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Diagnosis and Management of Critical Limb Ischaemia

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Critical limb ischaemia (CLI) represents the most advanced state of peripheral disease within the spectrum of chronic limb ischaemia. Rest pain, ischaemic ulceration, and gangrene attributable to vascular disease define the range of findings within CLI. Although dwarfed by the prevalence of asymptomatic peripheral vascular disease and intermittent claudication, CLI carries substantial social and economic costs.

The frequency of cases of critical limb ischaemia—estimated at 500 to 1000 cases per million—and high morbidity and mortality are under appreciated (Norgren et al. 2007). Consider, as an example, the expected outcome at one year: 25% mortality and 30% amputation, leaving only 45% alive with both limbs (Norgren et al, 2007). It is worth emphasising that critical limb ischaemia is a subset of chronic limb ischaemia and therefore distinct from acute limb ischaemia, with which it is sometimes confused. Clearly there is some overlap and patients with critical limb ischaemia will on occasion develop so-called acute-on-chronic limb ischaemia (e.g. the patient whose limb is entirely dependent on collateral flow and has had symptoms of rest pain may develop acute limb ischaemia from sudden occlusion of the collaterals), but the overall distinction is important because of its implications for approach and management.

Diagnosis

The cornerstone of diagnosis is a patient history consistent with rest pain or the presence of ulcerations or frank gangrene. Patients with rest pain typically describe pain in the toes or over the metatarsal heads in the absence of any exertion. Placing the feet in a dependent position, which is believed to augment blood flow, may partly or fully resolve these symptoms. Nighttime calf and thigh cramps and discomfort (common in the elderly population) do not represent rest pain. Many of these patients will also report a history of claudication in the past, as this is often a precursor to critical limb ischaemia. It is important to note that a significant percentage of patients with peripheral arterial disease have diabetes as well. For example, in the prospective PREVENT III trial by Conte and colleagues, 64% of patients with critical limb ischaemia who were undergoing vein bypass had diabetes. The associated neuropathy may make it very difficult to determine whether the patient has true critical limb ischaemia (Conte et al. 2005).

It is self-evident that any number of non-vascular conditions may mimic rest pain or ischaemic ulceration, ranging from neurologic conditions (e.g. spinal stenosis) to malignancy and vasculitis. As such, all diagnoses must be confirmed to have a vascular aetiology. The most basic technique relies on ankle brachial index, which is typically of a value lower than 0.4. Alternative confirmatory tests include ankle pressures less than 50 mmHg and toe pressures less than 30 mmHg. Note that meeting the precise cut offs for objective testing listed above is not technically necessary (e.g. a patient with an ABI>0.4 may still have CLI), but measurements that deviate substantially should raise the possibility of a non-vascular aetiology. Nevertheless, the evaluation of the diabetic patient is more challenging as objective pressure measurements can be falsely elevated due to calcification within the arteries, a finding which is common in the diabetic with vascular disease.

After diagnosis, it is imperative to define the extent and distribution of disease. Digital subtraction angiography (DSA) is widely held to be the “gold standard” test. The advantages of high imaging quality and the ability to simultaneously intervene must be balanced against the possibility of complications from the test itself (e.g. access site injury, distal embolisation, dissection, and so forth), renal toxicity, and radiation exposure. Carbon dioxide angiography mitigates the risk of renal injury, but at the cost of imaging quality. Computed tomographic angiography (CTA) is the noninvasive analogue to standard angiography and also involves iodinated contrast administration and radiation exposure. CTA imaging quality

is comparable to angiographic images and in some respects better with the use of 3-D reconstructions, which can provide significantly more information than 2-D angiography. Small vessel calcification and metal may produce significant artifact. Magnetic resonance angiography (MRA) avoids radiation and iodinate contrast; however, it (e.g. pacemakers) may not be compatible, and gadolinium is still contraindicated for those with severe renal insufficiency because of the risk of nephrogenic systemic fibrosis. Arterial duplex is a noninvasive modality that does not involve contrast or radiation. It is most useful in infrainguinal imaging. Obesity or significant limb oedema, painful ulcers, and dense vascular calcification may degrade image quality, however. Although blanket recommendations regarding imaging selection are impossible to make given the varying advantages and disadvantages of each modality, we generally prefer CTA or DSA.

Management

In contradistinction to the management for intermittent claudication, revascularisation remains the mainstay of CLI therapy. This should not be misconstrued to imply that medical management is irrelevant. In fact, optimisation of cardiovascular risk factors is an essential adjunct, without which any vascular reconstruction is bound to fail. Smoking, hypertension, dyslipidemia, diabetes, and hypercoagulable states should all be optimally controlled. Specifically, goals of blood pressure less than 130/80, lowdensity lipoprotein (LDL) less than 100 mg/dl (or less than 70 mg/dl for higher risk patients), and haemoglobin A1C less than 7% should be sought. Three classes of medication have been shown to reduce cardiovascular morbidity and mortality associated with peripheral vascular disease: antiplatelet agents, angiotensin-converting enzyme inhibitors (ACEI), and statins (Mangiafico 2011).

Vascular reconstruction may be undertaken through an open, endovascular, or hybrid approach. The Trans-Atlantic inter- Society Consensus II (TASC II) classification provides a basic framework for understanding the approach. Clearly, however, decisions must be tailored to individual circumstances. Other salient characteristics that influence the final decision include lesion morphology, including eccentricity and calcification, presence of significant tissue loss in the limb, and disease across a joint, all of which would favour open intervention.

There is a dearth of high-quality evidence for revascularisation, a fact that is reflected in the absence of firm guidelines for intervention. The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial is the only major randomised trial to compare surgical bypass and percutaneous intervention. Briefly, the BASIL trial examined the primary endpoints of overall survival and amputation-free survival in 452 patients with severe leg ischaemia, defined as rest pain or tissue loss with an arterial aetiology of greater than two weeks in duration, who were randomised between bypass surgery-first and angioplasty surgery- first strategies (Adam et al. 2005). Patients were enrolled from 1999 to 2004, and the trial concluded that patients with a life expectancy greater than two years benefited from open bypass while in those with a lower life expectancy and those in whom vein conduit was unavailable, percutaneous intervention should be preferred. Although a seminal trial in vascular surgery, the BASIL trial design has been widely criticised (Clair 2012) and there is clearly a need for better data to assist in decision-making regarding therapy.

Conclusion

Critical limb ischaemia—as indicated by rest pain, ulceration, or gangrene, and confirmed by objective testing to have a vascular aetiology—carries a high nearterm rate of mortality or amputation. Medical management of cardiovascular risk factors is a necessary element of successful therapy. Specific medications that have been demonstrated to improve outcomes include antiplatelets, ACEI, and statins. Revascularisation, undertaken via open surgery or endovascular intervention, remains the foundation of therapy for CLI.

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