Outpatient CLI Revascularization in the United States

The benefit of office interventional suites to the complex and at-risk CLI patient.

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This year in the United States, approximately 160,000 to 180,000 of the estimated 18 million Americans with peripheral artery disease (PAD) will undergo amputation of a limb as a result of PAD-related complications. An unacceptable amputation rate of > 30% without any vascular evaluation persists, despite the education and attention given to critical limb ischemia (CLI).[1] Epidemiologic studies have shown that there are differences in outcomes based on access to care and revascularization.

Fortunately, the treatment of CLI with revascularization is becoming more widespread, and the interest in comprehensive team-based limb preservation programs is growing. This parallels the marked growth of office interventional suites (OISs) throughout the country. These OISs (also known as *office-based labs*) can often provide treatment for CLI in a more time- and cost-efficient manner while maintaining safety outcomes on par with patients treated in the hospital setting.[2] Endovascular revascularization in OISs can help bring safe, effective, and appropriate therapies to a complex and at-risk CLI patient while improving access to care.

PAD AND CLI: THE EPIDEMIC AND THE IMPERATIVE

Improvements in technology have allowed for the migration of revascularization services from the hospital setting to same-day interventions in the office setting. Care in community-based, freestanding office facilities focuses on providing endovascular revascularization with minimally invasive techniques and offers a cost-efficient, patient-preferred alternative site of care for patients. In many cases, these freestanding office-based vascular care centers are located in geographically convenient areas and offer reduced wait times for treatment, making quality vascular care more accessible for patients in need.

Although challenges related to PAD and CLI treatment exist, current technologies are available that not only help diagnose PAD, but also help to treat it. Outpatient interventions, such as angiography and endovascular revascularization, that employ the various technologies available have helped decrease the incidence of major amputations by 75%.[3] Data suggest that increased accessibility to peripheral vascular intervention in the community setting may have contributed to the reduction in lower extremity amputations for patients with severe lower extremity PAD in the United States. According to one study, the rate of lower limb amputations among Medicare patients in the United States decreased by 45% from 1996 to 2011; during this time, endovascular treatment options and beneficiary access measurably improved.[4]

The accessibility of care in the community setting is also vital to addressing racial, geographic, and socioeconomic disparities that exist among the PAD patient population. For example, PAD is more common in African Americans than any other racial or ethnic group because conditions that increase the risk for developing PAD (eg, diabetes, high blood pressure) are more common among African Americans.[5] Data also show patients from a minority group are much less likely to receive preventive and therapeutic vascular screening and procedures.[6] Among PAD patients spe-

cifically, minorities are less likely to have limb-sparing procedures, such as angioplasty and lower extremity bypass, and more likely to undergo amputation.[7] In addition to these disparities in care, there is still an unacceptably high rate of amputations among all patients with CLI.

Leaders from the vascular care community, including care providers, physicians, patient advocates, and manufacturers, have come together to form the CardioVascular Coalition (CVC) to advance community-based solutions designed to improve awareness, prevention, and intervention of vascular disease with a primary focus on PAD and amputation prevention. In conjunction with the CVC, the Outpatient Endovascular and Interventional Society (OEIS) is developing policies designed to reduce lower-limb amputations by ensuring patients receive arterial testing and therapy, if indicated, in advance of nontraumatic, nonemergent amputations. Together, we must all do more by working to strengthen limb preservation efforts in the United States.

OFFICE INTERVENTIONAL SUITE VERSUS HOSPITAL FOR CLI TREATMENT: ACCESS TO CARE

The complex nature of CLI dictates that patients with CLI are typically the most demanding, time-consuming, and resource-intensive cases. Many of these patients are not only very sick, but also require treatment in an expeditious fashion. Many are elderly and have diabetes and advanced or end-stage renal disease, which means coordination of care is essential. Care coordination can often be more expeditiously achieved in the outpatient setting than in a large, complex, often fractionated hospital environment. Some of the basic differences between the two approaches based on our experience are presented.

In an OIS that focuses on the treatment of patients with CLI, resources will be devoted toward the streamlined treatment of patients. If the physician in an OIS setting decides that a patient requires urgent treatment, she/he will simply make that determination, and the patient receives prompt and timely therapy. In many hospitals, the patient is often at the mercy of a scheduler who has many impediments and often little to no incentive to facilitate this coordination. Additionally, the hospital staff has the challenge of accommodating the needs of multiple physicians, groups, and specialties.

There has been a perception that operators in an OIS "cherry-pick" straightforward cases from the hospital when, in fact, the situation in most OISs is exactly the opposite. To perform very complex cases, new and innovative technology is often needed. Our experience is that it is often much easier to obtain new devices and offer an array of needed technologies in an OIS than in a hospital, particularly when the hospital is part of a larger system. Many experienced operators in the OIS setting are more comfortable treating a complex patient in the office because of the availability of experienced and dedicated staff.

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To highlight safe, effective, and patient-focused decision making in the OIS in a real-world CLI patient, consider this example:

> A diabetic patient with CLI undergoing dialysis 3 days per week is seen on Monday afternoon. He has a significant ulceration with some necrotic tissue on his foot that needs debridement by his podiatrist as soon as possible with upfront revascularization. The patient wants his case to be done on Tuesday or Thursday to avoid his dialysis days and wants a morning-only time slot because of his diabetes. The patient receives the same endovascular therapy with the same devices performed by the same operator as he would have had in the hospital, but in a more timely fashion.

In the end, the focus of care in the OIS is that the patient receives the right care, at the right time, in the right place, by the right provider—a true demonstration of the role of the OIS in CLI.

ESSENTIALS FOR TREATING CLI IN THE OIS

The transition from hospital- to office-based endovascular care requires coordination and planning. From diagnosis to discharge and follow-up, the organization must function in a patient-centered manner to achieve the best outcomes for the patients. The OIS must be appropriately equipped and the operators and staff adequately trained and prepared for all possible situations and outcomes. This means an "all-in" commitment from the highest level toward building a suc-

TABLE 1. OEIS QUALITY INITIATIVES	
Safety	Having minimum equipment, policies, and procedures to ensure safety. Obtaining formal accreditation from an existing entity (ie, Joint Commission, AAAASF, AAAHC) and any future OEIS-sponsored or endorsed accreditation body
Credentialing	Ensuring that operators in each lab are trained and competent to perform the procedures
Outcomes measures	Participation in a national registry and/or tracking outcomes in individual labs to the established benchmarks and standards
Compliance	Following compliance standards with policies and procedures and coding compliance
Appropriateness	Following appropriate use criteria for performing procedures and patient selection
Peer review	Establishing and maintaining an internal peer review process and voluntarily participating in an independent external peer review

Abbreviations: AAAASF, American Association for Accreditation of Ambulatory Surgery Facilities; AAAHC, Accreditation Association for Ambulatory Health Care; OEIS, Outpatient Endovascular and Interventional Society.

cessful OIS. Imaging equipment needs to meet certain standards and must have digital subtraction ability to be able to perform high-quality CLI interventions. Patient safety and achieving successful outcomes must be the primary drivers for selection of equipment.

An investment into the development of vascular sonographic capability is highly recommended, if not essential. More advanced labs in the OIS report 100% usage of ultrasound-guided access for femoral or alternative access locations (ie, pedal, transtibial, etc).

To borrow from a well-known quote, "It takes a village" to build a successful office-based CLI program, and this begins with education and training. First and foremost, the physician operators should have experience, training, and credentialing to perform these complex CLI procedures as well as skill sets for bailout of potential complications. Support from the entire organization is essential to providing the timely and comprehensive care required by the patients.

Cardiovascular technologists must become adept in using the multitude of devices and techniques employed to treat CLI, and these competencies are often easier to attain and maintain in the OIS. All staff must be certified in advanced cardiovascular life support and trained to watch for and manage signs of access site- or procedure-related complications and to initiate emergency protocols. Practice-wide education (ie, mid-level practitioners, schedulers, etc) must be conducted to ensure that staff fully appreciates the importance of expedited access for the CLI patients. The importance of educating other community physicians, podiatrists, and other health care providers to deliver coordinated CLI care is also essential.

The care continuum does not stop when the patient gets out of bed following the procedure. Detailed dis-

charge instructions must be provided to the patient and his/her support person. Follow-up calls are essential, and a quick and easy path to postcare evaluation must be available for any issue that may need attention. Consideration should also be given to enrolling CLI patients into a chronic care management program or other coordinated care program to ensure appropriate and timely extended care.

Finally, to ensure that appropriate and quality care is given, a quality review program (such as recommended by the OEIS) must be initiated, watching for trends or concerns and promptly responding to any red flags.

MAINTAINING THE GAIN THROUGH OEIS

OEIS was formed in August 2013 by a multidisciplinary group of physicians who shared an interest in performing procedures in an OIS. These physicians were equally represented by vascular surgery, interventional cardiology, and interventional radiology specialties. It is a unique medical society in that these frequently competitive specialties work together to promote education and improvement of care in the OIS. There are many advantages to this health care delivery model, including more control of procedure scheduling, markedly improved physician efficiency, improved patient and physician satisfaction, a less stressful and confusing environment for the patient, physician ability to control quality, and the potential to save the health care system money.

The OEIS is very interested in promoting high-quality, ethical, and cost-effective care. The society's six quality initiatives include promotion of safety, credentialing of optimally trained operators, measuring outcomes, ensuring compliance with state and federal regulations and coding, procedure and patient selection appropriateness, and peer review (Table 1). Future goals for the OEIS include an organized national registry to collect data and participation in an existing or new accreditation pathway for all office interventional procedures to help further the quality and standards in the OIS.

CONCLUSION

Enhanced by the continued work of professional organizations and refinement of measurement tools, endovascular physicians are using the OIS as a unique site of service to help address the growing epidemic of CLI. OISs help bring safe, effective, and appropriate therapies to the complex and at-risk CLI patient and provide an option to improve a high-quality access to care to this underserved population.

For more information about the OEIS, please visit www.oeisociety.org, and for more information about the CVC, please visit www.cardiovascularcoalition.com. ■

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