

Chapter 12

In Patients with Aortoiliac Occlusive Disease, Does Endovascular Repair Improve Outcomes When Compared to Open Repair?

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Abstract Aortobifemoral bypass (ABF) has long been the gold standard for treatment of aortoiliac occlusive disease, proving to be a durable procedure with a 10 year patency rate of 80–90% in more recent reports. Peri-operative mortality of 1–3% can be achieved.

Endovascular treatment of aortoiliac lesions has evolved rapidly over the past two decades. Long segment stenosis and occlusion are now increasingly being treated with endovascular therapy, reflecting significant changes in practice patterns since the publication of the Trans-Atlantic Inter-Society Consensus Group (TASC) Guidelines in 2007.

Contemporary results demonstrate that compared to ABF, endovascular therapy has a lower primary patency rate, but similar secondary patency and limb salvage up to 5, and perhaps even 10, years after the index procedure.

Keywords Aortobifemoral bypass • Aortoiliac occlusive disease • Iliac stent • Iliac angioplasty • Endovascular therapy

Introduction

Aortobifemoral bypass (ABF) has long been the gold standard for aortoiliac occlusive disease (AIOD), proving to be a durable procedure with a 10 year patency rate of 80–90% in more recent reports [1–3]. Peri-operative mortality of 1–3% can be achieved [1, 2, 4, 5]. However, endovascular therapy is gaining an increasingly prominent role as a less invasive option in the treatment of aortoiliac occlusive lesions. Endovascular therapy offers revascularization of aortoiliac lesions while

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avoiding the morbidity of a laparotomy, arterial clamping and unclamping, general anesthesia, and large fluid shifts in the post-operative period.

In response to the early enthusiasm for endovascular therapy, the Trans-Atlantic Inter-Society Consensus Group (TASC) guidelines were published in 2000, in attempt to balance the appeal of minimally invasive therapies with their durability. The guidelines were subsequently amended in 2007, and recommended open bypass for TASC C and D lesions [6]. Since the latest update, results of endovascular therapies for TASC C and D lesions have been reported, with varying results based on indication, use of selective versus primary stenting, and concomitant procedures.

This chapter is intended to guide an evidence-based discussion on the contemporary treatment of patients with aortoiliac occlusive disease, by comparing aortobifemoral bypass with endovascular therapy in regards to patency, morbidity, mortality, and quality of life. It also serves to address patient-specific and intra-operative factors, with particular attention to endovascular treatments.

Search Strategy

A literature search of English language publications published between 2000 and 2014 was performed using the PICO outline (Table 12.1). The PubMed and PubMed Central database was used to identify articles. Suggested related articles, referred studies in retrieved articles, reviews, and referenced articles were also evaluated. Search terms were “aortoiliac disease”, “aortoiliac occlusive disease”, “aortofemoral”, “aortobifemoral bypass”, “iliac stent”, “iliac angioplasty”, “TASC”, “endovascular therapy”, “endovascular treatment”, “hybrid”, “quality of life” and combinations thereof.

Results

Aortobifemoral Bypass

According to the TASC guidelines, patients with diffuse stenosis or occlusions, comprising TASC D lesions, are best suited to open surgical bypass. This procedure however requires general anesthesia, a laparotomy, and aortic cross clamping. Due to the extent of physiological insult with these maneuvers, mortality and systemic morbidity rates are substantial.

Table 12.1 PICO table

Patients	Intervention	Comparator group	Outcomes
Patients with aortoiliac occlusive disease	Endovascular therapy	Aortobifemoral bypass	Primary patency, primary-assisted patency, secondary patency, limb salvage, LOS, complication rate, quality of life

The weighted average of 30-day mortality was 2.4% for ABF in studies published since 2000. A recent meta-analysis by Chiu, which spans four decades of data, reports 4% mortality, 16% systemic complications, and 6% local complications in 5738 cases [7]. Dimick reported ABF procedures from the 1997 Nationwide Inpatient Sample, which is a 20% sampling of 483 U.S. hospitals of various sizes and types. In-hospital mortality in this report was 3.3% [8]. This number is the same as de Vrie's reported mortality rate of 3.3% in "recent" (post-1975) ABF results [9].

It may be tempting to assume that with improved pre-operative optimization, patient selection, and critical care, operative mortality has significantly improved with ABF in the new millennium. However, this assumption has been refuted by published reports, and the reasons are multifactorial. First, as Back demonstrated, ABF is now utilized for patients with increasingly complex anatomy, often requiring suprarenal or supraceliac clamping, and visceral revascularization [10]. Second, fewer ABF are being performed, and Dimick's previously referenced work demonstrated mortality rate of 3.7% for low-volume hospitals (<25 ABF/year) compared to 2.2% for high-volume hospitals (>25 ABF/year) [8]. Third, as endovascular therapy further matures, newer vascular surgeons will have had less open training compared to their more senior counterparts, which will further exacerbate challenges with ABF. It is predicted that by 2015, vascular trainees will complete fellowship having performed only 10 open aortic repairs, and by 2020, only 5 [11].

Morbidity from ABF is generally categorized into systemic (e.g. MI, pneumonia, sepsis, stroke) versus local (e.g. hematoma, lymphocutaneous fistula, surgical site infection). A large proportion of systemic complications are pulmonary. A meta-analysis by de Vries reported a systemic morbidity of 12% and local morbidity of 7% in ABF results spanning four decades, whereas Chiu reported 16% and 6% respectively over a similar timeframe [7, 9] (Table 12.2).

Table 12.2 Aortobifemoral bypass outcomes

Author	Year	N	Mortality	Morbidity	Primary patency 1 year	Primary patency 5 years	Secondary patency 5 years
Faries	2001	370	0	18 ^a		93	
Back	2003	107	4	34			
Reed	2003	281	1	32		85	92
Dimick	2003	3073	3.3				
Hertzer	2007	255	1.2	26	96	88	
Kashyap	2008	86	7	14 ^a			
Chiesa	2009	822	0.1	8 ^a			
Burke	2010	118	0.8	51 ^a		89	
Sachwani	2013	101	4	40 ^a			
Weighted Avg		5213	2.4	30	96	89	92

^aRepresents sum of all complications, no overall morbidity was given, not included in weight averages

Aortoiliac Angioplasty and Stenting

Endovascular therapy for aortoiliac arterial occlusive disease (AIOD) is an appealing alternative to ABF. It can be performed percutaneously or with open femoral arterial exposure, without general anesthesia, and can be combined with adjunctive procedures without taking on significantly more risk.

Although endovascular therapy is often provided to those with prohibitive cardiopulmonary risk for open surgery, mortality is still less than 1%, based on a weighted average extracted from a recent systematic review of 1711 patients [12]. However, it is important to note that these are high-risk patients undergoing a low-to-medium risk procedure, and mortality in high volume single institution retrospective studies can sometimes be as high as 4%. Therefore, caution is advised even for endovascular therapy.

In contrast to ABF, morbidity resulting from endovascular treatment of AIOD consists predominantly of local or arterial complications. Hematoma, pseudoaneurysm, retro-peritoneal hemorrhage, arterial dissection, arterial perforation, and distal emboli have been described [13]. Systemic complications are less common, but MI, renal injury, pulmonary edema, stroke, and others, as a whole, occur at a range of about 3–4% [14]. Combined, the morbidity rate is about 13% when a weighted average is calculated from Jongkind's systemic review. A smaller meta-analysis of 323 TASC C/D cases reported a morbidity rate of 15%, of which three quarters were local complications [14] (Table 12.3).

Comparison of Endovascular vs Open Bypass

The results of endovascular therapy are difficult to directly compare with the results of aortobifemoral bypass. Most studies are retrospective single institution studies, and often, endovascular therapy is favored in patients with advanced cardiopulmonary disease that preclude an open operation, and aortobifemoral artery bypass is often limited to patients with more extensive arterial occlusive disease [15]. With this caveat in mind, ABF has a mortality rate of 3–4%, compared to about 1% for endovascular therapy. Morbidity is generally higher with ABF, with far more systemic complications, whereas endovascular treatment usually has local complications that are more easily managed, or arterial complications that can often be managed with endovascular techniques.

Compared with the gold standard of aortobifemoral bypass, endovascular treatment of aortoiliac lesions has inferior primary patency, but acceptable primary assisted and secondary patency. According to several meta-analyses, aortobifemoral bypass primary patency rates are 80–86% at 5 years, and 72–79% at 10 years, whereas primary patency rates with endovascular therapy are 60–86% at 5 years. Primary assisted and secondary patency however are comparable between the two interventions, with similar 5 year secondary patency for each procedure type ranging from 80 to 98%. Limb salvage rates closely track those of secondary patency.

Table 12.3 Endovascular outcomes

Author	Year	N	Mortality	Morbidity	Primary patency 1 year	Primary patency 5 years	Secondary patency 5 years
Schurmann	2002	110		8.2		66	79
Galaria	2005	394	1.8	7		53	79
Kudo	2005	151	0	0.7	76	49	99
Balzer	2006	89	0	14.6	95		
Leville	2006	89	3.4	12.3			
AbuRahma	2007	151	0	8.6	75		
Kashyap	2008	83	4	15 ^a	90		
Chang	2008	171	2.3	22		60	98
Sixt	2008	438	0	0.9	86		
Koizumi	2009	466	0	3		82	
Burke	2010	174	1.1	22 ^a		85	
Ozkan	2010	127	1	24		63	93
Pulli	2011	223	0	0		80	93
Ichihashi	2011	413	0	4.8	90	83	98
Chen	2011	121	1	8.9	86		
Ye	2011	787	2.9	15.3	89	64	83 ^b
Danczyk	2012	788	0.1	7.8			
Sachwani	2013	103	0	19 ^a			
Humphries	2014	254	0	1.6	90		
Weight Avg		5132	0.8	7.1	87	71	91

^aRepresents sum of all complications, no overall morbidity was given, not included in weight averages

^bOnly 91 pts included in this analysis

Given the disparity between primary and primary-assisted and secondary patency, the question arises: “How many patients treated with endovascular therapy require additional procedures to maintain patency?” Fortunately, it appears that the majority have durable results, and only about 15% require re-intervention at 5.7 years. Re-interventions after endovascular treatment tend to be endovascular, and therefore the minimally invasive advantages are maintained [16]. Though open surgery has higher primary patency rates, open operations are also susceptible to anastomotic stenosis, graft occlusion, and pseudoaneurysm, with a re-intervention rate as high as 18% in a high-volume series [2].

The few studies available unanimously conclude that quality of life is increased after either aortobifemoral bypass or endovascular treatment, though none compared outcomes by type of intervention. Functional outcome with open bypass was improved at 2 year follow up as measured by the SF-36 score in one study, and 80% sustained a “satisfactory” outcome at 4.5 years [17, 18]. The Dutch Iliac Stent Trial is one of the few studies reporting quality of life after endovascular intervention, and reported sustained Rand-36 score improvement among physical and functional parameters at 5 years [19].

Endovascular Considerations

Endovascular treatments continue to evolve. As such, there is still substantial uncertainty regarding evidence based endovascular management of aortoiliac lesions. A few of these matters are discussed.

TASC Classification

Although endovascular therapy has traditionally been limited to TASC A and B lesions, many institutions have reported favorable results after treating more extensive C and D lesions in the aortoiliac segment. Studies that compared their results by TASC level have found no statistically significant difference with regards to primary or secondary patency at up to 10 years [20–22]. In one study, there was also no difference in the rate of secondary interventions those who had isolated common or external iliac disease compared with those with diffuse iliac disease [13].

Several authors provide indirect explanations for the comparable success even in advanced lesions. Pulli noted that occlusive lesions were treated with more than double the length of stents than stenotic lesions, while Piazza and Ichihashi used more stents for TASC C/D lesions compared to A/B lesions [21, 23, 24]. Danczyk evaluated patients who had CIA-or-EIA versus CIA-and-EIA stents (one versus two segment disease), and noted no difference in need for secondary interventions at 7 years (16.8 % vs 14.2 %). Furthermore, Danczyk noted that of the 95 patients requiring additional endovascular interventions, only 49 were due to in-stent stenosis, which suggests that primary patency is significantly affected by progression of atherosclerosis in untreated arterial segments [13]. In summary, advanced aortoiliac lesions, whether classified as occlusive or TASC C/D, do not necessarily fare worse than more limited stenotic or TASC A/B lesions.

Technical Success

In treating aortoiliac occlusion, one consideration is the ability to cross the lesion. Ye's meta-analysis of mostly older studies reports technical success of 93.7 % and 90.1 % for TASC C and D lesions, respectively, with no significant difference. Contemporary technical success rates may be even higher with newer re-entry devices available. Indeed, many authors report 99–100 % technical success with iliac occlusions [14, 15, 23, 24].

One notable complication more frequently seen in C/D lesions is iliac perforation. This complication is presumably due to over-dilation of an area with significant atherosclerotic plaque. The majority of these iliac ruptures were successfully treated endovascularly with either temporary balloon occlusion or an insertion of a covered stent.

Primary Versus Selective Stenting

Generally speaking, TASC A/B lesions can be treated with selective stenting, whereas C/D lesions seem to benefit from primary stenting [25]. The Dutch Iliac Stent trial (randomized, controlled trial) compared selective and primary stenting and demonstrated no significant differences in primary patency, ABI, or rate of re-interventions at up to 8 years, though this patient cohort presented predominantly with claudication, and fewer than 10% had iliac occlusion [19]. In contrast, a meta-analysis demonstrated that for TASC C and D lesions, there was a statistically significant higher primary patency rate with primary stenting compared to selective stenting at years 2 and 3, with no significant difference at 1 and 5 years [14]. A single center retrospective trial with 10 year follow up demonstrated higher patency rates with primary stenting in TASC C and D lesions, but no difference for primary versus selective stenting in TASC A and B lesions [26].

Covered Versus Bare Metal Stents

The COBEST trial evaluated common and external iliac arteries treated with balloon expandable covered or bare metal stents, and found higher primary patency with covered stents [27]. However additional studies report conflicting results, some showing improved patency with covered stents, and some with bare metal stents [28, 29]. The Dutch Iliac Stent Trial (DISCOVER) is currently enrolling patients in a multicenter, double-blind, randomized, controlled trial to further clarify the role of covered versus bare metal stents in the common iliac artery for advanced disease [30].

Special Considerations

Vascular specialists have generally advocated conservative management for claudication in infrainguinal disease. The Comparing Exercise Therapy with Angioplasty for Claudication (CETAC) trial included patients with claudication and either aortoiliac or femoral-popliteal disease. In this intent-to-treat analysis, half of the supervised exercise group crossed over during the 7 years of follow up. However, the authors note two main findings to support a conservative approach to claudication. First, half of the exercise group were able to avoid procedures altogether, and had significantly improved treadmill performance and quality of life compared to baseline after 7 years. Second, among those who eventually crossed over, these patients still had half the number of procedures overall than the angioplasty first group, since 27% of the angioplasty group required secondary procedures [31].

The iliac arteries are larger with higher volume flow than the infrainguinal arteries, and endovascular procedures in the iliac arteries have favorable durability compared to femoral-popliteal interventions. For this reason, an endovascular-first approach for claudication due to aortoiliac disease is appealing. CLEVER, a multicenter, randomized, controlled trial for patients with claudication and aortoiliac disease, demonstrated greater improvement in the Peak Walking Time with supervised exercise compared to endovascular therapy at 6 months, with no difference in the Claudication Onset Time. Despite improved treadmill performance, disease-specific questionnaires (Walking Impairment Questionnaire and Peripheral Artery Questionnaire) suggest statistically better quality of life with endovascular therapy. Long term results from this trial are still in process [32].

Aside from the risk factors of cardiopulmonary disease and other comorbid conditions, other patient-specific considerations are relevant in choosing treatment. Younger patients (less than 50 years) in particular have been shown to have less durable results after either aortobifemoral bypass or endovascular therapy. Reed reported ABF results at 5 years, and primary and secondary patency rates were only 66 and 79% for those younger than 50, compared to 96 and 98% for the 60+ age group [4]. Schurmann reported that, in a group with a mean age of 57, primary and secondary patency rates of iliac stenting were 66 and 79% at 5 years, and 46 and 55% at 10 years [33]. In young patients, though they often have favorable cardiopulmonary status, an endovascular-first approach may be preferred due to poor durability of either intervention.

Older patients tend to have more durable results than younger patients with open bypass but with higher morbidity and mortality [2, 4, 8]. In addition, the advantage of the better durability of aortobifemoral artery bypass must be balanced against the upfront risks of mortality and systemic morbidity in elderly patients with limited life expectancy (Table 12.4).

Patients with previous laparotomy, and even previous aortobifemoral bypass, are not automatically excluded from subsequent open surgery. Scali and others recently reported outcomes of 19 redo-aortobifemoral bypass grafts and compared them to a case-control cohort of carefully selected patients with similar operative indications and co-morbidities undergoing primary ABF. Most of the redo-ABF patients underwent a trans-peritoneal ABF as their first procedure, and were subsequently treated with a retroperitoneal approach during their redo operation. Though there was greater blood loss and longer procedure times, there was no difference in major complication rates, length of hospital stay, or long term survival. There were no in-hospital or 30-day deaths [34].

Table 12.4 Mortality and durability by age

Author	Age	Mortality	1 year patency	5 year patency
Reed	<50	0		66
	50–60	1.0		87
	>60	2.1		97

Recommendations

Patients with aortoiliac disease presenting with claudication should primarily be managed medically, with risk factor modification and an exercise program. Such conservative management has been shown to have similar improvements in functional outcome without the peri-operative morbidity of intervention. However, failure of conservative management, with lifestyle limiting symptoms, is an appropriate indication for endovascular intervention.

Whereas TASC II recommended endovascular therapy in A and B lesions, data consistently demonstrate that good results can be obtained with TASC C and D lesions, with similar technical success and patency rates, particularly when these advanced lesions are managed with primary stenting. The data on covered versus bare metal stents are still evolving and a current randomized, controlled trial will help guide management in the future.

Endovascular therapy, even for advanced lesions, has similar primary-assisted and secondary patency, as well as limb salvage, compared to aortobifemoral bypass. Moreover, the majority of patients undergoing endovascular therapy do not require re-intervention. Although aortobifemoral artery bypass is typically avoided in patients with severe cardiopulmonary disease, endovascular intervention can typically be offered to these patients with low risk of mortality. In younger patients, the durability of open bypass is poor, and a less invasive treatment may be warranted, accepting the need for re-interventions. In older patients, while durability is good, there is higher peri-operative morbidity and mortality. Taken together, endovascular therapy should be considered as a first-line option for most patients with advanced aortoiliac occlusive disease.

Personal View of the Data

Management of claudication should primarily be conservative, with appropriate risk factor modification and an exercise program. Though endovascular interventions are safe, they are not without risk. Endovascular therapy for claudication should be reserved for those who fail conservative management with symptoms that are lifestyle-limiting.

In critical limb ischemia due to aortoiliac occlusive disease, we favor an endovascular-first approach.

The aortoiliac segment is large with high volume flow, making it an ideal anatomic region for endovascular intervention. Recent studies have provided consistent evidence that endovascular therapy is a reasonable first-line therapy not only for TASC A/B disease, but also more extensive C/D lesions. Though primary patency is lower with endovascular therapy, with adequate surveillance and re-intervention when indicated, secondary patency and limb salvage are nearly as good as aortobifemoral bypass. As with open bypass, ensuring adequacy of outflow with adjunctive procedures such as femoral endarterectomy and profundaplasty will likely yield better outcomes.

Recommendations

- Patients presenting with claudication due to aortoiliac arterial occlusive disease can achieve similar functional outcome with an exercise program compared to endovascular therapy, with fewer interventions over a similar period. Endovascular intervention can be offered for failure of conservative management (**evidence quality high; strong recommendation**).
- An endovascular-first approach is appropriate for aortoiliac intervention, regardless of TASC classification or the presence of occlusion. Endovascular therapy is particularly indicated in patients with prohibitive cardiopulmonary risk factors, short life expectancy, or previous laparotomy (**evidence quality medium; moderate recommendation**).
- Primary stenting should be considered for TASC C and D lesions (**evidence quality medium; moderate recommendation**).
- There are inadequate data to recommend a covered stent over a bare metal stent.
- Aortobifemoral bypass can be considered for patients with adequate cardiopulmonary reserve and anatomically extensive disease, and for those who fail endovascular therapy (**evidence quality low; weak recommendation**).

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