Tibial Intervention for Critical Limb Ischemia

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ABSTRACT

Diagnosis and treatment of critical limb ischemia (CLI) is increasingly important as the average age of the world population and the incidence of diabetes and metabolic syndrome increases. Fortunately, most patients will not progress to this stage of peripheral arterial disease, yet if left untreated, there is a high risk of future cardiovascular events. At the point of ischemic rest pain or tissue loss, there are significant implications for morbidity and mortality. There is a high prevalence of multisegment occlusive disease in the CLI patient with the infrapopliteal vessels frequently involved. Revascularization of the affected limb is of utmost importance as the prospects of wound healing and relief of ischemic rest pain are poor without reestablishing continuous flow to the distal extremity. With the advent of endovascular devices designed to treat this vexing problem, the ability to successfully treat this difficult patient population with less procedural morbidity has been greatly enhanced.

KEYWORDS: Peripheral arterial disease, angioplasty, endovascular therapy, ischemic rest pain

Objectives: Upon completion of this article, the reader should be able to identify the clinical and functional impact on patients with critical limb ischemia and state the available endovascular treatment options for patients with limb-threatening ischemia.

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Critical limb ischemia (CLI) is an increasingly recognized and clinically devastating manifestation of peripheral arterial disease (PAD). The morbidity and mortality and the clinical and economic impact of CLI has been well described by Allie et al.¹ Mortality can reach as high as 25% within the first year of being diagnosed with CLI. An additional 25% will require a major amputation. Limb salvage is the ultimate clinical goal for patients with CLI and for physicians treating these patients. Lower-extremity amputation is an unfortunate but often necessary treatment for many patients with CLI, yet its effects on functional status,

quality of life, and mortality are substantial. Although there is frequently minimal functional impact with digital and even transmetatarsal amputation, more extensive amputation is associated with increased morbidity and mortality. Nehler et al reported that 65% of patients with below the knee amputation (BKA) were ambulatory at 1 year following amputation, with just one-half of these patients being ambulatory indoors only. Twenty-nine percent of patients with above the knee amputation (AKA) were ambulatory at 1 year, with approximately two-thirds of these being ambulatory indoors only.² Further, it has been estimated that a

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Figure 1 (A,B) An 81-year-old white male with hypertension, coronary artery disease, and insulin-dependent diabetes mellitus with 3-month history of right lower-extremity ischemic rest pain. Resting ankle-brachial index = 0.45. Right lower-extremity arteriogram reveals diffuse disease of the midanterior tibial artery with two focal occlusions and a severe focal mid-distal stenosis. There is moderate disease of the tibioperoneal trunk and peroneal artery proximally and complete occlusion of the posterior tibial artery.

patient with BKA needs between a 50 to 100% increase in energy expenditure to ambulate.³ Patients with BKA and AKA have an increased risk of overall mortality with ~50% of BKA patients alive at 5 years.^{1,4} Interventional and surgical treatments for limb salvage have tremendous impact on this patient population. Fortunately, endovascular treatment of CLI patients has undergone significant improvement in recent years, primarily as the result of increasing awareness of the CLI epidemic and the rapid development of improved technology, enabling interventionalists the ability to treat more patients who otherwise would be subjected to amputation. Relatively little prospective data exist to definitively determine the most appropriate and beneficial role of endovascular intervention, primarily percutaneous transluminal angioplasty (PTA), for patients with CLI; however, the BASIL study provides some insight and support for a less invasive approach in certain patients.⁵ This study

evaluated an angioplasty-first approach versus surgery-first in 452 patients with rest pain, tissue loss, or gangrene due to infrainguinal occlusive disease. Although PTA was associated with higher rates of immediate failure and reintervention at 12 months, the primary end point of amputation-free survival was similar and nonstatistically significant at 12 months (71% PTA versus 68% surgery, $P = \text{NS}$). The higher initial cost of the surgery-first approach was shown, including technical costs and threefold higher incidence of intensive care unit admission in this group. Finally, a post hoc analysis showed that surgical patients had a lower amputation rate and lower mortality in patients alive at 2 years with the treated limb intact.

The challenges of endovascular intervention in the tibial segment are many and somewhat unique for the practicing vascular specialist. The high prevalence of heavy and extensive calcification, multiple vessels

Figure 2 (A,B) Following 3.0-mm percutaneous transluminal angioplasty of the midanterior tibial artery and tibioperoneal trunk and 2.5-mm percutaneous transluminal angioplasty of the peroneal artery, continuous pulsatile flow is noted into the right foot. Ischemic symptoms were relieved at 1-week follow-up.

potentially requiring intervention, frequency of occlusion versus stenosis, potential access difficulties (more proximal occlusion), and other anatomic considerations (lack of distal target) are just a few of the problems faced. Improved guide wire, balloon, and stent technology has enabled the delivery of devices to these small vessels with relative ease, the challenges of crossing these lesions notwithstanding. This has been largely accomplished through adaptations of preexisting coronary platforms with the adjustments to include better pushability (over-the-wire versus rapid exchange systems), longer balloon lengths (up to 220 mm to treat longer lesions with less inflations), longer stent lengths (to avoid overlap and decrease costs), and enhanced guide wire torqueability. Longer sheaths provide an additional advantage regarding wire/catheter exchanges and increased axial support and pushability. Off-label use of FDA-approved devices

in the tibial segment is frequently necessary to achieve an adequate procedural end point and is left to physician discretion.

DATA

There is a growing collection of data as the experience in below-the-knee (BTK) intervention accumulates. Although there is little randomized data, there are numerous studies describing various techniques and use of ancillary devices and standard adjunctive therapies to PTA. Outcomes remain the ultimate measure of success; however, debate exists as to what is the most appropriate end point.⁶ In studies involving CLI patients, limb salvage or amputation-free survival is the most frequent end point. In the interest of establishing the durable effects of tibial interventional techniques, vessel patency

Figure 3 (A,B) A 75-year-old white male with insulin-dependent diabetes mellitus, hypertension, and 4-month history of nonhealing wound of the left foot. Resting ankle-brachial index = 0.38. Left lower-extremity arteriogram shows moderate stenosis of tibiofibular trunk, occlusion of the midanterior tibial artery with distal reconstitution, and multifocal severe stenoses of the proximal posterior tibial artery with distal occlusion and subsequent distal reconstitution.

likely should be assessed and, in fact, may be required to prove efficacy of any particular device, if the goal is to achieve an FDA approval of that device for a BTK indication.

TECHNICAL CONSIDERATIONS

Experienced interventionalists will have some degree of preference regarding most aspects of BTK intervention. Considerations include access site (contralateral femoral versus antegrade femoral), use of atherectomy devices as an adjunctive treatment, availability of optimal imaging, and balloon/stent inventory. Comfort level with more extensive techniques (retrograde dorsalis pedis or posterior tibial artery access, “SAFARI” (subintimal arterial flossing antegrade-retrograde intervention) technique, transcatheter recanalization, antegrade popliteal access, etc.) will

vary among individual physicians but can be learned. As always, experience with what works for the individual physician must be coupled with newer techniques as they are developed and presented by experts in the field. The availability of certain devices may limit the treatment options for patients based on hospital restrictions, budgets, or physician training with these devices. A full inventory of available devices may be desired but also may not be practical for all institutions. With this in mind, BTK intervention requires at least a full inventory of small-vessel balloon and stent technology to achieve even a reasonable chance of procedural success.

EXISTING TECHNOLOGIES

In the following section, a brief summary of frequently employed devices and technologies for use in tibial vessel

Figure 4 (A,B) Following guide wire recanalization of the midanterior tibial artery and posterior tibial artery, laser atherectomy was performed followed by 2.5-mm cryoplasty of midanterior tibial artery, and posterior tibial artery and 3.0-mm cryoplasty of the tibioperoneal trunk. Completion angiogram demonstrates excellent, brisk inline flow through the treated segments. Clinical follow-up at 1-month postintervention showed 95% wound healing, with complete healing noted at 2 months.

endovascular intervention is presented; the section is not intended to be all inclusive. Although a complete analysis of the available data for each technology is beyond the scope of this article, a short discussion of the most pertinent data is given. As mentioned earlier, little data beyond single-center or individual case series are available, and in the United States, some of these devices are considered off-label use in the infrapopliteal segment.

PTA

There is more experience with PTA as a stand-alone therapy for BTK intervention than any other method. As with atherosclerotic lesions in other vascular territories, a more favorable response to PTA is seen with shorter, noncalcified stenoses compared with heavily calcified, longer occlusions. A certain amount of lesion recurrence is expected in the tibial vessels owing to the pattern of

disease, coexistent vascular risk factors, and overall clinical status. Device development specifically for this anatomic segment has received an enormous amount of attention in the last several years due to the rising interest in CLI and the previously inadequate technologies. Low-profile (0.014-inch/0.018-inch) balloons with varying compliance are widely available. Crossing catheters have become an important addition to the interventional toolbox and provide added support for traversing long, difficult lesions. Numerous reports of outcomes for infrapopliteal PTA have been published with technical success rates ranging from 77 to 100% and limb salvage rates up to 91%⁷⁻¹⁰ (Figs. 1 and 2). The difficulty in interpreting these data is the lack of standard clinical end point and follow-up period. In addition, most meta-analyses of tibial PTA date back to the late 1980s; currently available technology would presumably result in more favorable outcomes in both technical and clinical

success. Recently however, Giles et al reported outcomes in 176 patients with CLI and Trans Atlantic Inter Society Consensus (TASC) A-D lesions undergoing PTA with provisional stenting.¹¹ An 84% limb salvage rate at 3 years was noted. A secondary reintervention rate of 15% at 2 years was reported, reflecting the recurrent nature of the disease process in these small vessels. Studies investigating the use of PTA with adjunctive therapies (atherectomy, cryoplasty, cutting/scoring angioplasty) may provide more meaningful and current information regarding the role of PTA; however there is general acceptance of the value of PTA as a frontline method of revascularization in patients with limb-threatening ischemia, especially in the presence of medical comorbidities that increase the risk of surgical bypass.

"Modified" Angioplasty Techniques (Peripheral Cutting Balloon[®], Angiosculpt[®] Scoring Balloon, CryoPlasty[®])

Use of the Peripheral Cutting Balloon[®] (Boston Scientific Corporation, Natick, MA) for BTK intervention has been described as an effective alternative for infrapopliteal lesions with significant calcification and/or resistance to standard PTA. It is approved for PTA of obstructive lesions of synthetic or native arteriovenous dialysis fistulae. This noncompliant balloon catheter has four atherotomes that are exposed with balloon inflation with the effect of making precisely controlled incisions, locally disrupting the fibrotic component of the vessel wall that can cause elastic recoil. A multicenter study published by Cardon et al examined 53 extremities in 48 patients (56% diabetic, 45% over 80 years old) with CLI due to infrapopliteal lesions with no companion proximal lesions. The authors stated that in 82% of cases, the arterial lesions were "long, i.e. more than 1 cm." Certainly this point is debatable yet limb salvage rate at 1 year was 81%. Postprocedural mortality was 9%, and mortality at 1 year was 22.6%, reflecting the fragile nature of the study population. The authors concluded that cutting balloon angioplasty was safe and effective and can be used as a primary therapy for CLI patients with BTK disease.¹²

The AngioSculpt[®] Scoring Balloon (Angioscore, Inc., Fremont, CA) is a semicompliant balloon with a flexible nitinol scoring element that scores the target lesion with the intended effect of a more uniform and precise outcome. It is a 0.014-inch/0.018-inch over-the-wire system with 5-French/6-French sheath compatibility. An international, multicenter registry of 93 patients (79% with Rutherford-Becker grade ≥ 4) with 131 lesions (15% occlusions, 54% calcified, mean length = 28 mm) demonstrated a dissection rate of 9.9% that were minor or required stent placement. In 17 patients who had initially been scheduled for amputation, limb salvage was achieved.^{13,14}

CryoPlasty[®] involves use of the PolarCath[™] Peripheral Dilatation System (Boston Scientific Corporation), which has an FDA indication for treating stenotic lesions in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal, and subclavian arteries) among other indications. During inflation of the balloon, within a separate lumen in the balloon catheter, liquid nitrous oxide is converted to gas thereby cooling the surface of the balloon to -10°C . The theoretical mechanisms of action involve altered plaque response, reduced elastic recoil, and induction of apoptosis within the endothelium, thereby reducing the rate of restenosis. One-year outcomes of the Below-The-Knee Chill Study (111 patients with stenotic/occlusive lesions in popliteal and infrapopliteal arteries) have been published showing 93% and 85% freedom from major amputation rate at 6 and 12 months, respectively¹⁵ (Figs. 3 and 4).

Stents

Infrapopliteal stent placement has been historically used in limited fashion and mostly for failed initial angioplasty. The high dissection rate in complicated BTK occlusive lesions and limited data regarding vessel patency (despite positive clinical results, i.e., wound healing, relief of rest pain, etc.) has led to many investigations of the use of low-profile stents, both balloon-expandable/bare-metal (BMS) and self-expanding (SES), as well as drug-eluting (DES) and more recently, bioabsorbable variations.^{16,17} Several reports have established the safety and efficacy of DES below the knee. Commeau et al reported in their series a 100% technical success rate, 100% clinical success rate, and 100% freedom from amputation rate at a mean follow-up of 7.7 months.¹⁸ Perhaps more impressively, Rosales et al reported on their experience in 24 patients using two different types of DES, with longer follow-up and either angiographic or duplex-documented vessel patency. Eighty-three percent of patients achieved limb preservation (follow-up range 8 to 34 months; two minor [toe] amputations, two BKA). Angiographic or duplex follow-up (mean = 9.5 months) in 19/24 patients showed 95% patency rates.¹⁹ SESs have also been shown to be safe and effective in treating obstructive atherosclerotic lesions BTK.^{20,21} Patency and limb salvage rates with the use of BMS, SES, and DES are all quite similar in the short term, with limb salvage rates higher in general versus vessel patency rates (70 to 100% versus 60 to 80% at 1 year). It appears that the main use of stents in tibial intervention is for suboptimal PTA results, although primary stenting is being heavily evaluated as a first-line consideration. No consistent mid- or long-term data have been shown to define a role for the use of bioabsorbable stents in infrapopliteal intervention;

however, investigations are ongoing and short-term results are anticipated in the near future.^{22,23}

Atherectomy

The use of atherectomy in the infrapopliteal segment has become more widespread in the last several years due to the development of several devices. The concept of atherectomy has been an intriguing one, yet there has been a paucity of data that demonstrate it to be superior to other interventional techniques. Numerous registries and single-center studies have been published, but these have the inherent weaknesses of studies of this design, namely, there is no randomized or comparative data. The dynamic nature of infrainguinal intervention (including the BTK vessels) in the setting of myriad treatments for this segment makes a comparative study quite difficult to construct. Level I data are certainly desirable and should be the target, but in this rapidly evolving area, this may not be very practical. As a result, use of atherectomy as an interventional tool has been largely based on the idea that “debulking” or “lesion prep” will provide a more acceptable acute and more durable angioplasty or stenting result, as most physicians use atherectomy as an adjunct to PTA or stenting. This philosophy is thus based on whether the treating physician feels there is intuitive sense in atherectomy versus relying on trial data that proves its role.

The SilverHawk[®] Plaque Excision System (ev3, Inc., Plymouth, MN) has been commercially available for over 5 years and is an excisional atherectomy device with a rotating carbide atherotome that is able to capture the plaque in the nose cone of the device and therefore remove it. A large database (TALON Registry) has been accumulated from physicians around the world on the usage pattern of this device, and although no randomized data are included in this registry, there is a large amount of information available regarding the use of plaque excision for CLI. In a collection of data analyzed for CLI patients, a total of 212 patients (391 lesions, all infrapopliteal) with Rutherford-Becker grade 4 or greater were treated with plaque excision using the SilverHawk[®] device. Lesions were relatively short (mean = 36.8 mm) but fairly challenging (69% moderately to severely calcified, 35% occlusions) and 12-month freedom from reintervention of 77% and 12-month limb salvage rate of 90% were demonstrated.²⁴ In addition, Keeling et al²⁵ published their experience with plaque excision in 70 patients, 47 of whom presented with at least Rutherford-Becker grade 4 or greater. Seventeen patients underwent tibial atherectomy (all with at least one other vessel treated). Limb salvage rate for the entire cohort was 86% at 12 months, rivaling most available studies using other techniques. It should be noted, like most other atherectomy data sets, that 20% of patients needed adjunctive PTA and another

4.3% required stent placement. This study reflects the multifocal nature of atherosclerotic disease in CLI patients. Finally, Zeller et al published their 12-month and 24-month outcomes in 36 patients with infrapopliteal occlusive disease with an average lesion length of 48 mm (89% mean stenosis, 22% occlusions). Thirty-nine percent of patients required adjunctive PTA with an additional 4% requiring stent placement for dissection. Ninety-eight percent achieved procedural success with <30% residual stenosis by any method (stand-alone atherectomy and/or adjunctive treatment) with 12-month primary and secondary patency of 67% and 91%, respectively, and 24-month primary and secondary patency of 60% and 80% respectively.^{26,27}

The Diamondback 360[™] Orbital Atherectomy System (Cardiovascular Systems, Inc., St. Paul, MN) was commercially released in August 2007 and is based on the idea of differential “sanding” of complex and calcified plaque, using centrifugal force to orbit a diamond-encrusted crown within the vessel to create a more compliant vessel for adjunctive PTA or stenting. The OASIS trial was a multicenter, nonrandomized, prospective registry evaluating the safety and efficacy of the Diamondback[™] device. In this study, 201 lesions (39% occlusions, significant calcification = 42%, 50% lesions >30 mm) in 124 patients (30% Rutherford-Becker grade 4 or 5) were treated with orbital atherectomy. Ninety-four percent of lesions were at the popliteal artery or below. The primary safety and efficacy end points were acute reduction in stenosis and 30-day adverse events. Secondary end points included target lesion revascularization (TLR), 30-day and 180-day clinical outcomes, and procedural success. All these end points were compared with objective performance criteria and were shown to be noninferior to these criteria, including a 1.8% TLR rate and no unplanned amputations at 180 days.²⁸

The CLiRPath Turbo Elite laser catheter (Spectranetics, Inc., Colorado Springs, CO) uses an excimer (excited dimer) laser that generates 308-nm pulsed ultraviolet light to “photoablate” plaque, thereby creating a channel to perform additional intervention. Perhaps the most cited study regarding peripheral atherectomy is the LACI trial, a multicenter, nonrandomized registry of 145 patients (155 limbs) with primarily femoropopliteal disease and CLI. Procedural success (<50% residual stenosis) was noted in 85% of cases, but 96% of cases required PTA and 45% required stent placement. A limb salvage rate of 93% was achieved at 6-month follow-up.²⁹

The recently FDA-approved Jetstream[™] Atherectomy Catheter (Pathway Medical Technologies, Inc., Kirkland, WA) is another atherectomy system that has bidirectional cutting blades at two different diameters within a catheter that has both infusion and aspiration capabilities, to remove thrombus and/or excised tissue.

Although the adoption of atherectomy seems to be growing, these studies have not shown that atherectomy with PTA and provisional stenting performs better than PTA with provisional stenting alone.

ADVANCED TECHNIQUES: ACCESS

Numerous authors have described the use of retrograde pedal access as an alternative to the more common antegrade approach.^{30–32} The SAFARI technique, originally described by Spinosa et al,³³ involves a “combination” approach of antegrade and retrograde access in patients whose lesions cannot be addressed in standard fashion. The ability to recanalize tibial vessel occlusions from below is a viable option and often surprisingly successful given the extent of disease. Slight modifications of these techniques have been described extensively throughout the literature in publications of single-center experience.³⁴ Fusaro et al³⁵ recently described the use of a transcollateral approach to recanalize infrapopliteal vessel occlusion when standard antegrade recanalization was not possible. A patient with CLI presented with a patent anterior tibial artery (AT), tibioperoneal trunk (TPT) occlusion, and long proximal posterior tibial (PT) occlusion with distal reconstitution at the ankle. The approach was described using antegrade guide wire placement through the AT with retrograde recanalization of the occluded TPT via a prominent collateral from the AT to the peroneal 3 cm from the TPT origin. After successful PTA, a similar transcollateral approach was used through a collateral from the distal peroneal with retrograde recanalization of the long PT occlusion. This clearly illustrates the need for specific technology that enables these advanced techniques and also highlights the skill set needed to achieve procedural success.

PHARMACOLOGICAL CONSIDERATIONS

Pharmacotherapy can be an important adjunct to infrapopliteal intervention. There are numerous variations of antiplatelet therapy, anticoagulation, and use of intra-arterial vasodilatation. The combination of these agents has mostly been a matter of physician discretion as no standard approach has been shown to be of benefit more than another. Intuitively, the routine use of anticoagulation with heparin or bivalirudin in addition to pre- and postprocedural antiplatelet therapy enhances the probability of procedural success and increases the likelihood of long-term durability. Vasospasm is of some concern in the tibial vessels during intervention, but the standard use of short-term vasodilators and agents with more prolonged effects (calcium channel blockers) has not been demonstrated to have a predictable effect on procedural outcome.

CONCLUSION

With the increasing incidence of the metabolic syndrome, diabetes mellitus, and the advancing age of the population, it is expected that the incidence of PAD will commensurately increase. With significant improvements in medical therapy for cardiovascular disease, including statin and antiplatelet therapy, it is likely that the elderly population will live longer with their PAD; however, they may have a higher likelihood of developing more severe manifestations of the disease. CLI has profound impact on functional capacity, quality of life, and mortality. With the rapid evolution of endovascular technology, the ability to treat more patients with more complex and diffuse atherosclerotic burden is a reality. For the vascular interventionalist, it is imperative that the data are known, the tools are familiar, and the skills are developed to achieve ideal outcomes and preserve limbs.

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