Review Article

Peripheral Vascular Intervention: A Review

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Abstract :

The prevalence of peripheral artery disease (PAD) continues to increase worldwide. It is important to identify patients with PAD because of the increased risk of myocardial infarction, stroke, and cardiovascular death and impaired quality of life because of a profound limitation in exercise performance.Lower extremity PAD affects approximately 10% of population, with 30% to 40% of these patients presenting with claudication symptoms. Peripheral arterial disease is common, but the diagnosis frequently is overlooked because of subtle physical findings and lack of classic symptoms. Screening based on the ankle brachial index using doppler ultrasonography may be more useful than physical examination alone. Noninvasive modalities to locate lesions include duplex scanning, computed tomography angiogram, magnetic resonance angiography and invasive modalities peripheral angiogram is the gold standard. Major risk factors for peripheral arterial disease are cigarette smoking, diabetes mellitus, older age (older than 40 years), hypertension, hyperlipidemia, and hyperhomocystinemia. Intermittent claudication may be improved by risk-factor modification, exercise, and pharmacologic therapy. Based on available evidence, a supervised exercise program is the most effective treatment. Effective drug therapies for peripheral arterial disease include aspirin (with or without dipyridamole), clopidogrel, cilostazol, and pentoxifylline. By contrast, critical limb ischemia (CLI) is considered the most severe pattern of peripheral artery disease. It is defined by the presence of chronic ischemic rest pain, ulceration or gangrene attributable to the occlusion of peripheral arterial vessels. It is associated with a high risk of major amputation, cardiovascular events and death. The management of CLI should include an exercise program, guideline-based medical therapy to lower the cardiovascular risk. Most of the cases, revascularization is indicated to save limbs; an “endovascular first” approach and lastly surgical approach, if all measures were failed. The choice of the intervention is dependent on the anatomy of the stenotic or occlusive lesion; percutaneous interventions are appropriate when the lesion is focal and short but longer lesions must be treated with surgical revascularisation to achieve acceptable long-term outcome.

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Introduction:

The prevalence of peripheral artery disease (PAD) continues to increase worldwide. It is important to identify patients with PAD because of the increased risk of myocardial infarction, stroke, and cardiovascular death and impaired quality of life because of a profound limitation in exercise performance and the potential to develop critical limb ischemia[1,2]. Despite effective therapies to lower the cardiovascular risk and prevent progression to critical limb ischemia, patients with PAD continue to be under-recognized and undertreated. The management of PAD patients should include an exercise program, guideline-based medical therapy to lower the cardiovascular risk, when revascularization is indicated, an “endovascular first” approach and lastly surgical

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approach, if all measures were failed [3].The indications and strategic choices for endovascular revascularization will vary depending on the clinical severity of the PAD and the anatomic distribution of the disease. In this chapter, we discuss peripheral vascular intervention (PVI) management of patients with PAD.

Endovascular Therapy

Endovascular revascularization plays a key role in the management of patients with PAD. Patients with stable claudication have a low risk of limb loss but may be severely limited by their symptoms. If the patient is not improved after a trial of medical therapy, endovascular revascularization can be considered. Patients with CLI require more urgent revascularization because of an increased risk of tissue loss and amputation, as well as an extremely high risk of cardiovascular events.[4]There are 2 well-established classification schemes to describe the severity of PAD. The first is a functional assessment (Fontaine or Rutherford classification [RC]) (Table 3), and the second is an anatomiclesion classification (Trans-Atlantic Inter-SocietyConsensus [TASC]) (Table 4)[5,6]. If the patient is a candidate for either endovascular or open surgery, the less invasive option (i.e., an endovascular-first strategy) is the current standard of care. The selection of a complex lesion (TASC D), for endovascular therapy will vary with the skill and experience of the interventionist.The goal intreating a patient who has functional impairment because of claudication is durable relief of symptoms. In patients with CLI and a threatened limb or tissueloss, the goal is rapid reperfusion of the ischemic tissue to relieve the ischemia, prevent amputation, and restore ambulation.

Strategies for PVI

Revascularization is typically considered in patients with PAD who have developed any 1 of 3 distinct clinical presentations: (1) lifestyle-limiting claudication no longer responsive to conservative therapy (IC); (2) critical limb ischemia (CLI); or (3) acute limb ischemia (ALI). Although the first 2 clinical syndromes represent separate yet related stages of progressive PAD, ALI is frequently because of peripheral thromboembolism rather than occlusive PAD. The urgency and goals of treatment depend on the presenting syndrome, comorbidities, and anatomy (Tables 1 and 2).

Technological improvements in the equipment used for endovascular revascularization have increased options for complex lesions once exclusively treated by open surgery.Lower risk endovascular techniques to revascularize focal anastomotic disease after bypass grafting or focal restenosis of peripheral artery stents are an attractive and feasible treatment strategy. Surgical revascularization is often preferred for disease in the common femoral or popliteal arteries; regions that may

Table-I

Goals for Endovascular Therapy for Peripheral Arterial Disease by Clinical Syndromes

	Clinical Goal	Angiographic Goal	Timing
Intermittent claudication	Symptom resolution without recurrence	Long-term vessel patency	Elective
Critical limb ischemia	Limb salvage	Restoration of in-line flow	Urgent/emergent
Acute limb ischemia	Limb salvage	Restoration of in-line-flow	Emergent

Table-II

Common Endovascular Revascularization Strategies Stratified by Anatomic Level

		Balloon Angioplasty		Stenting	
	Vessel Diameter	Conventional	Drug-Coated	Bare-Metal	Drug-Eluting
Aortoiliac	=7-10mm	Focal disease	No data	Provisional for simple lesions Primary stenting for Complex or ostail disease Balloon-expandable (ostial/occlusions) Self-expanding (tapered Artery of near hip joint)	No data
Femoropopliteal	=5-7mm	Focal Disease	Recently approved	Diffuse disease Self-expanding stents	
Infrapopliteal	=2-5mm	Focal or diffuse disease	Provisional for poor	Balloon result Coronary stents	

Table-III

Classification of severity of PAD

Fontaine		Rutherford		
Stage	Clinical	Grade Category	Clinical	
I	Asymptomatic	0	0	Asymptomatic
IIa	Mild claudication	I	1	Mild claudication
IIb	Moderate-severe claudication	I	2	Moderate claudication
		I	3	Severe Claudication
III	Ischemic rest pain	II	4	Ischemic rest pain
IV	Ulceration or gangrene	III	5	Minor tissue loss
		IV	6	Ulceration or gangrene

Table-IV

TASC classification

	TASC A	TASC B	TASC C	TASC D
Aortoliac	Unilateral or bilateral stenosis of CIA Unilateral or bilateral single short (≤3cm) stenosis of EIA	Short (≤3cm) stenosis of infrarenal aorta Unilateral CIA occlusion Single of multiple stenosis totaling 3-10cm involving the EIA, not extending into the CFA Unilateral EIA occlusion not involving the origins of internal iliac or CFA	Bilateral CIA occlusions Bilateral EIA stenosis 3-10cm long, not extending into the CFA Unilateral EIA stenosis extending into the CFA Unilateral EIA occlusion that involves the origins of internal iliac and/or CFA	Infrarenal aortoliac occlusion Diffuse disease involving the aorta and both iliac arteries Diffuse multiple stenosis involving the unilateral CIA, EIA and CFA Unilateral occlusions of both CIA and EIA Bilateral occlusions of EIA iliac stenoses in patients with AAA not amenable to endograft plafcement.
Femoral-popliteal	Single stenosis ≤10cm in length Single occlusion ≤10cm in length	Multiple lesions (stenoses or occlusion), each ≤5cm Single stenosis or Occlusion ≤5 cm , not involving the infragenicluate popliteal artery Heavily calcified occlusion ≤5 cm in length Single popliteal stenosis	Multiple stenoses or occlusions totaling ≤5 cm, with or without heavy calcification Recurrent stenoses or occlusions after failing treatment	Chronic total occlusions of CFA of SFA (>20 cm, involving the popliteal artery) Chronic total occlusion of popliteal artery and proximal trifurcation vessels
Infrapopliteal	Single focal stenosis, ≤5 cm in length, in the target tibial artery, with occlusion or stenosis of similar or worse severity in the other tibial arteries.	Multiple stenosis, each ≤5 cm in length, or total length ≤10 cm, or single occlusion ≤3 cm in length, in the target tibial artery with occlusion or stenosis of similar or worse severity in the other tibial arteries.	Multiple stenosis in the target tibial artery and /or single occlusion with total lesion length >10 cm with occlusion or stenosis of similar or worse severity in the other tibial arteries	Multiple occlusions involving the target tibial artery with total lesion length >10 cm, or dense lesion calcification or nonvisualization of collaterals; the other tibial arteries occluded or with dense calcification.

increase stent fracture because of greater compression, torsion, and stretch associated with flexion and extension of the hip and knee. However, even in these locations, single-center series suggest treatment comprised of percutaneous angioplasty with provisional stenting is associated with acceptable 12-month results particularly in high-risk surgical patients requiring limb salvage.[7] The development of drug-coated balloons (DCBs) with adjunctive atherectomy may address some issues associated with stent placement in these challenging arterial segments although any flow-limiting dissections, recalcitrant recoil, or residual disease would still limit such an approach.[8]

Aortoiliac Occlusive Disease

There has been a practice shift over the past 25 years as the treatment of aortoiliac disease transitioned from open surgery with aortobiiliacor aortobifemoral bypass to endovascular treatments for complex anddiffuse disease (TASC D). This preference for less invasive therapy is evidence based and driven byshorter length of stay and lower per procedural morbidity andmortality rates, while achieving comparable patency rates (4- to 5-year primary patency of 60% to 86%,with secondary patency rates of 80% to 98%) .[9]

In 2011, the European Society of Cardiology(ESC) [3]and ACC/AHA PAD guidelines [2] recommended an endovascular-first approach for aortoiliac lesions, recommended that borderline lesions be assessed with hemodynamic gradients, and supported primary stent placement in the aortoiliac arteries (Table 5).

For focal aortoiliac disease, balloon angioplasty alone provides excellent long-term patency with provisional stent placement reserved for suboptimal result.[10] No randomized studies comparing iliac stenting versus angioplasty only are currently available. The Dutch Iliac Stent Trial comparing stenting with balloon angioplasty and provisional stenting resulted in comparable clinical outcomes although this may have been caused by relatively low complexity TASC (Trans-Atlantic Society Consensus) A and B disease included in thetrial.[11,12] Given the increased recoil seen with ostial iliac disease and risk of dissection with the more complex disease now more frequently encountered (ie, total occlusions, ulcerated or calcified lesions, and aneurysmal segments) the use of primary stenting for aortoiliac disease has increased.[13]

BRAVISSIMO (Belgian-Italian-Dutch Trial Investigating Abbott Vascular Iliac Stents in theTreatment of TASC A, B, C, and D Iliac Lesions) reported100% technical success in 325 patients withaortoiliac lesions with a 24-month primary patency rate of 87.9% .[14] Neither TASC category nor lesion length was predictive of restenosis. These data further support the endovascular-first strategy,regardless of TASC classification, and take into consideration the evolution of devices (i.e., re-entrycatheters, crossing devices, and stents), which improve success rates for the most complex lesions.

Table-V

Aortoiliac Guideline-Based Recommendation for Stable Limb Ischemia

ACC/AHA PAD Guidelines(2006,2011)	ESC PAD Guidelines (2011)
Endovascular procedures are indicated for patients with a vocation or lifestyle limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and: 1) there has been and inadequate response to exerdse or pharmacological therapy; and/or2) there is a very favorable risk-benefit ratio(e.g., focal aortoiliac occlusive disease) (Class I, Level of Evidence:A)	When revascularization is indicated, an endovascular-first strategy is recommended in all aortoiliac TASC A-C lesions (Class I, Level of Evidence: C)
Translesional pressure gradients (with and without vasodilation) should be obtained to evaluate the significance of angiographic iliac arterial stenoses of 50% to 75% diameter before intervention (Class I, Level of Evidence: C)	A primary endovascular approach may be considered in aortoiliac TASE D lesions in patients with severe comorbidities, if done by an experienced team (Class IIb, Level of Evidence: C)
Stenting is effective as primary therapy for common iliac artery stenosis and occlusions (Class I, Level of Evidence: B)	Primary stent implantation, rather than provisional stendting, may be considered for aortoiliac lesions(Class IIb, Level of Evidence: C)
ACC = American College of Cardiology; AHA= American Heart Association; ESC = European Society of Cardiology; PAD = Peripheral artery disease; TASC= Trans – Atlantic Inter-Society Consensus.	

Femoral -Popliteal Disease

This segment begins at the bifurcation of the common femoral artery (CFA) into the superficial femoral artery (SFA) and the deep femoral (profundafemoris) artery. The SFA is subject to flexion, elongation,compression, and torsion unlike any other lower extremity artery. This complexity leads to many challenges for endovascular technology, but despite this, an endovascular-first approach is currently the standard of therapy for the majority of lesions because of the very high procedural success rate andlow risk.[3] Some of the most lengthy and complex lesions (TASC D) are more approachable because of the re-entry and crossing devices, more experienced operators, drug-eluting stents (DES) [15,16] and drug-coated balloons (DCBs) [17,18]that promise improved long-term patency for patients with claudication.[15,16]The ACC/AHA (2006, 2011) and ESC (2011) PAD guidelines recommend revascularization in femoral-popliteal lesions for patients with CLI or for patients with claudication who have had a suboptimal response to a trial of exercise (Table 6).An endovascular-first approach is recommended for TASC A through C lesions and is a reasonable option for TASC D lesions, depending on the experience of the operator, the patient's comorbidities, and procedure safety (Table 6).[2,3]

Table-VI

Femoral- Popliteal Guideline-Based Recommendation for Stable Limb Ischemia

ACC/ AHA PAD Guidelines (2006, 2011)	ESC PAD Guideline (2011)
Endovascular procedures are indicated for patients with a vocational or lifestyle-limited disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and:1) there has been an inadequate response to exercise or pharmacological therapy, and/or 2) there is a very favorable risk- benefit ration(e.g., focal stenosis) (Class I, Level of Evidence: A)	when revascularization is indicated, an endovascular- first strategy is recommended in all femoropopliteal TASC A-C lesions(Class I, Level of Evidence: C)
Stents (and other adjunctive techniques such as lasers, cutting balloons, atherectomy devices, and thermal devices) can be useful in the femoral, popliteal, and tibial arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g. persistent translational gradient, residual diameter stenosis >50% or Flow - limiting dissection (Class IIa, Level of Evidence: C)	Primary stent implantation should be considered in femoropopliteal TASC B Lesions(Class Ib, Level of Evidence: A)
The Effectiveness of stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of femoral-popliteal arterial lesions is not well established (except to salvage a suboptimal result from balloon dilation) (Class IIb . Level of Evidence: A	A primary endovascular approach may also be considered in TASC D lesions in patients with severe comorbidities if and experienced interventionist is available (Class IIb, Level of Evidence: C)
Primary stent placement is not recommended in the femoral, popliteal is not recommended in the femoral, popliteal or tibial arteries (Class III, Level of Evidence: C)	
Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower-extremity PAD (Class III, Level of Evidence: C)	

Stents – Balloon expandable and Self expandable Stents

Stents are broadly classified as either Balloon expandable (BE) or Self expandable (SE) based on how deployment is effected. In brief, BE stents are mounted in a crimpled state on a balloon that is inflated to deploy the stents against the vessel wall. In contrast, SE stents are manufactured an expanded state and are then crimped and constrained by a covering sheath that is retracted at the target site to allow the SE stent to expand to a predefined diameter and appose the vessel wall. In general, BE stents are made from steel that is composed of cobalt-chromium and nickel. Based on the properties of cobalt-chromium, these stents have the ability to be stronger than stainless steel stents with thinner metal struts and thus potentially can provide increased radial strength, lower crossing profile with enhanced flexibility and deliverability. ·Self-Expanding Stents are now mostly made of nitinol, self-expanding stents possess thermal shape memory and are more resilient to mechanical stresses by expanding on deployment at body temperature and then re-expanding after external radial compression. Because of rigidity, BE stents are typically employed in peripheral intervention for the treatment of disease in relatively static arteries, such as iliac arteries, where torsion and flexion forces are low and there is minimal risk of deformation or fracture. SE stents are used in peripheral intervention at sites that are subject to significant deformation (e.g., external iliac artery, SFA, popliteal artery and internal carotid artery).

Drug-Eluting Stents

Restenosis remains one of the major limitations associated with long segments of SFA stenting, and stimulated the development of drug-eluting stents. The first trials (Sirolimus Coated Cordis SMART Nitinol Self-Expandable Stent for the Treatment of SFA Disease [SIROCCO I and II trials]) compared sirolimus-coated versus bare-metal self-expanding stents. [19,20] Initial results were promising, but later results showed no clinical advantage with this particular stent platform, which was associated with a high rate of stent fracture (31% of all patients).Two studies have tested new platforms of self-expanding drug-eluting stents (DES) eluting other ant proliferative agents. The Superficial Femoral Artery Treatment with Drug Eluting Stents (STRIDES) trial was a multicenter, nonrandomized, single-arm study assessing an everolimus-eluting self-expanding stent.[21] Although stent fracture rates were low, the restenosis rates at 6 and 12 months were 6% and 32%, respectively. Although DES use for coronary revascularization requires a longer duration of dual antiplatelet therapy, the optimal length of treatment after peripheral DES implantation requires further investigation.

Drug coated balloons

A recent innovation, Drug coated balloons (DCBs) has potential benefits applicable to endovascular therapy. DCBs are effective in the coronary vasculature, particularly in small arteries, bifurcation disease, inStent stenosis and are used where avoiding stent implantation and its attendant risks, including thrombosis, fracture, and the need for prolonged antiplatelet therapy. The potential limitations include the lack of a mechanical scaffold to address elastic recoil or dissection and the uncertainty of delivering effective, homogenous concentrations ofant proliferative agents to calcified or tortuous arterial segments.

Infrapopliteal Disease

Infrapopliteal or below-the-knee disease begins with the popliteal artery at the knee joint and continues to the tibial and personal arteries to the ankle.Revascularization is indicated in patients with CLI and, rarely, for those with claudication. The ACC/AHA (2006, 2011) and ESC (2011) PAD guidelines agree that an endovascular-first approach is reasonable in patients with CLI and infrapopliteal arterial disease (Table 7).[2,3] In candidates for endovascular treatment, both guidelines support PTA as the initial approach, with the use of BMS as needed for bailout lesions (Table 7).[2,3]There are several issues unique to below-the-knee interventions that warrant consideration. Occlusive infrapopliteal disease is often complex with severely calcified, diffuse high grade stenosis or total occlusions. Successive, incremental balloon inflations to treat lengthy expanses of disease risks dissection and perforation, which may be reduced by specifically designed long balloons. Poor distal run-off elevates the risk of stent thrombosis, and distal embolization complicating below-the-knee interventions is poorly tolerated.The BASIL (Bypass Versus Angioplasty in Severe Ischemia of the Leg) trial compared PTA (balloon alone) to surgery in 452 CLI patients and found no difference for amputation-free survival but a lower cost with PTA.[22]

Table-VII
Infrapopliteal Guideline-Based Recommendation for CLI

ACC/ AHA PAD Guidelines (2006, 2011)	ESC PAD Guideline (2011)
For individuals with combine inflow and outflow disease with CLI, inflow lesions should be addressed first (Class I, Level of Evidence: C)	
For patients with limb-threatening lower –extremity ischemia and an estimated life expectancy ≥2 years in whom an autogenous vein conduit is not available, balloon angioplasty is reasonable to perform when possible as the initial procedure to improve distal blood flow (Class IIb, Level of Evidence: C)	For infrapopliteal lesions, angioplasty is the preferred technique, and stent implantation, and stent implantation should be considered only in the case of insufficient PTA (Class IIa, Level of Evidence: C)
The Effectiveness of uncoated /uncovered stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of infrapopliteal lesions (except to salvage a suboptimal result from balloon dilation) is not well established. (Class IIb, Level of Evidence: C)	When revascularization in the infrapopliteal segment is indicated, the endovascular first strategy should be considered(Class Ib, level of Evidence: C)
Primary stent placement is not recommended in the femoral, popliteal, or tibial arteries (Class III, Level of Evidence: C)	
Surgical and endovascular intervention is not indicated in patients with severe decrements in limb perfusion (e.g., ABI<0.4) in the absence of clinical symptoms of CLI (Class III, Level of Evidence: C)	

Infrapopliteal Balloon Angioplasty for CLI

Several clinical series have demonstrated that angioplasty alone can promote limb salvage in CLI patients with infrapopliteal disease with 12-month limb salvage rates as high as 75%.[23,24,25] Although higher complexity tibial disease has been traditionally treated surgically, Schmidt et al[26] reported 95.6% limb salvage at 12 months for complicated (average length 184 mm with 64.9% occlusions) infrapopliteal disease. A recent meta-analysis showed that even with severe tibial disease and poor distal run-off, reasonable rates of limb salvage can be achieved with angioplasty alone.[27]Infrapopliteal angioplasty with DCB is currently being investigated particularly for the potential to diminish the need for futurereintervention.

Infrapopliteal Stenting for CLI.

Because of the typically small diameter vessels, coronary BMS and DES have been used for infrapopliteal stenting. Several unique issues must be considered. Because of the diffuse nature of tibial disease, extensive infrapopliteal stenting in conjunction with poor outflow may elevate the risk of stent thrombosis. The use of DES, in particular, may amplify this risk further because of issues related to delayed re-endothelialization. Suboptimal stent expansion and apposition or flow-limiting dissection because of severely calcified small-vessel disease may also be encountered. Small, single-center nonrandomized studies have shown that rates of major amputation, surgery, and TLR are lower for patients

Fig.-1 : *A , 100% lesion in right common iliac artery and 70-80% lesion in Osteal left common iliac artery. B, Simultaneous BE stent implanted in both arteries.C, Good outcome – no residual stenosis.*

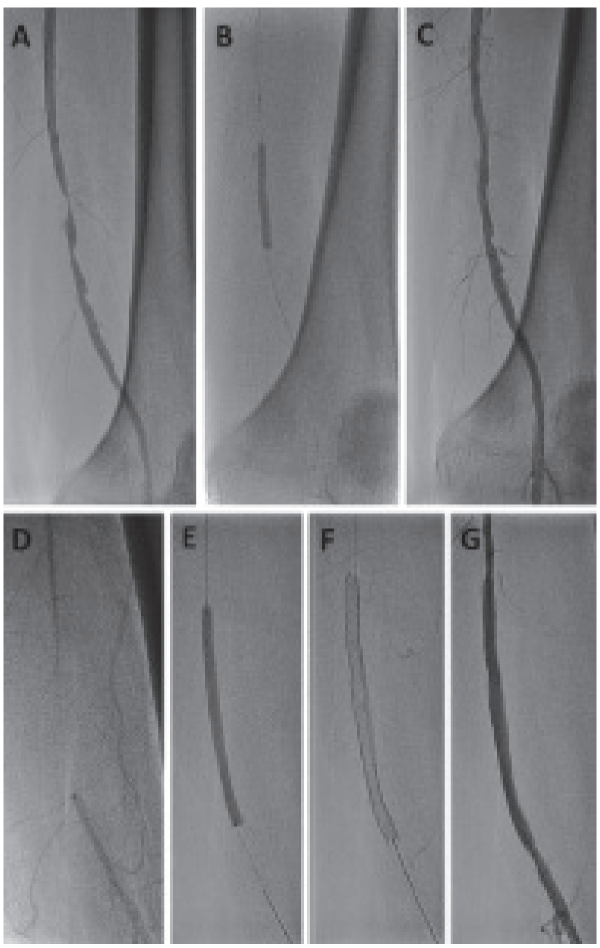

Fig.-2: *A-C, Balloon angioplasty for a short superficial femoral artery (SFA)lesion.A, Pretreatment stenosis, (B) balloon angioplasty, and (C), final result.D-G, Self-expanding nitniol stent to treat a long SFA occlusion, D, Occlusion in the mid- SFA. E, Balloon angioplasty, (F) stent deployed in the lesion, and (G), angiogram after stent deployment.*

with CLI treated with DES versus BMS.[28,29]Ongoing and future trials will hopefully clarify the clinical efficacy and cost-effectiveness of DES for this indication. Primary balloon angioplasty with provisional stenting, using either BMS or DES based on operator discretion, for a suboptimal angiographic result or flow-limiting dissection remains a reasonable strategy for infrapopliteal revascularization for CLI at this time.

Conclusion:

The past few decades have witnessed remarkable innovation in technology leading to an expanding use of endovascular

therapy to treat lower extremity peripheral occlusive arterial disease of increasing severity. This has resulted in a shift away from open surgical revascularization and toward percutaneous endovascular therapy as a first option. The use of DCBs increases patency and TLR outcomes in both femoropopliteal and infrapopliteal PAD. Stenting has a rising role in both bail-out and primary interventions and is particularly promising with the development of DES. The proposed advan-tages of atherectomy have not yet reliably translated into improved clinical outcomes, although the ef-fectiveness of this approach will increase with tech-nique optimization, refinement of the technology, and further study. Although the guidelines currently support PVI, particularly PTA with bail-out stenting conclusively in patients in a low TASC category who are otherwise not surgical candidates, further study of these emerging technologies in well-designed and highly powered trials are needed to determine the ideal treatment strategies for the management of pa-tients with PAD.

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