

IN THE OFFICE-BASED LAB

Five Essential Components to Treating Peripheral Artery Disease and Critical Limb Ischemia

BY NICHOLAS J. PETRUZZI, MD; LORI RICHWINE, DO; RAJESH PATEL, MD;
AND MICHAEL SCHMIDLING, MD

The ability to perform minimally invasive endovascular treatments for peripheral artery disease (PAD) and critical limb ischemia (CLI) in the office-based lab (OBL) is now a widespread reality. This is in part due to the ability to deliver effective arterial therapy in the outpatient setting via percutaneous access, while maintaining low rates of complications and morbidity/mortality.¹⁻³ Furthermore, there is potential for decreased exposure to hospital pathogens and a possible overall savings to the health care system. Therefore, it is not surprising that the number of OBLs for interventional procedures throughout the country has increased dramatically over the last decade and is expected to continue to increase at an exponential rate. This article focuses on what we consider the five major components to safely and effectively treat both PAD and CLI in the OBL setting.

1. CLINICAL EVALUATION WITH FOLLOW-UP PROTOCOLS

Clinical evaluation and close follow-up are a clear necessity in the treatment of PAD and CLI. It is important to understand the disease process in depth, have confidence in your physical examination skills, and maintain close

surveillance of any placed indwelling stents or recanalized chronic total occlusions over time. Ensure that you have adequate scheduling and nursing staff, purposeful and thorough history forms, a structured system for documentation and follow-ups, and the ability to store photo documentation of wounds. Create postdischarge nursing protocols to contact the patient and answer any questions or concerns that may arise in the immediate postprocedure time frame.

In the CLI population, wound healing overall may be more important than stent patency in terms of immediate limb salvage. However, failure to recognize a decrease in ankle-brachial index or in-stent restenosis can turn an easy fix into a longer, more involved procedure once complete occlusion has occurred. Therefore, it is critical to perform an ankle-brachial index at each visit. A protocol for scheduled arterial duplex surveillance specifically in the CLI population may help maximize outcomes. Many operators advocate surveillance at 3- or 6-month intervals for up to the first year after stent implantation.

2. LAB SETUP AND STOCK

Invest in a high-quality fluoroscopy unit. Not only will this potentially reduce your radiation exposure (a major consid-

eration), but it also can improve your arterial revascularization outcomes with better visualization of distal points of reconstitution, plaque characterization, device vessel sizing, and potential retrograde targets.

Choice of disposable equipment stock is a major consideration for any OBL that undertakes arterial interventions. OBLs should be outfitted appropriately before accepting even the simplest intervention. Because no two cases are exactly the same, a variety of crossing wires and exchange length wires, as well as a range of sheath sizes, angioplasty balloons, and stents should be readily available. In general, consignment can be achieved for a large number of these devices to help minimize start-up equipment costs.

Specifically, 0.035- and 0.018-inch balloons with long and short shaft lengths are required. Be sure to stock both standard- and extended-length stents to avoid placing numerous stents within another to achieve the same result, which can increase your product cost and potentially reduce long-term stent patency. In addition to bare nitinol stents, be sure to have stent grafts on the shelf. This will ensure the operator can appropriately manage the quite rare (but still real) possibility of rupture during intervention. Be aware of the characteristics of the stent grafts on your shelf; a rigid stent graft may not be a suitable long-term solution for the femoropopliteal territory. Another essential piece of equipment to consider is a mechanical thrombectomy device such as the Angiojet (Boston Scientific Corporation). A variety of suction thrombectomy devices and thrombectomy balloon catheters are also available. This can increase the safety of the intervention when treating acute or chronic arterial occlusions and acute/subacute in-stent occlusions that harbor soft thrombus.

Atherectomy devices are a must for any operator who regularly treats the CLI population. The choice of specific device should be based on operator experience and comfort. Do not forget to take into account the device setup and preparation time. Having to place larger-size sheaths or spend a significant amount of time on device setup will reduce room turnover and potentially increase the risk of groin complications. If you are treating a CLI population, consider stocking a device that fits through a 4- or 5-F sheath for pedal approach and treatment, which can reduce procedure time and overcome any difficulty tracking around very tortuous and diseased iliac arteries.

Intravascular ultrasound (IVUS) can also aid in characterizing plaque and vessel sizing for balloons and stents. Although not absolutely essential to arterial intervention, IVUS is becoming an increasingly used tool in the both hospital and OBL practices and can improve operator confidence in choosing the right device for the job.

Arterial closure devices are also frequently used in the OBL setting; however, their use adds an unreimbursed

cost to the procedure, and it is important to add this into any pro forma analysis. Closure devices can shorten overall recovery time, time to ambulation, and increase patient satisfaction and overall efficiency of the center. Consider stocking at least a few larger-vessel closure devices in the rare event a larger-diameter stent graft would have to be placed.

Appropriate medication for treating bleeding and/or thrombotic complications should also be available in your inventory, including but not limited to heparin, protamine, lytic agents, thrombin, nitroglycerin, and calcium channel blockers.

3. EXPERIENCED ENDOVASCULAR OPERATORS AND STAFF

Performing arterial procedures in the OBL is not for the inexperienced operator. Any physician treating patients in this setting should be confident in their endovascular skills and comfortable with the required devices. If the OBL treats the CLI population, the operator must have extensive experience with below-knee interventions, as well as the ability to safely and rapidly achieve retrograde pedal access in order to maximize outcomes.

Additionally, nursing staff should be well versed in sedation and recovery, as well as in the after care for arterial catheterization procedures, including proper pulse and groin examination and knowing what changes to expect postintervention. Nurses with emergency department and intensive care unit experience are likely to have already acquired much of the necessary skill set.

Experienced technologists are also a must. Try to work regularly with one or two techs so that they understand your preferences. This can greatly reduce the time and frustration involved in any case, thus increasing patient satisfaction and throughput of the center. Having one experienced technologist can go a long way toward educating the rest of the staff on what to expect for any particular procedure in terms of room setup, case length, and patient discomfort. Technologists are frequently in charge of managing equipment stock, and they should be regularly checking and modifying par levels and equipment expiration so as to minimize any loss in disposables.

4. USE OF AN ELECTRONIC MEDICAL RECORD

The necessity of an electronic medical record (EMR) applies to all treatments in the OBL, not just arterial-related interventions. However, as cases become more complex (eg, CLI), it becomes increasingly important to ensure comprehensive documentation and communication with the entire clinical care team. Consider an EMR that can track disposables and their lot numbers, which can be helpful in the unexpected event of a device recall.

EMRs can maximize efficiency of your pre- and postcare by integrating vital sign assessment and medication reconciliation by the technician or nurse into the chart. Physicians can then readily review and sign off at each step in the patient's care rather than spend extensive time on documentation during the day.

A robust EMR can help keep referring physicians informed and provide updates on any concerns and/or medication changes, which leads to better coordination of the patient's care. Surveillance imaging and follow-up visits can be scheduled while the patient is still in the office. Laboratory values can be more readily tracked and assessed, and depending on the vendor, photo documentation of wounds can be tied directly to the patient's chart and visit. This also allows for data mining of procedural and clinical outcomes, which may help in analyzing practice outcomes and implementing quality improvement projects.

5. ESTABLISH A CARE NETWORK

Performing arterial-based procedures in the OBL setting has been shown to be safe and effective, with high rates of patient satisfaction and limb salvage. However, it is important not to operate in isolation. Any practice planning on establishing an arterial-focused OBL should ensure that they have the appropriate network of care. This includes a properly thought out transfer plan with a nearby hospital, as well as a good working relationship and open communication with both open surgical and endovascular backups. Preferably, one should also have admitting privileges at the intended transfer site to facilitate optimal transition of care.

Having a true network of care extends beyond vascular specialists. When treating the CLI patient, there should be an established and strong working relationship with a multidisciplinary team, including but not limited to a wound care expert, podiatrist, infectious disease specialist, endocrinologist, primary care physician, general surgeon, and vascular specialist. These specialists are essential team members in the care of the CLI patient rather than simply referrers for the procedure.

Specifically in the case of advanced wound care for CLI, it is paramount to collaborate as members of a dedicated multidisciplinary care team in order to best serve the patient. A comprehensive vascular assessment is an integral component of the initial wound evaluation for advanced wound care in the outpatient setting. It is essential to determine the underlying etiology while maintaining a focus on the "whole patient," not just the "hole" in the patient. Closely and continually working together to manage these patients throughout their recovery helps support the wound care continuum in this high-risk group. Patients receive many benefits from this continuum of care, including a faster healing and shorter recovery period,

limb salvage, restoration of health and mobility, and overall improved quality of life. Advanced wound care specialists also provide a special focus on wound care education, helping patients gain a better understanding of their condition and helping to emphasize prevention.

CONCLUSION

The minimally invasive treatment of PAD and CLI and in the OBL is a rapidly expanding service model and provides increased access to care in this undertreated patient population, increasing both physician and patient satisfaction. There are many essential components to safely and effectively establish an OBL to treat arterial disease. Because no practice setting and patient population are exactly the same, this list is meant to serve as an introductory guide.

Joining an outpatient society, such as the Outpatient Endovascular and Interventional Society, can be an invaluable resource, providing a forum to answer common questions and help the lab operate safely and efficiently. This type of society also has the advantage of multispecialty involvement and perspectives. There are also a variety of resources available online from both state and federal agencies to help address regulatory concerns during the development and growth of your OBL. ■

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Nicholas J. Petruzzi, MD

Atlantic Medical Imaging
Galloway, New Jersey
npetruzzi@atlanticmedicalimaging.com
Disclosures: None.

Lori Richwine, DO

Atlanticare Wound Healing Center
Egg Harbor Township, New Jersey
Disclosures: None.

Rajesh Patel, MD

Atlantic Medical Imaging
Galloway, New Jersey
Disclosures: None.

Michael Schmidling, MD

Atlantic Medical Imaging
Galloway, New Jersey
Disclosures: None.