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Outcomes From the Multicenter Italian Registry on Primary Endovascular Treatment of Aortoiliac Occlusive Disease

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Abstract

Purpose: To report the results of endovascular treatment of iliac and complex aortoiliac occlusive disease (AIOD) in a multicenter Italian registry. **Materials and Methods:** A retrospective, multicenter, observational cohort study analyzed 713 patients (mean age 68±10 years; 539 men) with isolated iliac and complex aortoiliac lesions treated with primary stenting between January 2015 and December 2017. Indications for treatment were claudication in 406 (57%) patients and critical limb ischemia in 307 (43%). According to the TransAtlantic Inter-Society Consensus II (TASC) classification, the lesions were categorized as type A (104, 15%), type B (171, 24%), type C (170, 24%), and type D (268, 37%). Early (<30 days) endpoints included mortality, thrombosis, and major complications. Late major outcomes were primary and secondary patency and freedom from reintervention as estimated by Kaplan-Meier analysis; estimates are given with the 95% confidence intervals (CIs). Associations between baseline variables and primary patency were sought with multivariate analysis; the results are presented as the hazard ratio (HR) and 95% CI. **Results:** Technical success was achieved in 708 (99%) lesions; in-hospital mortality was 0.6% (n=4). The median follow-up was 11 months (range 0–42). The estimated primary patency rate was 96% (95% CI 94% to 97%) at 1 year and 94% (95% CI 91% to 96%) at 2 years. The estimated secondary patency was 99% (95% CI 97% to 99%) at 1 year and 98% (95% CI 95% to 99%) at 2 years. The estimated freedom from reintervention was 98% (95% CI 96% to 99%) at 1 year and 97% (95% CI 94% to 98.5%) at 2 years. Cox regression analysis demonstrated that the application of a covered stent was associated with an increased need for reintervention (HR 1.4, 95% CI 1.10 to 1.74, p=0.005). Chronic obstructive pulmonary disease was associated with decreased primary patency (HR 3.7, 95% CI 1.25 to 10.8, p=0.018). **Conclusion:** Endovascular intervention with primary stent placement for aortoiliac occlusive disease achieved satisfactory 2-year patency regardless of the complexity of the lesion. Almost all TASC lesions should be considered for primary endovascular intervention if suitable.

Keywords

aortoiliac occlusive disease, covered stent, iliac artery, kissing stent, occlusion, primary patency, reintervention, stenosis, stent, TASC C and D lesions

Introduction

Over the past decades, endovascular interventions have become first-line therapies for iliac occlusive lesions,[1] with aortobifemoral bypass graft repair recommended for more complex aortoiliac occlusive disease (AIOD).[1,2] Nevertheless, in recent years, there is no question that improvements in technology and experience have resulted in endovascular interventions, including primary stent placement, replacing open surgery in a variety of clinical situations, with documented safety, efficacy, and durability.[3,4]

Optimal management of AIOD is controversial, with limited data from single-center experiences and very few

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large multicenter databases or registries.[5–7] Furthermore, durability of aortoiliac stenting has not been clarified, as well as the influence of either the type of stent or the extent of calcification.[8,9] The aim of this study was to analyze the outcomes from a modern cohort of patients undergoing stenting for AIOD in a multicenter Italian registry.

Materials and Methods

Study Design

This was a physician-initiated, multicenter, retrospective study of patients treated with stenting for AIOD including isolated iliac lesions between January 2015 and December 2017 in 11 centers in Italy (collaborators listed in the Appendix). Data regarding consecutive endovascular interventions for AIOD were obtained from the prospectively maintained institutional database of each participating center. Delegates from each center selected fields for the main anatomical, clinical, diagnostic, and technical variables and merged the individual datasets into a single dedicated database. Approval for this retrospective study was obtained from each center's institutional review board according to the national policy on retrospective analysis of anonymized data and the Privacy Act.

Preoperative Evaluation and Indications for Surgery

Since this was a retrospective registry, inclusion and exclusion criteria for endovascular management were not required. Rather, each participating investigator adopted the preoperative protocols and intraoperative strategies for endovascular treatment of AIOD reported in the Italian Society for Vascular and Endovascular Surgery guidelines, which are in agreement with the most recent position statements of different societies.[10–12]

Primary stenting of iliac and aortoiliac occlusive disease was offered to individuals with a vocational- or lifestyle-limiting disability due to intermittent claudication (IC) when there had been an inadequate response to exercise or pharmacological therapy and clinical features suggested a reasonable likelihood of symptomatic improvement. Primary endovascular treatment was also considered for patients presenting with critical limb ischemia (CLI).

All patients underwent physical examination, continuous wave Doppler ultrasound with ankle-brachial index (ABI) assessment, duplex ultrasound imaging, and computed tomography angiography (CTA) of the aortoiliac segment bilaterally. As the TransAtlantic Inter-Society Consensus (TASC II) document[1] on management of peripheral arterial disease classification considers the aortoiliac segment in its entirety, for this study a patient was included only once regardless of whether both iliac arteries were individually treated.

Operative Details and Follow-up Protocol

Specific details of treatment approaches utilized have been described in various single-center experiences.[4,13–15] All interventions were performed by vascular surgeons, usually in an angiography suite with the patient under local anesthesia supplemented with intravenous sedation or analgesia when required. More complex or hybrid interventions were performed in the operating room under locoregional or general anesthesia. Specifically, complex lesions involving the femoral bifurcation were usually treated with a hybrid approach. In these cases, femoral endarterectomy was performed with a retrograde working sheath placed once inflow had been restored; the arteriotomy was closed primarily or with patch angioplasty. An intraluminal technique was initially attempted whenever possible. When the aortic bifurcation was involved, a kissing stent technique was employed. Additional infrainguinal procedures were left to the surgeon's discretion. Balloon-expandable bare stents were preferentially used for focal and ostial lesions, while balloon-expandable covered stents were preferred in severely calcified focal lesions. Covered stents were the choice for longer lesions and in more tortuous or calcified arteries.

Postoperative antithrombotic treatment was not standardized but left to the surgeon's preference. The choice was individually based on the patient's comorbidities and risk factors, according to particular technical aspects of the intervention. In general, preexisting oral anticoagulants were continued postoperatively, especially in the presence of atrial fibrillation and coagulation disorders.

Follow-up and surveillance included clinical visits with ABI and duplex ultrasound examination at 1, 6, and 12 months and then yearly. During ultrasound examinations, the patency of the treated vessels and the status of the inflow and outflow arteries were assessed. CTA was performed as needed to confirm ultrasound findings in case of symptom recurrence.

Definitions and Outcomes

Comorbidities and risk factors have been previously described.[13] The TASC II classification[1] was used to characterize the patterns of disease in the lesions, and the Rutherford category was employed to grade the clinical status of the patient.[16] A total occlusion was defined as absence of flow into and throughout the treated vessel. Calcium score was defined as "class 0" when calcifications were absent, "class 1" when mild, "class 2" when severe but limited in extent, and "class 3" when severe and extensive.[9]

Coronary artery disease was defined according to the Society of Thoracic Surgeons National Cardiac Surgery Database.[17] Chronic kidney disease referred to stage 3 or greater according to the National Kidney Foundation Kidney Disease Outcomes Quality Initiative.[18] Chronic

obstructive pulmonary disease (COPD) diagnosis was based on the Global Initiative for Chronic Obstructive Lung Disease guidelines.[19] Acute lung injury was defined according to Ragaller et al.[20] Acute renal failure was based on the RIFLE criteria.[21] Wound infection was defined according to Samson et al.[22]

Primary technical success was defined on an intent-to-treat basis as <30% residual stenosis remaining on completion angiography or by a reduction in the pressure gradient across the lesion to <10 mm Hg.[9] Procedural success was defined as successful treatment of the target vessels (technical success) in the absence of vessel rupture, distal embolization, thrombosis, access complications, and major adverse cardiovascular events.[9] These events were recorded at both ≤24 hours and ≤1 month after the procedure.

Complications were reported as <30 days or late and classified as device-related or procedure-related.[9] Complications were described as mild (when resolved spontaneously or with nominal intervention that did not prolong hospital stay or cause permanent disability), moderate [need for significant intervention, prolonged hospitalization (>24 hours), a minor amputation, or association with minor disability that did not interfere with normal daily activity], or severe (necessitating a major surgical, medical, or endovascular intervention and including prolonged convalescence, major amputation, permanent disability, or death).[9]

Primary patency was defined as uninterrupted patency without procedures performed on or at the margin of the treated segment. Significant restenosis was defined by a focal increase in peak systolic velocity (PSV) >300 cm/s, a PSV ratio >3.0, and uniform PSV <50 cm/s throughout the stent.[4] Loss of primary patency was diagnosed when ABI deterioration was associated with duplex ultrasound evidence of significant restenosis requiring treatment or thrombosis of the treated segment. Early (intraoperative and <30 days) outcome measures were mortality, thrombosis, and major complications. Late major outcomes were primary and secondary patency and freedom from reintervention.[9] Follow-up results were estimated at 1 year and 2 years in terms of survival, primary and secondary patency (defined as restored patency through the original treated segment), and freedom from reinterventions. The follow-up index for late survival in the study group was assessed.[23]

Patient Population

The merged database contained 713 patients (mean age 68±10 years, range 22–96; 539 men) who underwent endovascular interventions for AIOD. Recruitment at each center is detailed in Figure 1. Patient and lesion characteristics are reported in Table 1. Slightly more than half of the patients (406, 56.9%) had IC; of the 307 (43.1%) with CLI, 115 (16.1%) had tissue loss and/or gangrene. At the time of

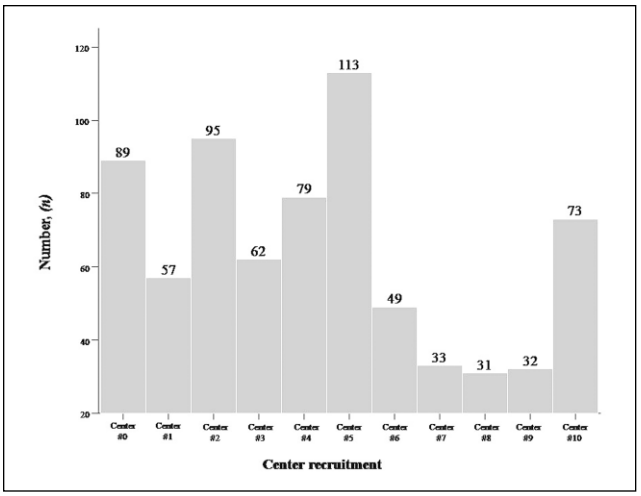


Figure 1. Recruitment distribution among the 11 centers involved in this registry.

treatment, the majority of patients (699, 98.0%) were on appropriate atherosclerotic pharmacotherapy (antihypertensive agent, aspirin/antiplatelet agent, and statins). For most patients (611, 85.7%), this was the first intervention; 64 (9.0%) patients had undergone 1 prior intervention on the same arterial segment and 9 (1.3%) had already received ≥2 interventions. When stratified by TASC II classification, more than half of the lesions (438, 61.4%) were types C and D; 385 (54.0%) were stenoses and 328 (46.0%) were total occlusions.

Statistical Analysis[24]

The merged data were tabulated in Excel (Microsoft Corp, Redmond, WA, USA) and analyzed retrospectively. Categorical variables are presented as frequencies and percentages and continuous variables as mean ± standard deviation (range) or median and interquartile range (IQR; Q1, Q3) on the basis of data distribution. Noncontinuous variables were analyzed with the chi-square or Fisher exact test (for samples <5). An independent samples Student *t* test was used for continuous variables, while the Wilcoxon signed-rank test was used to evaluate the difference in ABI measurements before and after intervention. Follow-up data were analyzed using the Kaplan-Meier method; groups were compared using the log-rank test, and the estimates are presented with the 95% confidence interval (CI).

A univariate analysis to identify potential clinical, anatomical, and technical predictors of primary patency was performed; variables that yielded $p<0.20$ were then entered into a forward stepwise Cox proportional hazards model ($p>0.05$ to remove). The strength of variable association with postoperative outcome was estimated by calculating the hazard ratio (HR) and 95% CIs. All p values were 2-sided, and $p<0.05$ was considered significant. Statistical

Table 1. Characteristics of the 713 Patients in the Study.[a]

Age, y	68±10
Men	539 (75.6)
Hypertension	586 (82.2)
Smoking (yes / former)	340 (47.7) / 197 (27.6)
Dyslipidemia	530 (74.3)
COPD[19]	275 (48.6)
Coronary artery disease[17]	241 (33.8)
Diabetes	229 (32.1)
Chronic kidney disease[18]	104 (14.6)
Rutherford category[16]	
1–3	406 (56.9)
4–6	307 (43.1)
TASC lesion type[1]	
A	104 (14.6)
B	171 (24.0)
C	170 (23.8)
D	268 (37.6)
Lesion location	
External iliac	197 (27.6)
Common iliac	221 (31.0)
Entire iliac axis	232 (32.5)
Aortoiliac	25 (3.5)
Isolated aorta	35 (4.9)
Stenoses	385 (54.0)
Total occlusions	328 (46.0)
Internal iliac artery occluded	219 (30.7)
Runoff vessel	
SFA + PFA	464 (65.1)
PFA	120 (16.8)
PFA + >50% stenotic CFA	99 (13.9)
Distal bypass	30 (4.2)
Calcium score[9]	
None	83 (11.6)
Mild	227 (31.8)
Severe, limited	237 (33.2)
Severe, extensive	165 (23.1)

Abbreviations: CFA, common femoral artery; COPD, chronic obstructive pulmonary disease; PFA, profunda femoris artery; SFA, superficial femoral artery; TASC, TransAtlantic Inter-Society Consensus.
[a]Continuous data are presented as the mean ± standard deviation; categorical data are given as the number (percentage).

analysis was performed using SPSS for Windows (version 24.0; IBM Corporation, Armonk, NY, USA).

Results

Early Outcomes

Revascularization was performed using percutaneous access in 485 (68%) cases, while 228 (32.0%) patients underwent a hybrid intervention using femoral endarterectomy prior to aortoiliac stenting. Table 2 describes the types of stents deployed in each class of TASC II lesion.

Table 2. Type of Stent Used in Each TASC II Lesion.

TASC II Class	Stent Type	Patients[a]
A	BM SE	43 (6.0)
	BM BE	48 (6.7)
	CS SE	10 (1.5)
	CS BE	3 (0.5)
B	BM SE	81 (11.3)
	BM BE	22 (3.1)
	CS SE	50 (7.0)
	CS BE	15 (2.1)
C	BM SE	72 (10.1)
	BM BE	18 (2.5)
	CS SE	42 (5.9)
	CS BE	38 (5.3)
D	BM SE	63 (8.8)
	BM BE	47 (6.5)
	CS SE	119 (16.7)
	CS BE	42 (5.9)

Abbreviations: BM BE, bare metal balloon-expandable; BM SE, bare metal self-expanding; CS BE, covered stent balloon-expandable; CS SE, covered stent self-expanding; TASC, TransAtlantic Inter-Society Consensus.
[a]Data are presented as the number (percentage).

According to clinical status, complex AOID was more frequent in patients suffering from CLI than IC (74% vs 26%, p=0.001). The number of complex AIOD lesions as well as the use of covered stents increased progressively over time (Figure 2).

Technical success was achieved in 708 (99.3%) patients; in 5 (0.7%) cases (all TASC D lesions) it was not possible to cross the lesion and the procedure was aborted. These patients (4 with CLI) underwent nonoperative management and observation. In technically successful cases, the median radiation dose was 184 mGy (IQR 69, 948; range 7–3102), and the mean contrast volume was 87±70 mL (range 15–450).

Procedural success was achieved in 701 (98.3%) patients. Ten early events (≤24 hours) occurred in 7 patients (7 embolic episodes, 2 femoral dissections, and 1 iliac artery rupture). Acute complications occurred in 40 (5.6%) patients. Of these, 27 (3.9%) were device-related, requiring surgical repair in 14 cases (Table 3). In-hospital mortality occurred in 4 (0.6%) patients. Mean ABI improved significantly after AIOD treatment (preoperative 0.4±0.2 vs 0.8±0.2, p=0.001). Median hospital length of stay was 4 days (IQR 2, 7; range 1–55).

The postoperative antithrombotic treatment is reported in Figure 3. At 30 days, thrombosis at the site of intervention occurred in 14 (2.0%) patients. Thrombosis arose more frequently in patients with total occlusion compared to those treated for stenoses [12 (3.7%) vs 2 (0.6%), p=0.006; odds ratio 7.51]. Of the variables analyzed, none had a statistically significant association with thrombosis, including

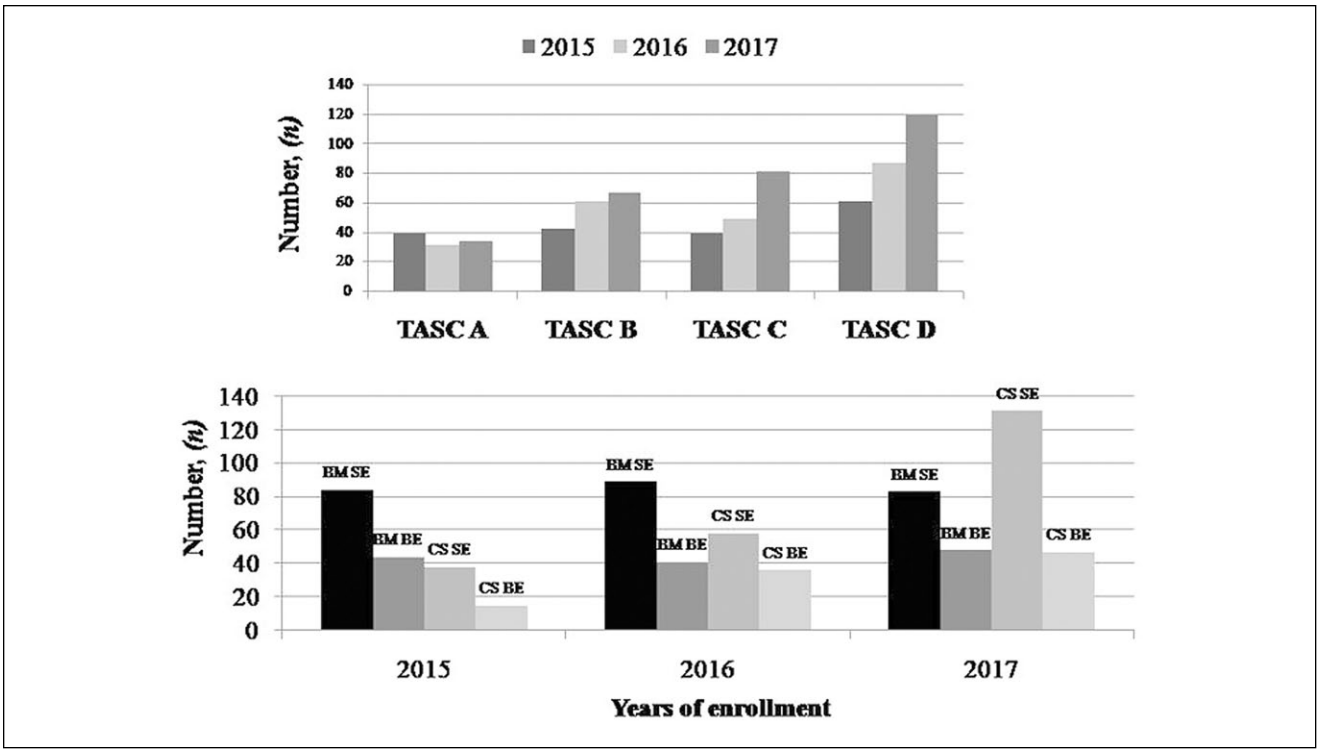


Figure 2. Distribution of aortoiliac occlusive disease according to the TransAtlantic Inter-Society Consensus (TASC) II classification and the type of stents used in the entire cohort in the different years of enrollment. BM BE, bare metal balloon-expandable; BM SE, bare metal self-expanding; CS BE, covered stent balloon-expandable; CS SE, covered stent self-expanding.

Table 3. Perioperative Complications.[9]

Nonsurgical	
Mild	
Wound dehiscence	3
Lymphatic leak	1
Non-flow-limiting dissection	1
Moderate	
Groin hematoma	7
Anemia	6
Atrial fibrillation	1
Gluteal embolization	1
Severe	
NSTEMI	2
Acute lung injury[20]	2
Acute kidney injury[21]	2
Surgical	
Mild	
Lymphatic fistula	1
Moderate	
Pseudoaneurysm	7
Flow-limiting dissection	2
Acute limb ischemia	2
Wound infection[22]	1
Severe	
Iliac rupture	1

Abbreviations: NSTEMI, non-ST segment elevation myocardial infarction.

TASC II classification (p=0.618), clinical status (IC vs CLI; p=0.720), or runoff (p=0.382). Of the 14 patients with early thromboses, 3 died in-hospital; the remaining 11 patients are alive. Four were managed medically and are without further intervention. Three patients underwent thrombolysis and redo stenting. Open repair was required in the remaining 4 (aortobifemoral bypass, iliofemoral bypass, relining with a second stent-graft, and open thrombectomy with embolectomy catheter). Two (0.3%) patients underwent major amputation.

Follow-up Results

A total of 651 (91.3%) patients were available for follow-up evaluation and surveillance, 62 (8%) patients were lost to follow-up. Median follow-up was 11 months (IQR 6, 20; range 0–42). The follow-up index was 0.54±0.32 (range 0–1). During follow-up, 30 (4.2%) patients died after a mean 10±8 months (range 2–25). Estimated overall survival was 97% (95% CI 95% to 98%) at 1 year and 92% (95% CI 88% to 95%) at 2 years. Restenosis occurred in 13 (2%) patients. Estimated primary patency (Figure 4) was 96% (95% CI 94% to 97%) at 1 year and 94% (95% CI 91% to 96%) at 2 years, while secondary patency was 99% (95% CI 97% to 99%) at 1 year and 98% (95% CI 95% to 99%) at 2 years.

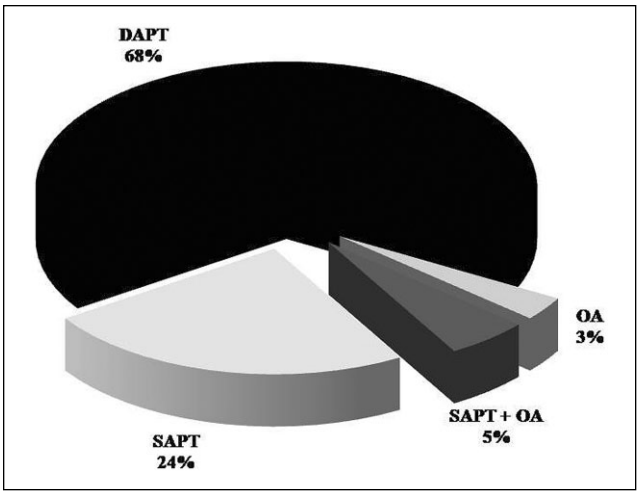


Figure 3. Postoperative antithrombotic regimen. DAPT, dual antiplatelet therapy; OA, oral anticoagulant; SAPT, single antiplatelet therapy.

Overall, 39 (5.5%) patients required a reintervention during follow-up. The estimated freedom from reintervention was 98% (95% CI 96% to 99%) at 1 year and 97% (95% CI 94% to 98.5%) at 2 years. Conversion to open surgical repair was required in 2 (0.3%) patients, both of whom received aortobifemoral bypass graft for recurrent thrombosis. Major amputation was needed in 14 (2%) patients. In the majority of patients, amputation was due to a progression of distal occlusive disease in 5 cases or because of unrelenting foot infections in 3.

Univariate analysis assessing the associations of baseline variables with primary patency and freedom from reintervention is reported in Table 4. Multivariate analysis determined that only COPD disease was associated with a decrease in primary patency during follow-up (HR 3.7, 95% CI 1.25 to 10.8, p=0.018); in contrast, the presence of an occlusion was not associated with worse results compared with a stenosis (HR 0.21, 95% CI 0.80 to 5.75, p=0.002). In addition, the use of a covered stent was associated with an increased need of reintervention during follow-up (HR 1.4, 95% CI 1.10 to 1.74, p=0.005).

Discussion

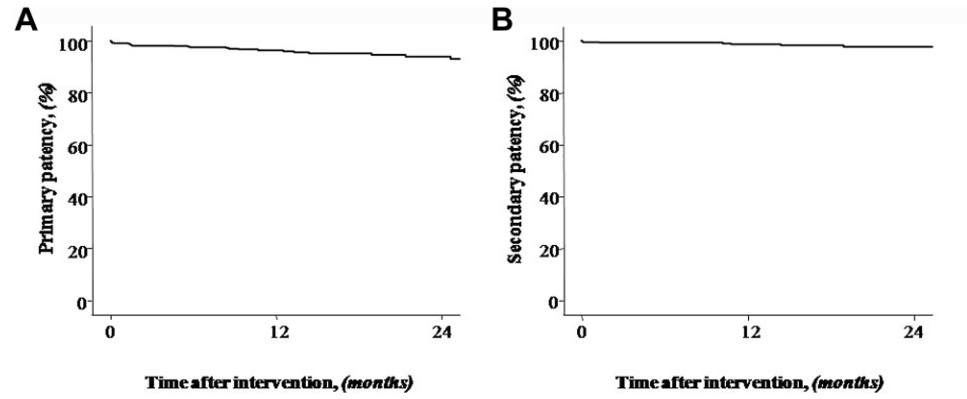
Most of the recent literature has focused on evaluation of results from the treatment of complex lesions of the aortoiliac segment.[3–6,14,25–29] Few large series have reported the results of iliac stenting for all TASC II lesions.[30–32] The present study adds to the body of knowledge and represents a recent "real-world" update of endovascular treatment options and their results in a large cohort of patients with AIOD. While a prospective randomized clinical trial represents the benchmark research methodology, registry data are a valid alternative means to obtain data on safety, efficacy, and durability of a specific treatment method.[33] Moreover, the registry presented herein involved several referral centers, all of whom adhered to national guidelines for patient care.

In our experience, stenting in the aortoiliac segment has a high feasibility rate (99% technical success) and is safe and effective. The mortality was acceptably low at 0.6%, the complication rate was ~50% lower than previously reported, and the number of immediate failures (1.8%) was satisfactorily low despite the presence of anatomically complex lesions.[7,10,27,28] In addition, the estimated 94% primary patency rate at 2 years is commendable, given the complexity of the treated lesions, and compares favorably with the pooled estimate of 80% at 3 years reported in a systematic review and meta-analysis of 1625 patients.[7]

The increasing experience of vascular specialists in treating complex vascular lesions with catheter-based interventions and the availability of new stent technology has led to substantial changes in practice patterns for AIOD over the past 2 to 3 decades.[1,12] Although the enrollment period in this present series was relatively short, there was a progressive increase in the number of TASC II type D lesions treated in the registry. It is undeniably true that current follow-up is short, and a propensity score analysis was not performed to draw additional conclusions; however, regression analysis demonstrated that the extent of disease did not significantly impair either patency or need for reintervention. Thus, in our experience, endovascular revascularization of AOID yields excellent results regardless of the complexity of the lesion. These data are consistent with both single-center experiences and recent guidelines from 2 prominent societies that considered an endovascular-first strategy appropriate for complex AIOD performed by an experienced team without compromising subsequent surgical options.[3,4,10,12,14]

In the aortoiliac segment, the type of obstructive disease may be a potential predictor of worse outcomes, but this has not been uniformly studied, with reported primary patency rates ranging from 54% to 92% at 5 years for stenoses and 48% to 85% at 3 years for occlusions.[13] It may be instinctive to consider total occlusions to be more challenging lesions compared to stenoses, but our results do not demonstrate this effect. In our study, there was no difference in technical success based on lesion severity; rather, it appears that the presence of an occlusion might be protective in terms of primary patency. These results are similar to the experience of Pulli et al,[13] who reported excellent early and long-term results for occlusive lesions comparable to those obtained in the treatment of stenotic lesions.

The rationale for this observation is challenging. First, the presence of an occlusion should not mean the lesion is a chronic total occlusion, which might be the most technically difficult scenario. In contrast, a stenotic lesion may



Period	T0	T12	T24
@ risk	624	289	113
Patency	99	97	94
95%CI	99-100	94-97	91-97

Period	T0	T12	T24
@ risk	624	287	111
Patency	99	99	98
95%CI	99-100	91-99	95-99

Figure 4. Kaplan-Meier curves estimating (A) primary and (B) secondary patency. CI, confidence interval.

Table 4. Univariate Analyses for Primary Patency and Freedom From Reintervention.

	Primary Patency		Freedom From Reintervention	
Variable	Log-rank	p	Log-rank	p
Gender	0.002	0.968	2.21	0.137
Smoking habit	1.69	0.436	4.53	0.104
COPD	5.47	0.019	0.16	0.686
Hypertension	2.93	0.087	0.81	0.368
Dyslipidemia	0.12	0.729	0.01	0.905
Diabetes	1.78	0.182	0.14	0.709
Coronary artery disease	0.99	0.318	0.23	0.634
Chronic kidney disease	49	<0.001	2.91	0.088
Critical limb ischemia	2.78	0.096	1.47	0.225
TASC class D	6.19	0.013	3.16	0.076
Stenosis vs occlusion	10.2	0.001	1.74	0.187
Calcium score	6.65	0.084	0.07	0.790
Hypogastric flow	3.33	0.068	0.99	0.320
Runoff type	3.01	0.390	0.97	0.808
Previous treatment	28.69	<0.001	3.89	0.048
Hybrid intervention	2.64	0.450	1.45	0.694
Type of device	11.4	0.022	10.3	0.036
Kissing stent	0.08	0.775	0.01	0.907
Postoperative therapy	13.6	0.003	7.12	0.068

Abbreviations: COPD, chronic obstructive pulmonary disease; TASC, TransAtlantic Inter-Society Consensus.

have other characteristics that increase the level of technical challenge, such as the presence of calcification, although in our analysis the presence of a severely calcified atherosclerotic lesion was not a predictor for worse outcomes. However, the presence and extent of calcification may have played a significant role in the setting of stenosis. Indeed, calcification extent is a relatively unstudied variable in the aortoiliac segment because experience with this factor has been extrapolated from coronary artery procedures. Second, extensive use (36%) of hybrid interventions, including surgical endarterectomy, by participating surgeons may have contributed to improved outcomes in occlusions.

Clinical status at presentation is an important predictor of outcomes for aortoiliac revascularization.[1,4] The presence of CLI often mandates revascularization of some type due to limb-threatening ischemia. CLI is almost never related to isolated AIOD but rather represents diffuse multisegment disease with concomitant downstream lesions.[10,12] In this cohort, CLI at admission did not predict worse patency and need for reintervention compared to IC. Amputations performed during follow-up were secondary to progression of the underlying atherosclerosis and distal popliteal-tibial disease even in the presence of a patent aortoiliac segment. This observation supports a strategy of more aggressive treatment including all lesions in a "one-shot" option for limb salvage in patients with multilevel disease. A similar observation has been made by Kashyap et al,[3] who showed that patients who required concomitant distal revascularization along with aortoiliac treatment had dismal outcomes, reflecting the more severe atherosclerotic burden in patients with CLI.

Generally, primary patency is the most frequently used outcome parameter for evaluating stenting effectiveness for extensive aortoiliac disease in comparison with open surgical repair.[4,6,7] In this analysis, neither anatomical nor technical factors were associated with worse outcomes. Rather, COPD was the only independent predictor associated with the loss of primary patency, which is a unique finding that has not been previously reported. However, COPD should be considered as a surrogate marker of severe systemic disease as it incorporates other factors such as long term or active smoking habit or the chronic use of steroids, both of which may decrease stent patency. There is some support in the literature for this observation. In one of the most extensive multicenter experiences Sixt et al[32] reported that nicotine abuse was one of the most significant factors associated with restenosis. In a review of the American College of Surgeons National Surgical Quality Improvement Program, Thomas et al[34] documented that smoking and chronic use of steroids were significant predictors of reintervention, which is frequently associated with loss of patency. Thus, we advocate the inclusion of COPD as a variable in evaluating patency.

The use of covered stents in AIOD has increased progressively based on the concept that they provide a mechanical barrier to intimal hyperplasia and also allow aggressive, safer dilation of calcified vessels.[5,8,15,35–37] Recently, good results have been reported with the use of self-expanding covered stents in challenging complex lesions.[14] Although bare metal stents and covered stents performed similarly in the cohort studied by Piazza et al,[15] when the specific TASC II D lesion subcategory was studied, self-expanding polytetrafluoroethylene (PTFE)-covered stents had significantly better patency rates during midterm follow-up. These promising results informed the practice of the physicians participating in this registry, which showed a trend of steadily increasing use of self-expanding PTFE-covered stents in recent years, though data supporting significantly better results with these devices are not yet available. In our experience, covered self-expanding stents are more frequently used in extensive and complex lesions, such as complete occlusion of the entire iliac axis or extensive aortoiliac lesions, compared with previously published results.[14,15,32,33] We acknowledge that the use in more challenging settings may impair the performance of self-expanding PTFE-covered stents.

There is a lack of data regarding medical management and postoperative therapies targeted at preventing restenosis or occlusion after endovascular procedures in patients with AIOD.[10,12] A recent systematic review did not demonstrate superiority of any type of postoperative regimen.[38] The most recent guidelines of the European Society for Vascular Surgery[12] suggest that dual antiplatelet therapy should be considered for at least 1 month following intervention irrespective of stent type, but no specific reference has been made to the aortoiliac segment. In our registry, the majority of patients were treated with dual antiplatelet therapy. All participating centers in the registry have very similar indication algorithms and postoperative medication and surveillance regimens. However, there was no significant difference in terms of patency among the different regimens. Furthermore, when only antiplatelet regimens were analyzed, no significant differences were noted. Again, this may be the result of the limited number of thromboses that occurred in the follow-up period. A longer observation period should help to define more significant data.

Limitations

The limits of the study lie in its retrospective, nonrandomized nature, thus selection bias and incomplete data collection cannot be ruled out. However, treatment criteria, even if not homogeneous among the different centers, were guideline-based, and changes in indications and treatment did not occur. Another limitation is the short follow-up time of 2 years, though the follow-up index was within an acceptable range. This may have led to a higher incidence of complications and mortality due to the number of patients lost to follow-up. This study represents one of the largest real-world series of endovascular procedures in the literature and provides an analysis that, even with all the described shortcomings, may inform current management of such complex patients as well as therapeutic algorithms.

Conclusion

This analysis reported the safety and efficacy of stenting for AIOD in a real-world setting, with few complications and excellent patency rates at 2 years' follow-up. Primary patency was predicted by the presence of COPD but not by anatomical parameters of the target lesions, despite the short

follow-up period. With the current technical expertise and wide availability of a variety of stent types, endovascular treatment for AIOD produces satisfactory results regardless of the complexity of the lesion. Although the use of self-expanding covered stents was associated with an increased risk of reintervention, their use increased over time, especially for the treatment of the most complex lesions. Thus, these data warrant additional further analysis to evaluate the existence of potential confounding factors.

Appendix

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