

Cardiovascular and Interventional Radiological Society of Europe Guidelines on Endovascular Treatment in Aortoiliac Arterial Disease

Michele Rossi · Roberto Iezzi

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Abstract

Purpose These guidelines are intended for use in assessing the standard for technical success and safety in aorto-iliac percutaneous endovascular interventions.

Methods Any recommendation contained in the text comes from the highest level and extension of literature review available to date.

Results The success of endovascular procedures is strictly related to an accurate planning based mainly on CT- or MR-angiography. TASC II A through C lesions have an endovascular-first option. Pre-procedure ASA antiplatelet therapy is advisable in all cases. The application of stents improves the immediate hemodynamic and most likely long-term clinical results. Cumulative mean complication rate is 7.51 % according to the most relevant literature. Most of the complications can be managed by means of percutaneous techniques.

Conclusion The design and quality of devices, as well as the ease and accuracy of performing these procedures, have improved over the last decades, leading to the preferential treatment of aorto-iliac steno-obstructive disease via endovascular means, often as first-line therapy, with high technical success rate and low morbidity. This is mirrored by the decreasing number of patients undergoing surgical grafts over the last years with patency, limb salvage, and survival rates equivalent to open reconstruction.

Keywords Arterial intervention · Clinical practice · Angioplasty/angiogram · Peripheral vascular · Stenosis/restenosis

Introduction

One-third of the lesions in patients with peripheral artery obstructive disease (PAOD) affect the aortoiliac segment [1]. Localised stenosis or occlusion of the infrarenal aorta occurs relatively infrequently and is usually associated with occlusive disease of the iliac arteries. The most important risk factors for localised occlusive disease of the infrarenal aorta are heavy smoking, abnormal blood lipid concentrations, and so-called hypoplastic aorta syndrome [2]. In contrast, patients with more diffuse or multilevel aortoiliac steno-obstructive disease are much more likely to have other risk factors, such as hypertension, diabetes, and associated atherosclerotic disease of the coronary or cerebral arteries [2].

Although percutaneous intervention was born and developed as one of the first “alternative” treatments to open surgical bypass with the advent of angioplasty and stenting, this technique has evolved very quickly during the last two decades [3, 4]. The design and quality of the devices for these procedures, as well as the ease and accuracy of performing them, have improved, thus leading to the preferential treatment of aortoiliac steno-obstructive disease by way of endovascular means with a high technical success rate and low morbidity [5]. This is mirrored by the decreasing number of patients undergoing surgical grafts during recent years [6–8]. Furthermore, due to the increasing experience and ability of interventionalists, endovascular procedures are also often used as the first-line therapy for extensive, complex aortoiliac occlusive disease.

M. Rossi (✉)
Interventional Radiology Unit, Sant’Andrea University Hospital,
Rome, Italy
e-mail: michele.rossi@uniroma1.it

R. Iezzi
Radiology Department, “Sacro Cuore” Catholic University,
Rome, Italy
e-mail: roberto.iezzi.md@gmail.com

Table 1 Disease severity classification

Rutherford stage	Fontaine classification	Definition
0	I	Asymptomatic
1	IIa	Mild claudication
2	IIb	Moderate claudication
3		Severe claudication
4	III	Rest pain
5	IV	Ischemic ulceration not exceeding the digits of the foot
6		Severe ischemic ulcers or frank gangrene

They have also been reported to have decreased morbidity and mortality with patency, limb salvage, and survival rates equivalent to open reconstruction without the preclusion of any surgical option in case of an unsuccessful outcome [9, 10].

These guidelines are intended for use in the assessment of the standard for technical success and safety in aortoiliac interventions and are considered an update of those previously published in 2008 [11]. The recommendations made in this text are based on the highest quality literature reviews available to date [12]. Recommendations (RC) and levels of evidence (LOE) are divided in classes as shown in Appendix (see Tables 8, 9).

Definitions

Anatomy

This document refers to and adopts the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) classification of aortoiliac lesions [13] (Appendix [Table 10]).

Clinical Symptoms

The Rutherford clinical classification of disease severity is similar to the Fontaine classification but is more commonly cited in newer publications due to its greater clinical accuracy (Table 1) [14].

Claudication

Muscle cramps in the leg(s) that occur after exercise and are relieved by resting. Symptoms of buttock claudication can occur, occasionally in association with erectile dysfunction, in patients with bilateral internal iliac artery stenosis or occlusion or common iliac artery involvement. A

Table 2 Posttreatment evaluation

Outcome timing	
Immediate	1–30 days after the interventional procedure
Short term	30 days–12 months after the procedure
Long term	>12 months after the procedure
Success	
Anatomic	<30 % final residual luminal stenosis without flow-limiting dissection (grade D)
Hemodynamic	Pressure gradient measurement when possible. ABI should be improved by ≥ 0.1 above baseline value and not deteriorated by >0.15 from maximum early postprocedural level
Clinical	Immediate improvement by at least one clinical category ^a
Technical	Both anatomic and hemodynamic success should be obtained during the immediate postprocedure period

^a QoL tests and walking tests may also help to ascertain the clinical improvement

constellation of symptoms termed “Leriche syndrome” occurs in cases of either preocclusive stenosis or complete occlusion of the infrarenal aorta. Buttock pain extending to both legs and remitting with rest should be distinguished from walking- and standing-induced leg weakness and lower back pain, which can mimic ischemic syndrome but is more likely to be related to spinal canal stenosis.

Rest Pain

Pedal pain in the feet and toes at rest with or without exacerbation when prone.

Critical Limb Ischemia

The clinical definition of critical limb ischemia (CLI) should be used for all patients with chronic ischemic rest pain, ulcers, or gangrene attributable to objectively proven arterial occlusive disease.

Clinical Signs

Patients often have weakened or absent femoral pulses and a decreased ankle/brachial index (ABI). A normal resting ABI index is 0.9–1.3, whereas an index of 0.49–0.20 occurs with rest pain and is indicative of a severe PAOD; ABI > 0.50 indicates claudication.

Posttreatment Evaluation

The timing of evaluation and outcomes to be expected after treatment are listed in Table 2. Quality-of-life and walking tests may also help to ascertain clinical improvement. The

Table 3 Imaging modalities and reference sources

Imaging modality	Sensitivity stenosis > 50 %	Specificity stenosis > 50 %	Advantages	Disadvantages/limitations	References	LOE
DUS	85/90	>90	Low cost, noninvasive	Operator dependent, obesity/gas interposition, lack of full arterial road map	[16]	A
MDCTA	96	98	Arterial wall and intravascular and perivascular evaluation	Contrast medium, x-ray exposition, “blooming” artefacts	[17]	A
CEMRA	93–100	93–100	Arterial wall	Pacemakers	[16]	A
			Low-invasive, well-tolerated contrast medium	Metal implant stent, claustrophobia	[17]	
DSA			Gold standard	Invasiveness		
			Dynamic flow evaluation	2D “flat” imaging		
				Contrast medium		
				Radiation		

definition of “improvement” used by Rutherford [14] includes the following clinical and hemodynamic measures:

- +3 = markedly improved; symptoms are gone or markedly improved; ABI increased to > 0.90
- +2 = moderately improved; still symptomatic but with improvement in lesion category; ABI increased by > 0.10 but is not normalised
- +1 = minimally improved; categorical improvement in symptoms without significant ABI increase (0.10 or less) or vice versa
- 0 = no change
- -1 = mildly worse; either worsening of symptoms or decrease in ABI of > 0.10
- -2 = moderate worsening; deterioration of the patient’s condition by one category or unexpected minor amputation
- -3 = marked worsening; deterioration of the patient’s condition by more than one category or major amputation

Complications

Graded as minor (not requiring therapy) or major (requiring therapy or an unplanned increase in the level of care, prolonged hospitalisation, permanent adverse sequelae, or death). All complications and deaths within 30 days or within the same hospitalisation should be considered to be procedure related.

Pretreatment Imaging

To correctly indicate and plan the endovascular procedure, it is mandatory to do the following:

- localise the target lesion
- evaluate its extension (involvement of the common femoral artery and involvement of the aortic or iliac bifurcation) to select the stent to implant
- evaluate the involvement of in-flow (arterial system located above the target lesion)
- evaluate the involvement of distal runoff (arterial system located below the target lesion, such as the femoropopliteal or infrapopliteal arteries)

The primary imaging modality to be used in the screening of PAOD is duplex ultrasonography (DUS) due to its noninvasive nature, lower risks and costs, and strict dependence on operator skill and experience. DUS is also useful as a posttreatment imaging modality. During the evaluation of pelvic arteries, DUS accuracy is impaired by obesity or gas interposition. The proximal part of the common iliac artery and the distal part of the external iliac artery can be visualised in ~80 and >90 % of patients, respectively. The middle part of the pelvic axis can sufficiently be examined by DUS in only ~25 % of patients. Alternative methods should be considered when the imaging is suboptimal.

Digital subtraction angiography (DSA) is the “gold standard” for imaging of PAOD. It is relatively invasive, expensive, and has a definite, although low, morbidity, with a 3–7 % complication rate. DSA’s mortality rate as a diagnostic procedure currently can be considered equal or close to zero and similar to other less-invasive techniques needing contrast medium injection [15].

Contrast-enhanced MR-angiography (CEMRA) and multidetector computed tomography (CT)-angiography (MDCTA) are both accurate and reliable noninvasive alternatives to conventional DSA. They provide a noninvasive assessment of the vascular anatomy as well as localisation and extension of vascular lesions, thus facilitating the planning of interventional or surgical approaches in patients with

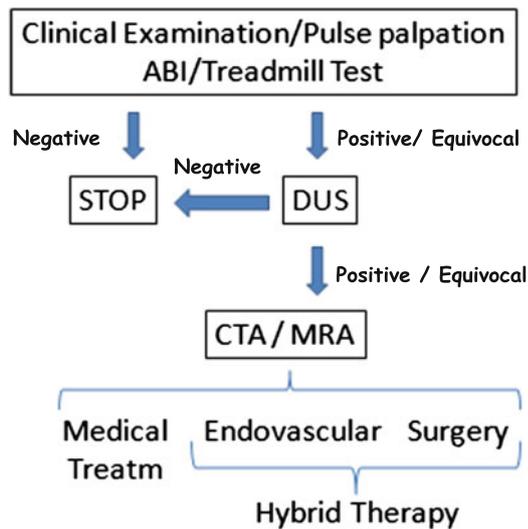


Fig. 1 Ideal diagnostic pathway of a patient with aortoiliac disease (RC I–LOE a and b)

PAOD. The resolution of CEMRA and MDCTA, however, are not comparable with the high-resolution potential of conventional angiography because they resemble a “static” image of vascular anatomy and pathology without the temporal resolution of DSA. The advantages of cross-sectional imaging compared with DSA are the noninvasive study of the wall and the ability to demonstrate pathological findings “around” the vessels. Both imaging modalities are currently capable of depicting vascular lesions with a high degree of sensitivity and specificity.

Data from anatomical imaging should always be analysed in conjunction with hemodynamic and clinical tests before therapeutic decisions. Table 3 lists the features of the aforementioned imaging modalities and the reference sources. The following flowchart (Fig. 1) summarises the ideal diagnostic pathway of a patient with aortoiliac disease (RC I–LOE a and b) [16, 17].

Indications

In symptomatic PAOD, there is a general consensus on the efficacy of supervised exercise to relieve symptoms and to improve time/distance walking capacity (RC I–LOE a) [18]. Supervised exercise and best medical treatment can have a long-term benefit comparable with endovascular treatment, especially in patients with mild to moderate claudication [19].

In femoropopliteal PAOD, inadequate response to conservative therapy should always be shown before starting any invasive procedures. However, in aortoiliac obstructive pathology, revascularisation can be considered without attempting to obtain results with conservative treatment, even in the case of claudication. In CLI, although rare, revascularisation is mandatory and is indicated when

clinical features suggest a reasonable likelihood of symptomatic improvement.

When revascularisation is indicated, the endovascular approach can be considered the first-strategy in all TASC A through C aortoiliac lesions due to the low morbidity and mortality rates and high technical success obtained (>90 %) (RC I–LOE c). Furthermore, endovascular treatment should also be considered for TASC D aortoiliac lesions (RC IIb–LOE c). These recommendations have low supporting evidence because there is a lack of data from published randomised trials [20–22].

Contraindications

General

Absolute

- Medically unstable patients
- Coagulopathy (unless corrected)
- Recent myocardial infarction, severe arrhythmia, or serum electrolyte imbalance

Relative

- Impaired renal function (estimated glomerular filtration rate 30 ml/min/1.73 m²)
- Severe allergic reaction to iodinated contrast media
- Buerger disease and Takayasu disease

Anatomical

- Some type D lesions, such as obstruction or severe stenosis of the common femoral artery and abdominal aortic aneurism (AAA [relative])

Preparation

Patient preparation with peripheral venous access, fasting, and good hydration follows the standards for any type of angiography and vascular intervention. All percutaneous procedures are generally performed with the patient under local anaesthetic (lidocaine or ropivacaine [7.5 mg/ml]) with full cardiorespiratory monitoring.

Antiplatelet Therapy

Preprocedural aspirin (ASA) antiplatelet therapy is advisable in all cases [23–26] (RC I–LOE b). Ideally, the

treatment of patients should commence with low-dose ASA (150 mg/day) at least 24 h before the procedure. Some investigators recommend preprocedural antiaggregation (ASA 100–325 mg/day) 5–7 days before the procedure [23–25], whereas others prefer a loading dose (clopidogrel 300 mg) on the day of the procedure.

Equipment Specifications

Angio-Suite

The angio-suite is the most widespread treatment environment for iliac intervention. The room must be equipped with a dedicated state-of-the-art C-arm and with standard anaesthesiologic and resuscitation facilities and drugs. US and DUS equipment should be available on site.

Operating Room

Unnecessary; possible only if supplied with high-level DSA equipment.

DSA Equipment

Large field of view, road-map options, and rapid and free arc movements are essential.

Catheters and Guidewires

A wide range of selective catheters, guidewires, semi-compliant or noncompliant balloons (6–10 × 40–150 mm), and stents (6–12 × 3–150 mm) should be available. In aortoiliac procedures, large stents ≤34 mm may be needed. In this vascular segment, the use of a 0.035-inch guidewire is still preferred over smaller guidewires. Hydrophilic and stiff guidewires are usually used.

Stent Type

Stents for peripheral applications are classified according to (1) their mechanism of expansion (self-expanding stent [SES] or balloon-expandable stent [BES]), (2) their composition (stainless steel, cobalt-based alloy, tantalum, nitinol, inert coating, active coating, or biodegradable), and (3) their design (mesh structure, coil, slotted tube, ring, multidesign, or custom design):

- Nitinol self-expandable stents are the most diffusely and frequently used stents. Their “open-cell” design gives them high conformability along curved tracts and provides adaptation to different calibres along the vessel to be treated, which is their main advantage.

Their use is largely commendable throughout the iliac area. Single self-expanding, long stents, which are now commercially available, should be favoured over the placement of multiple, overlapped stents because they allow for a faster and simpler procedure, thus avoiding the stiffening that occurs in overlapped tracts.

- Wallstent, an Elgiloy alloy metallic stent (Wallstent; Boston Scientific, Natick, MA), has been widely employed in the past as the first self-expandable stent. It has a “closed-cell” mesh design. Its advantages are possible “resheathing” before complete deployment and good radial force. Its worst feature is its unpredictable shortening and relative stiffness. Currently it has almost fallen into disuse in the aortoiliac district. The radial strength of some nitinol stents is equal if not superior to the Wallstent while preserving a high degree of flexibility.
- Stainless steel balloon-expandable stents have the advantage of significant radial strength. The main disadvantage is their stiffness and the need for a larger access introducer sheath. They are preferred in cases of heavily calcified, short stenoses/obstructions, particularly in the proximal segment of the common iliac artery [29, 30].

Special Devices

Re-entry Devices

Re-entry devices allow re-entry into the true lumen from the subintimal plane during intentional subintimal recanalisation (SR) to obtain quick satisfactory angiographic results and in-line blood flow reconstitution [31].

Covered Stents

Covered stents with Dacron or polytetrafluoroethylene membranes should always be available on site together with adequate sized sheaths for percutaneous use (8–9 F) to treat procedural complications, such as arterial ruptures/tears. The size of the stent used for implant should be 1–2 mm larger than the reference vessel diameter (RVD).

Procedural Features and Variation of Technique

Access

Stenoses

The ipsilateral retrograde approach can be considered the standard technique for interventions in the aortoiliac

arteries because it is safe and simple; >80 % of pelvic steno-obstructions can be treated using this approach. However, some lesions, including very distal stenoses of the external iliac artery, are not accessible from the ipsilateral common femoral artery. In these cases, the crossover technique (contralateral approach) may be helpful to perform this procedure.

Particularly for reconstruction of the aortic bifurcation and procedures in the aortic segment, a bilateral retrograde femoral access or a combined femoral and brachial access is necessary because these treatments are typically performed by the double-balloon/stenting technique (kissing balloon or kissing stent). Whenever possible, the left brachial approach should be performed to avoid crossing the aortic arch with the attendant risk of cerebral embolisation. Direct puncture of the axillary artery, which was performed in the early days of angiography, has largely been abandoned. Future developments may lead to a broader use of the transradial approach, which currently has an evolving role as a minimally invasive approach for coronary procedures.

Occlusions

While the percutaneous treatment of iliac artery stenoses is mostly a relatively simple procedure, the recanalisation of a totally occluded iliac artery may be technically challenging. Similar to the treatment of stenoses, possible approaches for treatment of iliac artery occlusions include the following: retrograde, crossover, and brachial access.

Although frequently used, the ipsilateral retrograde approach has the disadvantage of a more difficult arterial puncture distal to the occluded segment. Furthermore, it can be difficult to navigate the guidewire intraluminally through the occlusion. This may result in extensive dissection of the vessel wall, which, particularly in the region of the aortic bifurcation, may cause significant problems/complications.

Once the fibrous cap has been broken, the antegrade catheter and guide advancement will more likely remain intraluminally; however in the case of subintimal passage, true lumen re-entry can occur in the iliac segment. Long obstructions, especially when involving the origin of the common iliac artery, often require a combined approach: both antegrade and retrograde.

Puncture

In the presence of a palpable femoral pulse: standard technique.

In case of an absent or poorly palpable femoral pulse:

- US guidance (advisable when possible)
- Fluoroscopic guidance (calcifications as landmarks)
- Road-map guidance (needs contralateral or brachial access)

Sheath Introduction

The majority of balloons, self-expandable stents, and re-entry devices can be delivered through sheaths as small as 6 F. Devices working with 0.018-inch guidewires can also be delivered through smaller sheaths. In contrast, covered stents need larger sheaths (7–9 F). The routine use of larger sheaths (6–7 F) could be useful to perform a flush control with the stent in place just before its deployment.

Aortoiliac Recanalisation

Infrarenal long aortoiliac steno-obstructions are the most challenging lesions to be recanalised. A retrograde intraluminal recanalisation should be performed through the bilateral transfemoral approach with combined arm access to manage and apply tension along guidewires; in selective cases, it could also be useful to insert a guidewire into the renal and superior mesenteric arteries because this precaution allows bailout for vessel salvage.

Large balloon-expandable stents can be deployed into the aorta followed by the deployment of self-expandable stents into the iliac axis (bilateral or unilateral eventually followed by femoral–femoral bypass) [38, 39]. If the lesion involves aortic bifurcation, a kissing-stent technique should be performed by deploying the stents simultaneously and recreating the aortic bifurcation [38].

Covered stents, both self-expandable or balloon-expandable, seem to have longer patency and can be safely used in aortoiliac bifurcation reconstitution although they are not widely and routinely used [40]. Retrograde SR with re-entry into the aorta above the obstruction has been described as safe but only in a small series (RC I Ib–LOE c).

Iliac Recanalisation

Intraluminal recanalisation should be the first procedural option for PAOD because it is characterised by a decreased chance of inducing arterial wall rupture. The subintimal approach should be the secondary procedural option; usually it requires a stent implantation to stabilise the intimal flap.

In recent literature, the subintimal technique appears as a recurrent topic [32–35]. Iliac SR seems to be as safe as femoral SR [32–34]. However, the number of patients who have undergone this procedure is still low, and data are lacking that compare the subintimal versus intraluminal approaches in terms of complication rates and long-term patency.

A stiff, J-shaped, hydrophilic, looped guidewire advanced subintimally, together with an angled support catheter, is the technique of choice. Spontaneous true lumen re-entry in a relatively healthy segment is possible with this procedure. Antegrade dissection distal to the origin of the superficial epigastric artery must be avoided. Procedures requiring SR and re-entry devices are the most complex ones and generate an increased risk of rupture with angioplasty.

However, intentional re-entry into the true lumen is possible with the commercially available devices to date, and there is adequate evidence of the safety and efficacy of these devices with a success rate ranging from 71 to 100 % [36, 37] (RC IIa–LOE c).

Angioplasty and Stenting

Percutaneous transluminal angioplasty (PTA) is characterised by the possibility of acute technical failure, such as elastic recoil and dissections and late restenosis. These limitations have advocated the use of stent placement. The question of whether all iliac steno-obstructive lesions should undergo stent treatment has been addressed in multiple published articles. It has been shown that the application of stents improves the immediate hemodynamic and long-term clinical results of iliac PTA [44, 45].

Regarding the primary versus secondary stenting issue, the superiority of primary or direct stenting compared with selective secondary stenting has not yet been proven [47, 48].

To date, stand-alone angioplasty is reasonable for relatively short, nonocclusive lesions; however, for more complex iliac lesions and occlusions, primary stent implantation rather than provisional stenting should be considered (RC I–LOE b).

In these cases, predilation before stenting could be performed [29, 39–42]. Predilation should be performed in any case where advancement of the catheter is difficult, or where the stent shaft is located in heavily calcified lesions, to avoid incorrect/partial expansion of the stent with possible difficulty in balloon advancement for postdilation. In

contrast, primary stenting without predilation may prevent distal embolisation by fixation of the atherosclerotic or thrombotic material to the vessel wall [24, 43] (RC IIa–LOE c).

Stent and Balloon Size

The length of the stent should be determined by the measurement of the diseased tract.

The self-expandable stent diameter should match the RVD or be minimally oversized: 1 mm larger than the RVD. For postdilation balloons and balloon-expandable stents, the diameter should be the same as the inner vessel diameter. Diameters mismatched along a vessel require the use of self-expandable stents to increase the possibility of optimal wall apposition. Overlapping two or more stents seems to be a factor that increases the risk of late restenosis/obstruction [24].

Medication and Periprocedural Care

Anticoagulation Therapy

Provided that contraindications for comorbidities are absent, intraprocedural anticoagulation is always practiced.

Dosage

An intra-arterial bolus of 5,000 IU of unfractionated heparin, which diffuses during the course of 1 h, is the most common and routine method of dosage administration. The dose may be adjusted from 30 to ≤ 80 UI/kg according to the patient's body weight [26]. A lower incidence of complications and a substantial corresponding efficacy in the administration of < 60 UI/kg of heparin with a target ACT < 250 s, compared with major dosage during peripheral arterial endovascular procedures, have been proven [49].

Patient Monitoring

Patients should receive continuous monitoring of vital signs, including blood pressure, cardiac frequency, oxygen saturation, and electrocardiographic tracing, especially when sedation is contemplated. Pain should be closely monitored; it is typically moderate and localised in the pelvic site during dilation and usually does not require

treatment. In addition, pain persistence after balloon deflation is suspicious of arterial wall fissuring. A slowly growing retroperitoneal hematoma that went undetected during the procedure can unfold with bladder wall extrinsic impaction. US should be available on-site to exclude or confirm this contingency.

Vasovagal syndrome with hypotension, bradycardia, and sweating may occur. Heart rate and blood pressure should be monitored to determine the need for atropine administration at a dosage ranging from 0.5 to 1 mg.

Post Procedural Follow-Up Care

Initial Steps

- Local access site compression and elastic compressive medication
- In case of day-surgery or one-day surgery procedures, the use of closure devices are preferable
- Pain, renal function, and blood pressure monitoring
- Peripheral pulses and access site control
- In selective cases, in long and complex recanalisations, CT scan should be performed to exclude poorly symptomatic tears/hematomas before patient discharge

Follow-Up

FU should be composed of clinical examination and palpation of pulses. Clinical evaluation remains a cost-effective follow-up method. DUS is highly useful for follow-up after angioplasty [50]: It should be performed 30 days after treatment and repeated in case of clinical worsening. MD-CTA or CE-MRA should be considered when imaging is suboptimal or when sided dull pain is persistent.

Medications

Postprocedural anticoagulation therapy, although administered by some investigators in early reports (1992–2000), can now be limited to selected cases because antiplatelet therapy has replaced it. Dual-antiplatelet therapy, composed of ASA combined with clopidogrel or ticlopidine, was used in the majority of the studies and was usually maintained for at least 1 month in the carotid, femoral, and tibial districts. To date, there is no evidence of a dual-antiplatelet therapy benefit in aortoiliac interventions. ASA

is recommended as a periprocedural therapy as well as for maintenance according to the concurrent clinical conditions of the patient [26]. Dicumarol anticoagulation and antibiotic therapy coverage are not indicated in standard cases (RC I–LOE b).

Outcomes

The endovascular technical success rate is high in almost all series (>90 %). Regarding the issue of primary versus secondary stenting, the superiority of primary or direct stenting compared with selective stenting has not yet been proven [47, 48]. In the Dutch Iliac Stent Trial, 279 patients were randomly assigned to direct stent placement or primary angioplasty with subsequent stent placement in cases with a residual mean pressure gradient >10 mmHg across the treated site; the stent frequency in this group was 43 %. Because there were no significant differences in the technical results and clinical outcomes of the two treatment strategies both at short- and long-term follow-up, provisional stenting in the case of an insufficient angioplasty result can be considered state-of-art treatment for iliac artery stenoses. The immediate postprocedural results of a randomised trial of PTA, which compared provisional stent placement (stent placement for unsatisfactory balloon angioplasty results) with primary stent placement in iliac arteries, showed that pressure gradients across the lesions after primary stent placement (5.8 ± 4.7 mmHg) were significantly lower than after PTA alone (8.9 ± 6.8 mmHg) but not lower than after provisional stent placement (5.9 ± 3.6 mmHg) [46, 47]. The primary clinical success rate, defined as an improvement of at least one clinical grade category, was not different for the primary stent group (81 %) compared with the PTA plus provisional stent group (80 %). By using provisional stenting, the investigators avoided stent placement in 63 % of lesions and still achieved an equivalent acute hemodynamic result compared with primary stent placement. At mean follow-up of 5.6 years, there was no difference in repeat interventions between the two groups with a target-vessel revascularisation rate of 18 % in the primary stent group and 20 % in the provisional stent group [48].

Generally, the immediate success is greater in A and B TASC II lesions compared with C and D lesions. However, a meta-analysis published in 2011, which enrolled 16 studies published between 2000 and 2010 comprising 958

patients, showed that early and mid-term outcomes of endovascular treatment for TASC D aortoiliac lesions were acceptable with a technical success rate and a 12-month primary patency rate of 90.1 and 87.3 %, respectively [20]. Furthermore, during the last few years, a prospective, nonrandomised, multicentre, multinational trial (BRAVISSIMO study), which enrolled a total of 325 patients, was performed. That study aimed to validate the endovascular technique in TASC A and B lesions (190 patients) and to answer the question of whether endovascular treatment can be extended as the primary approach for TASC C and D lesions (135 patients). The published study confirmed that endovascular therapy is the preferred treatment for patients with TASC A and B aortoiliac lesions [28].

Although these results have not yet been published, no significant differences in the 12-month primary patency between TASC C (55 patients) and TASC D (80 patients) groups, with a rate of 91.3 and 90.2 %, respectively, were found. These and other preliminary data seem to support an endovascular-first approach for TASC D aortoiliac lesions [21, 22].

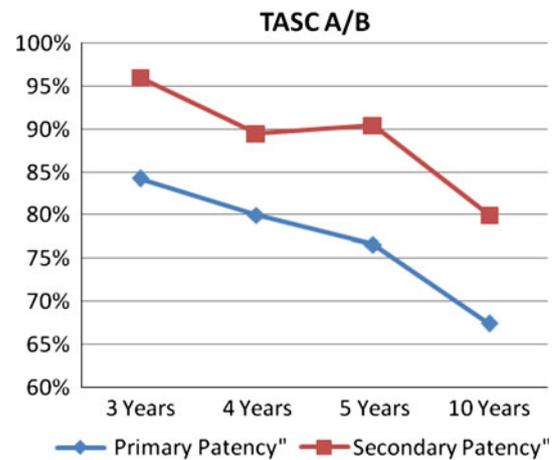
Patency rates with stenting of iliac arteries compare favourably with those of surgical revascularisation. However, a direct data comparison is difficult due to the lack of patient stratification.

A study comparing open repair versus percutaneous recanalisation angioplasty or stenting for extensive aortoiliac occlusive disease reported a limb-based primary patency rate at 3 years that was greater for aorto bifemoral bypass (93 vs. 74 %, $P = 0.002$). Secondary patency (97 vs. 95 %), limb salvage (98 vs. 98 %), and long-term survival (80 vs. 80 %) were similar [10].

The 5- and 10-year patient-based mean patency rate has been reported as being 85 and 79 % for claudication and 80 and 72 % for CLI, respectively. The aggregated systemic morbidity ranged from 13.1 to 8.3 % in more recent studies [7].

To date there is no proof of the superiority of SES versus BES in terms of patency [28]. There has been debate about whether stent architecture or composition has any effect on restenosis rates. The Cordis Randomised Iliac Stent Project trial failed to show any difference in outcomes between iliac artery stents made of nitinol (S.M.A.R.T. Vascular Stent System; Cordis, a Johnson & Johnson Company, Miami Lakes, FL) and Elgiloy alloy of stainless steel (Wallstent; Boston Scientific) at 1-year after surgery [27].

Table 4 and the underlying graphical representation summarise the mean 3- to 10-year primary and secondary patency rates after endovascular aortoiliac intervention obtained from the main series available in the literature since 1995.



Unexpectedly, the patency of TASC C and D lesions in recent articles (2011) appears to be longer than that of TASC A and B lesions reported from 1995 to 2011. This could be explained by the fact that the data on TASC C and D lesions comes from more recent studies on patients treated by stenting, whereas data on TASC A and B lesions include older-data publications that analysed cumulative outcomes, including treatments with stand-alone angioplasty or with old-generation stent types.

Complications

Some cases of retroperitoneal hematoma and haemoglobin decrease, although not requiring intervention, have been reported in literature [9]. Iliac artery rupture during angioplasty/stenting is one of the most dangerous, life-threatening complications [32–35, 38]. The most frequent complications and their mean occurrence rates from the relevant literature references are listed in Table 5. Table 6 lists management strategies of the main complications.

Table 4 Mean 3- to 10-year primary and secondary patency rates after endovascular aortoiliac intervention

	3 years	4 years	5 years	10 years
TASC A/B (%) ^a				
Primary (average)	84	80	77	68
Secondary (average)	96	90	90	80
TASC C/D (%) ^b				
Primary (average)			80	71
Secondary (average)			95.4	98

^a References [15, 23, 28, 31, 39, 41, 44, 50–53] (publication years 1996 to 2011)

^b References [23, 28] (publication year 2011)

Table 5 The most frequent complications and mean occurrence rates from relevant literature references

Complication	Mean rate (minimum–maximum)	References
Arterial rupture (%)	1.73 (0.2–3.4)	[23, 25, 29, 32, 33, 41, 42, 53, 55]
Arterial dissection (%)	1.95 (0.2–3.6)	[29, 41, 53, 55]
Treated vessel thrombosis (%)	1.32 (0.4–3)	[23, 25, 42, 55]
Distal embolisation (%)	1.70 (0.4–3.9)	[23, 25, 29, 33, 41, 42, 52, 55]
Pseudoaneurysm (%)	1.40 (0.4–2)	[29, 32, 41, 55]
Groin hematoma (%)	3.20 (1.3–4.3)	[32, 41, 42, 55]
Retroperitoneal hematoma (%)	1.00	[32]
Device malfunction (%)	0.43 (0.1–1)	[29, 32, 55]
Acute aortic occlusion (%)	0.20	[29]
Cumulative complication rate (%)	7.51 (4.1–16)	[23, 25, 29, 32, 33, 41, 42, 51, 53–55]

Table 6 Management strategies of the main complications

Arterial rupture pseudoaneurysm	Local high-compliance balloon inflation or cases of failure to stop blood extravasation: covered stent or occlusion balloon followed by surgical repair or by-pass
Arterial dissection	Prolonged ballooning for flap stabilisation or stenting
Treated vessel thrombosis or distal embolisation	Catheter-based thrombo aspiration or fibrinolysis [55]
Groin hematoma Retroperitoneal hematoma	Conservative management; clinical observation and instrumental follow-up; covered stent or surgery

Table 7 Final conclusions/guidelines

Conclusions	Class	LOE
Clinical indications are lifestyle-limiting claudication (Rutheford category 2–3) in motivated patients who are not responding or are poorly responding to conservative therapies or who are Rutheford category 4–6	I	B
TASC II A through C lesions have an endovascular-first option	I	B
Some TASC II D lesions can have an endovascular-first option in experienced centres	IIa	C
DUS is a “first-level” and CE-MRA/MD-CTA I a “second-level” imaging examination. They must be supplemented with clinical and physical examination before making therapeutic decisions	I	B and C
Preprocedure ASA antiplatelet therapy is advisable in all cases. A clopidogrel loading dose is suggested only in selected cases	I	B
Stent placement and PTA have similar complication rates	I	A
The application of stents improves the immediate hemodynamic and most likely long-term clinical results of iliac PTA. However, the superiority of primary or direct stenting compared with selective stenting has not been proven	I	A
SR is feasible at a sufficient safety level, and re-entry devices increase the immediate recanalisation success rate without affecting patency	IIb	C
ASA is recommended as a standard therapy for maintenance according to the concurrent clinical conditions of the patient	I	B

Conclusion

In conclusion, the complete guidelines are listed in Table 7.

Conflict of interest The authors have no conflict of interest.

Appendix

See Tables 8, 9, and 10.

Table 8 Classes of recommendations

Classes of recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, and effective	Is recommended/is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure	
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective and in some cases may be harmful	Is not recommended

Table 9 Levels of evidence

Levels of evidence	
A	Data derived from multiple randomized clinical trials or meta-analyses
B	Data derived from a single randomised clinical trial or large nonrandomised studies
C	Consensus of opinion of the experts and/or small studies, retrospective studies, and/or registries

Table 10 Classification of aortoiliac lesions

Classification of aortoiliac lesions	
A	Unilateral or bilateral stenoses of CIA Unilateral or bilateral single short (≤ 3 cm) stenosis of the EIA
B	Short (≤ 3 cm) stenosis of the infrarenal aorta Unilateral CIA occlusion Single or multiple stenosis totalling 3–10 cm involving the EIA that does not extend into the CFA Unilateral EIA occlusion not that does not involve the origins of internal iliac or CFA
C	Bilateral CIA occlusions Bilateral EIA stenoses 3–10 cm long that do not extend into the CFA Unilateral EIA stenosis that extends into the CFA Unilateral EIA occlusion that involves the origins of internal iliac and/or the CFA Heavily calcified unilateral EIA occlusion with or without involvement of the origins of internal iliac and/or CFA

Table 10 Classification of aortoiliac lesions

CIA common iliac artery, EIA external iliac artery, CFA common femoral artery

Classification of aortoiliac lesions
D Infrarenal aortoiliac 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 EIA
Bilateral occlusions of EIA
Iliac stenoses in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery

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