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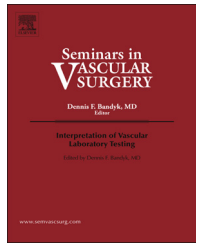

Endovascular intervention for tibial artery occlusive disease in patients with critical limb ischemia

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ABSTRACT

Surgical bypass has traditionally been the gold standard for treating critical limb ischemia caused by isolated infrapopliteal arterial disease (IP CLI). However, as endovascular techniques continue to progress, they are increasingly applied to this patient population, especially to the high-risk surgical cohort or patients with limited surgical options. This enthusiasm to employ endovascular interventions in IP CLI is accompanied by persistent controversies, as demonstrated in the recent literature. Percutaneous transluminal balloon angioplasty has been the predominant endovascular intervention applied to treat IP CLI and recent literature supports its role. The durability of percutaneous transluminal balloon angioplasty is limited, and thus this intervention is recommended for high-risk patients with limited life expectancy. Bare-metal stents for IP CLI currently do not have supportive data to warrant their use as a primary treatment. Newer drug-eluting stents improve patency and prevent restenosis, but they do not significantly improve patient clinical status compared with bare-metal stents alone. Drug-coated balloons are still relatively new tools in this arena and evidence of their safety and clear efficacy are still lacking. The data on atherectomy, in all of its forms, for IP CLI are overall variable, without any clear benefit to justify its increased complication risks and costs over other modalities. Use of retrograde tibial/pedal access for treating IP CLI as a viable alternative to antegrade access and treatment from a totally retrograde approach has recently been described. Level I evidence to aid in clarifying the true efficacy for each of these endovascular modalities is greatly needed. As we await these data, we must remember that, as with any arterial intervention, proper patient selection is extremely important and the intervention, whether endovascular or open surgical repair, should be tailored to the individual patient's anatomy and disease characteristics.

1. Introduction

Peripheral arterial disease (PAD) affects >10 million people in the United States and this number is projected to rise as the general population continues to age and the incidence of vascular comorbidities, such as diabetes and renal disease, increases. For those patients that have intermittent claudication, 1% to 2% will ultimately progress to critical limb ischemia (CLI) within 5 years [1]. Patients with diabetes and PAD are at even higher risk and have a 10-fold increased risk of developing CLI when compared with nondiabetic PAD patients [2]. Patients with CLI can have either single or

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multilevel arterial occlusive disease, but isolated infrapopliteal disease is more common in diabetic patients. Endovascular therapy for CLI due to lesions involving the femoropopliteal arteries has been well studied [3] and consensus treatment guidelines have been published [2]. However, for atherosclerotic disease affecting the infrapopliteal (IP) arteries causing CLI, there is a less well-defined treatment course with regard to endovascular interventions. Open surgical revascularization with autologous saphenous vein graft has traditionally been the gold standard in limb salvage for IP arterial occlusive disease resulting in CLI. However, open IP bypass carries significant morbidity and many patients with CLI might be ineligible for open revascularization due to prohibitive pre-existing anatomic and physiologic factors.

Continued advances in endovascular techniques have affected a paradigm shift from open bypass toward endovascular therapy as an adjunct treatment method at the very least, to a primary therapeutic modality for limb salvage in patients with IP CLI. This emerging trend was appropriately acknowledged in the TransAtlantic Inter-Society Consensus (TASC) II guidelines: "Endovascular procedures below the popliteal artery are usually indicated for limb salvage and there are no data comparing endovascular procedures to bypass surgery for intermittent claudication in this region … There is increasing evidence to support a recommendation for angioplasty in patients with CLI and infrapopliteal artery occlusion where in-line flow to the foot can be re-established and where there is medical co-morbidity" [2]. Since then, numerous studies/reviews on this subject have been published that reinforced the feasibility of this concept [4–6].

More recently, Varela and colleagues [7] demonstrated IP endovascular techniques (specifically, angioplasty and stenting) as noninferior to open bypass based on the Society for Vascular Surgery's objective performance goals (OPG). They determined that the incidence of major adverse cardiovascular events, major adverse limb events (MALEs), and major amputations at 30 days to be 5% (95% confidence interval [CI], 2%–10% [OPG-major adverse cardiovascular events <10%]), 2.5% (95% CI, 0.5%–7% [OPG-MALE <9%]), and 1.7% (95% CI, 0.2%–6% [OPG-major amputation <4%]), respectively. In addition, the freedom from MALE + postoperative death at 12 months was 76% (95% CI, 67%–83% [OPG-MALE + postoperative death >67%]) and an amputation-free survival (AFS) was 78% (95% CI, 69%–85% [OPG-AFS >68%]). Singh et al [8] recently reviewed their single-institutional experience with an endovascular-first approach to selected patients with IP CLI. A total of 187 patients with CLI underwent endovascular interventions for 356 IP lesions that included 41% patients with IP occlusions that resulted in an overall 1-year limb-salvage rate of 84%; supporting endovascular therapy as a viable primary treatment modality in IP CLI.

The lack of overly convincing level I evidence has prevented wide adoption of primary endovascular interventions for IP CLI and yet, despite this, there is fervent enthusiasm for incorporating endovascular interventions into the treatment armamentarium for IP CLI. In this review, we present the current literature on endovascular therapies for CLI involving the IP arterial vasculature, which span a broad spectrum of techniques ranging from fundamental percutaneous transluminal angioplasty (PTA)/stenting (traditional and with drug elution) to various atherectomy and other adjunctive treatment modalities.

2. Tibial artery balloon angioplasty

By far the predominant endovascular treatment modality employed and studied for IP CLI has been standard PTA (see Figure 1). In 2005, the Bypass Versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial reported its initial findings [9]. As the first multicenter, randomized controlled trial (RCT) comparing open bypass versus PTA as the first approach for infrainguinal severe limb ischemia, it served as a catapulting platform by demonstrating comparable AFS outcomes at 2 years in patients treated with endovascular therapy.

Fueled by these promising results, Giles and colleagues [4] published their experience with PTA for IP CLI. Their retrospective review of 163 patients (176 limbs) with IP CLI who underwent primary IP PTA demonstrated an inverse relationship between outcomes and increasing TASC II scores. TASC D lesions predicted diminished technical success (75% TASC D *v* 100% TASC A, B, and C; $P < .001$), primary restenosis, reintervention, or amputation (hazard ratio [HR] = 3.4; 95% CI, 2.1–5.5; $P < .001$), primary patency (HR = 2.2; 95% CI, 1.3–3.9; $P < .004$), secondary restenosis (HR = 3.2; 95% CI, 1.6–6.4; $P = .001$), and limb salvage (HR = 2.6; 95% CI, 1.1–6.3; $P < .05$). Despite a high overall technical success of 93%, freedom from the composite endpoint of restenosis, reintervention, or amputation at 1 and 2 years were only 39% and 35%, respectively. Primary patency for 1 and 2 years for the same periods were 53% and 51%, respectively, and freedom from secondary restenosis and reintervention were 63% and 61%, respectively. Limb salvage was 84% at 3 years. The authors concluded that PTA for IP CLI due to TASC A, B, or C lesions is a reasonable primary treatment, but bypass might be preferred for TASC D lesions.

These results were recently reaffirmed in Lo and colleagues' [10] retrospective review of IP PTA for CLI that expanded on Giles and colleagues' earlier publication. They analyzed IP PTA in 459 limbs (413 patients) from 2004 through 2012 stratified by TASC classification. Technical success was 93%, with all technical failures involving TASC D lesions. One-year and 5-year primary patency rates were 57% and 38%, respectively, and limb-salvage rates were 84% and 81%, respectively. Restenosis rates were greater with increased TASC severity: TASC C (HR = 2.2; 95% CI, 1.2–3.9; $P = .010$) and TASC D (HR = 2.4; 95% CI, 1.3–4.4; $P = .004$). Also, amputation rates were higher in patients with TASC D lesions (HR = 3.8; 95% CI, 1.1–12.5; $P = .03$). They concluded that IP PTA was an effective primary treatment for IP CLI in TASC A, B, and C lesions, and that for TASC D lesions, surgical bypass should be offered to those patients who are surgical candidates. However, very recent studies by Sadaghianloo et al [11] in 2013 and Tewksbury et al [12] in 2014 have demonstrated the potential benefits of endovascular interventions for TASC C and D lesions involved in IP CLI.