



Management of Critical Limb Ischemia

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Critical limb ischemia (CLI) is an advanced form of peripheral arterial disease (PAD) that typically affects the lower extremities. It is highly prevalent in the US with 12% afflicted in varying degrees.¹

Caused by inadequate blood supply to an extremity, the clinical presentation of CLI varies from little to no pain to open ulcers and gangrene, and due to high incidence of cardiovascular comorbidities, CLI is a life-threatening condition. Studies show that at one year, only 45% will keep both limbs, 30% will require amputation, and 25% will die. Mortality at 5 years is greater than 60%.¹ Surgical treatment options for CLI are extensive, so by understanding the pathophysiology, various surgical techniques, and post-operative considerations for the disease, the Certified Surgical Technologist (CST) will be better equipped for a successful operation and provide each patient the best outcome possible.

Limb ischemia can be categorized in two ways: chronic or acute. Chronic limb ischemia is when symptoms last longer than two weeks, and acute limb ischemia is when a patient presents with symptoms 14 days or less. The most common causes of limb

LEARNING OBJECTIVES

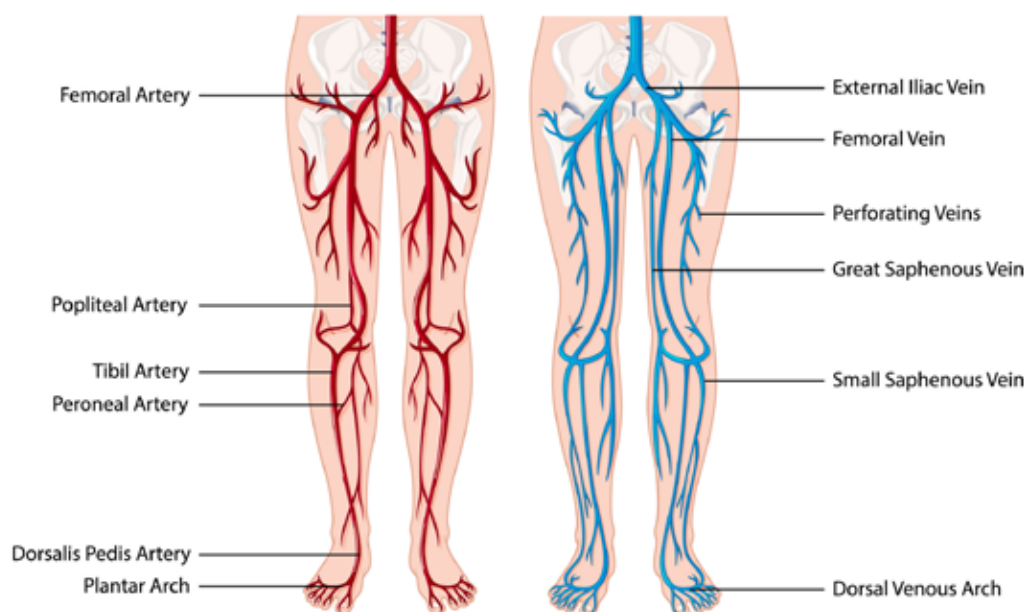
- ▲ Explore critical limb ischemia and the anatomy it affects
- ▲ List the risk factors for CLI
- ▲ Explain the treatments options for CLI
- ▲ Detail the role of the CST in procedures to treat critical limb ischemia
- ▲ Describe the outcome possibilities for patients affected by CLI

ischemia are thrombotic or embolic events. Patients with thrombotic occlusions of the iliac, femoral, or popliteal arteries will have a history of claudication which is pain, aching or fatigue of the muscles in the buttocks, thigh, and calf. Symptoms often intensify with activity and diminish with rest. The most common cause of thrombotic lesions is from atherosclerotic disease. Atherosclerotic plaques build up in arteries and narrow blood vessels. In comparison, acute limb ischemia is caused by an embolic event and the patient will not necessarily have a history of chronic occlusive arterial disease or claudication. Often the patient will have a history of atrial fibrillation. Less common risk factors for CLI are systemic thrombophilia, dissection, intimal hyperplasia, vasculitis, and aneurysm thrombosis.²

have a thicker elastic muscular tissue than a vein because it accommodates the high pressure from the heart. Lastly, the tunica intima or inner layer consists of endothelial cells which gives a smooth passage for blood. Whole blood is composed of plasma and blood cells. Plasma transports nutrients, hormones, and proteins. Red blood cells transport oxygen and carbon dioxide to and from tissues; white blood cells are part of the immune system which detects and fights infection; and platelets, composed of cell fragments, help form blood clots.

In a healthy body, blood clotting is a mechanism to protect against bleeding. In an injured blood vessel, chemical messengers flow to the site of the injury and signal for the vessel to constrict. The coagulation is activated, and platelets

Arteries and Veins of the Leg



ANATOMY OF THE VASCULAR SYSTEM

The peripheral vascular system includes all the blood vessels in the body beside the heart. Arterial blood vessels from the heart nourishes tissues and organs with oxygenated blood and nutrients, and veins deliver deoxygenated blood back to the heart. The blood vessels are composed of three layers: the adventitia or outer layer gives structural support and shape to the vessel; the tunica media or middle layer regulates the inner diameter of the vessel. Arteries

become sticky and attach to the vessel wall to form a plug. Molecules from platelets turn on clotting factors, like fibrin, to form a fibrin clot, and start to repair the vessel. However, this clotting cascade can become activated in an intact vessel when a narrowing or blockage impedes substantial blood flow. An embolus differs from thrombus because it originates anywhere and at any time with no injury needed. It is composed of clotted blood cells or ruptured atherosclerotic plaque, and it flows in the blood stream until it gets stuck in a bifurcation or small vessel. Whether thrombotic

or embolic in origin, surgical therapies help to restore flow and alleviate tissue ischemia.

SIGNS AND SYMPTOMS

An accurate clinical evaluation of a patient is imperative. Clinical presentation of CLI may vary from minor to extreme symptoms. These may include new or worsening claudication, change in temperature and color of the affected extremity, numbness, absent motor function, resting leg pain, open sores, or gangrene. The symptoms may be remembered with the “6 Ps”: pain, paresthesia, paralysis, pallor, poikilothermia (cool extremity), and pulselessness.² After physical examination, the findings are categorized using the Rutherford classification system. Rutherford Grade I describes a patient who is asymptomatic or has mild claudication symptoms. The grading system advances based on pain during activity and tissue presentation. The most advanced grades (V and VI) designate tissue loss.¹ This classification determines the appropriate timing and treatment for CLI. Proper evaluation and timely intervention are important because claudication symptoms may limit a patient’s activity affecting both their physical and mental wellbeing. It could also increase their risk of cardiovascular morbidities such as heart attack and stroke.

RISK FACTORS

Certain factors put individuals at high risk of developing CLI. Non-modifiable risk factors are sex and age; men are affected slightly more often than women and nearly 20% of adults 70 years or older have CLI.¹ Modifiable risk factors

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include hypertension, hyperlipidemia, history of smoking, and a sedentary lifestyle. Diabetics suffer from complex vascular disease and have poor arterial collateralization (growth of blood vessels to form alternate tissue perfusion pathways); 50% of diabetic patients suffer from chronic limb ischemia.¹ Hypertension increases cell dysfunction and stress, and hyperlipidemia causes elevated serum triglycerides and low high-density lipoprotein levels which causes endothelial dysfunction and atherosclerosis. Smoking is a major risk factor with 70-90% of CLI patients current or ex-smokers.¹ Inflammation within the blood vessels is a strong predictor of vascular disease, C-reactive protein is one example of a biomarker of inflammation and is associated with peripheral arterial disease and high cardiovascular risk.⁸

RUTHERFORD CLASSIFICATION SYSTEM		
Grade	Category	Clinical description
0	0	Asymptomatic
I	1	Mild claudication
I	2	Moderate claudication
I	3	Severe claudication
II	4	Ischemic rest pain
III	5	Minor tissue loss - nonhealing ulcer, focal gangrene with diffuse pedal ischemia
III	6	Major tissue loss - extending above transmetatarsal level, frank gangrene

TESTS AND SCANS

After a thorough physical examination, noninvasive tests and scans can confirm the presence of disease. One option is a duplex ultrasound. High frequency sound waves can identify the site of the occlusion or narrowing by observing a change in fluid velocity in the vessels. Another option is an ankle brachial index (ABI) which is calculated by dividing an ankle pressure by the highest brachial artery pressure. An ABI <0.9 is abnormal, 0.7-0.9 indicates a mild disease, 0.3-0.69 is moderate disease, and an ABI less than 0.3 is severe disease and is a predictor of increased mortality from cardiovascular events.¹ If imaging is pursued, the preferred study is a computed tomography angiography (CTA) of the abdomen and pelvis with run-off images. It is useful for identifying the level of occlusion and visualizing prior vascular interventions. Another option that may be useful is a magnetic resonance angiography (MRA), but it may not be feasible in some cases because images take longer to acquire, and patients may not hold still long enough if they are in pain. Catheter-based angiographic findings using contrast can also identify sites of occlusion and evidence of collateral vessels and offer the benefit of therapeutic intervention.

Laboratory evaluation can help prepare for surgical management. Lab abnormalities such as hyperkalemia and acidosis are indicators of limb ischemia; a hemoglobin and hematocrit test and a type and screen are useful if a blood transfusion is needed during surgery. Coagulation studies should be obtained if the patient undergoes heparinization or thrombolysis, and renal function should be evaluated in anticipation of delivering intravenous contrast that can damage the kidneys.²

TREATMENTS FOR CRITICAL LIMB ISCHEMIA

Once CLI is diagnosed, management should aim to stop the propagation of thrombus, and a plan of intervention should be decided based on clinical severity. The first line of treatment against CLI is noninvasive medical management. Anticoagulation therapy, commonly with heparin, prevents the propagation of clot as the patient is evaluated and prepared for intervention.⁴ New treatments focusing on gene and molecular therapies are advancing. These treatments promote the body's natural capacity to create new blood supply around blockages or increase capillary density. Clinical trials show some support for therapies with vascular endothelial growth factor (VEGF) and fibroblast growth factor (FGF). Cell-based therapies such as endo-

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thelial progenitor cells (EPCs) and bone marrow-derived mononuclear cells (BM-MNCs) show promising results to promote angiogenesis, arteriogenesis and neovascularization for CLI.⁵ Many conservative measures aim to promote lifestyle changes. Exercise/walking programs for 30 minutes 3-4 times a week can improve collateral vessel growth and improve symptoms of claudication. Additional standard of care conservative treatments includes smoking cessation, blood pressure management, and correction of lipid profiles. Statins (the most commonly prescribed antihyperlipidemic) can improve overall patient survival by stabilizing atherosclerotic plaque and improving arterial remodeling. Diabetics should also have a glucose control goal of Hgb A1C <7.¹¹

A minimally invasive endovascular approach to treating CLI is advantageous in some cases. Compared to open surgery, an endovascular approach is less stressful, and the recovery time is shorter which is especially helpful for older debilitated patients. Some patients are candidates for catheter-directed thrombolysis where thrombolytic agents, anticoagulation and antiplatelet agents are administered directly to the diseased vessel to promote breakdown of clot.² Percutaneous thrombectomy is another option for management of acute thrombotic or embolic arterial occlusion. Several devices are on the market that use simple aspiration, lysing and aspirating, mechanical thrombus fragmentation, or a combination to remove the clot from obstructed vessels.

When the endovascular intervention includes challenging anatomy, combining open surgical techniques to expose vessels for endovascular revascularization is possible. One endovascular practice is a balloon angioplasty. A balloon

catheter dilates narrowed arteries by stretching the adventitia and media to increase the diameter of the vessel. An over-the-wire (OTW) system uses a guide wire that enters the distal end of the catheter and exits out the front. This balloon type requires an CST to assist the surgeon by pinning the wire in place while the balloon is advanced. Most balloons have a nominal, or low pressure, and a rated burst high pressure value. Having a CST voice these pressure values to the surgeon will assist them while inflating the balloon.

In some situations, a balloon angioplasty isn't enough, and placing a stent can facilitate a better outcome. Two types of stenting methods are available: balloon-expandable and self-expanding. In balloon-expandable stents, metal mesh tubes, usually stainless steel, are mounted on a balloon dilation catheter. These stents are more rigid and can be more precisely placed compared to self-expanding stents. Self-expanding stents are made of nitinol. Nitinol has better memory than other metals and conforms to their intended shape after deployment. They offer flexibility, longer stent lengths, and are crush resistant.¹³ Balloons and stents can be coated in a drug called Paclitaxel to treat new or recurrent stenosis. The drug prevents scar tissue from forming on arteries that are at risk of re-narrowing thereby reducing in-stent restenosis. The drug can prevent the need for repeat procedures.⁶

Despite advances in minimally invasive endovascular treatments, or when endovascular methods aren't possible, open surgery plays a major role in the care of patients with vascular disease. The balloon thrombectomy is the standard. Manual thrombectomy allows clot to be evacuated with Fogarty balloon catheters, which is a catheter with a small balloon at the tip that is advanced beyond the occlusion, inflated, and then drawn back to evacuate the clot out through the arteriotomy. It restores blood flow quickly and allows pathological examination of the clot. Another surgical option is an arterial bypass which reroutes blood flow around a blockage. Bypasses can be performed with harvested autologous saphenous vein graft, cadaveric homograft, or synthetic graft material such as Dacron and PTFE. Autogenous vein is the preferred conduit for bypass.¹² Additionally, an endarterectomy, a surgical maneuver that scrapes atherosclerotic plaque from an artery, is an option. There is no clear evidence in favor of bypass surgery over angioplasty in terms of improvement of symptoms, amputation rate, need for further procedure, vessel patency and long-term mortality,¹² so whether open, percutane-

ous, endovascular, or a hybrid procedure combining many approaches, the surgeon will use preoperative imaging to choose the appropriate treatment and access site.

PROCEDURAL OVERVIEW

For a standard thrombectomy of the common femoral artery, the patient should be positioned supine with their arms tucked at their sides. After induction with general anesthesia, the affected limb is prepped circumferentially, and both groins are prepped down to the bed and up to the umbilicus. A universal drape is the ideal choice for draping and using an angiography drape allows the CST and surgeon to utilize the bed controls, if applicable. An Ioban drape is applied across both groins, and a clear foot isolation bag covers the prepped foot to monitor for any skin color changes intraoperatively.

After prepping and draping the patient, a surgical time out is conducted. After the time out, the surgeon makes a skin incision over the groin with a #15 blade. Following a skin incision, the surgeon dissects with electrocautery and Metzenbaum scissors down to the vascular sheath containing the common femoral artery. Care is taken to ligate lymphatic structures and veins with 3-0 and 2-0 silk ties. Proper visualization using self-retaining retractors like a Weitlaner, and springs, will help expose the artery and help the surgeon dissect close to the adventitia. When the vessel is circumferentially dissected, a vessel loop or umbilical tape is applied with a right-angle clamp to isolate the artery proximally towards the inguinal ligament. More distally, the profunda femoris artery is identified at the transition between the common femoral artery and the superficial femoral artery and encircled with a vessel loop.

After gaining adequate exposure, the surgeon requests anesthesia to give unfractionated heparin to prevent blood clotting when the vessels are clamped shut. Anticoagulation is monitored throughout the procedure by measuring the activated clotting time (ACT), aiming for more than 250 seconds.³ After the recommended circulation time elapses, the surgeon stops the blood flow with vascular clamps, occlusion devices, or vessel loops. A small transverse or longitudinal incision is made with a #11 blade and Potts-Smith scissors on the artery. A 4F Fogarty balloon catheter is advanced beyond the thrombotic segment proximally, the balloon is inflated, and the catheter is withdrawn through the arteriotomy. By pulling back on the vessel loop between passes, excessive blood loss is managed.

After repeating this process in the distal vessels, back

bleeding can indicate the clot burden has been removed, but this sign may be misleading. If unsure of patency, fluoroscopy-guided thrombectomy is recommended to avoid leaving behind thrombus. Incorporating fluoroscopy-guided management is recommended even for the most seasoned vascular surgeon because it offers additional information such as vessel anatomy and catheter course. Intraoperative imaging can be taken to confirm elimination of clot burden and satisfactory reperfusion. It is important to wear radiation protection including a lead apron, lead thyroid and lead-lined glasses to protect oneself from the long-term harmful effects of ionizing radiation.

The surgical technologist should be prepared to transition to an endovascular intervention during open surgery. If an arteriotomy has already been made, a sheath is usually advanced directly into the arteriotomy, or the arteriotomy is closed with suture, and a needle and wire are used to gain arterial access. A sheath has a hemostasis valve and side port. The sheath provides stable access to the vessel when wire, catheter, and device exchanges occur. A guide wire comes in varying diameters, lengths, flexibility, and coatings to facilitate advancement into a vessel. A hydrophilic coating lowers the friction against catheters, sheaths, and blood vessel walls. Guide catheters are introduced on a wire to help direct wires to distal locations and inject contrast distally. Catheters come in various sizes and have different tips and radiopaque markers to facilitate strategic manipulation in the vascular system. The CST plays an important role throughout the endovascular intervention just like in an open procedure. They pass heparinized saline flushes and contrast filled syringes to the surgeon, wipe down the wires and catheters with heparinized saline after each exchange to prevent blood from drying and hindering future passages, and facilitate catheter exchanges by pinning the wire firmly.

When the surgeon is satisfied with the revascularization. The arteries and branching vessels are flushed, and using a fine vascular needle driver such as a Ryder or Castroviejo the edges of the arteriotomy are re-approximated with a 5-0 Prolene on a C-1 or BV-1 needle in an interrupted fashion. Closing in an interrupted fashion prevents narrowing the vessel. Hemostasis is achieved with electrocautery and hemostatic agents, and when hemostasis is satisfactory, the fascia is closed with 2-0 and 3-0 Vicryl suture. The skin is closed with a 4-0 Monocryl or staples, and dressed with skin glue, dressings or a vacuum dressing sponge to remove fluids and infection.

CST CONSIDERATIONS

To facilitate the ease and efficiency of surgery, the CST will need to ensure items are prepared preoperatively. They will check for all scans and angiograms to be available prior to starting the case. Additionally, the surgical technologist should prepare balloons and endovascular supplies during the case set-up or have endovascular supplies available for use intraoperatively. The umbilical tapes may need to be cut in half; mosquitos should have shod covers to tag Prolene suture with during vessel anastomoses. Contrast and heparinized saline should fill labeled syringes, and hemostatic agents should be cut and ready for intraoperative bleeding. The surgeon might like their hands wetted with irrigation while tying Prolene suture together, so certified surgical technologists should have a bulb syringe full and ready. CSTs should always have extra Prolene suture and 2-0 silk on an SH needle available in case bleeding is encountered. It is also wise to have occlusion balloons available, so the surgeon can occlude leaky blood vessels intraluminally, if necessary.

POST-OPERATIVE COMPLICATIONS

Complications during and after an endovascular procedure or open thrombectomy are possible. Arterial dissection, distal embolization, acute stent thrombosis, or hemorrhage at the access site may occur.⁷ Postoperative ischemia-reperfusion (I/R) injury and compartment syndrome can happen when the lower extremity is reperfused.

When tissue is starved of oxygen for a long time, intracellular pH levels decrease, and lactic acid accumulates. Consequently, prolonged ischemia leads to enzyme degradation of proteins, membranes and eventually cell death. Microvascular endothelial barriers are affected by hypoxia. When blood flow is restored, pH levels increase, but reactive oxidative stress signals recruit inflammatory responses which results in more tissue damage. As a result, ischemia-reperfusion injury may cause compartment syndrome, arrhythmias, and multi-organ and central nervous system complications. Post-ischemic compartment syndrome after embolectomy, thrombolysis and bypass surgery has a 21% incidence rate¹⁴, it results from prompt extremity revascularization. The arterial blood flow increases intracompartmental pressure which compresses neurovascular bundles and can lead to permanent extremity dysfunction, muscle ischemia, rhabdomyolysis, and renal insufficiency if fasciotomy is delayed.⁹ The surgeon should consider prophylactic fasciotomies to prevent compartment syndrome.

CONCLUSION

The primary goal of an interventional treatment of CLI is to restore blood flow, heal ischemic ulcers, prevent limb loss, improve the patient's functional capacity and quality of life. A study done in 2011 analyzed clinical outcomes over 4 years for 72,199 patients with CLI, and the results showed that 46% survived on average 3.5 years, 87% avoided a major amputation, 38% survived with an endovascular revascularization, and 40% survived with a surgical revascularization.¹⁰ Although studies show impressive results, there is still an aging population, rising prevalence of diabetes, and continued tobacco abuse. More research is needed to understand tibial and small vessel disease, develop effective pharmaceuticals and wound care products to improve limb salvage and increase life expectancy. CLI is a significant yet often overlooked disease. With a thorough understanding of systemic risk factors and interventions available, the CST can be an active member in the management of CLI.



ABOUT THE AUTHOR

B. Rylee Rickett, CST, has been a Certified Surgical Technologist since 2019. She is currently employed at St. Thomas West Hospital in Nashville, Tennessee, on the vascular team. Her love of human anatomy and physiology prompted her

enrollment in a surgical technology program in Madison, Wisconsin, but her pursuit of higher education didn't end there. She completed her bachelor's degree in biology at Belmont University in Nashville in the spring of 2022 and is currently applying to medical school.

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Management of Critical Limb Ischemia

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1. **CLI is a highly prevalent disease. What percent of the US population is affected?**
 - a. 7%
 - b. 12%
 - c. 32%
 - d. 50%
2. **What term describes the pain, aching or fatigue of the muscles of the buttocks, thigh and or calf that occurs with exertion due to poor perfusion?**
 - a. Claudication
 - b. Compartment Syndrome
 - c. Critical Limb Ischemia
 - d. Cytokines
3. **True or false: Most common causes are of CLI are thrombotic and embolic events.**
 - a. True
 - b. False
4. **What is the name of the drug that coats endovascular balloons and stents that prevents scar formation and restenosis?**
 - a. Paxil
 - b. Pepcid
 - c. Paclitaxel
 - d. Paracetamol
5. **What percent of CLI patients will die after 5 years?**
 - a. 5%
 - b. 10%
 - c. 30%
 - d. 60%
6. **Patients with acute limb ischemia are more likely to have what condition?**
 - a. Ventricular fibrillation
 - b. Atrial fibrillation
 - c. Claudication
 - d. Diabetes
7. **An ABI of 0.3-0.69 indicates what severity of peripheral vascular disease?**
 - a. Asymptomatic
 - b. Mild disease
 - c. Moderate disease
 - d. Severe disease
8. **During a patient examination, which symptom is not indicative of CLI?**
 - a. Parathesis
 - b. Poikilothermia
 - c. Pulselessness
 - d. Paclitaxel
9. **Activated clotting time (ACT) monitors anticoagulation levels throughout surgery. It should be more than:**
 - a. 30 seconds
 - b. 60 seconds
 - c. 250 seconds
 - d. 1 hour
10. **What is it called when a patient presents with limb ischemia symptoms less than 14 days in duration?**
 - a. Chronic limb ischemia
 - b. Ischemic ulcers
 - c. Acute limb ischemia
 - d. Gangrene

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