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Original Studies

SCAI Expert Consensus Statement for Infrapopliteal Arterial Intervention Appropriate Use

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Intervention to treat infrapopliteal arterial disease can be challenging because the patients' comorbidities, the anatomic variables, and the limitations of our techniques. Clinical scenarios based on anatomic and clinical variables are presented. Recommendations regarding intervention (appropriate care, may be appropriate care, rarely appropriate care) are made based on best evidence. © 2014 Wiley Periodicals, Inc.

Key words: peripheral intervention; appropriate use; peripheral arterial disease

INTRODUCTION

Infrapopliteal (IP) arterial disease or "below the knee" arterial disease is commonly seen in patients with long-standing diabetes mellitus, chronic kidney disease, or the elderly. The most concerning manifestation of peripheral arterial disease (PAD) in these high risk patients is the development of critical limb ischemia (CLI: ischemic rest pain or ischemic ulcers). This arterial bed consists of relatively small caliber vessels, which are often calcified and associated with diffuse, multilevel disease. Due to the complexity of this patient population, their co-morbidities, and severity of vascular disease, there is a paucity of scientific evidence for the generalizability of percutaneous revascularization.

In general, non-ambulatory patients with a short life expectancy and extensive necrosis or gangrene should undergo primary amputation. Ambulatory patients who are acceptable surgical candidates, expected to survive more than two years with a patent IP artery that provides direct flow to the foot (considered to be a good distal target), and an adequate autologous venous conduit should be considered for surgical bypass. Patients with significant medical co-morbidities that limit life expectancy, those at increased risk for surgery, those without an adequate distal target for bypass, or with poor venous conduit should be considered for an endovascular-first approach.

This document was developed to guide physicians in clinical decision-making in the modern practical application of endovascular intervention for patients with IP arterial disease.

ANATOMIC CONSIDERATIONS

Patients with CLI typically have disease involving multiple levels (i.e., aorto-iliac, femoropopliteal (FP) and IP), but less than 10% of patients with CLI have hemodynamically significant disease in all three levels [1–3] (Table I). Infrainguinal disease (FP and IP) can be further subdivided into those with predominantly isolated IP disease (~33%) and those with both FP and IP disease (~67%) [4–7].

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TABLE I. Rutherford Classifications for Peripheral Arterial Disease

Classification 0	Asymptomatic
Classification 1	Mild Claudication (calf pain climbing more than two flights of stairs)
Classification 2	Moderate Claudication (calf pain climbing less than two flights of stairs)
Classification 3	Severe Claudication (calf pain climbing less than one flight of stairs)
Classification 4	Ischemic Rest Pain (foot pain due to inadequate perfusion that improves with placing the foot in a dependent position)
Classification 5	Minor Tissue Loss (cutaneous ischemic ulceration)
Classification 6	Major Tissue Loss (skin necrosis and gangrene)

Isolated IP disease is mainly seen in the elderly (>80-years old), diabetic, or dialysis-dependent patients [5]. These patients are at higher risk for amputation and have a shorter amputation-free survival compared to those with FP and IP disease (median amputation-free survival: 17 months (95% CI = 9–24 m) versus 37 months (95% CI = 28–44 m), $P = 0.001$) [6]. Clinical and non-invasive criteria have been used to determine which CLI patients would benefit from revascularization. These include Rutherford categories 4–6, systolic ankle pressure < 50 mm Hg, non-pulsatile plethysmographic tracing, and/or transcutaneous oxygen pressure <30 mm Hg [8,9].

The candidacy of patients with extensive IP disease for surgical bypass is often compromised by inadequate autologous vein, poor skin integrity, significant medical comorbidities, and calcified or diseased target arteries. With the development and evolution of catheter-based technology, the TASC II document states that "there is increasing evidence to support a recommendation for angioplasty in patients with CLI and IP artery occlusion." [10].

Procedural success is defined as the re-establishment of direct "in-line" pulsatile flow to the foot through at least one IP artery. It is currently unknown whether healing rates are improved when in-line flow to the foot is established through more than one IP artery, but maximizing blood flow through more than one artery is particularly attractive in patients with inadequate collaterals, plantar arch vessels, or limb-threatening ischemia. Consequently, the size, location, and extent of the necrosis may impact the necessity for multi-vessel revascularization. Furthermore, revascularization of the angiosome (a three-dimensional vascular territory supplied by specific source artery), has been shown to improve healing rates, using either endovascular or surgical therapies, when compared to revascularization of the non-angiosome territory [11–13]. However, realistically the angiosome-based revascularization strategy may be limited by the length and/or complexity of disease, the extent of collateralization, and the anatomic variability among patients, including anatomic anomalies [5].

CLINICAL CONSIDERATIONS

The goals of therapy for patients with IP arterial disease and CLI (Rutherford 4–6) include: relief of pain, healing of ulcerations, preservation of the limb from major amputation, improvement in the patient's quality of life and functionality, and prolonging survival.

Arteriographically severe IP stenosis is defined as a luminal reduction of 70–99% or occlusion in at least one IP artery [6,14,15]. Moderate IP stenoses is defined as a luminal reduction of 50–69% and mild IP stenosis is defined as a luminal reduction of <50%. Obstructive disease in the below-knee popliteal artery limits blood flow to the three tibial vessels (anterior, posterior and peroneal) and is equivalent to three vessel disease, while narrowing of the tibioperoneal trunk affects two tibial arteries (peroneal and posterior tibial) and is considered two-vessel disease. Tibial artery occlusions can be classified according to length as short (<2 cm), medium (2–4 cm), or long (>4 cm) [10]. Prior to considering IP intervention, all hemodynamically significant inflow disease (aortoiliac and/or FP) should be treated to normalize inflow to the IP circulation. Then, if deemed clinically necessary, one may proceed with management of the IP disease (Figs. 1–8, available online at wileyonlinelibrary.com).

Table II lists the appropriate use for IP interventions and provides a management strategy of IP disease. Only moderate to severe IP arterial obstructions should be considered for treatment, since the evidence for benefit for treatment of milder obstructions is unclear. The clinical scenarios in Table II assume that inflow disease has been revascularized. At the present time, patients with IP disease and claudication should be preferentially treated pharmacologically and a walking program before considering any revascularization procedure and the clinical scenarios in Table II assume that life-style limiting claudication has been refractory to pharmacologic and exercise therapy. The categories of Appropriate Care (AC), May Be Appropriate Care (MBAC), and Rarely Appropriate Care (RAC) were assigned by consensus based on the best available evidence (Table II).

TECHNICAL CONSIDERATIONS

Techniques for IP intervention vary widely and it is beyond the scope of this manuscript to detail each one. However, it is important to describe some fundamental elements of procedural strategy. Ideally the re-establishment of pulsatile flow to the limb should restore pedal pulses. Non-invasive studies should be performed during longitudinal follow-up with the goal of normalizing the ankle:brachial index, improving toe

TABLE II. Clinical Scenarios in Which Treatment of Infrapopliteal Artery Disease May Be Considered

Appropriate Care	• Moderate–severe claudication (RC 2–3) with two, or three-vessel IP disease (if the arterial target lesion is focal) • Ischemic rest pain (RC4) with two, or three-vessel IP disease (to provide direct flow to the plantar arch and to maximize volume flow to foot) • Minor tissue loss (RC 5) with two, or three-vessel IP disease (to provide direct flow to the plantar arch and to maximize volume flow to foot) • Major tissue loss (RC 6) with two, or three-vessel IP disease (to prevent major amputation[a] and to facilitate healing a minor amputation[b])
May Be Appropriate Care	• Moderate–severe claudication (RC 2–3) with two, or three-vessel IP disease (occlusion or diffuse disease) • Ischemic rest pain (RC 4) with one, or two-vessel IP disease (to provide direct flow to the plantar arch and in two-vessel, to maximize volume flow to foot) • Minor tissue loss (RC 5) with one-vessel IP disease (to provide direct flow to the plantar arch and to maximize volume flow to foot)
Rarely Appropriate Care	• Mild claudication (RC 1) with, one, two, or three-vessel IP disease • Moderate–severe (RC 2–3) claudication symptoms with one-vessel IP disease • Major tissue loss (RC 6) with one-vessel IP disease

RC = Rutherford Classifications for chronic limb ischemia. One-vessel infrapopliteal disease implies that two tibial arteries are without hemodynamically significant stenosis or occlusion; two-vessel infrapopliteal disease implies that one tibial artery is without hemodynamically significant stenosis or occlusion; three-vessel infrapopliteal disease implies that all three tibial arteries have hemodynamically significant stenosis and/or occlusion; no significant infrapopliteal disease implies that all three tibial arteries are without hemodynamically significant stenosis or occlusion; Severe stenosis = luminal narrowing 70–99%; Moderate stenosis = luminal narrowing 50–69%; Mild stenosis = luminal narrowing <50%; Occlusion = No flow through the arterial segment. Tibioperoneal trunk disease affects both the posterior tibial and peroneal arteries so would be consistent with two-vessel disease. Focal infrapopliteal lesion = discrete area of narrowing that can be treated with a single 15 mm long balloon/stent; Multiple lesions = more than one focal lesion in non-contiguous arterial segments; Diffuse lesion = a continuous segment of disease treated with > 15 mm long balloon/stent.

[a]Major amputation = removal of leg either above, or below the knee but above the ankle.

[b]Minor amputation = removal of the foot or portions of it [i.e., isolated toe(s).]

perfusion pressure (>30 mm Hg), and/or transcutaneous oxygen pressure (>40 Torr) [8,9].

Access

The ideal arterial access site for IP intervention should maximize access to the lesion and allow visualization throughout the procedure, with limited use of remote contrast injections. The most common site of access is either the contralateral, retrograde, common femoral artery with a cross over technique, or the ipsilateral, antegrade, common femoral artery approach. Other less common access strategies include: Ipsilateral antegrade superficial femoral artery, ipsilateral antegrade popliteal artery, and retrograde tibio-pedal access. These are usually facilitated with fluoroscopic, angiographic, or ultrasound guidance.

Each approach has advantages and disadvantages, and the success rate is largely dependent upon physician experience. Ipsilateral, antegrade common femoral artery access allows for easier guidewire control and device pushability/deliverability compared to a contralateral approach. Antegrade access can be challenging in obese patients, those with a high takeoff of the superficial femoral artery, and those with extensive scarring of the groin. Retrograde tibio-pedal access is generally reserved for lesions that cannot be crossed from an antegrade approach. Access can be obtained with visualization using ultrasound or angiographic visualization after injecting contrast from the primary access site and inserting the needle directly into the contrast column.

Percutaneous Transluminal Angioplasty

Percutaneous transluminal angioplasty (PTA) or balloon angioplasty is the current standard of therapy, with a technically successful result (<30% residual stenosis) in the majority of cases (77–100%), but is limited by high restenosis rates [16,17]. Flexible, low profile, balloons have enhanced the ability to cross, and successfully treat, focal, multi-focal, diffuse, and occlusive lesions.

Balloon catheters are available in lengths that can treat the entire IP artery with one or two inflations. Clinical studies are limited by the heterogeneity of disease, lack of randomized trials, multiplicity of techniques used, exclusion of early treatment failures, and crossover to open bypass during follow-up [17,18].

Restenosis after IP balloon angioplasty is common within the first year and is dependent upon the size of the artery and length of diseased segment. Negative predictors include: the presence of diabetes mellitus, chronic kidney disease, non-ambulatory status, and increasing severity of ischemia at the time of presentation [19].

Cutting Balloon Angioplasty

Balloon angioplasty has been the subject of most clinical studies, but several modified balloons have been used, i.e., cryoplasty or cutting/scoring balloons. There are no comparative data for these newer

modalities versus balloon angioplasty for IP arteries, although studies in other vascular territories have been negative [20,21]. Cutting balloon angioplasty (Boston Scientific, Natick, MA) may be appropriate for lesions resistant to plain balloon angioplasty that are fibrous or calcified, but the added cost, and lack of comparative evidence, makes these balloons not ideal for routine use.

Drug-Coated Balloons

Drug-coated balloons deliver anti-proliferative drugs to the arterial wall at the time of dilation. With inflation times of 30–60 sec, anti-proliferative drug (paclitaxel, sirolimus, and everolimus) levels have been shown to reach the adventitia of the artery, and remain detectable for weeks. The inhibition of the intimal hyperplastic response to arterial injury can potentially limit the amount of clinical restenosis [22]. This promising technology is not yet approved for use in the United States.

Atherectomy

Atherectomy devices help modify arterial compliance and/or remove plaque in order to facilitate lesion crossing, and to debulk lesions prior to balloon angioplasty. Devices are designed to *ablate the atheroma* (Excimer laser, Spectranetics, Colorado Springs, CO), *longitudinally excise* the atheroma (TurboHawk/SilverHawk, ev3 Inc., Plymouth, MN), or *rotationally excise* the atheroma (Jetstream G3, Pathway Medical, Kirkland WA and Orbital Atherectomy System CSI, St. Paul, MN) [23,24]. The clinical efficacy of these devices remains to be proven in randomized controlled clinical trials. Currently, there is no comparative evidence to support the use of any atherectomy devices in the IP arteries to improve clinical outcomes.

Infrapopliteal Stenting

Stenting of recalcitrant, restenotic, short or long IP lesions have been done with self-expanding nitinol stents, bare-metal stents (BMS), and drug-eluting stents (DES). [14,15,25–31]. These devices are associated with significantly better primary patency, primary-assisted patency, and fewer secondary interventions at 3-year follow-up than balloon angioplasty. DES seems to enhance this effect over BMS. The Drug-Eluting stents in The Critically Ischemic Lower Leg Trial (DESTINY Trial), a prospective randomized trial of 140 patients with IP lesions >50% with a reference diameter of 2.0–3.5 mm and length < 4 cm, were randomized to either BMS (Multi-Link Vision) or DES (Xience V, everolimus eluting). Primary patency (85% vs. 54%), late lumen loss, mean in-stent diameter stenosis, and target lesion revascularization were all significantly in favor of DES treatment. However, neither final Rutherford class 0 or 1 at 1 year, nor 1-year survival, was different between the groups [14]. Limitations of balloon expandable stents include: their lack of significant flexibility, the potential for fracture or compression from external trauma (particularly in the distal anterior and posterior tibial artery), and their high-cost expense (particularly when using multiple stents for long lesions).

The prospective randomized multicenter comparison of balloon angioplasty and IP stenting, with the sirolimus-eluting stent in patients with ischemic peripheral arterial disease (ACHILLES Trial), compared percutaneous balloon angioplasty to sirolimus-eluting stents (SES) for symptomatic IP artery disease. Two hundred patients (mean age 73 years; 64% diabetic) were randomized with the primary endpoint of arteriographic patency at one year. The authors found that SES significantly lowered angiographic restenosis (22.4% vs. 41.9%, $P = 0.019$) and improved vessel patency (75.0% vs. 57.1%, $P = 0.025$). There were no differences in death, amputation, target vessel revascularization, or functional improvement (Rutherford category) rates between SES and PTA [31]. These data support the perception that stents improve patency over PTA, even for short lesions in the tibial arteries.

The XCELL trial, a study to evaluate the safety and performance of the Xpert ™ stent in treating below-the-knee lesions in patients undergoing percutaneous intervention for chronic CLI, screened over 700 patients and enrolled 120 CLI patients to evaluate the role of nitinol stents for IP disease [15]. The majority of these patients also required inflow artery treatment. Overall, the mean lesion length was 4.7 ± 4.2 cm with stenoses averaging 3.6 ± 3.5 cm, and occlusions averaging 7.1 ± 4.5 cm. The angiographic binary restenosis rate was 68.5%, with a 6-month ulcer-healing rate of 43%. These data provide important lessons: prompt wound healing may require more than improved perfusion (<50% healing at six months), limb salvage rates were comparable to historical surgical rates, restenosis rates were higher for IP intervention, and the stent did not prevent restenosis in the majority of patients. Consequently, the use of stents in the IP arteries is still under scrutiny and is felt to be most effective in focal, proximal lesions that fail primary therapy with balloon angioplasty. Furthermore, the patency advantage of stenting may be more applicable to Rutherford 3 and 4 than Rutherford 5 and 6 where stenting has not been consistently shown to affect limb salvage rates.

Unresolved Issues

There are many unanswered questions regarding the role of endovascular intervention for the treatment of CLI in patients with IP atherosclerotic disease. The role of bio-absorbable stents, or the combination of drug-coated balloon following atherectomy or stenting in the IP vessels, remains to be determined [32].

CONCLUSION

CLI is the predominant clinical indication for treatment of IP arterial disease and occurs when arterial perfusion is reduced below a critical level resulting in ischemic pain and/or skin breakdown. Prompt revascularization is aimed at symptom relief with improved limb salvage and ulcer healing. Multilevel disease is more common than isolated IP disease, and a systematic approach to achieve straight-line flow from the iliac to pedal arch with complete revascularization is necessary to optimize outcomes.

PTA is the current standard for endovascular therapy for clinically significant IP disease. Bailout bare metal and drug eluting stents in the tibial arteries should be considered for failures of balloon angioplasty. Studies are currently enrolling patients to address the use of combined strategies (i.e., atherectomy and drug-coated balloons). Further data are needed regarding the utility of atherectomy devices, drug-coated balloons, DES, and bioabsorbable stents in IP interventions. However, until these results are available, given the increased costs of other modalities (e.g., cutting balloons, cryoplasty, laser, orbital, rotational, and directional atherectomy catheters), and the lack of comparative data to support their efficacy, balloon angioplasty should remain the initial endovascular therapy for most IP disease.

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