Iliac Arteries: How Registries Can Help Improve Outcomes

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Abstract

Keywords

- interventional radiology
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There are many publications reporting excellent short and long-term results with endovascular techniques. Patients included in trials are often highly selected and may not represent real world practice. Registries are important to interventional radiologists for several reasons; they reflect prevailing practice and can be used to establish real world standards of care and safety profiles. This information allows individuals and centers to evaluate their outcomes compared with national norms. The British Iliac Angioplasty and Stenting (BIAS) registry is an example of a mature registry that has been collecting data since 2000 and has been reporting outcomes since 2001. This article discusses the evidence to support both endovascular and surgical intervention for aortoiliac occlusive disease, the role of registries, and optimal techniques for aortoiliac intervention.

Objectives: Upon completion of this article, the reader will be able to describe the role of endovascular and surgical techniques in the treatment of aortoiliac occlusive disease, as well as the advantages and limitations to using registries in diseases such as this

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The prevalence of peripheral arterial disease (PAD) is estimated to be 3% in middle-aged patients, increasing to

20% in patients >70 years of age.^{1,2} Approximately one-third of lesions are in the aorto-iliac segment. Aorto-iliac stenotic and occlusive disease (AIOD) is commonly associated with widespread atherosclerosis with isolated aorto-iliac disease in only 5 to 10% of cases.³ Noninvasive imaging permits accurate anatomical assessment allowing selection of the optimal therapeutic strategy and preprocedural planning. Aortoiliac lesions can be anatomically classified in accordance with the Trans-Atlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) (see appendix).⁴ Endovascular treatment is the preferred option for TASC II A–C lesions and is increasingly used for selected TASC II D patients.

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individuals and centers to evaluate their outcomes compared with national norms. The British Iliac Angioplasty and Stenting (BIAS) registry is an example of a mature registry that has been collecting data since 2000 and has been reporting outcomes since 2001.

This article discusses the evidence to support both endovascular and surgical intervention for aortoiliac occlusive disease, the role of registries, and optimal techniques for aortoiliac intervention.

Endovascular and Surgical Intervention for AIOD

Outcomes of Surgery for AIOD

The most widely utilized anatomical open surgical reconstructions are aortofemoral bypass (AFB) and iliofemoral bypass (IFB).⁵ The operative mortality reported for AFB and IFB are 4.1 and 2.7%, respectively, and systemic morbidity rates are reported at 16% for AFB and 18.9% for IFB ($p < 0.0001$). The overall 5-year primary patency rates are 86.3 and 85.3% for AFB and IFB, respectively ($p < 0.12$). Outcome is closely linked to clinical presentation, with higher patency in patients with intermittent claudication (IC) than in those with critical ischemia (CLI). Overall 10-year mean patency rates for AFB are reported as 79% for claudication and 72% for CLI.⁶ This is the benchmark to which endovascular techniques must be compared, particularly in younger patients with a long life expectancy.

Outcomes of Endovascular Treatment of AIOD

Over the last decade, endovascular treatment options have emerged as a robust alternative to traditional open surgery.^{7–10} Endovascular techniques avoid the need for general anesthesia, do not carry the inherent risks of laparotomy, and therefore allow shorter postoperative hospital stays.

Aortic Angioplasty and Stenting

Studies have shown technical success rates of 95 to 100% for angioplasty of the infra-renal aorta and angioplasty of the aortic bifurcation.^{7–9,11–15} Stenting the aorta yields similar success rates of 87 to 100%, with a primary patency of 80 to 100% at 3 to 10 years.^{10,16–21} Whether stenting increases patency rates over balloon angioplasty alone remains unclear.

Iliac Artery Angioplasty and Stenting

A prospective randomized multicenter trial comparing iliac artery angioplasty and stenting reported on 112 patients, with predominantly TASC B lesions. Technical success was found to be significantly higher after stenting versus angioplasty (98 vs. 84%, $p = 0.007$); in addition, major complications were significantly more frequent following percutaneous transluminal angioplasty (PTA) versus stenting (20 vs. 5%; $p = 0.010$). However, there was no difference in primary patency at 1 and 2 years.²² The short- and long-term outcomes from the Dutch Iliac Stent Trial (DIST) support a policy of selective stenting for iliac arterial disease.²³ The 2-year patency rates

were comparable at 77% (PTA and selective stenting) and 78% (primary stenting).²³ 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.²⁴ It should be noted that the patients in DIST were exclusively claudicants, and the majority of patients had TASC A and B lesions. The absence of patients with critical limb ischemia and the fact that less than 10% had total occlusions must also be remembered as this is not representative of current real world practice. Nonetheless, the results are important and indicate that an angioplasty-first approach is appropriate for stenotic disease with stenting reserved for patients with a suboptimal angioplasty (mean pressure gradient >10 mm Hg). Using this selective stenting approach, almost 60% of patients with TASC A and B stenoses can be managed without a stent.

A recent large review of 958 patients with TASC C and D lesions reported significantly better outcomes for primary stenting versus selective stenting. The technical success and 12-month primary patency rates for primary stenting were 94.2 and 92.1%, respectively; for selective stenting, these rates were 88.0 and 82.9%, respectively. The 4-year primary patency rates for patients receiving primary stenting were also significantly better than those receiving selective stenting.²⁵

All TASC grades of lesions are treatable by using endovascular techniques, but it is not surprising that immediate success is greater for “simpler” lesions (TASC A or B). The review on TASC C and D lesions has also demonstrated that early results of endovascular treatment for TASC D aortoiliac lesions were also acceptable with a technical success rate of 90.1% and a 12-month primary patency rate of 87.3%.²⁵ Surprisingly, the patency rates of TASC C and D lesions reported in this article appear to be greater than that of TASC A and B lesions reported in earlier studies (1995 and 2011).

Data from the recent BRAVISSIMO study have confirmed that endovascular treatment is justified for patients with TASC A and B aortoiliac lesions.²⁶ In addition, however, data presented in abstract form from the same study have shown no significant differences in the 12-month primary patency rates of around 90% for TASC C (55 patients) and TASC D (80 patients) lesions. These findings indicate that an endovascular-first approach can be considered for TASC D aortoiliac lesions in appropriately selected patients.^{10,17,25}

Stent Type

There does not appear to be any significant difference in the patency rates between the different types of available stents, in particular, self-expanding versus balloon expandable stents or between different self-expanding stents. The Cordis Randomized Iliac Stent trial showed no 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, Natick, MA) at 1 year.²⁷ Covered stents have also been evaluated in a small number of studies. In the Covered Versus Balloon-Expandable Stent Trial (COBEST), 125 patients

were randomly assigned to receive a covered balloon-expandable stent or bare metal stents; a total of 168 iliac arteries were treated. At 18 months, covered stents and bare metal stents performed similarly in TASC B lesions; however, covered stents performed better in TASC C and D lesions. Overall, covered stents were more likely to remain free from binary restenosis than those lesions treated with a bare-metal stent (hazard ratio [HR], 0.35; 95% confidence interval [CI], 0.15–0.82; $p < 0.02$).²⁸

Registries

There have been very few high quality prospective randomized trials comparing outcomes of endovascular treatments on which to base practice. Registries allow the collection and synthesis of a large amount of contemporaneous data on outcomes in real world practice. The British Society of Interventional Radiology (BSIR) established the BIAS registry to assess current practice in the endovascular treatment of iliac artery disease.

To date, there are data from over 4,000 patients in the BIAS registry documenting immediate technical success, complication, and mortality rates. BIAS has issued three summary reports, most recently in 2008. In addition, individual practitioners and centers can request their personal outcome data at any time. The summary reports indicate that intermittent claudication remains the commonest indication for treatment (62.4%). Immediate technical success crossing the stenosis or occlusion was reported as >98%, with an overall procedural success of >97%. Stents were used in 57% of procedures; this suggests appropriate usage in keeping with DIST, and also confirms that real world outcomes can come close to results reported in the literature. The proportion of day case patients has increased from 13 to 25% over the past 8 years.²⁹

The BIAS dataset includes reporting of complications relating to the treated limb and systemic complications (e.g., myocardial infarction) and whether the complication required further intervention. Complications are more common in patients with CLI compared with claudicants (11.6 vs. 5.8%, respectively). Although leg complications were reported in 3.2% of limbs, <1% of patients had either a worsening level of ischemia or an unexpected amputation as a consequence of intervention. The overall mortality from the BIAS data was 2.0%; unsurprisingly, there was a lower reported mortality (0%) in patients selected for day case procedures.

Every doctor should be able to tell a patient how their performance compares to national practice. The BSIR has chosen iliac artery intervention to be the “index endovascular procedure” for interventional radiology. The BIAS registry generates funnel plots that stratify outcomes and define 99, 99.9, and 99.99% confidence limits. The BIAS data allows individual interventional radiologists and centers to demonstrate that their performance falls within a nationally defined range.

Since BIAS III, the REAL-AI registry from Japan has been published. This confirmed excellent procedural success (97.6%), complication (6.4%), and 30-day mortality (0.7%) rates. REAL-AI also reported primary patency rates of 92.5, 82.6, and 77.5% at 1, 3, and 5 years, respectively; assisted primary patency was 97.0, 92.7, and 91.9% at 1, 3, and 5 years,

respectively; and secondary patency was 99.0, 98.7, and 98.5% at 1, 3, and 5 years, respectively.³⁰

The BIAS dataset represents an excellent commitment to collection of data; however, data entry into the BIAS registry is voluntary and variable participation by individuals and centers means that datasets are incomplete. In addition, unlike the REAL-AI registry, the BIAS registry does not collect longitudinal data on outcomes beyond patient discharge. To overcome these problems, external validation and integration of clinical datasets to permit longitudinal data collection may provide the best model of collection. In the UK, a national vascular database was launched in 2013 and all operators carrying out vascular surgery and/or intervention are expected to enter data into this for specified vascular procedures, including peripheral vascular interventions. These data will be compared with data from the national hospital episode statistics (HES) and will allow external validation of outcomes.

Endovascular or Surgical Approach in the Real World

Direct data comparison of surgery with endovascular treatment is difficult due to the lack of patient stratification; there are currently no published comparative randomized trials. A retrospective cohort study compared open repair (161 limbs) with percutaneous recanalization (127 limbs) with angioplasty and/or stenting for extensive acute and chronic aortoiliac occlusive disease. Lesion severity was matched in the two groups, and all patients had complete iliac occlusions and 80% had TASC C or D lesions. Sixty-one percent of the surgical patients and 21% of the endovascular patients had concomitant femoral endarterectomy, profundaplasty or distal bypass. There was a greater 3-year primary patency rate for AFB (93 vs. 74%; $p = 0.002$) but similar secondary patency (97 vs. 95%), limb salvage (98 vs. 98%), and long-term survival (80 vs. 80%) rates.³¹ Patency was worse in both groups for patients requiring distal revascularization. The authors concluded that although primary patency was greater in surgically treated patients, endovascular treatment afforded a less invasive alternative with broadly comparable midterm results.

It is clear that surgery can achieve excellent long-term results with high patency rates up to 10 years postprocedure, and that few trials of endovascular treatment have such extensive follow-up. There is of course a tradeoff in patency to be made with endovascular techniques; however, published data do also suggest that compared with endovascular treatment, AFB is associated with a higher mortality rate (3.7 vs. 1.9%; $p < 0.001$) and increased hospital length of stay (LOS).³² A further recent population-based study in 4,119 patients with AIOD also showed that endovascular procedures were associated with lower complication rates (16 vs. 25%), shorter LOS (2.2 vs. 5.8 days), and lower hospital costs (\$13,661 vs. \$17,161) (all $p < 0.001$ compared with open repair).³³

Endovascular Treatment Strategy

All patients should be discussed at a multidisciplinary team meeting to allow decisions on the most appropriate

treatment. In the authors' practice, patients with isolated stenosis (>75%) of the iliac artery (TASC A and B lesions) are managed with angioplasty and selective stenting, and occlusions or more extensive iliac disease (TASC C and D lesions) with primary stent placement to minimize risk of distal embolization²² (→Fig. 1). Occlusions are generally approached from the ipsilateral side in the first instance; if this fails, an extraluminal approach from the contralateral side will often succeed. It is sometimes necessary to perform predilatation with a small low-profile balloon to allow the stent catheter to cross the occlusion. The procedure typically is typically performed in the following stages:

1. Digital subtraction angiography (DSA) is performed as required; if necessary, lesion length and vessel diameter measured.

2. Stents are chosen to completely cover the target lesion. Self-expanding stents are oversized by 10% and balloon expandable stents sized to the artery.
3. Angioplasty balloons are sized according to a normal segment of the ipsilateral or contralateral target artery.
4. Completion angiography is performed of the angioplasty/stent site and distal runoff vessels.
5. In case of residual stenosis >30%, flow limiting dissection and/or a residual mean pressure gradient of >10 mm Hg, repeat angioplasty with prolonged balloon inflation is used. A stent may be required if the gradient remains high.

Isolated Infra Renal Aortic Stenosis: Procedure

The main difference from the earlier-mentioned technique is the need for larger balloons and/or stents, which may require larger access size sheaths. Sizing the aorta may be

Figure 1 (A) A 61-year-old woman with a TASC D lesion with a tight right common femoral stenosis (open black arrow), right common iliac stenosis (solid black arrow), right external iliac occlusion (solid white arrow), and left common iliac occlusion (open white arrow). **(B)** A hybrid procedure was performed with right common femoral endarterectomy, and on bilateral common iliac kissing stents and right external iliac artery stent. The right external iliac artery occlusion was crossed retrogradely and combined antegrade and left common femoral access to cross the left common iliac occlusion. The left common iliac artery required a reentry device (Outback catheter) (solid black arrow) to gain access to the true lumen using the balloon (open arrow) as a target. **(C)** Completion angiogram demonstrating good flow into both iliac systems. The distal right external iliac artery is not filled due to clamping of the common femoral artery.

problematic when it tapers toward the bifurcation. A self-expanding stent can usually accommodate a range of diameters and is extremely useful in this situation. Sizing should be decided from the periprocedural cross-sectional imaging. Isolated aortic stenoses typically occur just below the inferior mesenteric artery (IMA). If there is a prominent marginal artery of Drummond or IMA appears a dominant vessel, the superior mesenteric artery should be assessed. Protecting a dominant IMA during angioplasty and/or stent placement should be considered. A short taper balloon should be chosen to avoid accidental damage to the iliac arteries. If the bifurcation is involved, kissing balloons may be the best option.

It is important to remember that lower balloon pressures (4–6 atmospheres) are required when dilating the aorta. Dilatation of the aorta is often painful, particularly if it is heavily calcified. The patient should be instructed to indicate as soon as they feel discomfort. Dilatation beyond this point should proceed with caution, and it is essential to have an occlusion balloon and stent graft ready in case of rupture.

Choice of Stent Type

The choice of the appropriate stent type depends on the lesion morphology and location. A balloon expandable stent is chosen when dealing with calcified or eccentric plaques at the ostium of the common iliac artery (CIA) or external iliac artery (EIA). Self-expanding stents are used in longer, less calcified vessel segments, particularly in tortuous vessels. Closed cell self-expanding nitinol stents tend to have greater radial force but are less flexible than those with an open cell construction. The latter are used for treating tortuous vascular segments and those that transit abruptly in size (e.g., from a CIA to an EIA).

Treatment of Restenosis

Early restenosis generally reflects technical failure, due to either elastic recoil or incomplete lesion coverage, and is usually managed by stenting. Later restenosis is due to disease progression beyond the treated segment or neointimal hyperplasia (NIH) at the angioplasty site or within the stent. Management options are influenced by factors such as the initial treatment and how long the vessel remained patent. If there was restenosis within a few months of angioplasty, then stenting or use of a drug-eluting balloon is indicated. Alternatively, if symptoms recurred after 2 or 3 years then repeat angioplasty would be reasonable. When there is extensive NIH within a stent repeat stent placement can show excellent short-term technical success; however, it bears the disadvantage of consequent arterial wall overexpansion with the potential of stimulating further NIH. Directional atherectomy has been used to reduce NIH prior to balloon dilation or further stent placement. In the authors' practice, once a stent has been relined and restented, the authors would not opt for a third stent if symptoms return. In these situations, multidisciplinary team discussion is warranted and surgical bypass management might be the only option available.

Follow-up and Imaging

Patients should be reviewed in the clinic 6 to 8 weeks post-procedure and assessed with ankle brachial pressure index (ABPI) assessment and, if indicated, a Duplex examination at that time. Patients are routinely followed annually with ultrasound scans to assess for restenosis. If any concern arises or there is a discrepancy with the ultrasound imaging, then a contrast enhanced computed tomographic angiogram or magnetic resonance angiogram would be performed depending on the type of stent used.

Conclusion

Registries provide an evolving real world picture of practice and allow the settings of standards of practice for procedures such as iliac intervention. Individuals and centers can use the data to demonstrate that their outcomes meet these standards. To be relevant, the data must be complete and systems should be in place to facilitate recording; this must be accompanied by quality controls to demonstrate satisfactory capture.

Open surgical and endovascular interventions are complementary therapeutic approaches and the decision regarding optimal management should be tailored to the individual patient. Surgery is most commonly offered to young patients and those with TASC II C and D aortoiliac lesions.⁴ In practice, many vascular units adopt an endovascular approach first, regardless of TASC classification in view of the lower morbidity and mortality.³⁴ Endovascular treatments rarely preclude or increase the complexity of any subsequent surgery performed for AIOD.

A selective stent approach to treating TASC A and B stenoses appears appropriate in the iliac arteries. In occlusions and type C and D lesions, a policy of primary stenting appears more effective. There is no evidence that stent material or type influence outcome. However, although it is technically possible to treat the vast majority of aortoiliac lesions by endovascular means, this does not mean that this is the optimal treatment strategy and surgery may still be the best option particularly in younger patients with a long life expectancy.

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Appendix

TASC 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 stenoses totaling 3 to 10 cm involving the EIA that does not extend into the common femoral artery (CFA)

Unilateral EIA occlusion that does not involve the origins of internal iliac or CFA

C

Bilateral CIA occlusions

Bilateral EIA stenoses 3- to 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

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 abdominal aortic aneurysm (AAA) requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery