

Midterm outcomes after primary stenting in treatment of atherosclerotic iliac arteries

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Submitted: 22 January 2021; **Accepted:** 7 February 2021

Online publication: 21 March 2021

Arch Med Sci 2022
 DOI: <https://doi.org/10.5114/aoms/133118>
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Abstract

Introduction: The purpose of this study was to report the midterm outcomes of primary stenting of iliac arteries with additional factors which affect the outcome and to compare the results between patients with simple and complex aortoiliac occlusive disease (AIOD).

Material and methods: The study took place from January 2015 to March 2018 and included 103 lesions in 93 patients with common iliac artery (CIA) and/or external iliac artery (EIA) lesions accompanied with severe claudication or critical limb ischemia. Balloon-expandable stents (BMS), self-expandable stents (SES) and covered stents (CS) were used to treat the lesions.

Results: Lesions of 93 patients that were in the CIA and/or EIA and treated with ET were included in the study ($n = 103$). Seventy-one (68.9%) lesions were classified in the simple AIOD group (TASC II A-B) while 32 (31.1%) were classified in the complex AIOD (TASC II C-D) group. In 72.8% of the lesions only mild calcification was detected while 27.2% of lesions had moderate or severe calcification. Mean stent diameter for CIA position was 8.26 ± 0.8 mm and for EIA position was 7.52 ± 0.8 mm. Mean lesion length in patients treated with BMS was 52.5 ± 21.0 mm while in SES it was 63.6 ± 28.3 ($p = 0.03$). Technical success was achieved in 101 (98.1%) lesions. Significant differences in primary (93% vs. 63%) and secondary (98% vs. 82%) patency rates at 24 months were found between patients in simple and complex AIOD groups ($p < 0.001$, $p = 0.001$).

Conclusions: In our study, it was found that the primary stenting in patients who had AIOD had satisfactory results with high immediate success, low complication rates and acceptable midterm outcomes.

Key words: iliac artery, atherosclerosis, endovascular procedures, stents, self-expandable metallic stents.

Introduction

Aortoiliac occlusive disease (AIOD) constitutes 30% of PAD and is classified in the Trans-Atlantic Inter Society Consensus II classification (TASC II) [1, 2]. Although there are some shortcomings in TASC II, the treatment approaches have taken shape based on the severity of the lesions [3]. Open surgery has been the gold standard method; however, revascularization approaches for AIOD are changing with developing technologies and experience, and TASC II recommendations can be reconsidered in some cases. Today one third of the endovascular treatments (ET) for chronic total occlusions (CTO) are applied to the iliac arteries [4, 5]. This

change has become more evident in the past two decades [6, 7]. Various types of ET approaches are performed for AIOD – plain old balloon angioplasty (POBA), drug-eluting balloon angioplasty (DEB), cutting balloons, bare-metal balloon expandable stents (BMS), self-expandable stents (SES), and covered stents (CS) – which are chosen according to the anatomical features. However, since it has better outcomes, the primary stenting method is one step ahead compared to other methods regardless of the stent type [8].

The ET options of AIOD have evolved from the effectiveness of the primary stenting; however, there is still insufficient evidence on the factors that affect the outcomes of the ET in AIOD lesions [9, 10]. In this study, we aimed to report the outcomes of primary stenting of AIOD, determine additional factors that affect the outcome and compare the results between patients with simple and complex AIOD.

Material and methods

Study design

The study was designed as a retrospective study. Patients treated with primary stenting for AIOD between January 2015 and January 2018 were included. The Clinical Research Ethical Committee of Tepecik Training and Research Hospital approved the study (2018/13-5). Medical data were searched for patient demographics, vascular disease risk factors, as well as procedural and follow-up data. The clinical status of patients was evaluated with the Rutherford classification. The study consisted of 103 lesions in 93 patients with common iliac artery (CIA) and/or external iliac artery (EIA) lesions accompanied with severe claudication (Rutherford category 3) or critical limb ischemia (CLI) (Rutherford category 4 or higher) and treated with ET. Individual limbs were counted separately; patients undergoing bilateral procedures were recorded as separate inputs. All procedures and follow-ups were conducted by the cardiovascular surgery department. Patients under 18 years old and patients with previous endovascular treatment other than primary stenting or with previous surgical treatment of the AIOD were excluded. Patients admitted with acute limb ischemia and history of severe renal failure with e-GFR < 30 ml/min/1.73 m² were also excluded. However, patients who had end stage renal disease were included.

Patients were directed from the outpatient clinic for elective procedures unless they had CLI. Patients with CLI were scheduled for urgent intervention.

Lesions were classified into two groups according to TASC II guidelines. Seventy-one (68.9%) le-

sions were classified as simple AIOD (TASC A-B) while 32 (31.1%) were classified as complex AIOD (TASC C-D).

Procedures and stents

For preoperative imaging, the first examination was done with Duplex ultrasound (DUS) in all patients. For patients with positive findings in DUS, further imaging was performed with computed tomography angiography (CTA). Calcium score was detected with CTA and defined as none-mild or moderate-severe. All procedures were performed in the interventional angiography laboratory (Siemens AXIOM Artis dTA, Siemens Healthcare, Erlangen, Germany). In case of ipsilateral infra-inguinal PAD accompanying AIOD, two-stage treatment was applied and AIOD was treated in the first step. Procedures were performed percutaneously under local anesthesia and no general anesthesia was utilized for any patient. Access was obtained via the retrograde common femoral artery (CFA) and proximal superficial femoral artery (SFA) or crossover from the contralateral CFA under ultrasound guidance. However, in unsuccessful attempts with these techniques, they were combined with antegrade approach via brachial artery. Depending on stent sizes, 6 Fr or 7 Fr vascular sheaths were inserted; afterward, intra-arterial heparin of 100 IU/kg dosage was applied. Anticoagulation efficacy was followed up with activated clotting time (ACT). If the ACT value was below 180 seconds, an additional dose of heparin was administered.

The intimal tracking approach was used. A 0.035-inch hydrophilic guidewire (ZIPwire, Boston Scientific, Natick, MA), with the help of support catheters (Navicross, Terumo, Somerset, NJ or Rubicon35, Boston Scientific, Natick, MA) was used to cross the CTO. The diagnostic catheter was advanced proximal to the aortic lesion, and a digital subtraction angiogram was performed via a power injector afterwards. In cases of CTO or near occlusion, predilatation was performed with 4 mm POBA to facilitate stent delivery. The delivery system was positioned to cover the stenotic or occluded segment. Stent diameter selection was determined by the diameter of the healthy section of the CIA and EIA. A BMS (Visi-Pro, Medtronic, Dublin, Ireland), balloon-expandable CS (Advanta V12, Atrium Medical Inc., Hudson, NH, USA), and SES (Epic Boston Scientific Corp., Natick, MA, USA) were implanted. Stent choice was left to the discretion of the treating physician. Completion angiogram was performed routinely to confirm patency and to rule out extravasation. Technical success was defined as an absence of residual stenosis over 30% on completion angiography. An Angioseal (Terumo, Somerset, NJ) closure device was used with the discretion of the physician.

Medical therapy

Dual anti-platelet therapy that included a 300 mg loading dose of clopidogrel and 100 mg of acetylsalicylic acid (ASA) was commenced immediately after the procedure. Afterward dual antiplatelet therapy was continued at least six months after discharge with a daily clopidogrel dose of 75 mg and an ASA dose of 100 mg.

Study end points

Primary patency was the primary endpoint of our study. Primary patency was defined as uninterrupted patency after the index procedure without reintervention on the treated segment during follow-up. Secondary patency was defined as the patency maintained with a reintervention for the treated segment during follow-up. Procedural success was defined as patency shown in the control angiogram after stent deployment in the index procedure. Restenosis was defined as a more than 30% diameter reduction on the angiogram of the target lesion with accompanying symptoms of claudication. Stent patency was based on clinical and radiological evaluations. Patients were followed up by aortoiliac DUS at 3, 6, 12, 18, and 24 months after intervention. If significant stenosis was detected with DUS, further imaging was performed with CTA.

Statistical analysis

Statistical analysis was performed using SPSS Statistics for Mac Version 20 (IBM Corp. Released 2011, Armonk, NY). Variables in numeric configuration were summarized as mean SD values and median (min.-max.) values. Cross table analysis was used to evaluate the categorical variables and shown numerically as percentages. Pearson's correlation test was used to measure the statistical relationship or association between continuous variables. Student's *t*-test was used for normally distributed data and the Mann-Whitney *U* test was performed for non-normally distributed data. Survival analysis with the Kaplan-Meier log rank test was used to analyze the stent patency. A *p*-value less than 0.05 was considered indicative of a statistically significant difference.

Results

Lesions of 93 patients that were in the CIA and/or EIA and treated with ET were included in the study (*n* = 103). The majority of the cohort was male (*n* = 64, 68.8%), and median age was 63 years (range 41-85). Patients' demographic data and risk factors are summarized in Table I.

All patients were symptomatic, and all lesions were classified according to TASC II criteria. Seventy-one (68.9%) lesions were classified in the

simple AIOD group (TASC II A-B) while 32 (31.1%) were classified in the complex AIOD (TASC II C-D) group. Preprocedural and periprocedural details are summarized in Table II.

Eighty-four percent of the lesions caused severe claudication (Rutherford 3) and 15.5% had CLI (Rutherford 4, 6.8%, Rutherford 5 4.9%, Rutherford 6 3.9%) on admission. Compared to the simple AIOD group, CLI was seen more frequently in the complex AIOD group (*p* < 0.001).

In 72.8% of the lesions only mild calcification was detected while 27.2% of lesions had moderate or severe calcification. In 54 (52.4%) lesions, the disease was located only in the CIA while in 22 (21.4%) lesions, the disease was located only in the EIA. Twenty-seven lesions (26.2%) were located in both the CIA and EIA. Among the complex AIOD group, nearly half of the lesions (*n* = 14, 43.8%) involved both the CIA and EIA.

Ipsilateral severe stenosis or occlusion of the internal iliac artery (IIA) accompanied 41 (39.8%) lesions, which were more frequently located in the CIA with or without EIA extension (*p* < 0.001).

Additional ipsilateral infra-inguinal PAD accompanied 27 (26.2%) lesions.

The retrograde CFA or proximal SFA approach was enough in 64 (62.1%) lesions. However, in 39 (30.1%) lesions, additional access (crossover from contralateral SFA, *n* = 31, 30.1%; antegrade from brachial artery, *n* = 8, 7.8%) was necessary for revascularization.

Table I. Preoperative demographic characteristics of patients

Parameter	<i>n</i> (%)
Patients (<i>n</i> = 93):	
Male	64 (68.8)
Age [years]	63 (41-85)
Smoker	76 (73)
Hypertension	85 (82.5)
Hyperlipidemia	76 (73.8)
COPD	36 (35)
CAD	53 (54.4)
Diabetes mellitus	65 (63.1)
Lesion (<i>n</i> = 103):	
Rutherford classification:	
3	87 (84.5)
4	7 (6.8)
5	5 (4.9)
6	4 (3.9)
Severe calcification	28 (27.2)
Simple (TASC II A-B)	71 (68.9)
Complex (TASC II C-D)	32 (31.1)

CAD – coronary arterial disease, TASC II – transatlantic intersociety consensus, COPD – chronic obstructive pulmonary disease

Overall median lesion length was 50 mm (17–118 mm).

Predilatation with plain old balloon angioplasty (POBA) was performed in 25 (24.3%) lesions. Predilatation for stent delivery was needed nearly 5 times more in the complex AIOD group ($p < 0.001$).

For CIA lesions BMS and for EIA lesions SES were preferred more frequently. The details of the lesions and stents that were used are given in Table II.

Immediate technical success was achieved in 101 (98.1%) lesions. Surgical treatment was planned in 2 (2.2%) patients where CTO could not be exceeded. Both patients had calcified and complex AIOD lesions with a mean lesion length of 111 ± 1.41 mm. The mean procedural duration was 47.2 ± 18.7 min. Procedural duration was 43.0 ± 14.8 min for simple AIOD lesions and 58.5 ± 23.4 for complex AIOD lesions ($p < 0.001$).

Peri-procedural complications occurred during the treatment of 8 (7.8%) lesions. Dissection requiring additional stent implantation was observed in 5 (4.8%) lesions. All lesions were treated

successfully with an additional stent implantation (BMS $n = 2$, SES $n = 3$). Distal embolization occurred during the treatment of 2 lesions and was treated with catheter directed thrombolysis. One EIA rupture was observed (0.97%) and treated with CS. In one patient the distal tip of the SES delivery system was separated from the system during crossing of the severe stenosis in the EIA; the 7 Fr vascular sheath was replaced with a 10 F vascular sheath and an attempt was made to catch the tip with a snare catheter. After unsuccessful attempts cut-down was performed via a small incision and the tip was removed with a Fogarty embolectomy catheter. Afterward, successful endovascular recanalization with an SES was performed. Periprocedural complication was observed more commonly in the complex AIOD group and in lesions with moderate or severe calcification ($p = 0.017$, $p = 0.001$) (Table III).

Median follow-up was 26 months (2–72). The overall primary patency rates at 12 and 24 months after ET were 95% and 85.1% respectively, while the secondary patency rates at 12 and 24 months were 95.9% and 94.1% respectively.

Significant differences in primary (93% vs. 63%) ($p < 0.001$) and secondary (98% vs. 82%) ($p = 0.001$) patency rates at 24 months were found between patients in simple and complex AIOD groups.

Subgroup analysis showed significant differences in primary and secondary patency at 24 months for different arterial segments. CIA + EIA lesions had significantly lower primary and secondary patency rates at 24 months compared with isolated CIA and EIA lesions (67% vs. 94% and 84%, log rank: 12.2, $p = 0.002$ for PP at 24 months and 82% vs. 100% and 94%, log rank: 11.2, $p = 0.004$ for SP at 24 months).

Table II. Procedural data of patients

Parameter	n (%), (min.–max.)
Access site (n = 103):	
Femoral retrograde	64 (62.1)
Additional accesses	39 (30.1)
Contralateral femoral retrograde, crossover	31 (30.1)
Brachial, antegrade	8 (7.8)
Target lesion (n = 103):	
CIA	54 (52.4)
EIA	22 (21.4)
CIA + EIA	27 (26.2)
Lesion length [mm]:	
CIA	50 (17–118)
EIA	49 (17–62)
CIA + EIA	42 (25–58)
Stent types:	
CIA	
BMS	72 (69.9)
CS	9 (8.7)
EIA:	
SES	42 (40.8)
BMS	5 (4.9)
CS	2 (1.9)
Mean stent diameter [mm]:	
CIA	8.28 ± 0.8
EIA	7.52 ± 0.8

CIA – common iliac artery, EIA – external iliac artery, BMS – bare metal stent, CS – cover stent, SES – self-expandable stent

Table III. Peri- and post-procedural complications and procedural duration of patients, $p < 0.001$

Complication or duration	n (%)
Peri-procedural complication:	
Dissection	5 (4.8)
Rupture	1 (0.97)
Distal embolization	2 (1.92)
Post-procedural complication:	
Pseudoaneurysm	2 (1.96)
Hematoma	4 (3.93)
Mean procedural duration (min):	
Simple group	43 ± 14.8
Complex group	58.5 ± 23.4

Lesions with severe stenosis or occlusion of IIA had inferior primary and secondary patency at 24 months when compared with lesions that had no or non-significant stenosis in IIA (PP at 24 months 70% vs. 93%, $p = 0.001$, SP at 24 months 87% vs. 98%, $p = 0.02$). Subgroup analysis in patients with severe stenosis or occlusion of IIA also revealed that these differences in primary patency at 24 months were more significant in CIA and CIA + EIA lesions compared with EIA only (85% and 53% vs. 100%, $p = 0.04$). However, we did not observe these significant differences in secondary patency ($p = 0.70$).

Lesions combined with ipsilateral infra-inguinal PAD also have significantly lower primary and secondary patency rates at 24 months when compared with healthy infra-inguinal peripheral arteries (66% vs. 93%, $p < 0.001$ for PP at 24 months, 83% vs. 98%, $p = 0.002$ for SP at 24 months). Primary and secondary patency rates are shown in Table IV.

During follow-up, significant in-stent restenosis or occlusion was observed in 13 (6.9%) lesion. Re-intervention in the complex AIOD group was more frequent ($p < 0.001$).

Eleven lesions (10.7%) which needed re-intervention were treated percutaneously either with POBA (7.8%, $n = 8$) or BMS (2.9%, $n = 3$). Due to unsuccessful re-intervention, 2 (2.1%) patients were scheduled for surgery. Patients who had lesion length more than 81 mm tended to undergo re-intervention ($p = 0.002$).

Postprocedural complication was observed in 6 (6.5%) patients. In 2 patients pseudoaneurysm and in 4 patients significant groin hematoma was detected. In both patients with pseudoaneurysm successful ultrasound-guided compression therapy was performed. The groin hematomas did not

have pseudoaneurysm formation and were managed conservatively.

Median duration of hospital stay was 1 day (1–13), and subgroup analysis revealed no significant differences between AIOD groups ($p = 0.22$). Median total cost for interventions was 1125 dollars (875-2950). In one patient with CLI on initial admission, unplanned amputation was performed (1.1%). No procedural or early mortality was detected during follow-up. Overall mortality was 3% (Figure 1).

Discussion

In this study, we investigated our mid-term results of AIOD, and compared outcomes of 103 lesions according to their differences in TASC categories and procedural properties and strongly focused on lesion characteristics which may affect the patency. Immediate technical success was achieved in 98.1%. Overall primary and secondary patency rates at 24 months were 85.1% and 94.1%, respectively, which demonstrate comparable results to open surgery [11, 12].

TASC classification was revised in 2007 to give more consistent recommendations for treatment approaches of AIOD, but there are still some gaps [3, 13, 14]. Endovascular treatments is mostly recommended for TASC A and B lesions while surgical treatment was recommended for patients who had complex lesions classified as TASC C and D lesions. The surgical treatment of AIOD provides good long-term outcomes, but perioperative morbidity has been far from negligible [15]. Therefore, ET in complex lesions gained attention with developing technologies and with the growing experiences, and recent results started to go in favor of ET [16, 17]. In addition, regardless of

Table IV. Primary and secondary patency at the 24 month

Parameter (%)	Primary patency	Secondary patency
Overall	85.1	94.1
Simple Group	93	98
Complex Group	63	82
<i>P</i> -value	< 0.001	0.001
EIA	84	94
CIA	94	100
CIA+EIA	67	82
<i>P</i> -value	0.002	0.004
IIA occlusion or stenosis –	93	98
IIA occlusion or stenosis +	70	87
<i>P</i> -value	0.001	0.02
Concomitant infrainguinal PAD –	93	98
Concomitant infrainguinal PAD +	66	83
<i>P</i> -value	< 0.001	0.002

CIA – common iliac artery, EIA – external iliac artery, IIA – internal iliac artery, PAD – peripheral artery disease

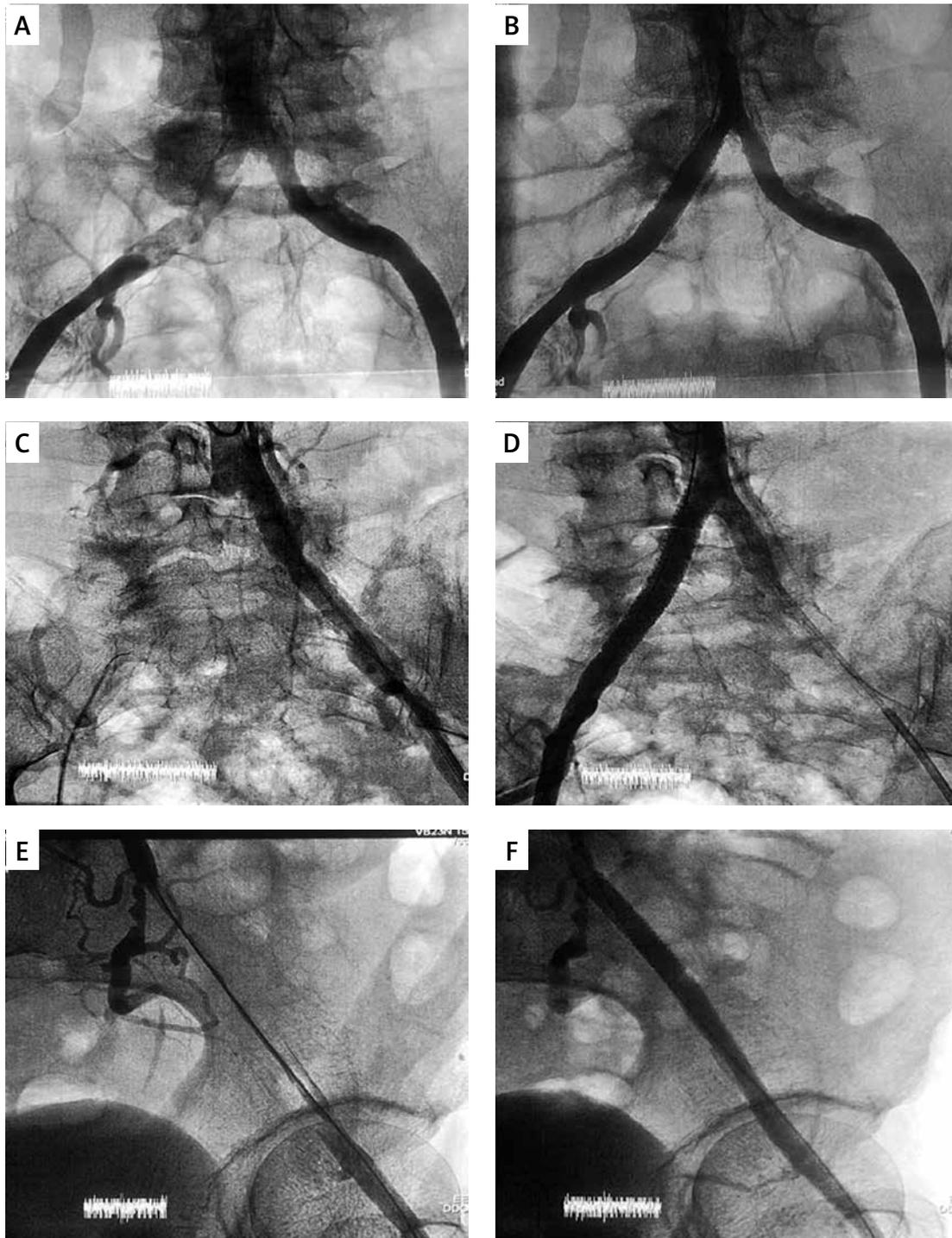


Figure 1. **A** – Retrograde angiography of right common iliac artery (CIA) showing chronic total chronic occlusion of highly calcified common iliac artery, using a right femoral artery approach. **B** – Final angiogram; lesion was treated with balloon expandable stent. **C** – Chronic total occlusion of common and proximal external iliac arteries. **D** – Final angiography; lesion was treated with 2 balloon expandable stents. **E** – Chronic total occlusion of highly calcified common iliac artery. **F** – Final angiography; lesion was treated with self-expandable stent

the success, duly performed procedures will not adversely affect the success of the subsequent surgical interventions. Therefore, similar to most centers, the ET approach has become the first-line treatment option for almost all AIOD [18]. In parallel, our study revealed that ET can be performed

safely and with a high level of technical success. Although there are studies showing better technical success rates in complex lesions compared with simple AIOD, complex AIOD lesions are usually expected to be more challenging compared with simple ones [17, 19, 20]. Accordingly, in our

study, the complex AIOD group had a lower level of technical success, which is similar to many previous studies [21-23]. The most common reason for technical failure was inability to cross the CTO segment, including inability to break the proximal or distal cap of the occlusion and reentry. Proximal access combined with retrograde access has been emphasized in several studies as a solution [21, 24]. Similarly, in the current study, when the ipsilateral retrograde approach was not successful, combined alternative approaches and CTO catheters were used to resolve the problem. Nevertheless, surgery has been successfully performed in all of our patients whose ET failed.

The overall primary and secondary patency of the CTO lesions reached 85.1% and 94.1%, respectively. Subgroup analysis showed significant differences in primary and secondary patency between simple and complex AIOD groups. Outcomes are in accordance with many studies concluding that complex TASC lesions have lower patency rates [21, 25-27]. In contrast, there are also studies showing similar results for different TASC categories [20, 28]. We think that these differences in studies may be associated with the limitations of TASC classification in assessing lesion severity. It is emphasized that lesion severity and extension are more prominent than in the TASC classification. In our study CTO or mixed type lesions were more commonly seen in the complex TASC group and it seems that the combination of lesion length with CTO in the complex TASC group tends to sustain the patency in the midterm.

Compared with the CIA, the EIA has lower patency rates in ET due to smaller diameter and more exposure to stress during movement. In our study, EIA lesions were more common in the complex AIOD group, which may also have affected our outcomes [29]. However, there are also studies showing no differences in patency between CIA and EIA [30, 31].

Another factor which affects our midterm patency rates may be the severe stenosis or occlusion of IIA. In our study, we observed lower primary and secondary patency rates at 24 months in patients with IIA involvement. Subgroup analysis in patients with IIA involvement revealed that this difference was more evident in interventions including the CIA and CIA + EIA. The patency of the intervention can be affected by the condition of the target outflow vessel, which has generally been regarded as a poor prognostic factor if outflow vessels are affected. An increase in the number of affected vessels may worsen the patency. Therefore it is not surprising as CIA + EIA lesions with affected IIA had worse patency when both major outflow vessels of the CIA were affected [32]. In parallel with our study, success rate in the

midterm can also be negatively affected by the presence of concomitant infra-inguinal lesions [8].

Another controversial issue is which treatment approach should be applied, primary stenting or selective stenting. All patients in our cohort were treated with primary stenting, and this approach is supported by recent studies [26, 33]. Although the DUTCH trial showed that selective iliac artery stenting was as effective as primary stenting, complex AIOD patients were mostly excluded from this trial [34]. Therefore, primary stenting is not only regarded as more advantageous in patency rates, but also in periprocedural complications including distal embolization and dissection when compared with balloon angioplasty alone [3, 8].

Morphology of the vessel and the location of the lesion are crucial for selecting the stent type. The BMS is superior in calcified lesion. Because of its greater radial force, recoil incidence can be lowered with BMS. Although radial force helped to reduce recoil incidence in calcified lesions, in non-calcified lesions radial force may cause an increase in the circumferential stress, which may lead to neointimal hyperplasia [35].

The EIA has a more tortuous course than the CIA, where SES can be more advantageous because of their high capability of flexibility. Therefore, in our daily routine, BMS were mostly used in the CIA and highly calcified short EIA lesions, and SES were mostly used in the EIA. CS were reserved for aneurysms, and iatrogenic complications due to their costs and low availability. Compared with BMS, mean stent diameter in SES was smaller and the mean length of lesions in which they were used was longer. Therefore, it is not surprising to find out that the BMS stents had better primary and secondary patency rates at 24 months. These results can be misleading because homogeneous groups could not be created. Here, we think that the effect of lesion characteristics on patency will be more significant than the stent type.

There are studies indicating that stent deployment without predilatation will reduce the incidence of distal emboli [36]. In our study, predilatation was performed only to facilitate the stent delivery in patients with CTO or near occlusion. The diameter of the balloon which is used during predilatation was far below the native vessel diameter and no periprocedural complication was observed due to predilatation. However, in our cohort, in a patient with severe stenosis treated without predilatation, the distal tip of the SES delivery system was separated from the system during crossing the severe stenosis in the EIA.

Our postprocedural complication rate was 5.9% (6 patients). Pseudoaneurysm emerged in two patients and it was treated with ultrasound guided compression, which has been shown to be an ef-

fective first-line treatment method in this issue and has been used for many years [37]. Also, four patients who had an inguinal hematoma were treated with a conservative approach and there was no need for surgery in any patient.

In-stent restenosis is the most important factor that affects mid and long-term patency for clinical success in patients with AIOD during the follow-up. In our study, in-stent restenosis was significantly higher in the complex AIOD group. Many factors have been identified for the cause of in-stent restenosis, including residual stenosis, stent fracture and stress, multiple stenting, long length of stent and lesion, diabetes and neoplasms [38-40]. Diabetes and its complications are important therapeutic problems in patients with vascular disease [41]. In the current study most of our patients had diabetes, and therefore high rates of restenosis can be expected in such a cohort. Although in our cohort the rate of reintervention due to restenosis or occlusion is high compared to the results of surgery, the reintervention in ET will be much easier, faster and more comfortable for the patient [42].

There are several limitations to our study, including non-randomization, retrospective design, single-center cohort, and short follow-up.

In our study, it was found that the primary stenting in patients who had AIOD had satisfactory outcomes with high immediate success, low complication rates and comparable midterm outcomes with surgery. Nonetheless, to confirm these favorable results, multicenter, randomized, controlled studies with larger sample size are needed.

Acknowledgments

Both authors contributed equally to this manuscript: Mehmet Atay, Onur Saydam.

Conflict of interest

The authors declare no conflict of interest.

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