Cardiovascular and Interventional Radiological Society of Europe

Quality Improvement Guidelines for Endovascular Treatment of Iliac Artery Occlusive Disease

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Introduction

The annual incidence of symptomatic peripheral arterial obstructive disease (PAOD) is 26/10,000 in men and 12/10,000 in women according to the results of the Framingham study; this means that PAOD is at least as frequent as angina in the U.S. population [1]. Using noninvasive testing the prevalence of the disease is estimated to be 3% in middle-aged patients, increasing to 20% in patients >70 years of age [2, 3]. About one-third of PAOD lesions in the body affect the aorto-iliac segment. The most common clinical manifestation of PAOD is intermittent claudication involving the upper thigh, often in combination with lower limb claudication. Patients presenting with critical limb ischemia usually have multisegmental disease with involvement of the infra-inguinal arteries. Erectile dysfunction may also be present in males. Occasionally ulcerated iliac plaques can result in cholesterol or thrombotic embolization leading to blue toe syndrome.

On clinical examination patients often have weakened femoral pulses and a reduced ankle/brachial index. Verification of iliac occlusive disease is usually made by color duplex scanning which reveals either a peak systolic velocity ratio ‡2.5 at the site of stenosis and or a monophasic waveform. Magnetic resonance angiography (MRA) and multiple detector-row computed tomography angiography (MDCTA) are increasingly used for determining the extent and type of obstruction, however, digital subtraction angiography (DSA) offers the unique advantage of incorporating diagnostic confirmation and endovascular treatment in a single session.

Patient Selection

According to the recently updated TransAtlantic Consensus Document on treatment of PAOD (TASC II), the choice between endovascular therapy and surgery depends on the lesion type in terms of complexity and length [4].

Indications

Pelvic and lower limb ischemia: claudication <200 m, limb-threatening ischemia, blue toe syndrome, renal transplantation, and vasculogenic impotence (TASC A and B).

Contra-Indications

Related to any percutaneous intervention (groin sepsis, bleeding diathesis, or severe coagulopathy) and TASC D.

Relative Contra-Indications
Anticoagulation, contrast allergy (CO2 or gadolinium can be used as alternative contrast), and TASC C.

Technique
Endovascular interventions are routinely performed with the patient under local anesthesia supplemented by intravenous sedation and analgesia when indicated (i.e., prolonged procedures as well as in anxious or confused patients). Monitoring is recommended (pulse, lood pressure, ECG and oxygen saturation) in all patients, particularly when sedated.

The most commonly used vascular access for aorto-iliac revascularization is retrograde common femoral artery (CFA) access. Contralateral femoral, ipsilateral popliteal, or brachial/axillary access has been used. However, a combination of approaches may be necessary in order to recanalize complex lesions.

In difficult punctures ultrasound guidance and/or imaging (i.e., ‘‘roadmap’’ type) software commonly available on modern angiographic equipment can be invaluable in guiding arterial access. A sheath is routinely placed; the size, length, and configuration will be determined by the size of devices used, lesion position, approach, and anatomy (i.e., Balkin-type sheath for a contralateral approach).

A stenosis is normally crossed from an ipsilateral approach with a combination of a soft-tip 0.035-in guidewire (i.e., Bentson type wire) or hydrophilic wire and a 5-Fr straight or selective catheter (i.e., Cobra type).

Both common iliac artery (CIA) and external iliac artery (EIA) total occlusions are negotiated first from an ipsilateral approach. If this approach fails, then a curved catheter (i.e., 5-Fr Sos-Omni, 5- to 7-Fr renal curved or Simmons 1) is inserted from the contralateral femoral artery, and the occlusion is transversed with a hydrophilic 0.035-in. guide wire. If the wires from both directions end up subintimally in the occluded segment, the wire from the contralateral side is snared and pulled through the sheath in the ipsilateral groin [5]. A limitation of subintimal recanalization is occasional true lumen re-entry remote from the level of vessel lumen patency, causing percutaneous transluminal angioplasty (PTA), stenting, or both to extend beyond the occluded segment. To overcome this technical challenge, catheters allowing passage of a needle and guide wire across the intima distal to the occlusion (i.e., the Pioneer and the Outback catheter) have been developed with promising initial results [6].

An alternative technique has been described in cases where re-entry into the true lumen cannot be achieved with the use of standard guide wires and catheters, when the subintimal space is entered from an ipsilateral approach; an 18-gauge sharp needle (i.e., Colapinto needle) is used to cross the space and indent an occlusion balloon inserted from the contralateral side, indicating proper orientation toward the true lumen of the aorta [7].

When the lesion is successfully crossed, balloons of an appropriate size and length are used (i.e., 8–10 mm for CIA, 6–8 mm for EIA). These are sized to the patient’s native vessel wherever possible. Inflation is performed with caution, especially in heavily calcified lesions, initially applying pressure of 8 atm for up to 60 s. However, higher pressures may be necessary for lesions where there is persistent waisting of the balloon.

Catheter-Directed Thrombolysis (CDT)

If guide-wire traversal appears relatively straightforward, the presence of a soft thrombus is likely and CDT may prove beneficial [8, 9]. However, other investigators have concluded that routine thrombolysis and balloon dilation of occluded arteries prior to stent placement are associated with an increased incidence of distal embolic events [10, 11]. If guide-wire traversal is challenging, it is unlikely that there is any benefit of CDT [12, 13].

Although percutaneous mechanical thrombectomy devices (i.e., Straub-Rotarex catheter) are now widely available, there are no convincing data on improved outcome in patients with chronic iliac artery occlusions. In addition, due to their relatively large caliber, hemolysis, complexity of manipulations, potential risks of downstream or crossover embolization, and elevated cost, they are not currently recommended for routine use [14, 15].

Indications for Stenting and Stent Selection

Accepted indications for iliac stent placement are failed or inadequate PTA as a result of elastic recoil and the presence of a flow-limiting dissection. Significant residual stenosis after balloon angioplasty is defined as residual stenosis >30% on angiography and/or a residual peak-to-peak systolic pressure gradient of >5 mm Hg [16, 17]. Primary (stent placement after predilation of the lesion regardless of the PTA outcome) or direct (stent placement without predilation of the lesion) stenting is generally accepted in clinical practice for patients with chronic iliac artery occlusions and with recurrent stenosis after previous iliac PTA, though there is still little evidence to support the latter approach. Many interventionists find it intuitive to apply primary or direct stenting along complex stenoses (eccentric, calcified, ulcerated plaques, or plaques with spontaneous dissection) which are prone to cause distal embolization [18]. The efficacy of this practice has not been proven.

The choice of the appropriate stent type depends on the lesion morphology and location. When dealing with lesions of high elastic recoil, such as calcified or eccentric plaques at the ostium of the CIA or EIA, a balloon-expanded stent would be more appropriate than a self-expanding stent, because of its greater hoop strength [19, 20]. A self-expanding stent should be chosen to stabilize longer, less calcified vessel segments. In tortuous vessels, the application of stainless-steel balloon-expanded stents is not recommended, due to the risk of angulation or kinking of the vessel at the end of the stent [20]. Self-expanding stents (i.e., Nitinol stents, Wallstent) should be used instead, assuring good flexibility and vessel conformability when employed. Nitinol stents (especially those which are lasercut from a single Nitinol tube) also seem appropriate for treating vascular segments that transit abruptly in size (e.g., from a CIA to an EIA 2 mm smaller in lumen size) [20].

Covered Stents

Covered stents are generally reserved for the treatment of isolated iliac aneurysms, iatrogenic perforation/ruptures, and arteriovenous fistulas. There have been limited studies in patients with PAOD.These devices are stainless steel, nickel-cobalt-titanium-steel alloy (Elgiloy), or Nitinol stents covered with Dacron or polytetrafluoroethylene (PTFE) [21–23]. In theory covered stents should reduce in-stent restenosis by excluding the diseased segment from the circulation, however, experimental data suggest that they induce more neointimal overgrowth compared to bare stents [21]. Early clinical reports show that the insertion of stent-grafts combined with CFA endartectomy may offer superior long-term patency in diffuse aorto-iliac occlusive disease (TASC C and D lesions) compared with bare stents [22]. Despite the encouraging early results, more studies are needed in order to justify the routine use of such devices in aorto-iliac occlusive disease.

Anticoagulation/Antiaggregant Therapy

The majority of operators give 5000 IU of heparin intraarterially at the time of the procedure. Full heparinization (500–1000 IU/h) can be continued for 12 to 24 h—particularly in difficult cases—to increase the activated partial thromboplastin time to two or three times normal [24]; alternatively, low-dose, low molecular weight heparin therapy is administered until hospital discharge [25, 26]. All patients should receive antiaggregant therapy, usually aspirin (100–325 mg/day), on a lifetime basis, alone [24, 25, 27] or in combination with clopidogrel [26, 28], although there is no evidence of improved outcome with the addition of clopidogrel to this regime.

Follow-up

Follow-up comprises the following: history and clinical examination, ankle-brachial index (ABI) measurement, and proof of patency, i.e., duplex ultrasonography, angiography, CTA, or MRA. Definitions of immediate technical and clinical success, clinical success during follow-up, and patency are given in Appendix II. Direct visualization with angiography is still considered by many to be the gold standard, however, duplex, CTA, and MRA now give a more acceptable noninvasive option. Duplex can be difficult in large patients and in the presence of heavy calcification, however, these can usually be overcome in the vast majority of patients [29]. CTA can overestimate the degree of in-stent stenosis, while heavy calcification can limit the diagnostic accuracy of the method by causing a ‘‘blooming artifact’’ [30]. MRA is contraindicated in some patients such as those with defibrillators, spinal cord stimulators, intracerebral shunts, cochlear implants, and cranial clips. The negative influence of metallic stents on image quality in contrast-enhanced depends on the stent architecture and material, with Nitinol stents producing minimal artifact [31].

Allowing for these limitations, direct imaging postintervention is feasible in the vast majority of patients. Currently there are no standardized protocols for imaging and surveillance postendovascular intervention, however, it seems reasonable to carry out imaging to document outcome at 6 and 12 months postprocedure.

Treatment of Restenosis

The currently accepted method for treating iliac in-stent restenosis, due to either intimal hyperplasia or disease progression following PTA/stenting, is repeated balloon dilation and/ or implantation of a second stent [32]. Repeat stent placement (resulting in a ‘‘stent sandwich’’) may show excellent short-term technical success, however, it bears the disadvantage of consequent arterial wall overexpansion, with the potential of the induction of further neointimal response [33]. There is no proof at present that stent placement in a restenosed vessel is beneficial to prevent future stenosis. Directional atherectomy appears to be a useful method by debulking the stent of its neointimal tissue prior to the upcoming balloon dilation or further stent placement [34]. Atheroablation techniques in general have not been widely accepted on the grounds of additional cost and skill demand [35]. Cutting balloon angioplasty offers an attractive therapeutic alternative for the treatment of iliac in-stent restenosis [36], however, adequate scientific evidence is still lacking.

Outcome

The reported technical and initial clinical success of balloon angioplasty in iliac artery stenoses exceeds 90% in most series and the 5-year patency rates range between 54% and 92% (Table 1). Becker et al. estimated a 5-year patency rate of 72% in an analysis of 2697 cases of iliac angioplasty and noted a better patency, 79%, in claudicants [44]. Less favorable results are achieved in long stenoses, external iliac stenoses, and tandem lesions [45]. It is important to note that the majority of these studies are retrospective and in the earlier ones the patency rates have generally been expressed as a percentage of technically successful procedures rather than of all PTAs attempted.

The reported technical and initial clinical success of balloon angioplasty in iliac artery occlusions ranges between 78 and 98% and the 3-year patency rates range between 48% and 85% (Table 2).

Stenting of the iliac arteries represents a durable and curative treatment, with a 3-year patency rate of 41%–92% for stenoses and a 3- year patency rate of 64%–85% and 4- year patency rate of 54%–78% for occlusions (Tables 3 and 4). Murphy et al. [67] recently reported a primary patency rate of 74%, 8 years after stent placement, and Schurmann et al. treated 126 iliac lesions (66 stenoses and 60 occlusions) and reported a 10-year patency rate of 46% [32].

Stents do seem to improve the results of iliac angioplasty without increasing the complication rate. A meta-analysis by Bosch and Hunink, who compared the results of aorto-iliac PTA versus stenting in 2116 patients since 1989, demonstrated that stenting of iliac artery stenoses contributed to a relative risk reduction of 39%

compared to balloon angioplasty, with respect to long-term patency, whereas complication rates and 30-day mortality rates did not differ significantly [68]. In a prospective randomized multicenter (>300 patients) trial comparing primary stenting and balloon angioplasty, the 5-year patency rate was 90% for stenting versus 68% for balloon angioplasty [69]. In contrast, primary stenting policy did not prove to be justified in another prospective randomized multicenter study which concluded that balloon angioplasty with selective stenting has an outcome similar to that with primary stenting, with comparable 2-year patency rates of 77% and 78%, respectively; however, 43% of the patients in the balloon-only treatment group were stented due to unsatisfactory angioplasty results [56]. The 5-year outcomes of the groups were also similar, with 82% and 80% of the treated iliac segments remaining free of the need for new revascularization procedures after a mean follow-up of 5.6 ± 1.3 years [70].

Factors stated to affect the patency of aorto-iliac endovascular interventions in a negative way include poor quality of runoff vessels, severity of ischemia, and extended length of diseased segments. It may have been suggested in the literature that location of the lesion at the external iliac artery adversely affects both primary and assisted-primary patency [71], but this has not been a uniform finding [72]. Female gender has also been associated with lower patency rates of the external iliac artery stents [73].

There has not been enough scientific evidence to prove the superiority of a specific stent type over the rest regarding immediate and/or long-term success. In a recent multicenter prospective randomized trial, comparison between two different self-expanding stents for the treatment of iliac artery obstructive lesions showed similar 1-year primary patency, complication, and symptomatic improvement rates [74].

Complications

Complication rates following PTA or stent placement in iliac arteries are shown in Tables 1–4. Major complications are defined as those that require therapy and hospitalization (not including overnight admission for observation only) or cause permanent adverse sequelae including death [26]. Pooled data are presented in Tables 5 and 6. Several patient factors such as obesity and cardiac and renal comorbidities contribute to increased complication rates [77].

The most frequent complication is hemorrhage from the access site (2.9%) resulting in a groin hematoma, although a retroperitoneal, properitoneal, or intraperitoneal hemorrhage may occasionally be met. In the suspicion of intraabdominal hemorrhage, a prompt pelvic CT scan is mandatory, since early diagnosis will enable prompt subsequent treatment to prevent unfavorable systemic events, such as myocardial infarction, acute tubular necrosis, and even death. Pseudoaneurysm formation at the site of the arterial puncture is less common (0.5%), with the treatment of choice for pseudoaneurysms >2 cm in diameter being percutaneous thrombin injection under ultrasound guidance.

Distal embolization occurs in 1.6% of iliac PTA/stenting procedures. Antegrade percutaneous catheter aspiration should be the treatment of choice for calf vessel embolus causing discontinuation of runoff. For larger emboli, such as those in the profunda femoris or common femoral arteries, surgical embolectomy is often required, as these emboli often contain plaque, not amenable to transcatheter aspiration or CDT.

Arterial rupture may complicate the procedure in 0.3% of cases. A patient complaining of persisting pain after balloon deflation prompts contrast administration in order to detect extravasation at the rupture site. Hypotension occurs quite often, usually due to vagal reaction and not volume depletion. Tamponade of the bleeding site with an angioplasty or occlusion balloon should be performed immediately and the placement of a covered stent should be considered. In case of failure, surgical treatment is required.

Although rare, stent infection has been increasingly encountered during the last 12 years [78–81]. This complication presents within 10–14 days after stent placement and clinical manifestations include fever, leukocytosis, bacteremia with positive blood cultures, hemodynamic instability, localized pain and/or mass, petechiae in the affected extremity, loss of pulse with symptoms of ischemia, and septic arthritis. Due to the devastating consequences of infection, some investigators advocate the administration of prophylactic antimicrobial agents, especially during long or repeated percutaneous access [82].

Table 1
PTA in iliac artery stenoses [37–43]: range

Patients	Claudicants	Technical and initial clinical success	Primary patency (5 yr)	Complications[a]
31–584	59%–91%	88%–99%	54%–92%	2.3%–13.4%

[a] Including major or ‘‘significant’’ complications, as far as distinguished in the text

Table 2
PTA in iliac artery occlusions [11, 42[a], 46[b], 47, 48 [b]]: range

Patients	Claudicants	Technical and initial clinical success	Primary patency (3 yr)	Complications[c]
42–82	64%–91%	78%–98%	48%–85%	3.1%–10.6%

[a] Patency rates based on an intention-to-treat analysis
[b] Initial failure rate not included in the analysis
[c] Including major or ‘‘significant’’ complications, as far as distinguished in the text

Table 3
Stents in iliac artery stenoses [11, 28, 49–58]: range

Patients	Claudicants	Technical and initial clinical success	Primary patency (3 yr)	Complications[a]
37–486	50%–100%	91%–100%	41%–92%	0–18 %

[a] Including major or ‘‘significant’’ complications, as far as distinguished in the text

Table 4
Stents in iliac artery occlusions [12, 59–66]: range

Patients	Claudicants	Technical and initial clinical success	Primary patency	Complications[a]
59–212	40.5%–87%	81%–97%	3 yr: 64%–85% 4 yr: 59%–78%	1.4%–15%

[a] Including major or ‘‘significant’’ complications, as far as distinguished in the text

Table 5
Complications: iliac PTA [43[a], 75[a]]

Procedures	Major complications	Requiring surgery	Mortality
6.676	2.7%	1.2%	0.2 %

[a] Pooled data from 38 studies´

Table 6
Complications: iliac stenting [76[a]]

Patients	Major complications	Requiring surgery	Mortality
1.948	6%	1.8%	0.4%

[a] Pooled data from 18 studies

Summary

1. Endovascular therapy is the treatment of choice for type A lesions and the preferred treatment for type B lesions. In selective patients, comorbidities, the local interventionist’s experience, and patient preference may justify the application of this type of treatment in type C and even type D lesions.

2. Lesions can be accessed from the ipsilateral femoral, contralateral femoral, and brachial approach and both the intraluminal and the subintimal space can be used for successful recanalization.

3. The application of stents has improved the immediate hemodynamic and probably long-term clinical results of iliac PTA. However, the superiority of primary or direct stenting over selective stenting has not been proven yet.

4. The choice of stent type depends on lesion morphology and location, but otherwise there is insufficient evidence to support the use of a particular stent design. There is insufficient evidence to justify routine use of covered stents.

5. All patients should receive antiaggregant therapy following endovascular recanalization of iliac arteries. Unless subsequently contraindicated, this should be continued indefinitely.

6. There is no consensus regarding prophylaxis with antibiotics in iliac recanalization procedures

Appendix I: TASC Classification of Aorto-iliac Lesions [4]

Endovascular therapy is the treatment of choice for type A lesions and surgery is the treatment of choice for type D lesions. Endovascular treatment is the preferred treatment for type B lesions and surgery is the preferred treatment for good-risk patients with type C lesions. The patient's comorbidities, the fully informed patient preference, and the local operator's long-term success rates must be considered when making treatment recommendations for type B and type C lesions.

Appendix II: Definitions

According to the standards of the Society of Interventional Radiology, immediate technical success is defined as <30% final residual stenosis measured at the narrowest point of the vascular lumen and restoration of rapid antegrade flow on DSA [83]. Immediate clinical success is defined as improvement by at least one SVS/ISCVS category. Patients with tissue loss must improve by at least two categories and reach the level of claudication to be considered improved [84]. Clinical success during follow-up is defined as sustained improvement by at least one SVS/ISCVS category above the pretreatment clinical level.

Primary patency is defined as uninterrupted patency, with no procedures performed on or at the margins of the treated segment. Secondary or assisted primary patency is defined as patency following reintervention to restore patency of the treated segment due to restenosis or occlusion [59, 83, 84].

Table A1 TASC classification of aorto-iliac lesions [4]

Type A lesions	Unilateral or bilateral stenoses of CIA
	Unilateral or bilateral, single, short (≤ 3-cm) stenosis of EIA
Type B lesions	Short (≤ 3-cm) stenosis of infrarenal aorta
	Unilateral CIA occlusion
	Single or multiple stenoses totaling 3–10 cm involving the EIA, not extending into the CFA
	Unilateral EIA occlusion not involving the origins of the internal iliac or CFA
Type C lesions	Bilateral CIA occlusions

	Bilateral EIA stenoses 3–10 cm long, not extending into the CFA Unilateral EIA stenosis extending into the CFA Unilateral EIA occlusion involving the origins of the internal iliac and/or CFA Heavily calcified unilateral EIA occlusion with or without involvement of origins of the internal iliac and/or CFA
Type D lesions	Infrarenal aorto-iliac occlusion Diffuse disease involving the aorta and both iliac arteries, requiring treatment Diffuse multiple stenoses involving the unilateral CIA, EIA, and CFA Unilateral occlusions of both the CIA and the EIA Bilateral occlusions of the EIA Iliac stenoses in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery

Note. CIA, common iliac artery; EIA, external iliac artery; CFA, common femoral artery; AAA, abdominal aortic aneurysm

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