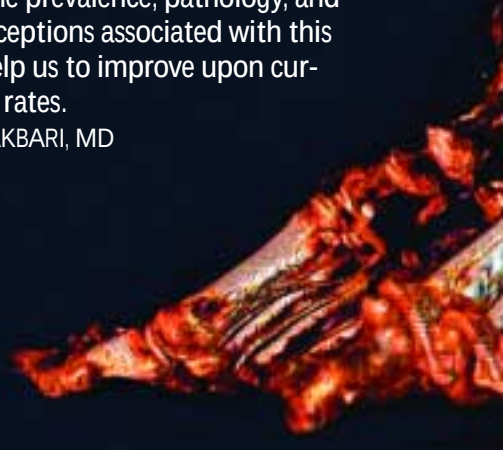
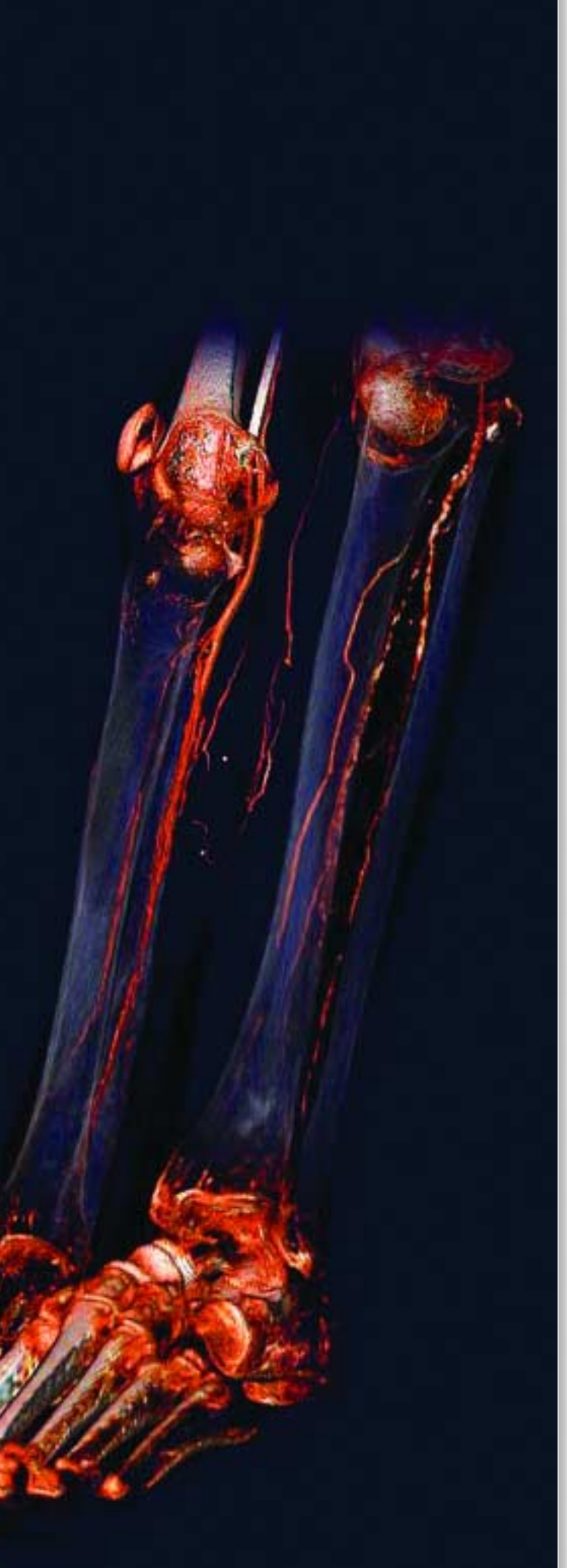
Conquering Critical Limb Ischemia

Do you know the dangers your patients face, and are you prepared to treat them?





An Overview of Critical Limb Ischemia

Today's therapeutic advances are changing the way we evaluate and treat this common and often fatal disorder.

BY MICHAEL R. JAFF, DO, AND GIANCARLO BIAMINO, MD

Amputation and mortality from cardiovascular diseases have historically been the grim prospects for people with severe peripheral arterial disease (PAD). Now, with the recent revolutionary advances in endovascular therapy, the future for many of these patients is considerably brighter. Because current surgical and pharmacological therapies are acceptable and effective for only a subset of patients, these new techniques for the many PAD sufferers will result in higher limb salvage rates, with acceptable secondary patency rates and considerable reduction in periprocedural complications.

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Some of the advantages of using interventional procedures over surgery to treat PAD are (1) the procedures can be repeated, if needed, (2) they avoid the potential complications of general anesthesia, (3) they may pose less systemic stress, and (4) they may result in fewer serious complications for this very ill patient

population.

Critical limb ischemia (CLI) is the most severe manifestation of peripheral arterial disease of the lower extremities. This brief survey of the current diagnostic approaches and treatment options summarizes and highlights the potential value and efficacy of endovascular therapy.

THE IMPACT OF CLI

An estimated 1% of adults over the age of 50 (roughly 1.5 million to 2.0 million patients in the US and Europe) suffer from CLI. The risk factors that result in this advanced form of PAD in the 30% of patients with PAD are (1) advanced age, (2) tobacco use, and (3) diabetes mellitus.[1-4] Patients with dialysis-dependent renal failure and PAD are also at increased risk of presenting with CLI.

Mortality rates are alarming: 25% at 1 year; 31.6% at 2 years; and more than 60% after 3 years.[1,5,6] Moreover, CLI results in 150,000 amputations per year in the US and Europe. Within 1 year of the onset of CLI, 25% of the patients will die and another 25% will require major amputation.[7,8]

TASC

The Transatlantic Inter-Society Consensus (TASC) has recognized the need for "increased focus on developing new surgical, endovascular, and pharmacological approaches to the management of this small, but very seriously ill group of patients." One response has been a diagnostic and treatment tool TASC created in 1999 that, despite subsequent leaps forward, can still be useful for the physician and hospital with only limited practice in interventional procedures.[5]

DIAGNOSIS OF CLI

PAD progresses in severity from the mildly disturbing indications of intermittent claudication to the profoundly troubling signs of chronic CLI, which is identified as the sustained, severe decrease of leg blood flow.

TABLE 1. THE EUROPEAN WORKING GROUP ON CRITICAL LEG ISCHEMIA DEFINITION[9]

Clinical Description		Objective Criteria
Persistent ischemic rest pain requiring analgesia for >2 weeks OR Ulceration or gangrene of the foot or toes	AND	Ankle systolic pressure ≤50 mm Hg and/or toe systolic pressure ≤30 mm Hg

TABLE 2. RUTHERFORD-BECKER CLASSIFICATION[10]

Grade	Category	Clinical Description	Objective Criteria
0	0	Asymptomatic—no hemodynamically significant occlusive disease	Normal treadmill* or reactive hyperemia test
	1	Mild claudication	
I	2	Moderate claudication	Completes treadmill exercise; AP after exercise >50 mm Hg but ≥20 mm Hg lower than resting value
	3	Severe claudication	
II	4	Ischemic rest pain	Resting AP <60 mm Hg, ankle or metatarsal PVR flat or barely pulsatile; TP <40 mm Hg
IV	5	Minor tissue loss—nonhealing ulcer; focal gangrene with diffuse pedal ischemia	Resting AP <60 mm Hg, ankle or metatarsal PVR flat or barely pulsatile; TP <40 mm Hg
	6	Major tissue loss—extending transmetatarsally; functional foot no longer salvageable	

*AP = ankle pressure; PVR = pulse volume recording; TP = toe pressure. *Treadmill protocol: 2 miles per hour, 12% constant grade.*

If left untreated, CLI will be manifest as limb pain while at rest, breakdown of the skin (ulceration or gangrene), and incipient limb loss. These clinical observations must be further weighed with a detailed patient history, physical examination, and objective, hemodynamic criteria, with such parameters as an ankle-brachial index ≤0.4, an ankle systolic pressure ≤50 mm Hg, or a toe systolic pressure ≤30 mm Hg.[1]

Two generally accepted classification systems of CLI are the European Working Group on CLI Definition (Table 1) and the Rutherford-Becker Classification (Table 2). Both systems use clinical and hemodynamic parameters.

INTERVENTIONAL TREATMENT

Revascularization must be performed promptly to preserve the limb. Although timely arterial reconstruction is imperative, CLI is often multilevel, diffuse, and distal, which makes thorough and accurate treatment challenging.

Detecting the extent and location of the disease prior to intervention is crucial. The TASC classification system can be used to determine the severity of the anatomical lesion(s) by assessing complexity based on lesion length, location, and presence of occlusion. The TASC is an adequate tool for physicians and hospitals that have limited experience with interventions, but it is less important for skilled and experienced endovascular specialists.

CLI AND DIABETES

Diabetes mellitus is one of the most important variables to consider when selecting a surgical or endovascular strategy. There are some unique aspects to the presentation of CLI in patients with diabetes mellitus: (1) atherosclerosis develops at a younger age in diabetics and progresses more rapidly; (2) atherosclerosis affects more distal vessels in diabetics; the aorta and iliac arteries are rarely involved, however, the infrainguinal and infrapopliteal arteries are commonly affected; (3) infrapopliteal lesions are historically less amenable to revascularization; and (4) there is a higher rate of limb loss due to atherosclerosis in distal arteries in patients with diabetes, especially in association with diabetic polyneuropathy, than in nondiabetics.[10,11]

Other important factors to consider are that (1) severe multilevel peripheral arterial disease limits candidacy for surgical revascularization—over 37% in one major study;[12] and, (2) only 20% to 30% of patients with infrapopliteal artery disease have anatomy favorable for traditional PTA; thus requiring alternative tools for revascularization.

GOAL OF REVASCULARIZATION

Revascularization should restore straight-line, pulsatile arterial blood flow, thereby allowing the wounds to heal and the ischemic pain to subside. The restoration of oxygenated blood may be important even when a primary amputation is planned to facilitate wound healing at the amputation site, and to potentially lessen the extent of amputation. Primary patency is less important in this patient population. As we initially noted, the new endovascular techniques result in increased limb salvage rates with acceptable secondary patency rates.

FOLLOW-UP

Patients with chronic CLI require lifelong monitoring of the intervened arterial segments. Although reintervention is generally needed over time, the high technical success rate of these procedures combined with the considerably reduced physical stress and risk to patients makes this an important primary approach to CLI treatment. However, endovascular revascularization still results in 4-year survival rates as low as 40%, with most deaths caused by coronary artery disease and cerebrovascular disease.[5] The good news is that continuing interventions for these diseases can considerably improve and extend life for these high-risk patients. ■

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