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Core Curriculum

SCAI Expert Consensus Statement for Aorto-Iliac Arterial Intervention Appropriate Use

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Aorto-iliac arterial occlusive disease is common and may cause a spectrum of chronic symptoms from intermittent claudication to critical limb ischemia. Treatment is indicated for symptoms that have failed lifestyle and medical therapies or occasionally to facilitate other interventional procedures such as TAVR and/or placement of hemodynamic assist devices. It is widely accepted that TASC A, B, and C lesions are best managed with endovascular intervention. In experienced hands, most TASC D lesions may be treated by endovascular methods, and with the development of chronic total occlusion devices, many aorto-iliac occlusions may be recanalized safely by endovascular means. Interventional cardiologists should be well versed in the anatomy, as well as the treatment of aorto-iliac disease, given their need to traverse these vessels during transfemoral procedures. Overall, aorto-iliac occlusive disease is more commonly being treated with an endovascular-first approach, using open surgery as a secondary option. This document was developed to guide physicians in the clinical decision-making related to the contemporary application of endovascular intervention among patients with aorto-iliac arterial disease.

Key words: aorto-iliac disease; appropriate use, peripheral arterial disease

INTRODUCTION

Aorto-iliac occlusive disease may cause a spectrum of chronic symptoms from intermittent claudication to critical limb ischemia. Surgical bypass, which includes aortofemoral bypass (AFB), iliofemoral bypass (IFB), and aorto-iliac endarterectomy (AIE), is effective in improving quality of life and relieving symptoms with acceptable mid- and long-term patency rates [1]. These

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operations, however, are associated with significant surgical risk (operative mortality for AFB, IFB, and AIE of 4.1, 2.7, and 2.7%, respectively [1]. In addition, open repair for aorto-iliac occlusive disease results in significant morbidity (e.g., impotence, wound infection) and requires an inpatient hospital stay. Endovascular aorto-iliac interventions have clinical success rates exceeding 90% and lower in-hospital mortality rates ($\leq$2.7%) [2,3].

According to ACC/AHA guidelines, aorto-iliac intervention is recommended in patients with lifestyle limiting claudication where the risk benefit ratio of the intervention is favorable [4]. Due to its high success rates, endovascular intervention may be considered as a first-line treatment strategy, prior to, or in addition to, medical/exercise therapy in select cases of aorto-iliac disease. This document was developed as a contemporary guide for physicians in the practical application of endovascular intervention for aorto-iliac occlusive disease.

ANATOMIC CONSIDERATIONS

The common iliac arteries (CIA) arise from the distal abdominal aorta and bifurcate to form the external and internal iliac (or hypogastric) arteries. The external iliac artery (EIA) becomes the common femoral artery while the internal iliac supplies the pelvis, buttocks, genitals, and in cases of severe mesenteric disease can also provide collateral circulation to the bowel. Normal diameters of the CIA range from 7 to 12 mm, and the EIA from 5 to 8 mm [5].

In 2007, the Trans-Atlantic Inter-Society Consensus (TASC) II document provided a classification of lesion subsets to help guide therapeutic decision-making (Figure 1) [3]. Type "A" lesions are the simplest, and have a high degree of success with endovascular interventions. Type "B" and "C" lesions offer satisfactory results with endovascular methods, such that this approach is preferred first, unless an open revascularization is required for other associated lesions in the same anatomic area. For Type "D" lesions, surgical bypass is the preferred treatment modality for revascularization. However, with improved operator techniques and newer re-entry devices/catheters, experienced endovascular specialists are able to approach TASC C and D lesions with an endovascular strategy [6]. Hybrid surgical-endovascular approaches have also been developed for patients with aorto-iliac and lower extremity occlusive disease [7].

Although the TASC recommendations provide a useful framework for decision-making, treatment decisions need to be based on a comprehensive evaluation of the individual patient and characteristics of the target vessel and target lesion. Patients with PAD often have lesions at multiple anatomic levels, thereby limiting the usefulness of this anatomic classification. Operator and institutional expertise should also be considered in the treatment algorithm, particularly for patients with extensive and complex aorto-iliac disease (TASC C and D lesions).

CLINICAL CONSIDERATIONS

The goals of therapy for patients with aorto-iliac disease are to eliminate symptoms, improve the patient's quality of life and functional status, and reduce the likelihood of atherothrombotic events through optimization of medical therapy and lifestyle change. Occasionally, intervention is necessary in asymptomatic patients to facilitate delivery of large sheaths (endovascular aneurysm repair, transcatheter aortic valve replacement), hemodynamic support devices [8], or to facilitate percutaneous coronary intervention. Significant aorto-iliac disease is defined as a stenosis >50% or occlusion or an inadequate luminal diameter to facilitate delivery of large access sheath. Lesion significance may also be confirmed by the documentation of a pressure gradient across the lesion. With respect to what constitutes a significant translesional gradient, differing opinions exist, ranging from a mean resting gradient of 5 mmHg (ACC/AHA guidelines) [4] to a mean resting gradient of 10 mmHg (DIST) [9] as significant. For indeterminate lesions, some have advocated the use of intra-arterial papaverine (20 mg) to measure a translesional gradient during hyperemia [10,11]. In one study, a moderate stenosis of 50% was predicted with 95% confidence by a resting systolic gradient of >34 mmHg, a mean resting gradient of 7 mmHg or a mean hyperemic gradient > 30 mmHg as induced by papaverine [10]. In an older surgical study of patients undergoing infrainguinal bypass, treatment of intermediate inflow lesions, as assessed by papaverine testing, irrespective of angiographic findings, eliminated treatment of unnecessary inflow lesions without any detriment to long-term success [12].

Table I lists several indications for aorto-iliac interventions. These clinical scenarios assume that life-style limiting claudication has been refractory to a pharmacologic and walking program. It is beyond the scope of this manuscript to detail the timing of revascularization of both aorto-iliac and infrainguinal disease (multilevel), but in general claudication is treated sequentially (providing aorto-iliac inflow first), whereas, patients with critical limb ischemia require simultaneous revascularization to establish straight-line pulsatile flow to the foot. The categories of appropriate care (AC), may be appropriate care (MBAC), and rarely appropriate

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TABLE I. Clinical Scenarios in Which Treatment of Aorto-Iliac Occlusive Disease May Be Considered

Appropriate care	• Distal abdominal aorta or common iliac artery (CIA) with moderate claudication to major tissue loss (RC* 2–6) with ≥50% stenosis and/or resting mean translesional gradient >5 mmHg after having failed pharmacologic and walking therapy.
	• Internal iliac artery (IIA) with moderate to severe symptoms of buttock or hip claudication or major tissue loss (RC 2–6) with ≥50% stenosis and/or resting mean translesional gradient ≥5 mmHg.
	• External iliac artery (EIA) with moderate claudication to major tissue loss (RC 2–6) and ≥50% stenosis and/or resting mean translesional gradient ≥5 mmHg after having failed pharmacologic and walking therapy.
	• Asymptomatic significant aorto-iliac arterial disease in a patient who requires vascular access for another device (e.g., mechanical circulatory support, or TAVR).
May be appropriate care	• Aorto-iliac artery stenosis ≥50% with lifestyle- or vocation-limiting claudication (RC 2–3) without having failed pharmacologic and walking therapy when the risk-benefit ration of the intervention is favorable.
	• IIA ≥50% stenosis with vasculogenic impotence.
Rarely appropriate care	• Aorto-iliac stenosis <50%.
	• Aorto-iliac stenosis <50% with mild (i.e., nonlimiting) claudication (RC 1).
	• Asymptomatic aorto-iliac stenosis absent the need to advance large bore interventional equipment for another purpose.

RC, Rutherford classifications for chronic limb ischemia; CIA, common iliac artery; IIA, internal iliac artery; EIA, external iliac artery; CTO, chronic total occlusion; IABP, intra-aortic balloon pump; PVAD, percutaneous ventricular assist device; TAVI, trans-aortic valve intervention.

care (RAC) were assigned by consensus based on the best available evidence (Table I).

TECHNICAL CONSIDERATIONS

A detailed description of various techniques employed for aorto-iliac intervention is beyond the scope of this manuscript. However, fundamental elements of procedural strategy are detailed below.

Vascular Access

The preferred site for arterial access depends on several factors including: (1) location of the target lesion(s), (2) presence/absence of any lesions in the contralateral iliac artery, (3) need to treat infrainguinal vessels, (4) presence of common femoral artery disease, (5) angulation of the aorto-iliac bifurcation, (6) severity of target lesion (occlusion or not), and (7) availability of radial or brachial artery access. Generally, ipsilateral retrograde access is recommended for CIA and proximal and mid EIA lesions. This approach can also be used for the antegrade treatment of contralateral CIA, IIA, and EIA lesions as well as contralateral infrainguinal vessels. For CIA occlusions, one approach is via a contralateral antegrade route using a variety of techniques and catheters, but such approach may fail to provide enough support and a retrograde approach may be favored. In the case of EIA occlusions/severe stenosis, an antegrade crossover approach is feasible if wiring of the internal iliac, to permit advancement of a crossover sheath, is possible. For distal EIA lesions there may be an advantage to contralateral common femoral artery (CFA) access, as the stent may need to be placed very close to the ipsilateral access site. In the case of ostial bilateral CIA lesions, bilateral femoral access is often used in order to facilitate kissing angioplasty (PTA) or stent placement (simultaneous inflation of bilateral balloons/stents at the aorto-iliac bifurcation). In the case of "kissing stents," this creates a new bifurcation of the aorta. More than one access site (a second site could be femoral or brachial/ radial) may be required to approach chronic total occlusions (CTO), in order to facilitate both antegrade and retrograde crossing and also for better visualization of the extent of occlusion [13,14]. For example, in long CIA to distal EIA CTOs, often bilateral access is required. In these complex cases, the non-target side or brachial/femoral is accessed to permit guidance of where the aortoiliac bifurcation is located via injections of contrast while retrograde access in the CFA or SFA is often needed to permit traversal of a long occlusion. Often with these occlusions, kissing stents are required and additional access is required and the second site could also be radial or brachial. For the target lesion side, a patent ipsilateral lateral femoral circumflex is helpful in these cases to provide wire support during sheath insertion to permit retrograde crossing. Initial arterial access via the radial artery or brachial artery is also an attractive option for some patients, but lesion location and equipment length should be taken into account during treatment planning.

Anticoagulation/Antiplatelet Therapy

Patients undergoing aorto-iliac intervention should be on aspirin (81–325 mg daily) prior to their procedure [4]. The role of dual antiplatelet therapy (e.g., thienopyridines: clopidogrel, ticagrelor, or prasugrel) in the setting of aorto-iliac intervention has not been well studied.

Most studies of endovascular treatment of iliac arteries have used unfractionated heparin (UFH) for intra-procedural anticoagulation. This seems to be a prudent practice, especially in the treatment of chronic

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TABLE II. Outcomes of Endovascular Intervention of Aorto-Iliac Disease

Author	Study type	Lesion	*N*	Technical success	Outcome	
Kasyap et al. [14]	Retrospective, Surgery vs. endo	TASC B/C/D	Surg:127 Endo:161	96% endo	3 year outcomes Surgery 1° patency: 93% 2° patency: 97% Limb salvage: 98% Survival: 80%	Endo 1° patency: 74% 2° patency: 95% Limb salvage: 98% Survival: 80%
Leville et al. [24]	Retrospective	TASC B/C/D	89	91%	1° patency: 74% 2° patency: 95%% Limb Salvage: 98%	
Jongkind et al. [18]	Meta-analysis 19 non RCTs	TASC C/D	1711	86–100%	Mortality: 1.2–6.7% (seven studies)	4 or 5 year outcomes 1° patency: 60–86% 2° patency: 80–98%
Ye et al. [19]	Meta-analysis 16 non RCTs	TASC C/D	958	92.8%	1 year outcome Composite 1° patency:88.7%	1 year Subgroup 1° patency TASC C: 89.6% TASC D: 87.3%

total occlusions and calcified lesions where risk of perforation may be higher. The effect of UFH can be immediately reversed with administration of protamine sulfate. Total UFH doses $\geq$60 U/kg and an activated clotting time of $>$250 sec are both associated with the increased need for post-procedural transfusion following peripheral vascular intervention (PVI) [13] Direct thrombin inhibitors, such as bivalirudin, are more costly than UFH, but have been used for PVI.

Crossing the Lesion(s)

Wiring techniques are similar to other interventional procedures, and 0.035-inch, 0.018-inch, and 0.014-inch guidewires may be used. For tortuous iliac arteries and complex lesions, steerable hydrophilic wires are helpful. For heavily calcified arteries, 0.035-inch wires may offer more support for delivery of stents and long sheaths. Smaller profile systems (4F–6F sheaths) are available with 0.018/0.014-inch systems for most iliac stents. In cases where there is the potential for iliac rupture, it is recommended that 7F or 8F sheaths be used as many covered stents require this, though there are some 6F sheath compatible covered stents. Given the potential for fatality with iliac rupture, a full array of covered stents and knowledge of their sheath compatibility should be part of treatment planning prior to any iliac intervention.

A variety of devices are available for CTO's, including specialty wires and dedicated CTO crossing devices [13,15–17]. The technique or device used depends both on lesion characteristics and physician experience. Using multiple techniques, the overall success rate of crossing even complex (TASC C and D) lesions is expected to be 85–95% for experienced operators [14,18,19].

Angioplasty and Stenting

Primary stent placement may minimize vessel recoil and prevent abrupt occlusion, but there is debate over the relative benefit of primary stenting vs. provisional stenting for reducing restenosis in this vascular territory. Several studies have compared the outcomes of percutaneous transluminal angioplasty (PTA) with provisional stenting to primary stenting for both iliac stenosis and occlusions [20–22] The Dutch iliac stent trial found that PTA with provisional stenting (for a residual gradient of $>$10 mmHg) had similar results to primary stenting [9] However, this study excluded patients with more complex lesions (lesions $>$10 cm or CTO's $>$5 cm). By employing a provisional stenting strategy in the iliac artery, stent placement was avoided in 63% of the lesions. After 5-years of follow-up there was no group difference in patency rates, ABI, and quality of life [23].

The stent data for more complex lesions such as TASC C/D and other CTO lesions are also encouraging (Table II) [14,18,19,22,24]. According to two recent meta-analyses [18,19], immediate technical success rates for aorto-iliac intervention exceed 90%, with 4–5 year primary patency rates of 60–86%, secondary patency rates of 80–98%, and limb salvage rates of 98%. The STAG trial compared primary stenting with percutaneous transluminal angioplasty for iliac occlusion and showed stents improved technical success and major procedural complication rates, but no statistical difference was noted between groups at 1 or 2 years in primary or secondary patency [22]. T2

Primary stenting is the preferred clinical practice for most aorto-iliac lesions, supported by a meta-analysis of more than 2,000 patients [2]. In this analysis, the

primary stent group had a 43% reduction in four-year failure compared to balloon angioplasty alone. These data were confirmed in the more recent study of 52 patients undergoing endovascular revascularization for 35 aortic (31 stenosis, four occlusions) and 17 aorto-iliac (14 stenosis, three occlusions) lesions. Technical success was 100%, with patency rates at 36 months of 85% in the aortic group and 86% in aorto-iliac group [25]. The current ACC/AHA guideline document supports primary stenting of the common and external iliac arteries with a Class I recommendation (Level of Evidence B) [26].

Anatomic location of the stent is a factor in patency. Patency rates have been shown to be higher in the CIA than in the EIA [22]. The long-term (10-year) results of aortic bifurcation arterial self-expanding stent placement show a 10-year primary stent patency rate of 68% with a secondary assisted patency rate of 86% [27].

Stent Selection

Either balloon expandable or self-expanding stents can be used for the treatment of aorto-iliac lesions. Balloon expandable stents can be placed more precisely and, if desired, may be further expanded (1–2 mm) after their initial deployment with larger balloons. They are used more often in ostial common iliac lesions and during placement of kissing stents. Furthermore, they may be better suited for heavily calcified lesions or lesions with greater recoil, where more radial strength may be needed [28]. Self-expanding stents, are characterized by their flexibility and their ability to conform to varying vessel diameters [7]. In addition, self-expanding stents are available in longer lengths and conform to a tapering vessel diameter of the vessel much better than balloon expandable stents.

Overall, no clinically available stent has been demonstrated as superior to any other in the aorto-iliac distribution. There has been debate on whether stent architecture or composition (i.e., nitinol versus stainless steel) has any effect on restenosis rates. However, the CRISP trial failed to show any differences in clinical outcomes at one-year between nitinol (SMART, Cordis, Miami Lakes, FL) and stainless steel (Wallstent, Boston Scientific, Watertown, MA) iliac artery self-expanding stents [29].

Covered Stents

Traditionally, covered stents had been reserved for iliac aneurysms, arterio-venous fistulae, and iatrogenic perforations. Recent studies have provided encouraging results compared to bare metal stents for iliac lesions [30,31]. The COBEST (a comparison of **co**vered versus **b**are **e**xpandable **s**tents for the **t**reatment of aorto-iliac occlusive disease) trial randomized 168 iliac arteries (TASC B-D) to balloon expandable expanded polytetrafluoroethylene (ePTFE) covered stents or a bare metal stent [32]. Aorto-iliac lesions treated with the covered stent had significantly lower restenosis rates than uncovered stents (hazard ratio [HR], 0.35; 95% confidence interval (CI) 0.15–0.82; $P = 0.02$). Subgroup analyses demonstrated significantly lower restenosis rates for covered stents in TASC C and D lesions compared with the uncovered stent (HR, 0.136; 95% CI 0.042–0.442). There was no significant difference across stent types for the less complex TASC B lesions (HR, 0.748; 95% CI 0.235–2.386).

It has been suggested that covered stents may be useful for lesions involving the distal aorta and for iliac arteries that are being treated with kissing stents [32,33]. The disadvantage of ePTFE covered stents is the difficult deliverability due to their stiffness, which often requires larger sheaths and may predispose patients to access site complications. Another disadvantage of covered stents is coverage of major side branches including the internal iliac artery, and/or major collaterals or sources of collaterals such as the lumbar, circumflex iliac, or inferior epigastric branches. It is currently unknown if the balloon expandable ePTFE covered stent is more thrombogenic than a bare metal stent as no episodes of stent thrombosis were reported in either arm of the COBEST trial. The duration of clopidogrel therapy was one-month post procedure in COBEST with chronic aspirin use.

Hybrid Procedures

Some patients with aorto-iliac occlusive disease will also have concomitant common femoral artery (CFA) stenosis that requires treatment. One option is to perform a hybrid procedure with open femoral endarterectomy (with or without profundoplasty) followed by iliac stenting [6,14,34]. This hybrid approach limits the open surgery to the groin and avoids complications associated with aortic cross clamping and laparotomy [14,24].

Complications

Complications associated with aorto-iliac interventions include contrast nephropathy, contrast reactions, perforations, dissections, embolization, and access site complications. If multiple access sites are used (especially brachial access), then risk of access site complications increases [35]. Kissing stents at the aortic bifurcation have also been used to prevent plaque shifting (the contralateral displacement of atheromatous material into the non-diseased iliac artery). Distal

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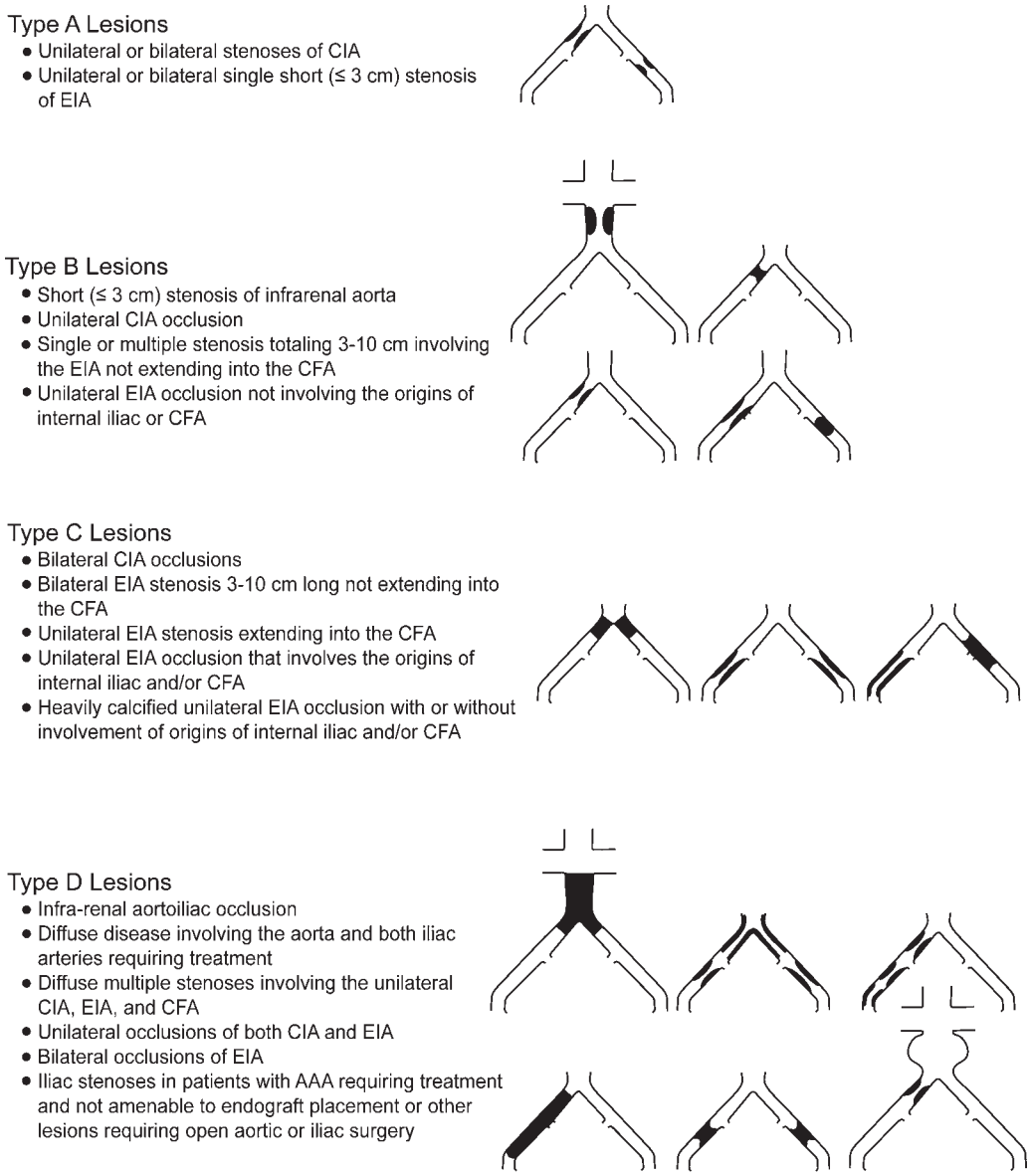

Fig. 1. TASC classification of aorto-iliac lesions. CIA, common iliac artery; EIA, external iliac artery; CFA, common femoral artery; AAA, abdominal aortic aneurysm (Fig. 1 reproduced with permission from Ref. 3).

embolization (DE) and iliac perforation are two very serious complications of aorto-iliac intervention. Following aorto-iliac intervention, it is important to perform a post intervention arterial run-off angiogram to rule out DE. DE may be treated with catheter aspiration, balloon inflation, stent placement, and occasionally, with surgical embolectomy. DE has been reported in most studies of iliac interventions; the incidence ranges from 0.4 to 9% [36–40].

Iliac artery perforation is a potentially fatal complication. In a systemic review of endovascular interventions in 1,711 patients with extensive aorto-iliac disease, Jongkind et al found an incidence of 0.5 to 3% for iliac perforation [18]. Perforation may be due to guidewire manipulation or device-mediated rupture (e.g., balloon inflation, stent deployment, extravascular CTO reentry device advancement). The EIA is particularly vulnerable to perforation. Pain during balloon inflation is a warning sign of impending rupture. Perforations can be stabilized with immediate balloon inflation proximal to the tear to tamponade the bleeding. Consideration of surgical repair, or percutaneous treatment with prolonged balloon inflations and/or use of covered stents are the next step [20,36]. It is important

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to have these life-saving devices (including large aortic occlusion balloons, covered stents, and large bore sheaths) available when performing aorto-iliac interventions.

CONCLUSIONS

Aorto-iliac occlusive disease is common, and treatment is indicated for symptoms that have failed lifestyle and medical therapies or occasionally to facilitate other interventional procedures such as TAVR and/or placement of hemodynamic assist devices. For disease involving the common femoral, and/or where multilevel disease needs to be addressed, "hybrid" surgical procedures may be considered. Interventional cardiologists should be well versed in the anatomy, as well as the treatment of aorto-iliac disease, given their need to traverse these vessels during transfemoral procedures.

It is widely accepted that TASC A, B, and C lesions are best managed with endovascular intervention. In experienced hands, most TASC D lesions may be treated by endovascular methods, and with the development of chronic total occlusion devices, many aorto-iliac occlusions may be recanalized safely by endovascular means. Overall, aorto-iliac occlusive disease is more commonly being treated with an endovascular-first approach, using open surgery as a secondary option.

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Author Relationships with Industry and Other Entities (Comprehensive) — *Appropriate Use for Aorto-Iliac Arterial Intervention: An Expert Consensus Document from the Society for Cardiovascular Angiography and Intervention (SCAI)*

Committee Member	Advisory Board/Board Member	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
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