

# Five-Year Patency and its Predictors after Endovascular Therapy for Aortoiliac Occlusive Disease

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**Aim:** Although current guidelines recommend surgical revascularization as the first-line therapy for chronic total occlusion of the abdominal aorta (Leriche syndrome), endovascular therapy (EVT) has been increasingly utilized because of the development of new technologies and techniques. EVT has demonstrated durable midterm outcomes for aortoiliac occlusive disease (AIOD). Nonetheless, little is known regarding their long-term outcomes and predictors of restenosis.

**Methods:** We retrospectively analyzed a multicenter database of 64 consecutive patients (age,  $73 \pm 10$  years; 64% male; 22% critical limb ischemia) undergoing EVT for aortoiliac occlusive disease between September 2005 and March 2016. The outcome measures were primary and secondary patency, following EVT, calculated using the Kaplan–Meier method. Independent predictors associated with restenosis were assessed using Cox proportional hazard regression model.

**Results:** Technical success was achieved in 61 patients (95%). In total, 214 stents (192 self-expandable stents, 22 balloon-expandable stents) were implanted. During the follow-up of  $33 \pm 28$  months, 11 patients experienced loss of patency. The primary patency rates were 88%, 70%, and 70% at 1, 3, and 5 years, respectively. The secondary patency rates were 98%, 87%, and 77% at 1, 3, and 5 years, respectively. In Cox regression analysis, E-Luminexx stent use (in 29 patients, 48%) was associated with restenosis [hazard ratio, 4.41,  $P=0.038$ ].

**Conclusion:** In this retrospective study, EVT for AIOD demonstrated favorable 5-year patency. E-Luminexx stent implantation was associated with restenosis in this population.

**Key words:** EVT, Leriche syndrome, Restenosis

## Introduction

In 1923, René Leriche first reported chronic total occlusion of the abdominal aorta (Leriche syndrome) as, “chronic thrombotic occlusion at the end of the abdominal aorta, which might induce specific ischemic symptoms including intermittent claudication, lower limb muscle atrophy, and impaired sexual function.” Since then, a number of reports on this disease have been published<sup>1,2</sup>. According to an autopsy evaluation, the morbidity rate for Leriche syndrome is

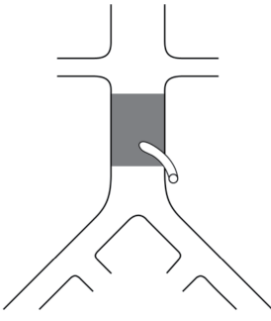
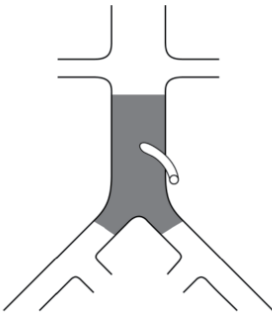
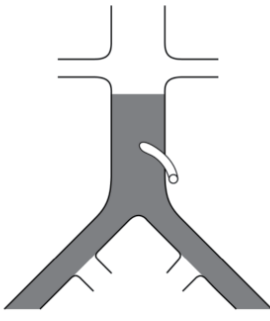
only 0.15%<sup>3</sup>. Traditionally, surgical treatments, such as bypass surgery and endarterectomy, have been considered the standard treatment modality for Leriche syndrome<sup>4</sup>. In such cases, aortobifemoral or axillofemoral bypass surgery is commonly recommended. Although the outcomes following aortobifemoral bypass surgery are acceptable with a 5-year patency rate ranging from 85%–94%<sup>4</sup>, surgical reconstruction is potentially associated with a number of clinical issues, including high mortality rates (3.3%–4.6%), high incidences of complications (8.3%–13.1%),

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Received: August 17, 2018 Accepted for publication: February 12, 2019

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Occlusion type	AIOD type I	AIOD type II	AIOD type III
			
Initial success rate	100% (5/5)	96% (26/27)	94% (30/32)
Perioperative complication	0% (0/5)	4% (1/27)	16% (5/32)
Primary patency (1Y/5Y)	100%/33%	90%/67%	76%/76%
Secondary patency (1Y/5Y)	100%/33%	100%/72%	95%/95%

**Fig. 1.** Classification of aortoiliac occlusive disease (AIOD) and its outcomes after stent implantation

AIOD was classified according to lesion distribution as follows. AIOD type I: Isolated aortic occlusion without involving the iliac artery. AIOD type II: Aortic occlusion with common iliac not extending into external iliac disease. AIOD type III: Aortic occlusion with both common iliac and external iliac diseases.

long-term hospital admission, and delayed recovery<sup>5</sup>).

With recent developments in medical devices and technologies, the outcomes of endovascular therapy (EVT) for aortoiliac occlusive disease (AIOD) are clinically promising, despite the severity of this disease<sup>6</sup>. Although few reports have described the outcomes of EVT for AIOD, the primary patency rates at 1 and 3 years after EVT have been reported as 88.4% and 80.1%, respectively<sup>7</sup>. However, EVT for the AIOD has not yet been standardized, and little is known regarding long-term results, especially beyond 3 years. Furthermore, predictors for loss of patency have not been well examined. Here, we investigated the long-term outcomes of EVT for AIOD and established predictors for restenosis.

## Methods

### 1. Study Design

The present study was a multicenter, retrospective, observational study on stent implantation for AIOD. The protocol was approved by the ethics committee of each participating medical institution. The study was conducted in accordance with the Declaration of Helsinki. EVT was performed after obtaining informed consent from all participants.

### 2. Subjects

EVT was performed in 64 patients with occlusive arteriosclerosis associated with total occlusion of

the infrarenal abdominal aorta between September 2005 and March 2016 (mean age  $\pm$  standard deviation [SD]:  $73 \pm 10$  years, proportion of men: 64%, proportion of patients with critical limb ischemia [CLI]: 22%). The selection and indication of revascularization strategy were determined based on each hospital manner. A group of vascular specialists including vascular surgeons and radiologists judged whether the endovascular approach was fit for each patient. The characteristics of subjects and details of lesions and surgical procedures were obtained from the database of each participating medical institution. The mean observational duration was  $33 \pm 28$  months.

### 3. Classification of AIOD According to the Anatomical Feature

The classification of AIOD in this study was according to the anatomical feature evaluated by computed tomography (CT) or diagnostic angiography before revascularization (Fig. 1). AIOD type I was defined as isolated aortic occlusion without involving the iliac artery. AIOD type II was defined as the aortic occlusion with common iliac not extending into the external iliac disease. AIOD type III was defined as the aortic occlusion with both common iliac and external iliac diseases.

### 4. Endovascular Procedure

EVT was performed under local anesthesia. A 6 F guiding sheath was inserted in a retrograde manner

into the bilateral femoral arteries and, if necessary, an antegrade approach from the brachial artery was added. After sheath insertion, a bolus dose (5,000 units) of heparin was intravenously infused. During EVT, the dose of heparin was controlled to attain an activated clotting time of 200 seconds or more. A 0.014-, 0.018-, or 0.035-inch guidewire was used based on the physician's discretion. After successful wire crossing, plain angioplasty as pre-dilatation was routinely conducted. After balloon dilatation, vessel morphology was assessed using intravascular ultrasound (IVUS), if necessary. Stent selection was determined based on lesion characteristics. In most patients, two stents were placed using the kissing stent method, and in other patients, an aortic stent and two aortoiliac kissing stents were placed using the combined stent method. The stents were dilated after placement. This endovascular procedure was judged successful if the residual stenosis was less than 30%, with a pressure gradient less than 10 mmHg, and with neither distal emboli nor vascular perforations.

### 5. Medications

Oral dual antiplatelet therapy (DAPT) with aspirin (100 mg/day) and thienopyridine (clopidogrel [75 mg/day] or ticlopidine [200 mg/day]) was routinely started at least 2 days before EVT. Subjects were required to take aspirin throughout their life. DAPT was performed for at least a month.

### 6. Follow-Up

In patients in whom EVT was successful, ankle-brachial index (ABI) measurement and other non-invasive tests were performed one month after hospital discharge and every three months thereafter to assess the subjective symptoms in the lower limbs. If recurrence was suspected, vascular ultrasound, CT, or angiography was conducted to evaluate the occurrence of restenosis.

### 7. Outcome Measures and Definitions

The outcome measures in this study were the primary patency rate, secondary patency rate, and predictors for restenosis. Initial success was defined as residual stenosis of less than 30%, with a pressure gradient of less than 10 mmHg. Perioperative death was defined as death occurring within 30 days. Major amputation was defined as surgical excision of the limb above the ankle. An occurrence of restenosis was defined as a decline in ABI on both sides by 0.15 or more, or documented stenosis of 50% or more as depicted on angiography. Primary patency was defined as a condition where the treated artery had no restenosis and needed no further treatment, and secondary

patency was defined as that achieved after one or more successful additional percutaneous procedures within the stent or the balloon angioplasty site or at its margins<sup>8</sup>). Regarding the severity of calcification, calcification projecting from the inner wall of the artery was deemed severe, while calcification through which the inner wall of the artery could be seen was deemed moderate. Other instances were deemed mild.

### 8. Statistical Analyses

Continuous variables were expressed as mean  $\pm$  SD. Categorical items were expressed as the total value and percentage (%). The level of significance was less than 5%. Kaplan–Meier survival curves were used to measure primary and secondary patency rates. The Cox proportional hazards regression model was used to identify predictors for restenosis. For all statistical analyses, Ekuseru–Toukei 2010 (Social Survey Research Information Co., Ltd.) was used.

## Results

### 1. Baseline Characteristics and Intervention Procedure

Patient characteristics are shown in **Table 1**. Twenty-three patients (36%) had diabetes and 32 (50%) had chronic kidney disease. In terms of lower limb severity, 45 (70%) were classified as Rutherford classification 3, and 14 (22%) had CLI. Lesion baseline characteristics and procedural results were shown in **Table 2**. Regarding the procedural approach, a bidirectional brachio-femoral approach was performed in 80% of patients, and IVUS in 38%. Regarding the strategy of stent implantation, the kissing stent method was used in 85% of patients. The average operation time was  $92 \pm 43$  minutes, and the average amount of contrast medium used was  $129 \pm 65$  ml. In terms of stent use in this population, self-expandable stents were mainly used in 90% of patients. E-Luminexx (BARD, Murray Hill, NJ) and SMART (Cordis, Miami Lakes, FL) stents were used in 34% and 33% of patients, respectively (**Table 3**).

### 2. Complications

Perioperative complications were observed in 9.8% (6/61). Major amputation or surgical conversion were not observed; however, there was perioperative death in 2 cases (sudden death due to cardiac event and non-occlusive mesenteric ischemia), transient renal insufficiency in 2 cases, distal embolization in 1 case, and hematoma at the puncture site resulting in need for transfusion in 1 case (**Table 4**).

### 3. Outcome Measures

**Fig. 1** shows the procedure results according to

**Table 1.** Patient baseline characteristics (*N*=64)

Age, years	72.9 ± 9.5
Female gender	23 (36)
Risk factors	
Hypertension	50 (78)
Dyslipidemia	27 (42)
Diabetes mellitus	23 (36)
Chronic kidney disease (eGFR < 60 ml/min/1.73 m <sup>2</sup> )	32 (50)
Hemodialysis	2 (3)
Smoking	33 (52)
CAD	24 (38)
CVD	12 (19)
Rutherford criteria	
2	5 (8)
3	45 (70)
4	8 (12)
5	5 (8)
6	1 (2)
ABI before procedure	
Right	0.50 ± 0.22
Left	0.48 ± 0.21

Values are mean ± SD or *n* (%)

CAD: coronary artery disease, CVD: cerebrovascular disease

**Table 3.** Type of deployed stents (*N*=214)

Balloon-expandable stent	22 (10)
Self-expandable stent	192 (90)
S.M.A.R.T	70 (33)
E-Luminexx	73 (34)
EPIC	43 (20)
Zilver	6 (3)

occlusion type. Most of the lesions were either AIOD type II or type III. AIOD type I was rarely revealed (8%) in this study. Perioperative complication more frequently occurred in AIOD type III, but there was no statistical significance. Primary and secondary patencies are shown in [Fig. 2](#) and [Fig. 3](#). The success rate of EVT was 95%. The primary patency rates at 1, 3, and 5 years after EVT were 88%, 70%, and 70% ([Fig. 2](#)), while the secondary patency rates at 1, 3, and 5 years were 98%, 87%, and 77%, respectively ([Fig. 3](#)). With regard to restenosis types, focal restenosis was found in 64% (7/11), while re-occlusion was found in 36% (4/11). After univariate analysis, implantation of E-Luminexx stent was significantly associated with loss of patency ([Table 5](#)). [Fig. 4](#) shows the patency rate after EVT with and without the use

**Table 2.** Lesion baseline characteristics and procedural results (*N*=64)

Occlusion type	
AIOD type I	5 (8)
AIOD type II	27 (42)
AIOD type III	32 (50)
Calcification	
none or mild	22 (34)
moderate	26 (41)
severe	16 (25)
Procedural approach	
Combined <sup>a</sup> , brachial and femoral arteries	51 (80)
Retrograde, from femoral arteries	12 (19)
Antegrade, from brachial arteries	1 (1)
Procedural strategy	
IVUS use	24 (38)
Thrombectomy	5 (8)
Distal protection	2 (3)
Stent implantation ( <i>N</i> =61)	
Kissing stents	52 (85)
Combined stents	6 (10)
Single aortic stent	3 (5)
Operation time, min	92 ± 43
Amount of contrast media, mL	129 ± 65

Values are mean ± SD or *n* (%)

AIOD: aorto-iliac occlusive disease, IVUS: intravascular ultrasound

**Table 4.** Complications (*N*=6)

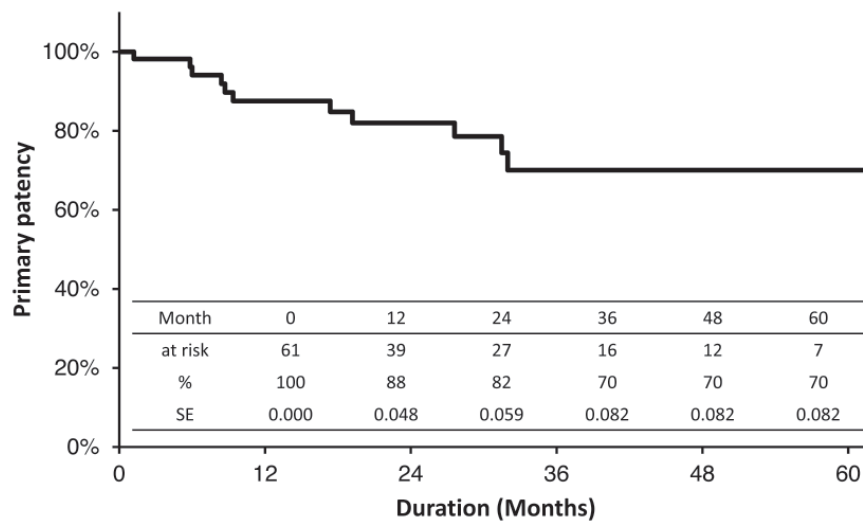
Perioperative death	2
Sudden death due to cardiac event	1
Non-occlusive mesenteric ischemia	1
Major amputation	0
Surgical conversion	0
Transient renal insufficiency	2
Distal embolization	1
Hematoma	1

of E-Luminexx stent using Kaplan–Meier survival curves. The results of a log-rank test suggest significant intergroup differences ( $P=0.038$ ).

## Discussion

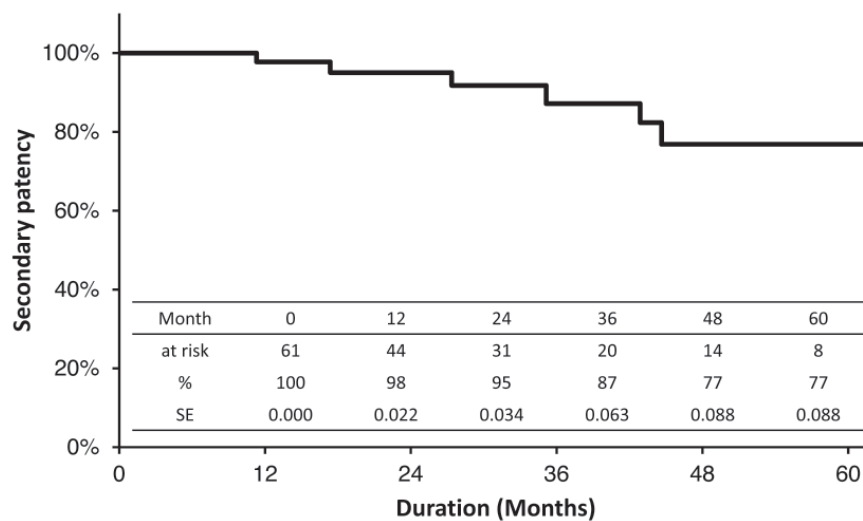
A multicenter, retrospective, observational study was conducted to investigate the long-term outcomes of EVT for AIOD and the predictors of subsequent restenosis. The primary patency rate at 5 years after EVT was 70%, while the secondary patency rate was 77%, demonstrating comparable results to surgical bypass therapy. In the current study, the selection of stents was independently associated with loss of patency.

Chronic total occlusion of the abdominal aorta is



**Fig. 2.** Primary patency

Primary patency was estimated using Kaplan–Meier method.



**Fig. 3.** Secondary patency

Secondary patency was estimated using Kaplan–Meier method.

mainly treated with bypass surgery, endarterectomy, or other surgical interventions<sup>4</sup>). Either aortobifemoral or axillofemoral bypass is generally conducted based on the anatomical feature and patient's comorbidities. The latest meta-analysis revealed that the primary patency rates at 5 and 10 years after aortobifemoral bypass surgery were 87.5% and 81.8%, respectively, demonstrating durable outcomes in severe AIOD<sup>4, 5</sup>). However, these surgical interventions have been associated with suboptimal rates of perioperative complications, including high mortality rates (3.3%–4.6%), high incidences of complications (8.3%–13.1%; sexual dysfunction, ureteral damage, intestinal ischemia,

and spinal cord injury), long-term hospital admission, and delayed recovery<sup>5</sup>).

### Initial Procedural Success

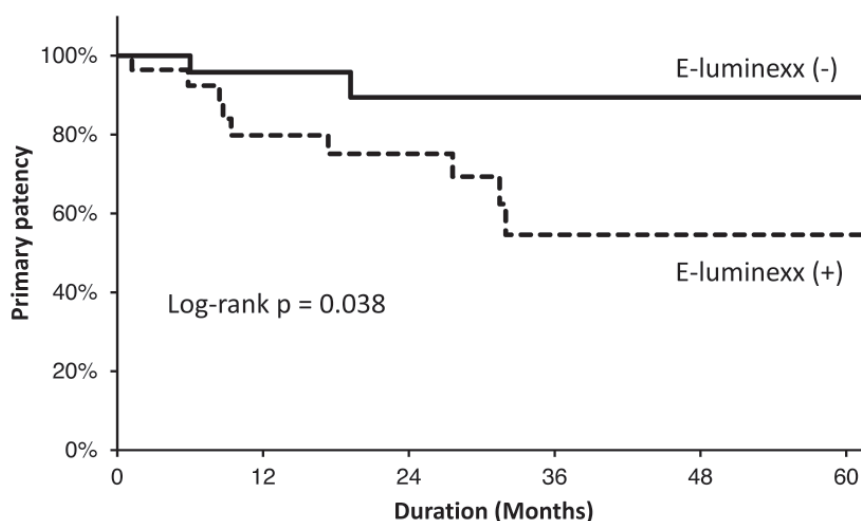
Few reports have described the outcome of EVT for AIOD. However, according to several recent reports, the success rate of EVT ranges from 73% to 93%<sup>7, 9, 10</sup>). In the present study, the success rate was 95%, which appears to be reasonable, given the previously reported range. This high success rate may be partially attributed to the bidirectional approach. Because there is no approval for re-entry devices, the

**Table 5.** Univariate analysis for restenosis

Variables	Univariate analysis		
	Hazard Ratio	95%CI	<i>p</i> value
Age, years	1.04	0.97-1.10	0.26
Female gender	1.88	0.57-6.18	0.30
Hypertension		†	
Dyslipidemia	2.15	0.63-7.37	0.22
Diabetes mellitus	0.90	0.26-3.08	0.87
Chronic kidney disease (eGFR < 60 ml/min/1.73 m <sup>2</sup> )	1.09	0.33-3.61	0.88
Hemodialysis	5.22	0.64-42.66	0.12
Severe calcification	1.84	0.49-6.96	0.37
Combined stenting	2.64	0.57-12.31	0.22
<b>Type of stent</b>			
Balloon-expandable stent	1.26	0.33-4.77	0.74
S.M.A.R.T	1.06	0.32-3.49	0.92
E-Luminexx	4.41	1.05-20.44	0.038
EPIC		†	
Zilver	1.96	0.78-4.93	0.15

CI; confidence interval

†: Calculation didn't converge

**Fig. 4.** Primary patency with or without E-Luminexx stent implantation

Restenosis rate with the E-Luminexx stent use was significantly higher than without them.

bidirectional approach is generally applied for recanalization of chronic total occlusion lesions in Japan. In this study, the bidirectional approach was performed in approximately 80% of cases. If the wire could not cross the lesion despite using the bidirectional approach<sup>11)</sup>, the Controlled Antegrade Retrograde Subintimal Tracking (CART) or Reverse CART Technique was occasionally conducted. As another reason, we speculated that high initial success rate is associated with the experienced operators in the high vol-

ume center and the use of multiple imaging modalities including preoperative CT, which is able to appropriately assess lesion distribution, and IVUS, which can assess wire passage and stent expansion.

### Perioperative Complications

The incidence of EVT-associated complications in the aortoiliac region ranges from 4% to 24%, depending on the length of the lesion<sup>12, 13)</sup>. In the

present study, the rate of perioperative complications after EVT for AIOD was 9.8%, which was lower than that in patients undergoing bypass surgery (8.3%–13.1%)<sup>5</sup>. Fatal complications including vessel perforation, rupture, and distal embolization would be avoidable when performing EVT for AIOD. To prevent vessel perforation and rupture, we precisely measured the vessel diameter by CT scan or IVUS before the procedure and selected an adequate balloon size. Furthermore, over dilatation should not be conducted. Patient symptom including back pain or abdominal pain under local anesthesia helps us to predict over dilatation during balloon dilation. To prevent distal embolization, sheath aspiration just after wire crossing was regularly conducted, and small-diameter balloons with low-pressure dilatation were used for post-dilatation. These technical aspects played an important role in preventing perioperative complications.

### Long-Term Results

In the present study, the primary patency rate at 5 years after EVT (70%) was lower than that of bypass surgery (80%–92%)<sup>5</sup>. However, the secondary patency rate was 77%, being almost comparable to the surgical result. Thus, EVT might be an acceptable alternative procedure for selected patients with AIOD, especially in populations with high risk for surgical therapy under general anesthesia.

In 2011, Kim *et al.* reported that when EVT was performed using stents for chronic total occlusion of the infrarenal abdominal aorta, the primary patency rates at 1 and 3 years after EVT were 88.4% and 80.1%, respectively<sup>7</sup>. In the present study, the primary patency rates were slightly lower than what is reported (88% and 70% at 1 and 3 years, respectively). We speculated that the present study included larger proportions of female patients, patients with diabetes, and patients with chronic kidney disease than most other studies, as Soga *et al.* reported that such conditions are predictors for restenosis after EVT for AIOD<sup>6</sup>. Although the above-mentioned report by Kim *et al.*<sup>7</sup> states that severe calcification is a causative factor for unsuccessful EVT for chronic aortic occlusion, calcification did not affect the outcome of EVT in the present study.

In the present study, the E-Luminexx stent was significantly related to the onset of restenosis. Stent fracture was seen at restenosis sites in 6 (55%) of the 11 patients with restenosis. Two of them were in patients treated with SMART stent, while 9 of them were with Luminexx stent. Among AIOD Types, the distribution of the stent fracture was as follows; 1 in type I, 3 in type II, and 2 in type III. There were no

statistically significant differences. Given that stent fracture has been reported to be related to the onset of restenosis<sup>14</sup>, a particularly high rate of fracture of E-Luminexx stents leading to restenosis is presumed in the present study. Stent fracture is an important issue after implantation of nitinol stents in the SFA. It is considered to be a risk factor for in-stent restenosis and re-occlusion in the chronic phase after SFA stenting, just as it has been suggested to be a cause of coronary restenosis. Differences in the structure of the segments and the number of connecting bridges between these two stents may be related to the differences in the stent fracture rate and patency at 1 year.

### Clinical Implication

To the best of our knowledge, the present study is the first to report the risk of restenosis after EVT for AIOD. While a standard treatment for chronic total occlusion of the infrarenal abdominal aorta has not yet been established, with methods left up to the judgment of individual operators, the findings from the present study will hopefully support the selection of appropriate stents and help improve patency. Because the anatomical characteristics of chronic total occlusion of the infrarenal abdominal aorta did not affect the treatment outcomes, complications, or chronic-phase patency, EVT for this disease is deemed reasonable.

### Limitations

Several limitations to the present study warrant mention. First, the study was a retrospective observational study using a small number of subjects. Second, the treatment was provided in accordance with the national healthcare insurance program, and thus, the devices used in some cases were quite old. Third, because our population comprised only of Japanese patients, different results might be obtained in non-Japanese populations. Fourth, stent size was selected based on the reference vessel diameter of the common iliac artery as well as abdominal aortic diameter. To avoid oversize stenting, the common iliac artery was mainly referred for stent selection. However, the data of the vessel diameter was not correctly acquired because of the retrospective study. Fifth, angiography was only performed in 11 patients, and all of them had recurrent restenosis for the reason that angiography was selected when the patient had recurrent claudication, and the examination (ABI, Duplex) revealed restenosis. Therefore, there is a possibility that the restenosis rate was underestimated. Finally, the treatment outcomes might have differed according to the

operators' techniques and experiences.

### Conclusion

In this retrospective study, EVT for AIOD demonstrated favorable 5-year outcomes. E-Luminexx stent implantation was associated with restenosis in this population.

### Conflicts of Interest

None.

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