data that continues to emerge, while continuing to improve existing skills.

Protocols

A provider should refer CLI patients should for evaluation by the vascular specialist within 24 to 48 hours of the first contact. Protocols and algorithms that govern timing of clinical and diagnostic evaluation (depending on severity and acuity of presentation) as well as planning of the revascularization strategy should be created. One of the most important aspects of the care of CLI patients is the creation and execution of follow-up

protocols that control how often these patients need to be seen and objectively re-evaluated with noninvasive testing after revascularization is deemed complete. A high index of suspicion with immediate referral for repeat selective angiography and/or intervention should be the center of this follow-up strategy.

Recommended Criteria for CLI Centers of Excellence

For the reasons aforementioned, standards should be set in an effort to guarantee quality and improve outcomes. The following elements are recommended to start a successful CLI COE:

- Institutional volume of at least 100 CLI procedures per year.
- Operator volume of at least 50 CLI cases per year.
- A CLI revascularization team that includes at least 2 operators to provide 24-hour coverage. The team should include endovascular and surgical vascular specialists as well as highly trained cath lab personnel (nurses, cath lab and ultrasound techs, physician assistants and other ancillary staff).
- An outpatient CLI team that includes outpatient nurses, schedulers, and midlevel providers who monitor patient flow and progress in an outpatient setting. This unique group of individuals needs to be trained in CLI-related protocols, evaluation of wounds and bedside performance of the ankle-brachial index, for them to understand the urgency and correct prioritization for these patients.
- A CLI program coordinator to oversee the workflows related to CLI care, which can only be accomplished successfully if all the stakeholders involved (the patient and family, vascular specialist, primary care physician, podiatrist, wound care and infectious disease specialist, endocrinologist, nephrologist, nutritionist, orthopedist, orthotics and rehabilitation specialists) are able to work together seamlessly. This person will establish and update protocols to improve efficiency (by early detection and correction of problem areas) as well as institute screening and educational programs for the community and physicians in and out of the center's network to increase awareness and promote amputation prevention.
- A scientific review committee, with the purpose of reviewing CLI cases. This should be done under the format of a vascular conference where the clinical, noninvasive, and invasive imaging data are discussed among the members of the team to elaborate a therapeutic plan. Decisions regarding endovascular vs open vs hybrid approaches occur in this setting. This forum is also intended to review short-term outcomes (to correct any detected deficiencies in the system) and to incorporate emerging technologies in an educational environment designed to foster a continuous learning model.
- A quality committee that tracks mid- to long-term outcomes and adverse events to create mechanisms that enable the necessary corrections to occur in a timely fashion. Examples of the quality metrics being measured include rates of blood transfusion and incidence of contrast-induced nephropathy.
- A proctorship program in which experienced physicians can train new generations of CLI therapists.

The idea behind establishing criteria based on number of cases revolves mainly around identifying adequate practice patterns and maximizing physician skills. While the number of procedures performed does not necessarily translate into successful outcomes, there have been a number of trials that suggest a relationship between improved outcomes and higher case volume for coronary angioplasties.[2,3] In patients with CLI, the "endovascular first" approach has been proven to provide excellent results in terms of limb salvage. However, these results differ between single-center and multicenter studies and the lack of experience of some of the centers has been proposed as a potential cause for this disparity.[4] When we consider the complexity (multilevel, multivessel, long and heavily calcified CTOs) of the arterial lesions found in as many as 74% of the CLI patients, it becomes clear that high-volume centers with expertise are more likely to obtain better long-term outcomes.[5]

Summary

The pathophysiology of CLI is complex and involves both micro- and macrovascular pathology. Therefore it is not surprising that therapeutic modalities are multifold, spanning many health care specialties and requiring substantial institutional infrastructure to provide optimal patient care. Though challenging, the future of CLI treatment is exciting with increasing focus on optimal wound care and prevention, adherence to proven medical therapies, improving revascularization results with novel endovascular and surgical techniques and devices, and ongoing investigation into promising therapies like therapeutic angiogenesis. Of paramount importance is the creation and establishment of CLI COE, with aggressive referral upon identification of skin breakdowns or any other factors that can predispose the CLI patient to a rapid decline and compromised prognosis. As the incidence of CLI is expected to continue climbing in years to come, the creation of CLI COE is a concept that should be brought to the forefront, as it will require the commitment of several stakeholders. The collection of registry data from these centers would help to create guidelines and protocols to standardize the treatment of CLI, which should, to the best of our abilities, cross social, political, and cultural barriers in the same way that CLI does not discriminate in taking limbs. The recommendations presented here constitute an early attempt at getting the ball rolling as we understand that there are many limitations at many different levels (local, state, national, and international). However, we should all learn to adapt to our different realities, and mold the clay our way, in an effort to globally unify strategies to be able to conquer and defeat the menace that CLI represents across the globe.

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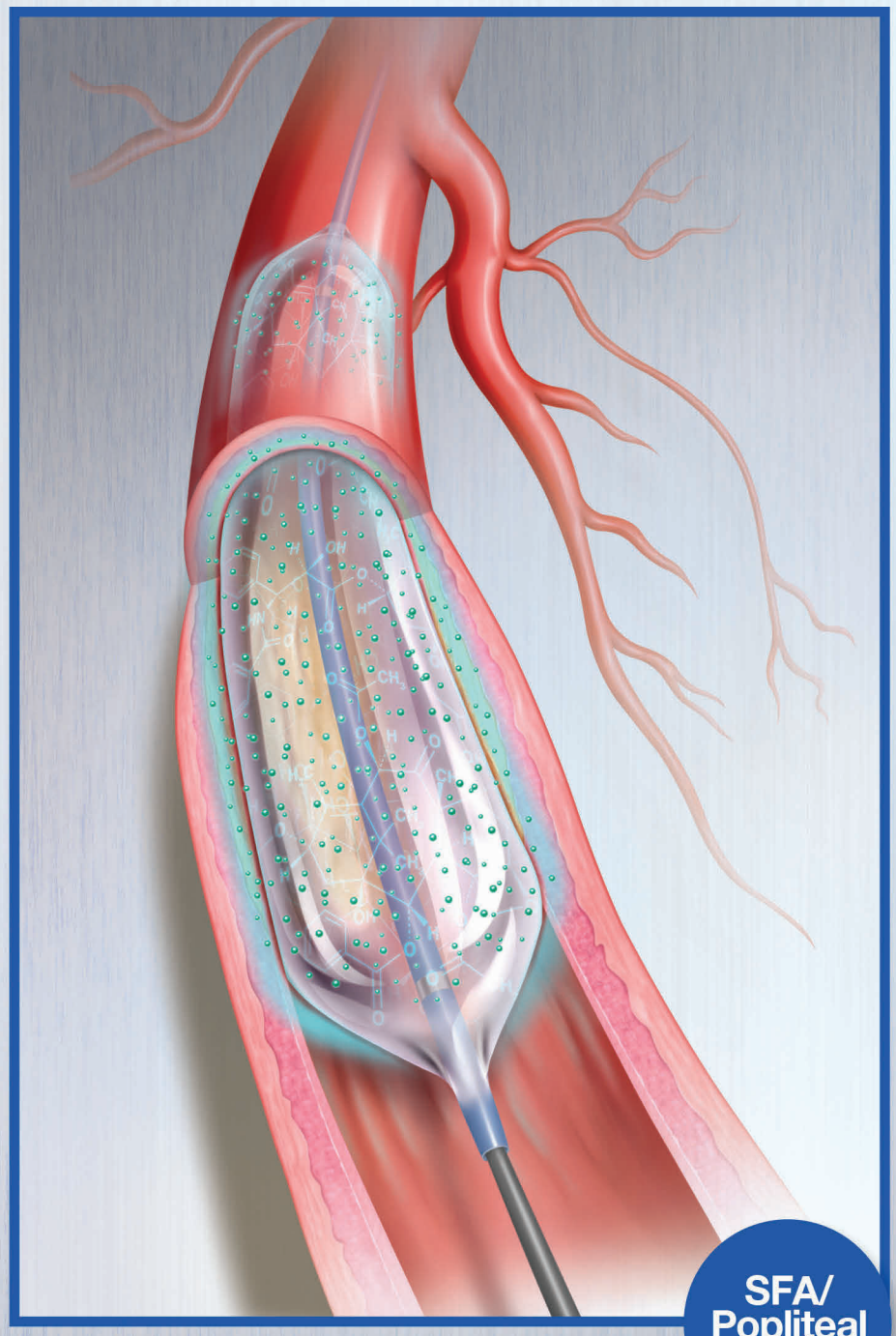

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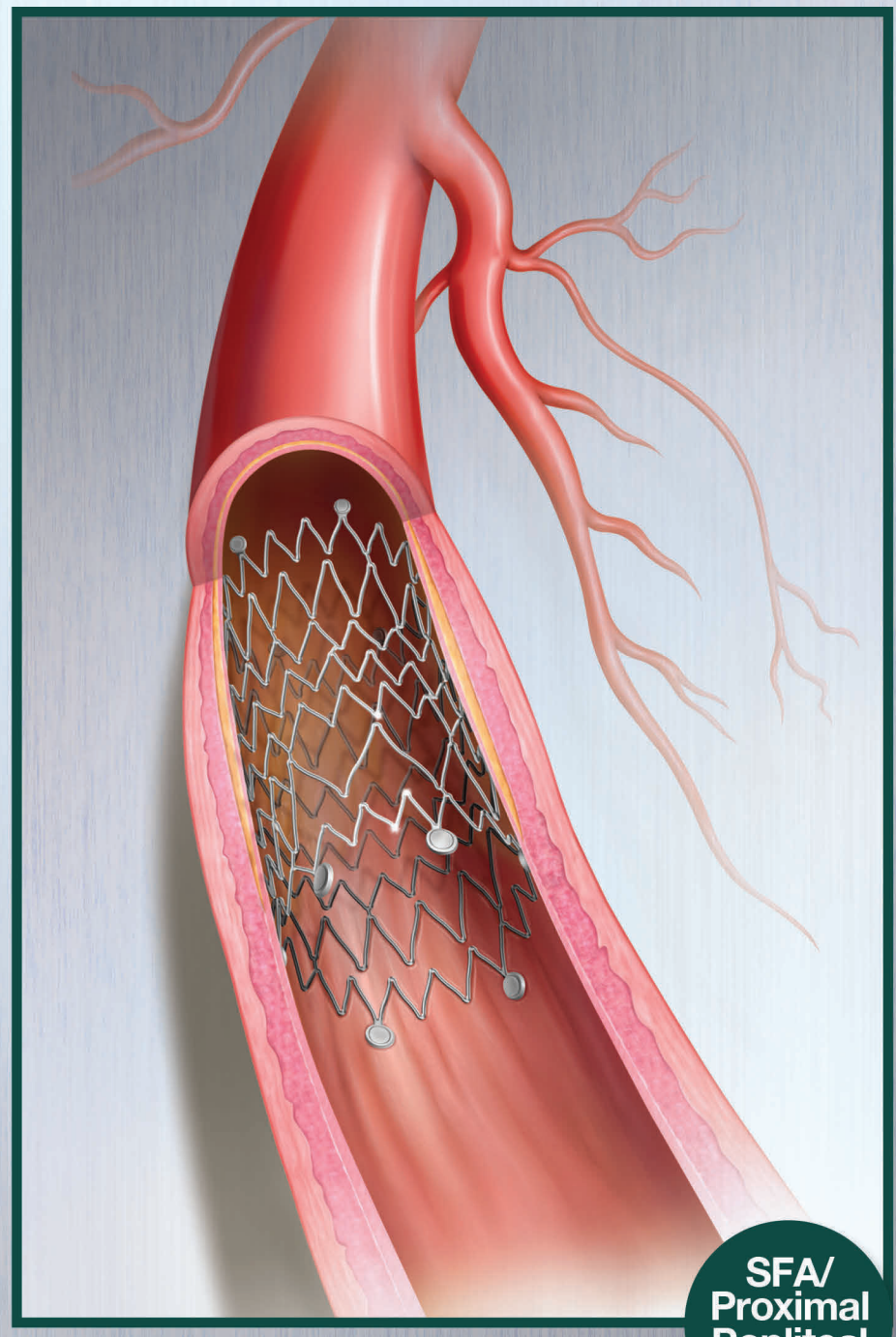

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