CLI Management and Outpatient Center Considerations

Factors to consider in providing specialized care for this patient population.

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Critical limb ischemia (CLI) represents the end stage of peripheral vascular disease where arterial flow is compromised to the lower extremities and risk of limb loss becomes imminent. Revascularization of the lower extremities is a cornerstone of limb salvage. Data showing poor outcomes after major amputation demonstrate the grim outcomes for these patients after amputation. Several pillars of support are necessary for the creation of a successful CLI center, be it in an in-hospital setting or in an outpatient setting. This article discusses the particular considerations when establishing a CLI center where patients can be treated in an outpatient setting.

PATIENT WORKUP

The initial workup of all CLI patients is critical and should include a detailed history and physical examination, with emphasis on identifying factors that may affect procedural risk and durability, short- and long-term recovery, wound healing potential, and overall survival. This can be accomplished in an office-based setting and a comprehensive CLI center should offer physiologic evaluation as well as an anatomic assessment of an individual patient's arterial disease, including ankle-brachial indices, segmental pressures, and Doppler waveform assessment. In the CLI patient, the unreliability and nonreproducibility of ankle/toe pressures have led to other potential evaluation options, such as transcutaneous oximetry, which has its own limitations.[1]

Imaging of the affected limb is helpful to plan potential interventions including access selection (single or multiple sites), lesion characterization (eg, length, occlusion versus stenosis, degree of calcification, cap configuration), and exit strategy.

Like physiologic assessment, noninvasive imaging modalities have some limitations. Duplex ultrasound (DUS) is painless and widely available in an office setting; however, the resolution may be a limitation, especially in smaller vessels below the knee. Heavy calcification can be a challenge to adequate imaging due to acoustic shadowing. CTA has much better spatial resolution than DUS or MRA but involves the use of 100 mL or more of iodinated contrast to ensure image quality, which may be an issue for CLI patients, as a significant proportion have chronic renal insufficiency. Further, heavy and/or concentric calcification in small vessels can limit luminal assessment. MRA avoids the use of contrast (and radiation) of CTA but has poorer spatial resolution, which can hinder distal vessel evaluation. Not all of these modalities may be available in the office-based setting but can be helpful in preprocedural assessment.

Angiography remains the gold standard for anatomic evaluation of the CLI patient and provides the opportunity for treatment at the same time. The trade-off of an invasive procedure for a complete and reliable road map of arterial disease is well worth it.

OUTPATIENT CLI CENTERS

Complex interventions can be and are being performed safely and effectively in an outpatient setting. Establishing a CLI center requires a highly skilled team of operators supported by a highly trained revascular-

Figure 1. Preparation of the entire leg allows antegrade and retrograde access, direct ultrasound visualization of arterial structures, and observation of complications.

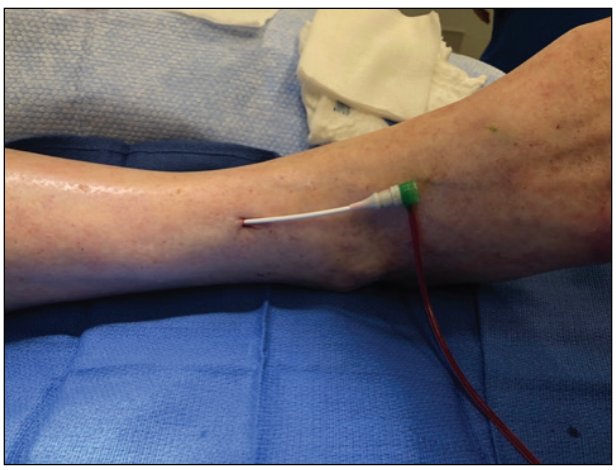

Figure 2. Retrograde tibial access with the tibiopedal artery minimally invasive retrograde revascularization technique for proximal arterial endovascular management.

ization team including nurses, radiology technologists, and experienced ultrasonographers.

Proper patient selection is the first step in any successful CLI intervention and involves many considerations, both technical and patient-specific. Suitability of a patient should be determined with consideration of whether the patient has adequate support at home, with an ambulant adult in the vicinity for 24 hours after the procedure. In addition, the patient or caregiver should be able to recognize complications and have access to communication systems and a hospital nearby.[2-4]

Other factors to consider include the presence of significant renal insufficiency that may require pre- and postprocedure hydration, conscious sedation risk (high American Society of Anesthesiologists score), and possible need for deep/general anesthesia (uncooperative patients or those with dementia who may not be able to remain still for long procedures). Multiple facilities employ certified nurse anesthetists who can aid in moderate sedation. Some risks can be mitigated, thus allowing complex CLI intervention to be done in an outpatient setting with a high degree of technical success and patient safety. Options to consider that may mitigate risk include:

- Use of carbon dioxide digital subtraction angiography to minimize risk in patients with renal insufficiency
- Use of nonradiation modalities to decrease the risk of complications and increase the success rate; the use of extravascular ultrasound (EVUS) and intravascular ultrasound (IVUS) increases safety, successful crossing of chronic total occlusions, and adequate assessment of revascularization in complex peripheral vascular disease and CLI patients[5]

Proper tools must be available to diagnose and treat complex CLI patients. First and very importantly, adequate imaging systems must be available. Access to high-quality imaging, including IVUS and EVUS, enhance the operator's ability to properly diagnose and treat complex CLI cases. Additionally, the operator must have a wide range of revascularization tools available including wires, catheters, atherectomy devices, stents, specialty balloons, drug-coated balloons, and closure devices.

The first step to success and potential complication management is to prep the entire leg so it can be accessed throughout the procedure (Figure 1). Complex chronic total occlusions of the pedal, tibial, popliteal, and femoral arteries are expected in CLI patients and often require combined antegrade and/or retrograde access (Figure 2). These techniques will allow complex revascularization, such as pedal loop reconstruction (Figure 3), to be performed.

COMPLICATION PREVENTION AND MANAGEMENT

Complication management is an important aspect of overall CLI patient management. Complication management starts with prevention and anticipation. Identifying patients at high risk of bleeding is important. Extreme body weight and advanced age both place the patient at a higher risk of bleeding. Using ultrasound to obtain arterial access helps to better identify the point of entry within the vessel and provide a more accurate prediction of vessel size. The use of closure devices can decrease the risk of access

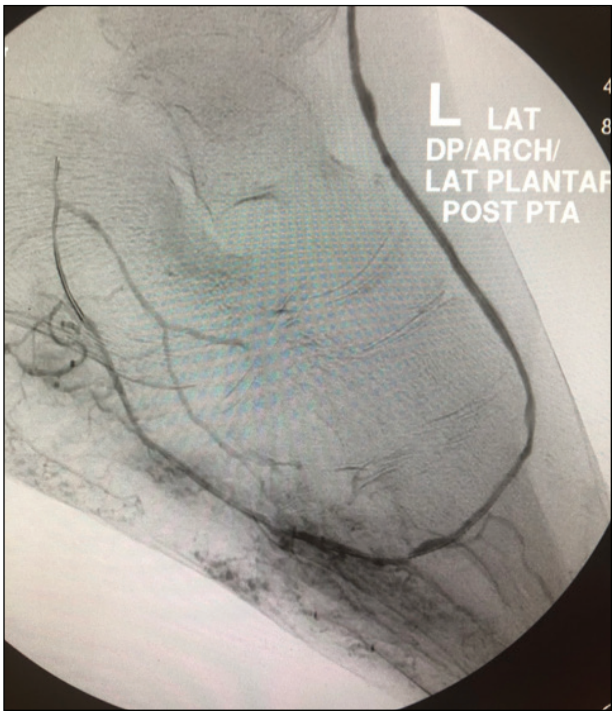

Figure 3. Pedal-plantar loop reconstruction of the dorsalis pedis and pedal arch to the lateral and medial plantar arteries.

site complications and decrease the postprocedure recovery time. Early recognition of an access site complication affords the operator a better opportunity to intervene immediately, increasing the chance of a good outcome. Access sites should be examined immediately after closure and frequently during the immediate postprocedural time frame. Utilization of well-trained and experienced staff who can identify bleeding at the access site is important.

In case of hematoma immediately after the procedure, the boundaries should be marked with a skin marker pen. Mobilization should be performed under supervision (100-m walking test) and discharge instructions should be provided concerning bleeding control, appearances of ecchymoses or hematoma, and pain/coolness of the limb, along with telephone numbers to obtain emergent assistance, if needed.[6,7]

Treatment options for hematoma formation range from manual compression to reintervention by obtaining contralateral access with endovascular balloon tamponade or placement of a covered stent in the setting of active arterial hemorrhage. The operator should never leave the patient's side or allow a patient to be discharged from the center if inadequate perfusion is present. Immediate and frequent perfusion assessments are vital.

Avoiding large vessel access and instead using radial or tibiopedal access provides an additional layer of safety in the prevention and reduction of complications in immediate postprocedure recovery. Manual closure is simple and optimal in many radial and tibiopedal access cases. Available radial closure devices may be utilized in pedal access. Patients are then able to walk within the hour and can be evaluated postambulation to ensure stability prior to discharge home.

OTHER CONSIDERATIONS FOR OUTPATIENT CLI CENTERS

An outpatient CLI center should be built around the unique needs of these particular patients. Such a center must be well equipped with the correct tools and properly trained staff. Large hospital-based medical centers must be prepared to accommodate a wide variety of patient cohorts, requiring operators and staff to maintain a broad skill set and in-depth knowledge of a vast number of devices and technology. Complex CLI revascularization requires a unique skill set and a wide knowledge base in and of itself. With rapid advancements in this space, it is important to have dedicated staff members who have a thorough understanding of the multiple types of equipment used in CLI revascularization. Additionally, a correlation between procedural volume and outcomes has been well established.

Participating in quality initiatives and tracking outcomes is an essential part of any clinical practice and the commitment to excellence in quality is paramount. It is important that each center has a system in place. Dedicated CLI centers must consider contributing to quality measuring registries like the Vascular Quality Initiative registry or the Outpatient Endovascular and Interventional Society registry, as examples. These databases allow centers to track complications and make improvements to enhance patient outcomes and safety. In addition, patient satisfaction surveys are a valuable tool to ensure patients' expectations, needs, and comfort are being met.

CONCLUSION

The treatment of patients with CLI requires highly specialized management and care. Outpatient facilities that are built around the needs of CLI patients are indeed capable of addressing the complexity of therapy. Building a CLI center of excellence is a daunting task; however, with balanced risk, there can be great reward for the patients, team, and physicians practicing within those centers. Developing a CLI center is no small undertaking, but CLI therapy is as

rewarding as it is complex. Advanced endovascular skills are required and the willingness to go the extra mile is essential. This environment, in our opinion, can be the best way to practice interventional care and vascular medicine for CLI patients while saving limbs and renewing lives. ■

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