

Clinical outcomes of endovascular treatment for chronic aortic occlusion: a retrospective multicentre registry



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KEYWORDS

- diffused disease
- iliac disease
- total occlusion

Abstract

Aims: The aim of this study was to evaluate the clinical outcomes of endovascular treatment (EVT) for chronic aortic occlusion (CAO) using multicentre registry data.

Methods and results: From April 2003 to December 2015, data on 73 consecutive patients (55 men and 18 women; aged 70.7±12.2 years) who underwent EVT for CAO were collected retrospectively from 15 centres in Japan. The primary endpoint was the primary patency at 12 months after EVT. Secondary endpoints were procedural success and periprocedural complication rates. We analysed 67 patients who underwent complete endovascular revascularisation after 2007. Initial procedural success was achieved in 63 cases (94.0%). Complications occurred in three patients (4.5%) (stroke, n=1; distal embolism, n=1; access-site haematoma requiring blood transfusion, n=1). In patients after successful EVT (n=63), the primary and secondary patency rates at 12 months were 90.7% and 97.7%, respectively. During a mean follow-up period of 17.8 months, restenosis/re-occlusion was observed in eight patients (12.7%).

Conclusions: EVT for CAO could be performed safely with a high procedural success rate. The short-term clinical outcome was acceptable despite lesion complexity.

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Abbreviations

ABI	ankle-brachial index
CAD	coronary artery disease
CAO	chronic aortic occlusion
CKD	chronic kidney disease
COPD	chronic obstructive pulmonary disease
CTO	chronic total occlusion
CVD	cerebrovascular disease
EVT	endovascular treatment
IVUS	intravascular ultrasound
TASC	Trans-Atlantic Inter-Society Consensus
TLR	target lesion revascularisation

Introduction

Although favourable results of endovascular treatment (EVT) for aortoiliac lesions have been reported¹⁻³, EVT for complex lesions, especially chronic total occlusion (CTO), still remains challenging³.

Chronic aortic occlusion (CAO) is defined as CTO of the infrarenal aorta with or without iliac artery occlusion; the specific ischaemic symptoms of CAO are commonly known as Leriche syndrome⁴. Surgical revascularisation has been the treatment of choice for patients with this disease. Only a small number of single-centre studies or single case reports have been published on the outcomes of EVT for CAO⁵⁻⁹. The purpose of this study was to evaluate the clinical outcomes of EVT for CAO using multicentre registry data.

Methods

STUDY DESIGN AND PATIENT POPULATION

This was a multicentre, retrospective observational study that included 73 Japanese patients (55 men, 18 women), who had a mean±SD age of 70.7±12.2 years (range, 34-90 years). The study was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of each participating hospital. Patients had CTO of the infrarenal aorta, and EVT was attempted between April 2003 and December 2015 at 15 Japanese medical institutions. Anonymised data were collected and analysed.

Treatment indications and strategies were decided at the physician's discretion at each institution. We excluded two patients who underwent hybrid therapy (unilateral revascularisation and femorofemoral bypass) and three patients who underwent unilateral revascularisation. Furthermore, we excluded the first of the remaining 68 patients who underwent complete EVT. The patient had been treated in 2003, and there were major restrictions on the devices and techniques available in Japan at that time. The second and subsequent procedures had been performed annually since 2007, four years after the first case.

EVT PROCEDURE

The cardiologists at each hospital decided on the procedural strategies. Therefore, treatment strategies were not unified in each institution. Here, we describe one of the EVT procedures for CAO (**Figure 1**)⁹. Three sheaths were inserted from the bilateral femoral arteries and the left brachial artery under local anaesthesia.

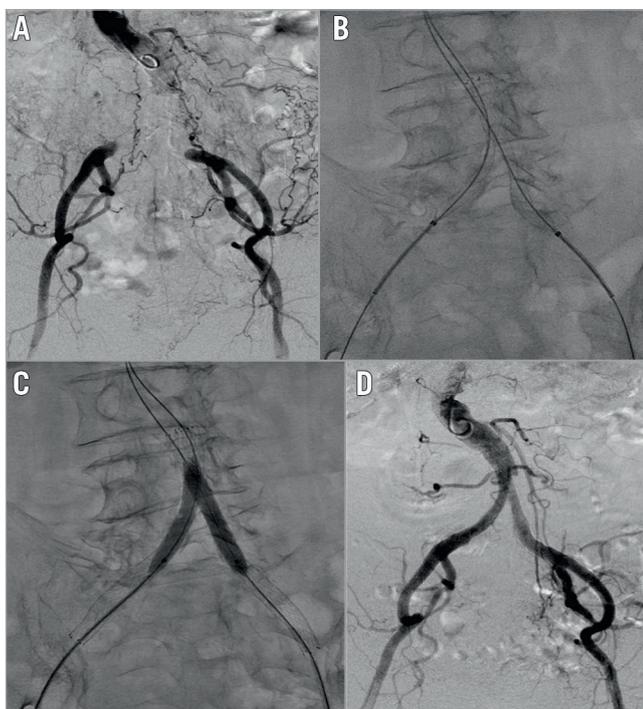


Figure 1. One of the interventional procedures. A) Preprocedural angiography showed total occlusion of the terminal abdominal aorta and bilateral common iliac artery. B) Kissing stent with self-expanding nitinol stents after guidewire crossing. C) Post balloon dilatation. D) Postoperative angiography showed a favourable flow.

Guidewire manipulation was performed intraluminally with a 0.014-inch guidewire. After the guidewire had successfully passed through the bilateral occlusive lesions, kissing stenting with two self-expanding nitinol stents followed by post-dilatation was performed.

STUDY OUTCOMES

Study outcomes comprised procedural success, procedural safety, and patency. The primary endpoint was primary patency at 12 months after EVT. Secondary endpoints were procedural success and periprocedural complication rates. Initial success was defined as <30% residual stenosis without any flow limitation noted on the final angiography. A procedural complication was defined as any adverse event caused by endovascular treatment including death, stroke, emergent surgery, blue toe syndrome/distal emboli, vessel rupture, access-site complication with prolongation of the in-hospital stay, blood transfusion, gastrointestinal haemorrhage, worsening renal function (a 50% increase in serum creatinine), and other critical complications.

DEFINITIONS

Primary patency was defined as the treated vessel without restenosis and repeat revascularisation that remained patent. Secondary patency was defined as patency achieved after reintervention for restenosis or re-occlusion of the treated vessel. Restenosis was defined as >2.4 peak systolic velocity ratio on duplex, >50% stenosis on angiography or computed tomography. Coronary artery disease (CAD) was defined as angina with documented CAD, previous myocardial infarction, a history of percutaneous coronary intervention, and history of coronary artery bypass graft surgery. Cerebrovascular disease (CVD) was defined as a history of stroke or transient ischaemic attack, carotid artery stenosis of >80%, history of carotid artery stenting, or history of carotid endarterectomy. Chronic obstructive pulmonary disease (COPD) was defined as patients with a forced expiratory volume in 1 s (FEV1) of <70% or COPD diagnosis requiring medical treatment. Chronic kidney disease (CKD) was defined as an estimated glomerular filtration rate (eGFR) less than 60 mL/min/1.73 m².

STATISTICAL ANALYSIS

Results are expressed as the mean±standard deviation or numbers with percentages. Statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria)¹⁰.

Results

PATIENTS AND LESION CHARACTERISTICS

The baseline clinical characteristics of the patients are presented in **Table 1**. A total of 30 patients (44.8%) had CAD, 18 (26.9%) had CVD, 8 (11.9%) had COPD, and 25 (37.3%) had CKD. All patients were symptomatic. Fifty patients (74.6%) presented with claudication (Rutherford classification 2 or 3¹¹), 9 (13.4%) with

Table 1. Patient and lower limb characteristics (N=67).

		Mean±SD or N (%)
Age (years)		70.3±12.5
Body mass index (kg/m ²)		21.4±3.2
Male		50 (74.6)
Coronary artery disease		30 (44.8)
Cerebrovascular disease		18 (26.9)
Congestive heart failure		11 (16.4)
Hypertension		55 (82.1)
Dyslipidaemia		38 (56.7)
Diabetes		25 (37.3)
Smoking history		49 (73.1)
Chronic obstructive pulmonary disease		8 (11.9)
Chronic kidney disease (eGFR <60 ml/min/1.73 m ²)		25 (37.3)
Haemodialysis		5 (7.5)
BUN (mg/dL)		17.8±9.9
CRE (mg/dL)		1.38±2.0
Hb (g/dL)		12.8±2.1
Ht (%)		38.6±5.8
LDL (mg/dL)		104±49
HDL (mg/dL)		49.1±16
HbA1c (%)		6.31±1.3
Rutherford classification before treatment	1	0 (0)
	2	6 (9.0)
	3	44 (65.7)
	4	9 (13.4)
	5	6 (9.0)
	6	2 (3.0)
ABI before treatment	Right	0.46±0.20
	Left	0.40±0.25

ABI: ankle-brachial index; BUN: blood urea nitrogen; CRE: creatinine; Hb: haemoglobin; HDL: high-density lipoprotein; Ht: haematocrit; LDL: low-density lipoprotein

rest pain (Rutherford classification 4), and 8 (12.0%) with an ulcer (Rutherford classification 5 or 6). The mean preprocedural ankle-brachial index (ABI) was 0.46±0.20 on the right side, and 0.40±0.25 on the left side.

Lesion characteristics are summarised in **Table 2**. A total of 56 lesions (83.6%) were associated with occlusion from the aorta to the iliac artery, and 11 (16.4%) were associated with solitary aortic occlusion. The mean lesion length was 121 mm. Thirty-four lesions (50.7%) showed moderate or severe calcification.

INTERVENTIONAL PROCEDURE OF COMPLETE REVASCULARISATION

Interventional procedures and initial outcomes of complete EVT are summarised in **Table 3**. The procedural success rate was 94.0% (63/67). Procedural failures were due to guidewire passage failure in four patients. Complications occurred in three patients

Table 2. Lesion characteristics.

		Mean±SD or N (%)
Occlusion pattern	Aortoiliac occlusion	56 (83.6)
	Isolated aortic occlusion	11 (16.4)
Lesion length (mm)		121±78.0
Calcification	None	13 (19.4)
	Mild	20 (29.9)
	Moderate	16 (23.9)
	Severe	18 (26.9)
Presence of FP lesion		23 (34.3)
FP: femoropopliteal		

(4.5%) (stroke, n=1; distal embolism, n=1; access-site haematoma requiring blood transfusion, n=1). One case of distal embolism was improved by thromboaspiration only.

Most of the procedures were performed with a bidirectional approach. An intraluminal approach using 0.014-inch and/or 0.018-inch guidewires was performed in more cases (76.1%) compared with a subintimal approach using a 0.035-inch guidewire. A total of 88.1% of the procedures were performed with intravascular ultrasound (IVUS) guidance. The average number of stents per case was 3.2±1.2, and 90.0% of the stents were self-expanding. The kissing stent technique with bare metal stents was performed in 57 cases (90.5%). Most of the procedures (92.5%) were performed without a distal protection device. Five procedures of distal protection were performed with an occlusion balloon guiding catheter (OPTIMO; Tokai Medical Products, Aichi, Japan).

The ABI and clinical symptoms improved markedly in all patients with successful EVT.

CLINICAL FOLLOW-UP

Clinical follow-up after successful EVT is summarised in **Table 4**. Primary and secondary patency rates at 12 months were 90.7% and 97.7% (n=43), respectively (**Figure 2**). During the mean follow-up period of 17.8 months, either restenosis or re-occlusion was

Table 3. Initial outcome and interventional procedure (N=67).

		N (%) or Mean±SD
Procedure success		
Success		63 (94.0)
Failure		4 (6.0)
Guidewire crossing failure		4
Periprocedural complication		3 (4.5)
Stroke		1
Distal embolism		1
Access-site complication		1
Before and after successful EVT (N=63)		
Preprocedural ABI		
Right side		0.46±0.20
Left side		0.41±0.24
Post-procedural ABI		
Right side		0.90±0.16
Left side		0.86±0.18
Improvement of the clinical symptoms		63 (100)
Contrast medium (ml)		155±79.6
Fluoro dose (Gy)		1.4±1.3
Wiring strategy		
Intraluminal		51 (76.1)
Subintimal		16 (23.9)
IVUS usage		59 (88.1)
Number of stents (per case)		3.2±1.4
Total number of stents		201
Self-expanding stent		181 (90.0)
Balloon-expandable stent		20 (10.0)
Kissing stent technique		57 (90.5)
Distal protection		5 (7.5)
Occlusion balloon guiding catheter		5
In the intraluminal wiring strategy, a 0.014- or 0.018-inch guidewire was used to cross the occlusive lesion; in the subintimal wiring strategy, a 0.035-inch hydrophilic guidewire was used.		

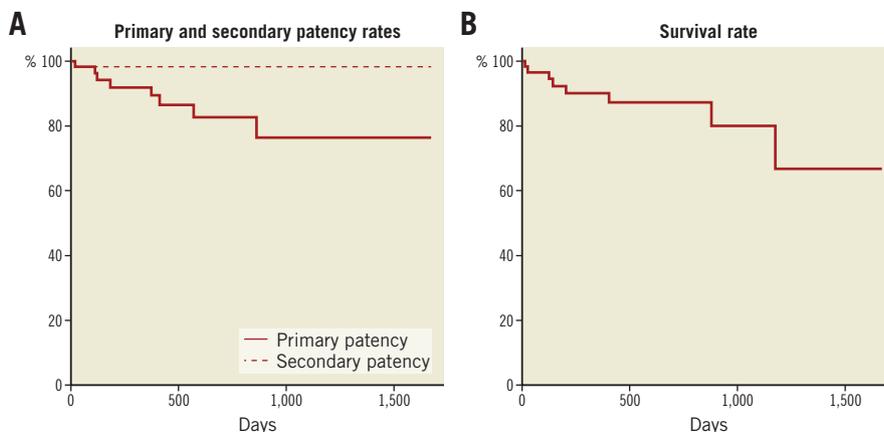


Figure 2. Kaplan-Meier life-table analysis of primary and secondary patency rates. A) After EVT. B) Survival rate.

Table 4. Clinical follow-up after EVT (N=63).

	N (%) or Mean±SD
12-month primary patency (N=43)	90.7 (39)
12-month secondary patency (N=43)	97.7 (42)
Follow-up period (months)	17.8±13.9
Restenosis/re-occlusion	8 (12.7)
TLR	7 (11.1)
Balloon angioplasty	2
Stent implantation	4
Fogarty catheter embolectomy	1
Death	8 (12.7)
Malignancy	3
Sudden death	1
Heart failure	1
Sepsis	1
Ischaemic colitis	1
Unknown	1
Amputation	1 (1.8)
Toe amputation	1
Bleeding	3 (4.4)
Intestinal haemorrhage	1
Chronic subdural haematoma	1
Other	1
EVT: endovascular treatment	

observed in eight patients. Among them, seven patients underwent reintervention (additional stent implantation, n=4; balloon angioplasty, n=2; Fogarty catheter embolectomy, n=1), five of whom were subsequently relieved of TLR. In one case, intensive medical therapy was maintained, because the patient did not desire reintervention. The incidence of all-cause death was 12.7% (sudden death, n=1; congestive heart failure, n=1; malignancy, n=3; sepsis, n=1; ischaemic colitis, n=1; unknown cause, n=1). There was only one death within 30 days of EVT as a result of sepsis; the patient died 11 days after EVT. The patient presented with severe infectious foot gangrene and was in poor general condition before EVT.

Discussion

Favourable results of EVT for aortoiliac lesions have been reported¹⁻³. Furthermore, in aortoiliac lesions, the primary patency after successful stenting does not differ between TASC II lesion categories³.

Recently, EVT of complex lesions has been increasingly performed, yielding high success and low complication rates¹². Even CTOs are now treated endovascularly with favourable early and long-term results¹³. Hans et al¹⁴ reported that aortoiliac stenting can be an alternative to aortobifemoral bypass in TASC C and D lesions. However, EVT for extensive aortoiliac occlusive disease is considered for patients unsuitable for surgical treatment in the present circumstances^{15,16}.

CAO is defined as CTO of the infrarenal aorta with or without iliac artery occlusion. Specific ischaemic symptoms of CAO are commonly known as Leriche syndrome⁴. Surgical revascularisation has been the treatment of choice for patients with this disease¹⁷. Surgical revascularisation for CAO can be divided roughly into anatomical and extra-anatomical bypass (aortobifemoral and axillobifemoral, respectively). Favourable results of aortobifemoral bypass have been reported¹⁸⁻²². However, in older patients, or those at high risk for anatomical bypass, axillofemoral, extra-anatomical bypass is often selected¹⁸. Although axillofemoral bypass is less invasive, its patency is generally lower than that of aortofemoral bypass^{17,18,23,24}. On the other hand, only a small number of single-centre studies have been reported on the outcomes of EVT for CAO^{5,6,25}. We evaluated the safety and efficacy of EVT for CAO using multicentre registry data in this study.

In the present study, we collected data on 73 treated cases of CAO. The average age of the patients was over 70, and many patients had some comorbidities.

In this study, three patients underwent unilateral revascularisation. Two of them with a non-ambulatory status had an ulcer on only one leg. The remaining one had already undergone unilateral limb amputation. Another two patients underwent the hybrid procedure, comprising unilateral endovascular treatment and femorofemoral bypass surgery. The occlusive lesions of the two patients showed severe calcification. It is considered to be a valid decision to shorten the procedural time based on the age and status of the patient, as well as the lesion characteristics.

Complete EVT procedures failed in four cases, all of which were due to guidewire passage failure. In all these cases, the guidewire could not be crossed through the occlusive lesion due to marked calcification. A markedly calcified lesion is still one of the greatest challenges of EVT despite progress in techniques and therapeutic devices.

Next, we would like to consider procedural safety. The periprocedural complication rate was low in this study. There was no arterial rupture or procedure-related death. Another serious complication in aortoiliac intervention is distal embolisation. Only one patient developed minor distal embolisation in this study, although most procedures were performed without distal protection. It should be noted that most of the procedures in this study were performed with IVUS guidance (88.2%). IVUS images provide much information – on the vessel size, plaque characteristics, location and degree of plaque calcification, and the location of the guidewire in the CTO lesion. The usefulness of IVUS-guided EVT for improving procedural success and post-procedural patency has already been reported^{26,27}. Moreover, IVUS usage might contribute to a safe procedure.

In this study, all of the successful EVT cases were treated with bare metal stents, and most cases were treated with the kissing stent technique. The covered endovascular reconstruction of an aortic bifurcation (CERAB) technique²⁸ may become one of the useful options.

Even when EVT is successfully and safely completed, a risk of restenosis remains. In this study, one-year primary and secondary patency rates were 90.7% and 97.7%, respectively. This result is comparable to past reports of overall aortoiliac lesions³ and chronic aortic occlusion^{6,25}. In this study, either restenosis or re-occlusion was observed in eight cases (12.7%) during a mean follow-up period of 17.8 months. Among them, seven patients underwent reintervention, five of whom subsequently showed TLR resolution. Soga et al³ reported that the individual predictors of primary patency in aortoiliac lesions are female sex, diabetes, renal failure, non-use of aspirin, reference vessel diameter <8.0 mm, and an outflow lesion. In this study, various collected parameters did not show significant differences between the restenosis and non-restenosis groups (Table 5). The statistical power may not have been sufficient.

Table 5. Various parameters between the ISR and non-ISR groups.

	ISR (n=8)	non-ISR (n=55)	p-value
Female gender (%)	37.5	23.6	0.328
Age (years)	68.1±14.9	69.9±12.1	0.495
Diabetes (%)	25.0	41.8	0.265
CKD (%)	25.0	38.2	0.432
CLI before treatment	12.5	27.3	0.970
Aortoiliac occlusion (%)	87.5	81.8	0.503
Lesion length (mm)	118±74	119±80	0.662
Moderate or severe calcification	50.0	47.3	0.805
FP lesion	25.0	32.7	0.831
IVUS usage rate	100	87.3	0.994

CKD: chronic kidney disease; CLI: critical limb ischaemia; FP: femoropopliteal; ISR: in-stent restenosis; IVUS: intravascular ultrasound

The incidence of all-cause death was 12.7% (sudden death, n=1; congestive heart failure, n=1; malignancy, n=3; sepsis, n=1; ischaemic colitis, n=1; unknown cause, n=1). The life prognosis of patients with peripheral artery disease is generally poor¹⁷, and the indication for revascularisation should be carefully considered.

This is the first report on the clinical outcome of EVT for CAO using multicentre registry data including a relatively large number of patients. More long-term durability of EVT for CAO is expected.

Limitations

There are some limitations of this study that should be noted. Firstly, this study was a non-randomised, retrospective registry, and decisions on the treatment strategy were not unified in each institution. Secondly, the sample size was small, although this study contains the highest number of cases reported to date. Thirdly, the follow-up period was relatively short. Finally, the racial background of all patients was Japanese, and the results

may not be representative if the methods are applied to a broader patient population. Despite these limitations, the results of this study provide important information regarding EVT for CAO.

Conclusions

In conclusion, EVT for CAO could be performed safely with a high procedural success rate, and the short-term clinical outcome was acceptable despite lesion complexity. The evolution of techniques and materials may contribute to a further increase in the success of such procedures in the future.

Impact on daily practice

The evidence of clinical outcomes of EVT for CAO is insufficient despite the marked advances in complex EVT over the past few years. This is a first report of multicentre analysis of EVT for CAO, and the clinical outcome was acceptable. Especially in patients who are not candidates for surgery and/or older patients, EVT for CAO can be an alternative choice.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

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