

Determining End Points for Critical Limb Ischemia Interventions



Kyle J. Cooper, MD, Constantino Peña, MD, and James Benenati, MD

Critical limb ischemia is a condition that has increased in prevalence and carries a high degree of morbidity. Although endovascular therapy for treatment of patients with critical limb ischemia has undergone significant advances with improved outcomes over the past decade, these patients often have multilevel disease, and it may take weeks or months for ulceration healing. For this reason, the acceptable therapeutic end points during and immediately following revascularization remain somewhat obscure. There are multiple tools available to guide the treating vascular specialist in this regard. Establishment of in-line flow to the foot and the angiosome containing the ulceration, appearance of a "wound blush," restoration of pulses, and bleeding at the ulcer site are basic tenets intraprocedurally. Postprocedural noninvasive testing including the ankle-brachial and toe-brachial indices, segmental pressure measurements, pulse volume recordings, transcutaneous oxygen tension, skin perfusion pressures (SPPs), and toe pressures all play a role in determining the likelihood of clinical improvement. Newer technologies such as two-dimensional (2D) perfusion angiography, fluorescence angiography, and tissue oxygen saturation mapping may allow better real-time assessment of flow restoration. In combination with close clinical follow-up and wound care, these tools provide treating physicians with a better grasp of the necessary end points to optimize patients for clinical improvement.

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Introduction

Critical limb ischemia (CLI) is defined as the presence of ischemic limb pain at rest or the presence of tissue loss or gangrene, corresponding to Rutherford Classes 4-6 and Fontaine Classes III and IV.¹ This condition has reached epidemic proportions in recent years, in major part because of the continuous rise in the rates of diabetes mellitus and renal insufficiency. It is estimated that up to 23% of patients older than age 55 may suffer from peripheral arterial disease (PAD), including more than 8 million in the United States and greater than 200 million worldwide.² Patients with CLI comprise approximately 2-3% of all cases of PAD, and the diagnosis portends a dismal prognosis.³ Major amputation and limb loss rates are at least 10% in these patients at 1 year.⁴ The risk of all-cause mortality in patients with CLI

was 26.8% at 2 years in the BASIL trial, predominately from cardiovascular events⁵; furthermore, it is estimated that the likelihood of death approaches 50% at 5 years and 70% at 10 years in this population.⁶

Given the significant advances recently in endovascular techniques for the treatment of distal lower extremity PAD, the attempted revascularization of these patients before amputation has increased markedly. Unfortunately, there is still much debate on the most appropriate clinical and therapeutic approaches, and it remains unclear just how good is "good enough" when it comes to increasing the blood flow to critically ischemic limbs. The goal of this article is to review the tools and techniques available to help interventionalists determine an acceptable end point for CLI intervention and the methods by which treatment success can be measured both during and after a revascularization procedure.

The Angiosome Concept

The restoration of blood flow is of utmost importance in CLI as the improvement of rest pain, healing of ulcers, and

Miami Cardiac & Vascular Institute, Miami, FL.

Address reprint requests to Constantino Peña, MD, Miami Cardiac & Vascular Institute, 8900 N Kendall Dr, Miami, FL 33176. E-mail: constantinop@baptisthealth.net



Figure 1 Angiosome sock helps depict major vascular territories of the lateral (image left) and medial (image right) lower calf and foot. (Color version of figure is available online.)

prevention of limb loss are dependent on adequate tissue perfusion. An important tenet of revascularization is establishing in-line flow from the aorta to the affected foot, particularly in the setting of tissue loss. Ideally, the patient's normal vascular anatomy would be restored, treating all hemodynamically significant stenoses or occlusions extending from the aorta and iliac inflow vessels to the femoropopliteal segments with a patent 3-vessel runoff into the ankle and a complete pedal arch; however, this may be impractical or impossible depending on the severity and distribution of the disease.

The overwhelming majority of patients with CLI present with distal tibial vessel disease. Two concepts are important when determining the ideal target vessel(s) for infrageniculate revascularization. The first is the idea that "complete" revascularization is better than "incomplete." Simply stated, this concept implies that 1 runoff vessel is better than none, 2 or 3 is better than 1, and that the tibial arteries are more important than the peroneal artery (as they enter the foot directly).⁷ The second concept involves the selection of a particular target vessel that is most likely to perfuse the area of tissue loss—the so-called "wound-related artery" theory. When determining which vessel is supplying the region of an ulcer, conceptualizing the foot in terms of specific "angiosomes" is extremely helpful. The anterior tibial and dorsalis pedis arteries supply the tissue comprising the anterodorsal surface of the calf, ankle, and foot; the posterior tibial artery supplies the plantar surface of the foot and posteromedial calf, ankle, and heel through its plantar and medial calcaneal branches; and the peroneal artery supplies the posterolateral calf and ankle as well as the lateral heel (Fig. 1). Of course, not all ulcers are confined to a single angiosome; however, this paradigm

provides the interventionalist with a framework from which to start. It is important to note that there is still much controversy regarding the necessity of angiosome-guided revascularization, with multiple studies falling on both sides of the debate.

Periprocedural Predictors of Success

After choosing the target vessels, a variety of techniques exist to reestablish flow, a discussion of which is beyond the scope of this article. Following intervention, a lower extremity angiogram with runoff imaging is performed which is compared to the preintervention survey. Patency of previously occluded vessels, improved vessel caliber and flow velocity within treated arteries, decreased collateral flow, and increased distal branch opacification are the intended result. In addition, several clinical factors can often be observed during and soon after intervention, which can assist in confirming successful revascularization. The most basic and important of these is the return of a palpable pedal pulse, considerably more reassuring than the return of Doppler signals alone. Real-time ultrasound imaging can be performed on the angiography table, with assessment for distal runoff patency and improvement of spectral waveforms. Restoration of normal limb coloration can be seen quite rapidly, although often the patient will exhibit signs of rubor for some time after the procedure due to capillary dilatation from prolonged ischemia. Furthermore, physical examination and performance of a capillary refill time, often greater than 20 seconds in patients with CLI, may decrease to the normal range of

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