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Standards for the Endovascular Management of Aortic Occlusive Disease

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Introduction

In patients with ischemic peripheral atherosclerotic disease, the infrarenal abdominal aorta and the iliac arteries are the most commonly involved sites affected by the atherosclerosis [1]. Lesions are generally diffuse and involve the aorta and iliac segments [1]. Localized stenosis or occlusion of the infrarenal aorta above the aortic bifurcation, however, occurs relatively infrequently. In contrast to the male predominance in chronic multilevel atherosclerotic disease (male-female ratio, ~6:1), most patients with localized aortic lesions are women aged 30 to 50 years [2]. The most important risk factors are heavy smoking, abnormal blood lipid concentrations [3, 4], and so-called hypoplastic aorta syndrome [5], Size criteria for aortic hypoplasia include infrarenal aortic diameter <13.2 mm, or <10.3 mm just above the aortic bifurcation [4]. Patients with more diffuse or multilevel stenotic lesions are much more likely to have other risk factors, such as hypertension, diabetes, or associated atherosclerotic disease of the coronary or cerebral arteries.

Traditionally, endarterectomy was the treatment of choice for localized aortic stenosis and aortobifemoral or extra-anatomic bypass for more extensive disease. However although surgery delivers durable results, it is associated with significant peri-operative mortality and morbidity [6, 7]. The potential for graft infection is a particular drawback of extra-anatomic bypass. Endovascular treatment delivers hemodynamically acceptable results that are likely to be better than those of extraanatomic bypass. It is likely that recovery and mobilization can occur much sooner after endovascular procedures, with a potential for lower morbidity, mortality, and costs.

After Dotter and Judkins [8] introduced percutaneous transluminal angioplasty (PTA) in 1964, balloon angioplasty became a feasible alternative treatment for small and medium occluded or stenotic arteries. With the introduction of larger balloons it was possible to treat stenosis in major vessels such as the aorta, with the first reported cases in 1980 [9, 10]. Initially, however, this still required the use of a "kissing balloon" technique, with simultaneous inflation of two or more balloons in the aorta to give an adequate diameter, and this

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technique is also advocated for treating lesions involving the distal aorta and common iliac arteries [11–14].

With the development of larger stent technology, selective [15–17] and, more recently, primary stenting of the aorto-iliac segments has been advocated with bare stents [18–22] and covered stent-grafts [23, 24]. Many subsequent studies have demonstrated the initial advantages ofPTA over surgery, including shorter hospital stay, lower complication rate, and less invasive technique [25–28].

Indications include pelvic and lower limb ischemia (short-distance claudication, critical ischemia, blue toe syndrome) due to atherosclerosis or Takayasu's disease (TASC A and B).

Contra-indications are related to any percutaneous intervention (groin sepsis, bleeding diathesis, or severe coagulopathy) or TASC D-type lesion. Relative contraindications include anticoagulation, contrast allergy (CO2 or gadolinium can be used as alternative contrast), heavy concentric calcification of the aorta, active arteritis, and TASC C-type lesion.

Technique of Intervention

Imaging

Patient selection has evolved from using a combination of clinical assessment, including ABPI followed by angiography, to include duplex assessment [20, 29] and/or computed tomography (CT) [15, 17, 21] prior to invasive angiography to allow accurate assessment and sizing of lesions. Noninvasive imaging, wherever possible, is now widely used to select patients for endovascular management. At our institution we use duplex ultrasound as the first line to assess the peripheral circulation including the aorto-iliac segments for occlusive atherosclerotic disease. If this is inconclusive, we use either CT angiography (CTA) or magnetic resonance angiography (MRA) to plan management prior to invasive angiography and intervention. MRA is particularly useful in patients with heavily calcified vessels, which results in shadowing on ultrasound and artifact on CT, and in obese patients with impaired renal function or iodinated contrast medium allergy.

Angioplasty

The procedures are normally performed under local anesthetic with full cardiorespiratory monitoring. For difficult and prolonged procedures, facilities for sedation and analgesia should be available. Ideally patients should be commenced on low-dose asprin (150 mg/day) at least 24 h prior to the procedure. Access is usually obtained percutaneously using a single femoral arterial approach for single-balloon angioplasty or aortic stenting, or bilateral common femoral access is established when carrying out kissing balloon angioplasty and/or stenting. Although some authors have also used formal surgical cutdown [19], in which case procedures were performed under general anesthesia. This is followed by the administration of 5000 U of heparin. Duplex ultrasound can be very useful to guide percutaneous arterial

puncture in patients with poorly palpable arterial pulses, particularly in obese patients. The lesion/lesions are then often crossed using hydrophilic guide wires and selective catheters, e.g., C 2 Cobra, which are then exchanged for stiffer wires. Sometimes a brachial approach may also be required to help cross difficult lesions [30] and is useful for reference imaging. Thrombolysis can be used safely to help open up even chronically occluded aorta's [31, 32], however, this does prolong the procedure. Before a sheath is positioned across the lesion or a balloon dilatation is performed, luminal position of the wire beyond the occlusion should be confirmed. Appropriately sized sheaths are then advanced proximal to or across the lesion over a stiff guide wire such as the Amplatz superstiff.

Initially balloon sizes were limited and a kissing technique was employed, with two or even three balloons, in order to give the required diameters. However, now a wide variety of balloons is available for use in the aorta, including cutting balloons [33]. For stenosis just proximal to the aortic bifurcation or involving the common iliac artery origins, the ''kissing balloon'' technique is employed [11–14]; otherwise a single balloon is used for aortic dilatation. Balloon size is determined by preprocedural imaging but should be less than the maximum of the measured aorta diameter and, for kissing balloons, the ipsilateral common iliac arteries and the distal aorta [34, 35]. However, care should be taken during inflation if patients experience severe pain (not possible to assess in patients under general anesthesia). Using a smaller balloon initially may be safer, and if the patient does not experience severe pain, a larger balloon may then be employed. The inflation times, number of inflations, and pressure developed inside balloons vary with operators and equipment and there is no evidence of any difference in outcome with these different practices.

Stenting

Stenting may be performed as a primary or secondary procedure. The majority of stents to date have been placed following angioplasty on the basis of selective criteria, including nearly or totally occlusive aortic lesions, a persistent transstenotic mean pressure gradient >5 mm Hg (or >10 mm Hg higher during pharmacologically induced vasodilatation), ≥30% residual stenosis, and occurrence of dissection.

Predilatation may also be performed to facilitate primary placement of stents [20, 29], however, primary stent placement without predilatation (so-called ''direct'' stenting) has been advocated by some authors [22] as the treatment of choice, as there is some evidence that this results in less intimal hyperplasia [35]. It is suggested that primary (or direct) stenting may be particularly good for complex stenosis (irregular, eccentric, ulcerated, or calcified lesions) and occlusions. In these cases immediate success may be improved by eliminating luminal irregularities such as protruding plaques and intimal dissections [36]. A further theoretical rationale for primary stenting is to potentially reduce distal embolization by trapping atheroma and clot between the stent and the arterial wall [36, 37]. However, there is no solid evidence in the literature to recommend primary (or direct) stenting for specific lesion types. A variety of balloon-mounted and self-expanding bare stents is now available on the market. Some self-expanding stents

up to 14 mm in diameter can be delivered through sheaths as small as 6 Fr. Although experimentally self-expanding stents appear to cause less neointimal hyperplasia compared to balloon-mounted stents [38], currently there is no clinical evidence of any long-term advantage of one type of stent over the others. However, accurate placement can be difficult with the Wallstent due to stent shortening during delivery, and for larger aortas sometimes a balloon-mounted stent such as the Palmaz is necessary. Balloon-expandable stents should not always be sized to a maximum of the native aorta immediately proximal or distal to the diseased segment, depending on the patient's experience of pain during predilatation PTA. Self-expanding stents should be oversized by 10%.

As described for angioplasty, the lesions are crossed, the sheaths are placed (ideally for balloon-mounted stents across the lesion), the stent or stents are then positioned, and the stents are deployed (the sheaths first having been withdrawn for balloon-mounted stents). Postdeployment PTA is often necessary to fully and uniformly dilate self-expanding stents, particularly if there is a significant resting transstenotic gradient of >10 mm Hg.

Kissing Stents

It is now common practice to use the "kissing stent" technique by deploying the stents simultaneously and recreating the aortic bifurcation when dealing with the distal aortic segment including the origins of the common iliac arteries [30, 36, 39–44]. Kissing stents should ideally extend 5–15 mm into the distal aorta [41, 42]. However, care should be taken to prevent overhanging of one iliac stent over the other in the distal aorta, as this may lead to a significant increase in contralateral stent failure [41, 43, 45]. Another potential disadvantage of this technique is that uncovered metallic struts of the opposing stents protruding into the distal aorta may cause thrombosis and hemolysis. To avoid overdilatation, final balloon diameters should be sized based on the distal iliac reference segment [40].

Aftercare

The vast majority of procedures are carried out percutaneously, and femoral compression has traditionally been used for hemostasis in these patients, with bedrest for 4–6 h. With the development of closure devices, the time to ambulation can be significantly reduced without an increase in complications and with greater comfort for both operator and patient [46, 47]. Using the Prostar suture device (Abbott Laboratory, Redwood City, CA) or Perclose technique, puncture sites as large as 26 Fr can be closed percutaenously [48].

Antiaggregant /Anticoagulation Postprocedure

There is variability in practice, however, all patients should receive anti-aggregant therapy (aspirin, 100 to 325 mg/day) at the time the indication for PTA is made, which should be continued for at least 6 months [39] and, preferably, for life, if there are no contra-indications. Dypridamole may be added (50–325 mg) for 3–6 months or Ticlodipine [43, 49]. Clopidogril may also be substituted. Some authors continue heparin for a period of 24–48 h postprocedure, particularly in difficult cases [22, 29, 39, 44], and a few have placed patients on long-term warfarin anticoagulation [31, 39].

Follow-up

It is incumbent on all interventionists carrying out endovascular procedures to document objective outcomes (e.g., treadmill testing), symptomatic improvement, quality of life, and proof of patency (i.e., duplex ultrasound, CTA, MRA, or angiography).

Immediate technical success has generally been defined as a <30% residual stenosis and or a mean resting transstenotic gradient of <5 mm Hg (or <10 mm Hg peak systolic).

There has been no consistent approach to long-term follow-up. Clinical assessment, including ABPI, is commonly performed [20, 31, 32, 40, 44, 50], with or without femoral Doppler. A persistent increase in ABPI of >0.1 compared to pretreatment is considered significant. Many other authors also carry out duplex ultrasound in addition to this to directly assess patency [21, 30, 39, 40, 51, 52], with selective angiography in a few cases where problems are identified. Only a few have routinely performed follow-up angiography [22, 41].

Outcomes

Over the years several studies have been published on the endovascular management of aorto-iliac occlusive disease. However, the number of patients treated in the majority of these has been small, and there been an inconsistent approach in assessing outcome and follow-up protocols, as well as marked heterogeneity of lesions treated in the abdominal aorta. This makes direct comparison of these studies difficult. With the development of stent technology, this was initially performed on a selective basis following failure of angioplasty [16, 46, 61, 64], but more recently it has been advocated as the primary treatment in selective patients [18–20]. Although initial results show some improvement with angioplasty alone, the small number of cases make any firm conclusions impossible. A randomized trial would help to resolve this question.

Although surgery provides an excellent long-term outcome in patients with aortic occlusive disease, it has also been associated with a perioperative mortality rate of up to 1%–7% and a major early complication rate of 9%–27%, including sexual dysfunction, ureteral damage, intestinal ischemia, and spinal cord injury [6, 7, 22].

Endovascular management appears to be a safe and effective alternative to the surgical management of these patients, with low morbidity and high technical and clinical success (Tables 1 and 2). Durability results have also been encouraging. d'Othee et al. (35 patients) reported 85% primary patency at 3 years; de Vries et al. (69 patients) reported primary and secondary patency of 75% and 97%, respectively, at 5 years; and Feugier et al. (86 patients) reported primary patency rates of 89% and 77% at 3 and 5 years, respectively [16, 17, 46].

Complications

Complications following endovascular interventions compare very favorably with those following surgery (Tables 1 and 2). Total mean complications are 10.4% for angioplasty (major complications, 3.6%) and 12.3% for stenting (major complications, 0.4%). The major complications on the whole have been occlusive, i.e., iliac artery occlusion, iliofemoral thrombosis, distal embolization, and aorto-iliac dissection [19], the others being access-site hematoma, pseudo-aneurysm, puncture-site infection, infected stent, and myocardial infarction. Good technique with adequate anti-aggregant therapy and periprocedural heparinization is therefore vital in minimizing complications.

Table 1
Balloon angioplasty [11, 29, 31, 34, 49–51, 53–65]

Patients (6–102)	Technical success	Clinical success	Primary patency: 1 yr/2 yr/4 yr/5 yr	Major complications	Mortality
Range	83%–100%	66%–100%	90%–100%/80%–89%/70%–93%/64%–70%	0%–18.5%	0%–3%
Mean	96%	94%	85% (mean follow-up 4–52 mo)	3.6 %	0.4%

Table 2
Stenting [18–22, 30, 32, 39–45, 52, 66–69]

Patients	Technical success	Clinical success	Primary patency: 1 yr/2 yr/3 yr	Major complications	30-day mortality
Range	93%–100%	83%–100%	100%/91.6%–100/83%–100%	0%–25%	0%–6.0%
Mean	96%	99%	92% (mean follow-up 3–19 mo)	0.4%	0.5%

Conclusion

Recognition that occlusive disease of the infrarenal aorta can be safely treated by endovascular therapy is essential for the promotion of this technique. Prospective studies are required to compare endovascular techniques with the conventional surgical alternatives in terms of safety, efficacy, durability, and economy.

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