Primary patency and amputation free survival after endovascular management of infrarenal aorta total occlusions

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Abstract

Objective: Endovascular therapy (EVT) has increasingly been used even after the development of new techniques and technologies. EVT has displayed durable early and mid-term outcomes for infrarenal aorta occlusions (IAO). Nonetheless, little is known regarding their long-term outcomes and predictors of restenosis.

Methods: A total of 55 consecutive patients (age, 58.8±6.97 years; 67.2% male; 42% critical limb ischemia) from a single-center database, undergoing EVT for IAO disease between January 2011 and March 2019 were retrospectively analyzed. The outcome measures were primary patency rate and amputation free survival calculated by the Kaplan–Meier method. Independent predictors of restenosis were assessed by Cox proportional hazard regression model.

Results: In 49 patients (89.1%), technical success was achieved. In total, 190 stents (65 self-expandable stents, 60 balloon-expandable stents) were implanted. During the follow up of 34.5±28 months, 7 patients experienced loss of patency. Primary patency rates were 96%, 82%, and 75% at 1, 3, and 5 years, respectively, and amputation free survival rates were 100%, 90%, and 82% at 1, 3, and 5 years, respectively.

Conclusion: In this study, five-year outcomes of primary patency and amputation free survival for EVT of infrarenal aorta total occlusive lesions were favorable. None of the demographic, lesion, and device factors were independently associated with loss of primary patency.

Keywords: endovascular therapy, aortoiliac occlusive disease, infrarenal aorta occlusion, primary patency rate, amputation free survival

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Introduction

Infrarenal aorta occlusion (IAO) disease may affect to varying degrees and extent both the aortic bifurcation and the common iliac arteries (1). IAO has been assigned in 3% to 8.5% of patients existing with aortoiliac occlusive disease (AIOD) (2, 3). Traditionally, surgical treatments, such as bypass surgery and endarterectomy, have been considered the standard treatment of AIOD. According to the 2007 Trans-Atlantic Inter-Society Consensus II (TASC-II) guidelines for peripheral arterial disease (PAD) management, AIOD is categorized as type D lesions, for which endovascular therapy (EVT) reconstructive surgery is the treatment choice (4). In patients with extensive AIOD, reconstruction by surgery has been considered for the treatment, verifying perfect early and late results with 5-year primary patency rates (PPR) of 85%–90%, however sustaining a surgical mortality rate of 4%, and frequent peri-operative complication rates from 21% to 30% (5, 6). Nevertheless, the improvements in recent years of technology and experience have resulted in the growth of endovascular interventions, including primary stent placement, replacing open surgery in a variety of clinical situations with documented safety, efficacy, and durability (7-9). Although few reports have described the outcomes of EVT for IAO, the PPR at 1 year after EVT have been reported as 88% and 3 years after EVT as 80.1% and 70% (10, 11). EVT for IAO has not yet been standardized, however, there is small knowledge regarding long-term results, particularly beyond 3 years. Furthermore, loss of patency predictors have not been clearly examined. We performed a retrospective, single-center study analyzing early and long-term results of patients with TASC D IAO disease who were submitted for EVT.

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HIGHLIGHTS

- Type of Research: Retrospective cohort study
- Take Home Message: In 55 patients who underwent endovascular treatment (EVT) of infrarenal aorta total occlusions, five-year outcomes of primary patency and amputation free survival for EVT of infrarenal aorta total occlusive lesions were favorable.
- Recommendation: The authors recommend careful patient selection, use of preventive medicine, and strategies to avoid serious complications and immediate convenient diagnostics against complications to advance the outcomes of EVT of infrarenal aorta total occlusions.

Methods

The present study was a single-center, retrospective, and observational study on EVT for IAO of AIOD. The protocol was approved by the Ethics Committee of the participating medical institution.

EVT was performed in patients with occlusive arteriosclerosis associated with infrarenal abdominal aorta total occlusion between January 2011 and March 2019. Acute or chronic, primary occlusions of infrarenal abdominal aorta with or without involvement of iliac arteries were included in the study. Patients who had previous surgical and/or endovascular therapy performed with new onset re-occlusions, active malignancies with less than 12 months of expected survival and vasculitis were excluded from the study. The selection, indication of revascularization strategy and whether the endovascular approach was fit for each patient were determined and judged based on a group of vascular specialists including cardiologists, vascular surgeons, and radiologists. The characteristics of patients and lesion details, and endovascular procedure information were obtained from the database of our medical institution.

In our cohort, all lesions were TASC D aortailiac occlusions. The AIOD classification in this study was made according to the anatomical feature evaluated by diagnostic angiography before revascularization. AIOD type I was defined as IAO without involving the aortic bifurcation and iliac artery. AIOD type II was defined as the IAO with common iliac arteries not extending into the external iliac arteries. AIOD type III was defined as the IAO with both common iliac and external iliac arteries.

All EVTs were carried out under local anesthesia. At least 3 days before the operation, a combination of aspirin (100 mg/d) and clopidogrel (75 mg/d) were given to all patients. After sheath insertion, intravenous heparin bolus (5000 IU) was administered and dose adjusted continuously to achieve an activated clotting time of 200 seconds or more.

In 42 patients (76.2%), a combined antegrade and retrograde approach from the brachial and femoral arteries was used. A 7F sheathless catheter was inserted through the left brachial artery, and the tip was placed above the proximal part of the aortic occlusion. Bilaterally, additional vascular accesses were gained into the common femoral arteries. The initial attempt for occlusion crossing was almost always made with a 0.035 inch hydrophilic guidewire using the antegrade approach. If the wire passage collapsed using the antegrade approach, a retrograde approach was tried from femoral arteries. If the wire could not cross the lesion despite using the bidirectional approach, the Controlled Antegrade Retrograde Subintimal Tracking (CART) or Reverse CART Technique was occasionally conducted with the use of support catheters and 0.014 inch guidewires.

When wires were successfully passed to iliac arteries from the brachial sheath, they were grasped with a snare inserted from the common femoral arteries and the procedure was completed from there. In 11 other patients (20%), a retrograde transfemoral access alone was attempted from bilateral femoral arteries in case of distal short aortic occlusions involving both iliac arteries. All femoral and brachial access sites were maintained percutaneously using a vascular sheath. Surgical cutdown was not required in any of the patients.

After a successful wire crossing, plain angioplasty was routinely conducted and thereafter, the occlusive lesions were predilated with an undersized balloon in all patients. Selection of stent types were determined in accordance with lesion characteristics. Balloon-expandable stents were favorably used in calcified lesions and/or when reconstruction is needed, whereas uncovered aortic and/or self-expanding stents were preferred generally in large thrombotic burden lesions. When the lesion was confined only to the infrarenal aorta, aortic stent was implanted. Kissing stent method applied always when aortic bifurcation was involved.

If the occlusive lesions extensively cover the infrarenal aorta and iliac arteries, a combined method of an aortic stent and two aortoiliac kissing stents was applied. The aortic stent and kissing stents were transferred through the femoral arteries. The aortic stent was placed first and then the two kissing iliac stents were implanted in overlap with the aortic stent. Angiography was done to document the final results and to case distal embolization or vessel perforation.

With less than 30% residual stenosis, less than 10 mm Hg pressure gradient, and without any vascular complications, the EVT was judged to be successful. A representative pre-, post- and follow up computed tomography scan of EVT for chronic IAO is shown in Figure 1. Dual antiplatelet therapy was performed at least six months continued with lifelong aspirin.

Patients with distal embolization or multiple visible mobile thrombi after predilation or stent implantation were considered to have high thrombotic burden. In such patients, tissue plasminogen activator (tPA) was administered using a catheter as a bolus (5–10 mg in 5 minutes) or continuous infusion (1 mg/h for 12–24 hours) after the first balloon predilation or after the procedure, at the operator's discretion.

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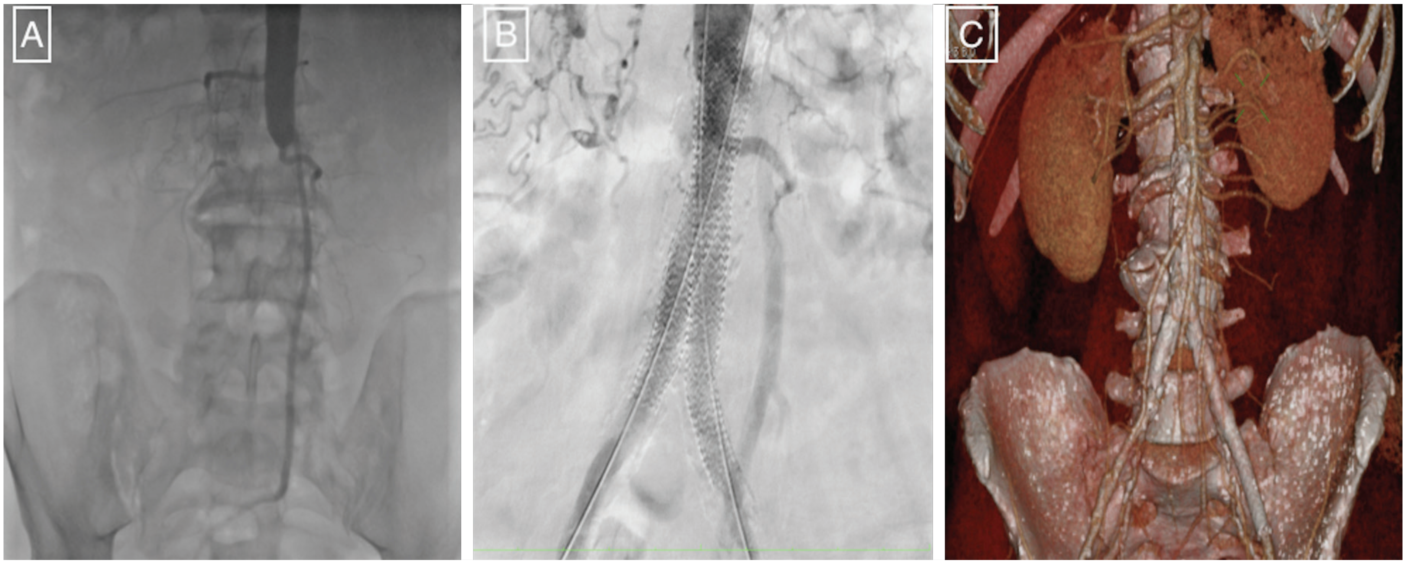

Figure 1. (a) Antegrade aortic occlusion angiography; (b) Completion angiography after aortoiliac kissing stent deployment; (c) 24th month follow up CT scan

In juxtarenal aortic occlusions (high take off), 0.014 inch guidewires were readily crossed through renal artery ostiums before EVT was performed. This was achieved so it can be used if any acute thrombosis or plaque-shifting occurs.

All patients having successful EVT were clinically monitored in the first month after hospital discharge and every 3 months thereafter. Follow up evaluation with color duplex ultrasound imaging was performed 1 month after the procedure and thereafter every year or when there is symptom deterioration. At the time when recurrence is suspected, duplex ultrasound, computed tomography or peripheral angiography was applied to evaluate the incident of restenosis.

The outcome measures in this study were the PPR, amputation free survival (AFS), and predictors for restenosis. Primary patency was defined as the condition where the EVT performed artery had no restenosis occurrence and needed no further treatment. AFS was defined as freedom from major amputation, which is amputation above the ankle.

Statistical analysis

Kolmogorov-Smirnov test was used as a normality test for the distribution of each continuous variable and is expressed as mean standard deviation (SD). Chi-square test was performed between three AIOD groups comparing rates of initial success, preoperative complications, restenosis, amputation, and in-hospital mortality. The categorical variables were expressed in frequencies and percentages. The Kaplan–Meier estimates was used to evaluate time to event data. PPR and AFS were measured using Kaplan–Meier survival curves. The univariable Cox proportional hazards regression model was applied to identify predictors for restenosis and to estimate hazard ratio. A value of $p<0.05$ was considered statistically significant. The SPSS 20.0 software (SPSS Inc, Chicago, IL, USA) was used to perform all statistical test.

Results

Baseline clinical characteristics of the patients are presented in Table 1. The cohort consisted of 55 symptomatic patients of mean age 58.8±6.97 years and mean body mass index 25.9±4.44. Thirty-two patients (58.1%) had hypertension and 40 patients (72.2%) were former or current smokers. In terms of lower limb severity, 28 (50.9%) were classified as Rutherford classification

Table 1. Patient baseline characteristics (n=55)

Characteristics	Mean±SD No. (%)
Patients, n	55
Age, years	58.8±6.97
Male gender	37 (67.2)
Body mass index, (kg/m²)	25.9±4.44
Risk factors	
Hypertension	32 (58.1)
Diabetes mellitus	23 (41.8)
Chronic kidney disease (eGFR < 60 mL/min/1.73 m²)	11 (20)
Dyslipidemia	31 (56.3)
Smoking	40 (72.2)
Coronary artery disease	26 (47.2)
Cerebrovascular disease	2 (3.6)
Peripheral artery disease	9 (16.3)
Heart failure (left ventricular ejection <40%)	5 (9.1)
Rutherford classification	
2	4 (7.2)
3	28 (50.9)
4	18 (32.8)
5/6	5 (9.2)

3, and 23 (42%) had critical limb ischemia were classified as Rutherford 4–6 (CLI).

Lesion baseline characteristics and procedural results are shown in Table 2. Regarding the procedural approach, a bidirectional brachio-femoral approach was performed in 76.4% of patients, and retrograde transfemoral access alone in 20%. Regarding the strategy of stent implantation, the kissing stent method was used in 90.2% of patients. The average operation time was 98±43 minutes.

In terms of stent used in this population (Table 3), self-expanding stents (Epic self-expanding Nitinol stent, Boston Scientific, USA) 34.2% and bare balloon-expandable stents (Express LD Vascular OTW, Boston Scientific, USA) 31.6% were mainly used. Stent grafts (Atrium Advanta V12 OTW PTFE covered stent, Atrium Medical, USA) and aort type stents (Andramed Cobalt-Chronium, Andramed GmbH, Germany and Numed covered CP stent, NuMED Inc, USA) were the other two stent types used. Mean variety of stent types used were 1.88±0.64.

There were 14 perioperative major complications (Table 4) observed in 20% (11/55) of the patients, including 2 in-hospital deaths (both were hyper acute stent thrombosis with concomitant renal artery thrombosis). Hyper acute stent thrombosis developed in two CLI patients. Immediate angiography was performed and large thrombotic burden revealed. Repeat balloon dilatations successfully maintained distal blood flow, however, it did not clear residual thrombosis. Catheter delivered tPA bolus dose started for residual thrombosis. The tPA infusion continued in intensive care unit. Despite tPA infusions, both patients still developed recurrent thrombotic occlusions. Three patients experienced two distinct complications. Major amputation was not observed during perioperative period but one surgical conversion occurred. Acute thrombosis was observed in four patients and was generally at multiple locations. In total, 3 renal artery thrombosis that needed stent implantation and 2 distal embolisms occurred and was man-

Table 2. Lesion characteristics and procedural results (n=55)

Characteristics	Mean±SD No. (%)
Patients, n	55
Occlusion type	
AIOD type I	5 (9.1)
AIOD type II	21 (38.2)
AIOD type III	29 (52.7)
Take off	
High take off	17 (30.9)
Low take off	38 (69.1)
Procedural approach	
Transfemoral and brachial access	42 (76.4)
Only retrograde transfemoral access	11 (20)
Only antegrade transbrachial access	2 (3.6)
Procedural outcome	
Angioplasty approached	53 (96)
Lesion crossed	51 (92.7)
Technical success	49 (89.1)
Stent implantation (n=51)	
Single aorta stent	5 (9.8)
Aorto bi-iliac stenting	46 (90.2)
Kissing stents	46 (90.2)
Operation duration, min	98±43
Follow up, months	34.5±28

AIOD - aortoiliac occlusive disease

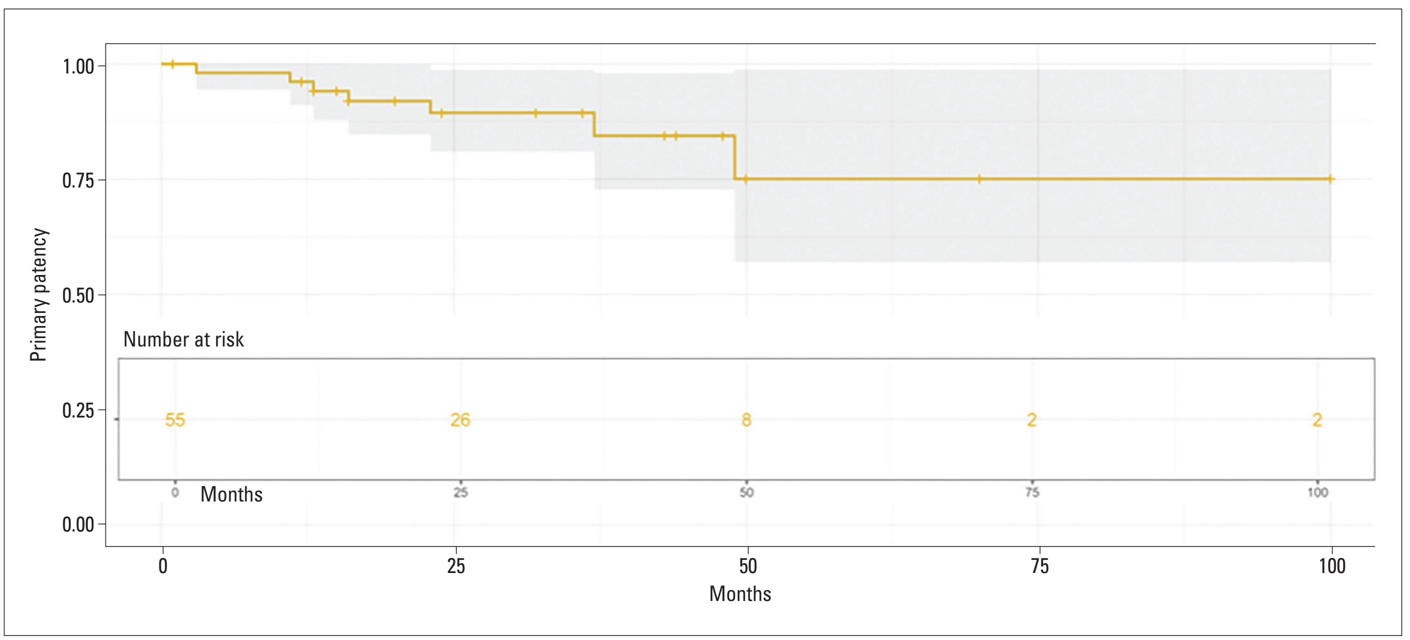

Figure 2. Primary patency was estimated using Kaplan–Meier method

Anatol J Cardiol 2021; 25: 258-65
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Table 3. Type of deployed stents

Stent types	Mean±SD No. (%)
Total number of stents deployed, n	190
Aortic stent	16 (8.4)
Balloon-expandable, bare	6 (3.2)
Covered	10 (5.2)
Stent grafts	49 (25.8)
Balloon-expandable stent	60 (31.6)
Self-expanding stent	65 (34.2)
Variety of stent types	1.88±0.64
Total number of stents per patient	3.45±0.95

Table 4. Total perioperative complications*

In-hospital mortality	2
Acute myocardial infarction	1
Cerebrovascular accident	1
Renal insufficiency needed dialysis	2
Iliac rupture	4
Acute arterial thrombosis	4

*Three patients had two distinct complications

aged by tPA infusion. Four iliac artery ruptures occurred, two were after balloon-expandable stent dilatation, one was after post-dilatation of self-expanding stent (SES) and one was after balloon pre-dilatation. All four were promptly managed by EVT (stent graft deployment) without causing hemodynamic instability.

Technical success was achieved in 89% (49/55). In 2 cases, we failed to cross through the occlusion and in 2 other cases, stents were deployed. However, no reflow was observed. Table 5 shows the procedure results and comparison according to occlusion type. AIOD type I was rarely revealed (9.1%) in this cohort. Most of the lesions were either AIOD type II or type III and perioperative complications occurred at the same rate in both types. Seven restenosis were diagnosed during follow up, and six of them underwent repeat angioplasty. Balloon dilatation was performed as restenosis crossed. If there was <30% residual stenosis or a pressure gradient less than 20 mm Hg, additional stent implantation was not performed. During the follow up period, ten patients (18.1%) were lost due to all-cause mortality. PPR and AFS are shown in Figure 2 and Figure 3, respectively. The PPR at 1, 3, and 5 years after EVT were 96%, 82%, and 75% (Fig. 2), while the AFS at 1, 3, and 5 years were 100%, 90%, and 82%, respectively (Fig. 3). Regarding restenosis types, focal restenosis was found in 29% (2/7), while reocclusion was found in 71% (5/7). After univariate analysis, none of these variables were significantly associated with loss of patency (Table 6).

Discussion

In our single-center, EVT of the total occluded infrarenal aorta demonstrated 75% PPR and 82% AFS at 5 years that were comparable to surgical bypass therapy. In the current study none of the demographic, lesion, and device factors were independently associated with loss of patency.

Total occlusion of abdominal aorta is an infrequent type of AIOD, typically surgical process has been the treatment of choice such as axillofemoral or aortobifemoral bypass surgery. Either of the bypasses generally conducted were based on the comorbidities and anatomic features of the patients. Regarding aortobifemoral bypass grafting, a meta-analysis elicited ap-

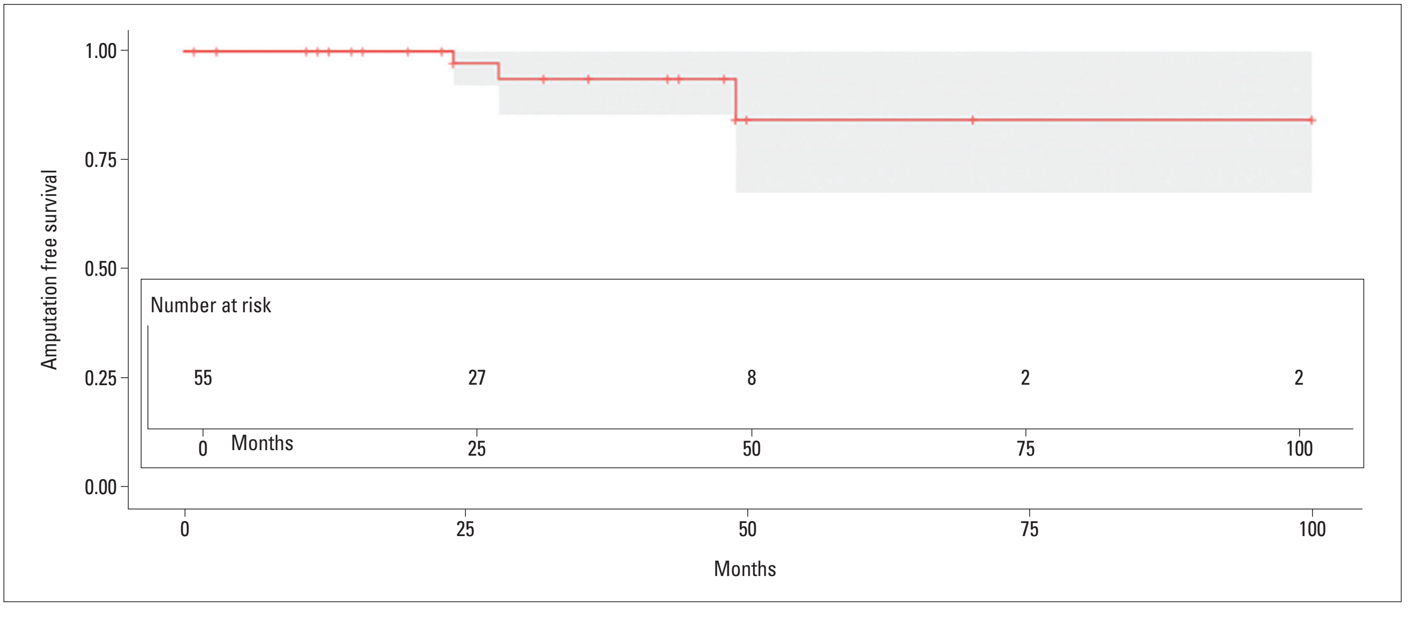

Figure 3. Amputation free survival was estimated using Kaplan–Meier method

Table 5. Classification of aortoiliac occlusive disease and its outcomes after stent implantation

	AIOD type 1	AIOD type II	AIOD type III	*P* value
Initial success rate	100% (5/5)	90.5% (19/21)	86.2% (25/29)	0.766
Perioperative complications	0% (0/5)	19% (4/21)	24% (7/29)	0.269
Restenosis	0% (0/5)	9.5% (2/21)	18% (5/29)	0.678
Amputation	0% (0/5)	4.7% (1/21)	6.9% (2/29)	0.469
In-hospital mortality	0% (0/5)	4.7% (1/21)	3.4% (1/29)	0.748

According to lesion distribution; AIOD type I was defined as isolated infrarenal aortic occlusion without involving the aortic bifurcation and iliac artery. AIOD type II was defined as the infrarenal aortic occlusion with common iliac arteries not extending into the external iliac arteries. AIOD type III was defined as the infrarenal aortic occlusion with both common iliac and external iliac arteries
AIOD - aortoiliac occlusive disease

Table 6. Univariable cox regression analysis for predicting restenosis

Variables	Univariate analysis		
	Hazard ratio	95% CI	*P* value
Age, years (52 to 63)	1.35	0.41-4.42	0.623
Male gender	3.23	0.38-27	0.269
Diabetes mellitus	0.42	0.05-3.52	0.424
Hypertension	1.21	0.26-5.42	0.802
Dyslipidemia	2.10	0.55-7.13	0.323
Chronic kidney disease (eGFR <60 mL/min/1.73 m^2)	1.52	0.54-4.27	0.423
Smoking	0.48	0.10-2.12	0.335
Coronary artery disease	2.01	0.43-9.22	0.374
Self-expandable stent	1.08	0.24-4.84	0.917
Balloon-expandable stent	2.44	0.46-12.90	0.293
Greft stent	1.61	0.35-7.30	0.538
Aortic stent type	1.01	0.19-5.21	0.987
Variety of stent types	1.59	0.67-3.77	0.283
Total stent length, (120 to 341 mm)	1.82	0.58-5.77	0.299

proximately 85% PPR at 5 years (12). Durable outcomes, major perioperative mortality, and morbidity have been associated with surgical treatments of severe AIOD. A previous meta-analysis revealed a mortality rate of 3.3% to 4.6% and high morbidity indices of long-term hospital admission, delayed recovery, and significant complications like ureteral damage, sexual dysfunction, spinal cord ischemia, and intestinal ischemia at a rate of 8.3% to 13.1% (12).

Throughout recent decades, EVT in the management of PAD has continued to develop and there is growing evidence of its efficacy. Nevertheless, only few reports have defined the long-term outcome of EVT for IAO. According to two recent reports of study populations that exclusively included patients with total occlusion of the infrarenal aorta, the success rate of EVT was 81.9% and 95% (10, 11). In our study, the success rate was 89%, which appears to be reasonable, given the formerly reported range. Less success rate was achieved comparing the report of Nanto et al. (11) may be partially attributed to the high percentage of AIOD type III patients in our study (50% vs. 53%), and also proximal occlusion site was juxtarenal (high take off) in 31% of IAO. Therefore, longer length of occlusions might have provoked challenges to penetrate through lesions.

In the totally occluded iliac arteries, EVT related complications ranges from 4% to 24%, depending on the length of the lesion (13-15). Considering the two studies involved of totally occluded infrarenal aorta, major complication rates were 16.3% and 9.8% (10, 11). The rate of perioperative major complications in our report was 20%, higher than above mentioned studies, which can be attributed to the following reasons. Firstly, the rate of CLI in our study was 42%, considerably superior to that of the previous reports. CLI is almost never related to isolated AIOD but rather represents diffuse multisegment disease with concomitant downstream lesions. Therefore, performing EVT becomes more challenging and CLI at admission is a significant prognostic of consequences for aortoiliac revascularization (16-18). Secondly, Kim et al. (10) and Nanto et al. (11) deployed SES in majority of the patients (91.4% and 90% respectively, whereas 34.2% in our report), performing less balloon angioplasty that might

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avoid some major complications like vessel rupture and distal emboli. Thirdly, Kim et al. (10) and Nanto et al. (11) included only chronic total IAO, however, in this present cohort we included acute IAO patients as well. Acute total occlusions increase risk of thrombosis, thus complications, and the two in-hospital mortalities were due to thrombosis of aortic stents and renal arteries in acute IAO patients.

In the present study, none of the device factors (stent types) were independently associated with loss of primary patency. A multi-centered study conducted on iliac artery EVT in 2019 found device factor as indicator of restenosis. However, that study had included all TASC lesion types (18) whereas, our study based on only TASC D AIO lesions. We speculated that our device factors did not associate with patency as consequences of multiple stents (3.45±0.95) and variety of stent types (1.88±0.64) used per patient. Recent study on AIO lesions revealed only one type of SES causing loss of patency, however this SES type was not used in any of our cases. Also they had no data on stent grafts (11). In our study, stents were deployed according to the operator's decision, however, balloon-expandable stents (bare and covered) were preferred more. This was mainly due to high percentage of severe calcification and the need for reconstruction of aortic bifurcation in TASC D aortoiliac occlusions.

In this study, the PPR after EVT was 75% at 5 years was lower than 80%–92% rates of bypass surgery (12), thus. EVT for selected patients might be an appropriate alternative procedure with IAO, especially in high risk patients for bypass operations under general anesthesia. Nanto et al. (11) in 2019 reported PPR at 1 and 5 years after EVT for chronic total occlusion of the infrarenal abdominal aorta were 88% and 70%, respectively. In our present study the PPR (96% at 1 years and 75% at 5 years) was slightly higher than what was reported. Our speculation was based on patient's characteristics because both studies included relatively small populations. Lesion calcification did not measure in our study, however, there are conflicting data in the literature of calcification affecting the outcome of EVT (10, 11).

The rates of amputation free survival of patients is revealed by AFS parameter. In a 2019 study, initial EVT was associated with better AFS compared with an open first therapy in patients with CLI (19). In the present study, the amputation free survival at 1, 3, and 5 years were 100%, 90%, and 82%, respectively, which can be compared with the surgical results of primary aortobifemoral bypass (90% 3-year rate of AFS) (20).

Study limitations

Our study has several limitations. Firstly, the study was a single-centered, retrospective, observational research using a small number of patient population. Secondly, because our cohort consisted only of Turkish patients, different results may be achieved in different ethnic populations. Thirdly, there were versatility in the methods of EVT at different time periods and among operators. Fourthly, there is a probability of underestimating restenosis because peripheral angiography was performed when patient had recurrent claudication despite maximal medical treatment, lifestyle changes, and duplex displayed restenosis. Finally, the EVT results might have varied according to the experiences and techniques of operators.

Conclusion

Five-year outcomes of primary patency and AFS for EVT of infrarenal aorta total occlusive lesions were favorable. However, relatively frequent complications related to the procedure requires attention. To advance the outcomes of EVT of IAO, careful patient selection, use of preventive medicine, and strategies to avoid serious complications and immediate convenient diagnostics against complications seem to be essential.

Conflict of interest: None declared.

Peer-review: Externally peer-reviewed.

Authorship contributions: Concept – E.Ö.Ç., İ.A.İ., C.K.; Design – E.Ö.Ç., İ.A.İ., C.K.; Supervision – E.Ö.Ç., İ.A.İ., C.K.; Fundings – None; Materials – None; Data collection and/or processing – M.S., Z.Ş., Ş.K., A.K., Ç.G., Ç.K.; Analysis and/or interpretation – E.Ö.Ç., M.S., Z.Ş., Ş.K., A.K., Ç.G., Ç.K.; Literature search – E.Ö.Ç., M.S., Z.Ş., Ş.K., A.K., Ç.G., Ç.K.; Writing – E.Ö.Ç.; Critical review – E.Ö.Ç., M.S., Z.Ş., Ş.K., A.K., Ç.G., Ç.K., İ.A.İ., C.K.

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