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Peripheral Arterial Occlusive Disease

Endovascular and Hybrid Revascularization for Complicated Aorto-Iliac Occlusive Disease: Short-Term Results in Single Institute Experience

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Background: Treatment for extensive aortoiliac occlusive disease (AIOD) includes endovascular interventions, hybrid procedures and surgical reconstruction. This study evaluated the short-term outcomes of endovascular and hybrid procedures in patients with Trans-Atlantic Inter-Society Consensus II (TASC-II) D AIOD lesions.

Materials and Methods: From January 2013 to June 2015, 41 patients with TASC-II D AIOD lesions who underwent revascularization at our institute were retrospectively included. Nineteen underwent endovascular procedures and 22 underwent hybrid procedures with a postoperative surveillance program for at least 1 year. Patient demographics and short-term outcomes were analyzed.

Results: The procedural success rate in all patients was 100%. The accumulative postoperative complication rate was 20.2%, and the major complication was acute kidney injury (14.6%). The time of freedom from target lesion revascularization was 18.9 months. The primary patency rates in the endovascular group were 89.5% and 84.2% at 1 and 2 years, respectively, compared to 95.5% at 1 and 2 years in the hybrid group; however, the difference was not significant (p = 0.234). The secondary patency rates were 94.7% and 93% at 1 and 2 years, respectively, in the endovascular group, and 95.5% and 94% at 1 and 2 years, respectively, in the hybrid group; however, the differences was not significant (p = 0.916).

Conclusions: Our study revealed that endovascular and hybrid procedures are favorable treatment choices for patients with TASC-II D AIOD lesions. In patients with multilevel steno-occlusive lesions, hybrid procedures improved distal runoff flow and reduced the complexity of endovascular procedures.

Key Words: Aorto-iliac occlusive disease • Hybrid operation • TASC-II D lesion

INTRODUCTION

Aortoiliac occlusive disease (AIOD) is a multilevel arterial occlusive disease that frequently leads to multiple chronic symptoms such as impotence, claudication, critical limb ischemia, and pelvic ischemia. Therefore, adequate revascularization may improve a person's quality of life.

According to the 2007 Trans-Atlantic Inter-Society Consensus II (TASC-II) guidelines for the management of peripheral arterial disease, AIOD is categorized into type D lesions, for which reconstructive surgery is the treatment of choice rather than endovascular therapy.[1] Open surgical management, including anatomical bypass and endarterectomy, has been shown to provide improved procedural success and long-term patency.[2] Nevertheless, in the past ten years, interventional techniques and medical instruments have evolved considerably, and some studies have reported that the outcomes of endovascu-

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lar therapy for extensive AIOD lesions are not inferior to those of surgical reconstruction.[3-5] In addition, a shorter length of hospital stay as well as lower complication and 30-day mortality rates have been reported after endovascular therapy compared with surgical revascularization.[5]

However, for complicated cases, surgical revascularization remains an important treatment option to ensure a positive distal runoff flow.[7,8] A hybrid procedure that combines both endovascular and surgical interventions can provide satisfactory distal arterial runoff flow and balance treatment efficacy with minimized perioperative complications. Chang in 2008 and Maurizio in 2014 reported that hybrid treatments are an effective method in selected patients;[9,10] however, adequate evidence supporting the superiority of hybrid procedures, particularly for extensive AIOD treatment, has yet to be established. Therefore, the present study was conducted to compare the short-term outcomes of endovascular and hybrid treatments in patients with Trans-Atlantic Inter-Society Consensus II (TASC-II) D AIOD lesions.

MATERIALS AND METHODS

Patient population

From January 2013 to June 2015, 44 patients with TASC-II D aortoiliac occlusive lesions who underwent revascularization at our institute were reviewed retrospectively. Three patients who underwent only open reconstructions were excluded because of an inadequate number of cases for statistical analysis.

Table 1 lists the demographic characteristics and risk factors. Of the 41 patients, 19 (46%) and 22 (54%) received endovascular and hybrid treatments, respectively. The median age of the study population was 68 years (42-89 years), and 82.9% of the patients were men. Regarding the common risk factors for and underlying diseases of AIOD, no statistical differences were observed between the endovascular and hybrid treatment groups; however, the majority of the study population smoked, had hypertension and diabetes mellitus (63.4%, 65.8%, and 65.8%, respectively).

Table 2 shows the clinical symptoms of the patients. According to the Rutherford grading scale, eight patients (19.5%) had ischemic rest pain (category 4) and 33 patients (80.5%) experienced minor or major tissue loss (categories 5 and 6). The two groups did not exhibit significant differences in symptom severity.

Endovascular and hybrid procedures

Table 3 presents the characteristics of the endovascular and hybrid procedures. All procedures were performed under general anesthesia. Before surgical management, the surgical plan was individually designed according to preoperative lower limb computed tomographic angiography (CTA). Patients with highly severe multilevel steno-occlusive lesions were more likely to undergo a hybrid procedure than an endovascular procedure.

Table 1. Demographic characters and risk factors

	Total (N = 41)	Hybrid group (N = 22)	Endovascular group (N = 19)	p value
Age, median (range)	68.0 (42-89)	66.0 (42-89)	70.0 (51-82)	.071
BMI	24.5 (19.2-28.7)	24.8 (21.6-28.7)	23.5 (19.2-25.7)	.077
Male sex, n (%)	34.0 (82.9)	19.0 (86.3)	15.0 (78.9)	.499
Smoking	26.0 (63.4)	11.0 (50)	15.0 (78.9)	.185
Hypertension	27.0 (65.8)	18.0 (89.8)	9.0 (47.3)	.059
Diabetes mellitus	21.0 (65.8)	8.0 (36.3)	13.0 (68.4)	.214
Hyperlipidemia	16.0 (39)	9.0 (40.9)	7.0 (36.8)	.522
CVA	3.0 (7.31)	2.0 (9.1)	1.0 (5.2)	.990
CAD	18.0 (43.9)	10.0 (45.4)	8.0 (42.1)	.991
Carotid stenosis (> 75%)	11.0 (26.8)	5.0 (22.7)	6.0 (31.5)	.725
COPD	16.0 (39)	9.0 (40.9)	7.0 (36.8)	.991
Acute kidney injury*	10.0 (24.3)	6.0 (27.2)	4.0 (21.1)	.291
Gastroduodenal ulcers	9.0 (21.9)	7.0 (31.8)	2.0 (10.5)	.140

BMI, body mass index; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; CVA, cerebral vascular accident; SD, standard deviation.

* Acute kidney injury was classified according to RIFLE criteria.

Table 2. Clinical presentations according to Rutherford classification

Rutherford		Total [N = 41 (%)]	Hybrid group [N = 22 (%)]	Endovascular group [N = 19 (%)]	p value
Category	Presentations				
4	Ischemic rest pain	8.0 (19.5)	5.0 (22.7)	3.0 (15.8)	.702
5	Minor tissue loss	20.0 (48.7)	11.0 (50)	9.0 (47.4)	.998
6	Major tissue loss	13.0 (31.7)	6.0 (27.3)	7.0 (36.8)	.737

Table 3. Characteristic of endovascular and hybrid procedures

Procedural success, n (%)	41 (100)
Endovascular procedure, n (%)	
Aorta to uni-iliac stenting*	3 (7.3)
Aorta to bi-iliac stenting	
Preservation of IIA, unilateral	14 (34.1)
Preservation of IIA, bilateral	4 (9.8)
No preservation of IIA	20 (48.8)
SFA remote stenting	18 (43.9)
Recanalization route	
Retrograde using transfemoral access alone	3 (7.3)
Antegrade using transbrachial access alone	5 (12.2)
Both transfemoral and transbrachial access	33 (80.5)
Associated open procedure, n (%)	
Common femoral endarterectomy	22 (53.6)
Femoral-femoral bypass	3 (7.3)

IIA, internal iliac artery; SD, standard deviation; SFA, superficial femoral artery.
* Internal iliac artery was preserved in all patients.

The hybrid procedure involved combining iliac stenting with femoral artery endarterectomy with or without femoral-to-femoral bypass, and was designed to treat concomitant common femoral artery disease and achieve adequate distal blood flow runoff, particularly to the profund a femoral artery. Femoral endarterectomy was occasionally used to resolve a difficult puncture on a severely calcified artery, followed by direct puncture on the prosthetic material for the endovascular intervention.

The endovascular procedure was initiated with a transbrachial or transfemoral puncture. In this study, most endovascular recanalization procedures were performed using simultaneous antegrade transbrachial and retrograde transfemoral approaches in 33 patients (80.5%). Floppy wires (0.035 and 0.018 in) and low-profile catheters were used in all procedures. Once the stenotic or chronic total occlusion (CTO) lesions of bilateral iliac arteries had been recanalized subintimally or intraluminally, polytetrafluoroethylene (PTFE)-covered, self-expanding nitinol stents (Viabahn, W. L. Gore and Associates Inc., Flagstaff, AZ, USA) were selected and deployed in a parallel configuration.

Follow-up protocol

All patients were followed at our outpatient department within 1 month after surgery and every 3 months thereafter. The follow-up program included the assessment of symptoms and physical examinations every 3 months, ankle-brachial index (ABI) measurements, and lower limb CTA at 6, 12 and 24 months postoperatively. If restenosis was observed, angiography with additional interventions was arranged.

All patients received dual antiplatelet therapy (aspirin, 100 mg; clopidogrel, 75 mg) at 12 months after the procedure, followed by at least one antiplatelet agent thereafter. However, patients with severe occlusive lesions or relatively poor distal outflow were treated with lifelong dual antiplatelet therapy.[12]

Statistical analysis

The clinical characteristics of the study population were summarized by descriptive statistics. Because of a relatively small sample size, the data were nonnormally distributed; therefore, nonparametric statistical tests were performed. The two groups were compared using Fisher's exact test and the Mann-Whitney U test for categorical and continuous variables, respectively. Short- and midterm patency rates were determined using Kaplan-Meier analysis. Individual differences were considered to be statistically significant at $p < 0.05$. All statistical analyses were performed using MedCalc for Windows (version 16.8, MedCalc Software, Ostend, Belgium).

RESULTS

Short-term results

A procedural success rate of 100% was achieved in

all patients, with a limb salvage rate of 97.5%. Two patients (4.9%; one each in the endovascular and hybrid treatment groups) underwent major amputation due to critical limb wound deterioration.

The mean ABI values of the bilateral limbs increased significantly after successful interventions in all patients (from 0.37 to 0.92, p = 0.001), and no significant differences were observed between the two groups. In addition, the clinical symptoms of all patients were relieved after the interventions.

Three patients (7.3%; endovascular treatment group, n = 1; hybrid treatment group, n = 2) experienced intraoperative complications due to iliac rupture; all of whom were immediately treated with covered stent deployment without sequelae. Furthermore, no perioperative flow-limiting intraluminal dissection or distal artery embolization was observed.

Postoperative short-term complications (within 30 days after the surgical intervention) included acute kidney injury (classified according to the RIFLE criteria) (n = 6, 14.6%), acute myocardial infarction (n = 3, 7.3%), and stroke (n = 2, 4.9%). The accumulative complication rate in the study population was 20.2%. The two groups did not exhibit significant differences in postoperative short-term complications (all p > 0.05). However, the hybrid treatment group had a higher rate of acute kidney injury than the endovascular treatment group (22.7% vs. 5.3%, p = 0.190), probably because of more intraoperative contrast usage in highly extensive lesions. Acute postoperative colon ischemia was not observed in any of the patients, even though only seven patients (17.1%) had preserved bilateral internal iliac arteries during revascularization.

Regarding mortality, one patient (2.4%) in the hybrid treatment group died due to severe sepsis induced by a chronic ulcerative wound infection, and one patient (2.4%) in the endovascular treatment group died from acute myocardial infarction attacks during hospitalization. Table 4 presents the complications and comorbidities in detail.

Mid-term results

The median follow-up duration of all patients was 24 months (range 1-24 months). Of the 41 patients, four (9.8%) underwent target lesion revascularization (TLR; hybrid treatment group, n = 1, 4.5%; endovascular treatment group, n = 3, 15.8%; p = 0.321). The time of freedom from TLR was 18.9 months in all patients, and no significant difference was observed between the endovascular and hybrid treatment groups (18.6 vs. 19.1, p = 0.417) (Table 5).

The cumulative postoperative primary patency rates in all patients were 91.2% at 1 month and 88.2% at 6 months as well as 1 and 2 years. The postoperative secondary patency rate in all patients was 95.8% at 1 and 6 months as well as 1 and 2 years.

The postoperative primary patency rates in the endovascular treatment group were 89.5% at 1 month and 84.2% at 6 months as well as 1 and 2 years, compared to 95.5% in the hybrid treatment group at 1 and 6 months as well as 1 and 2 years (Figure 1). However, the two groups did not exhibit a significant difference (p = 0.234).

The cumulative postoperative secondary patency rates in the endovascular and hybrid treatment groups were 94.7% and 95.5%, respectively, at 1 and 6 months as well as 1 and 2 years (Figure 2). However, no significant difference was observed between the two groups (p = 0.916).

The mid-term postoperative complication of stent edge restenosis was observed in only one patient (2.4%)

Table 4. Perioperative complications and comorbidities

	Total [N = 41 (%)]	Hybrid group [N = 22 (%)]	Endovascular group [N = 19 (%)]	p value
Iliac rupture	3 (7.3)	2 (9.1)	1 (5.3)	.995
AMI	3 (7.3)	2 (9.1)	1 (5.3)	.995
Stroke	2 (4.9)	1 (4.5)	1 (5.3)	.998
Acute kidney dysfunction	6 (14.6)	5 (22.7)	1 (5.3)	.190
Malperfusion of bowel	0 (0)	0 (0)	0 (0)	
Major amputation	2 (4.9)	1 (4.5)	1 (5.3)	.998
PAD related mortality	1 (2.4)	1 (4.5)	0 (0)	.997
All-cause mortality	2 (4.9)	1 (4.5)	1 (5.3)	.998

AMI, acute myocardial infarction; ISR, in-stent restenosis; PAD, peripheral artery disease.

Table 5. Surgical outcomes

	Total (N = 41)	Hybrid group (N = 22)	Endovascular group (N = 19)	p value
Follow-up duration, median (range)	24 (1-24)	12 (1-24)	24 (1-24)	
TLR, n (%)	4 (9.8)	1 (4.5)	3 (15.8)	.321
Time to free from TLR (month), mean (range)	18.9 (1-24)	19.6 (1-24)	18.1 (1-24)	.417
Pre-op ABI				
Right	0.37 (0.21-0.49)	0.37 (0.22-0.47)	0.36 (0.21-0.49)	.380
Left	0.37 (0.13-0.49)	0.35 (0.13-0.49)	0.41 (0.34-0.48)	.049
ABI increase*				
Right	0.55 (0.23-0.76)	0.52 (0.23-0.71)	0.60 (0.46-0.76)	.057
Left	0.54 (0.22-0.80)	0.51 (0.22-0.70)	0.57 (0.34-0.80)	.225
Post-op ABI (6 months)				
Right	0.92 (0.65-1.07)	0.90 (0.65-1.07)	0.94 (0.68-1.05)	.302
Left	0.91 (0.65-1.10)	0.89 (0.65-1.04)	0.94 (0.67-1.10)	.092
Post-op ABI (12 months)				
Right	0.94 (0.84-1.04)	0.93 (0.84-1.02)	0.95 (0.84-1.04)	.205
Left	0.96 (0.86-1.09)	0.98 (0.87-1.05)	0.95 (0.86-1.09)	.104

ABI, ankle-brachial index; OP, operation; SD, standard deviation; TLR, target lesion revascularization.
* ABI increase level within 3 months after surgery.

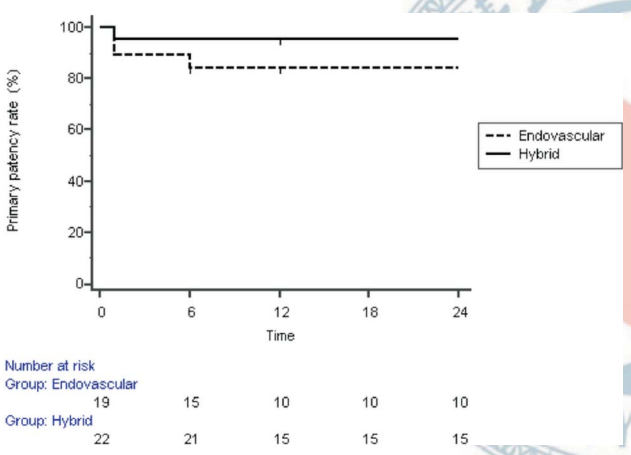

Figure 1. *Kaplan-Meier curves for the primary patency rates of the endovascular and hybrid treatment groups.*

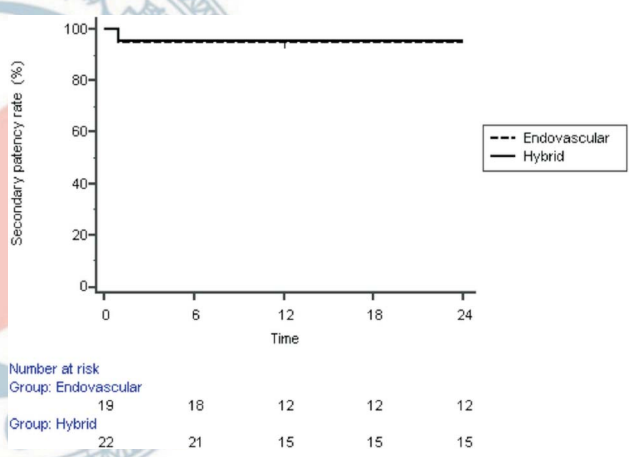

Figure 2. *Kaplan-Meier curves for the secondary patency rates of the endovascular and hybrid treatment groups.*

in the endovascular treatment group; this patient was successfully treated with covered stent extension deployment over the lesion. No significant stent migration or fracture was observed in any of the patients during the 2-year follow-up period.

DISCUSSION

As recommended by the TASC-II guidelines in 2007,[1] open surgery used to be the optimal treatment choice for extensive aortoiliac (TASC-II C and D) lesions, however endovascular interventions have since been more preferred. Hans and colleagues[8] in 2008 were the first to compare the outcomes of endovascular and surgical interventions in patients with TASC-II C and D lesions. They reported that the endovascular intervention group had a significant reduction in postoperative morbidity and length of hospital stay; however, these patients had a lower 2-year primary patency rate than the surgical intervention group (69% vs. 93%). Nevertheless, due to increasing operator experience, advanced operative techniques, and the development of materials and devices, endovascular interventions have yielded favorable outcomes of primary and sec-

ondary patency.[3-6] A systematic review and meta-analysis study in 2013[5] on the management of all types of AIOD reported improved cumulative primary patency rates of 86%, 80%, and 71% in the endovascular cohort at 1, 3, and 5 years, respectively. In the present study, the 2-year primary and secondary patency rates were 88% and 95% after successful endovascular techniques, providing noninferior evidence on the management of extensive AIOD with endovascular interventions.

Nevertheless, longer and severely calcified steno-occlusive lesions are frequently observed in extensive AIOD. To achieve optimal treatment outcomes, ahybrid procedure ensures a positive distal arterial runoff flow and likely improves the long-term patency rates. Chang and colleagues[9] in 2008 performed a hybrid procedure with femoral artery endarterectomy and simultaneous iliac stenting to treat occlusive disease, and they reported acceptable 5-year primary, primary-assisted, and secondary patency rates of 60%, 97%, and 98%, respectively. Furthermore, Maurizio et al.[10] reported in 2014 primary patency rates at 1, 2, and 3 years after hybrid treatment of 93.3%, 90.2%, and 86.6%, respectively, with no significant differences between the hybrid and endovascular treatment approaches (p = 0.14). In our study, the hybrid procedure yielded an excellent 2-year primary patency rate; however, the difference between the two groups was not significant (96% vs. 84%, p = 0.23). Piazza and colleagues[13] conducted a retrospective study in 2011, and reported that the 30-day morbidity (3% vs. 5%, p = 0.55) and mortality (1.1% vs. 1.4%, p = 0.85) rates were equivalent in the hybrid and open reconstruction groups, and that no significant difference was observed in their 3-year primary patency rates (91% vs. 97%, p = 0.29).

Endovascular intervention alone is sufficient to treat aortoiliac lesions with a patent distal outflow; however, a hybrid procedure might be considered for the treatment of severe steno-occlusive lesions including common femoral artery disease to provide a favorable distal runoff flow and simplify the stenting procedure, particularly in patients with a higher risk of complete reconstructive surgery.

Major factors influencing long-term patency include the characteristics of the implanted stents and the configuration of stent deployment. For severe aortoiliac steno-occlusive lesions, the clinical efficacy of covered stents compared with that of bare-metal stents remains debatable. Humphries et al.[14] in 2014 reported that balloon-expandable bare-metal stents had a significantly higher patency rate than balloon-expandable covered stents for the management of all four AIOD types. In contrast, in 2016, Hadjibendah and colleagues[15] reported that although covered stents did not significantly improvethe primary patency rate, they were associated with a higher postoperative ABI and a lower reintervention rate (odds ratio, 0.19). Nevertheless, by dividing patients with AIOD into different subgroups based on the TASC-II classification, the prospective multicenter Covered versus Balloon Expandable Stent Trial demonstrated that covered and bare-metal stents yielded similar results in the treatment of TASC-II B lesions; although covered stents had more favorable long-term patency in the management of TASC-II C and D lesions.[15,16] Moreover, in multivariate analysis, covered stents showed significant survival benefits compared with bare-metal stents in TASC-II C and D lesions (hazard ratio, 8.239).[16] In the present study, all stents were PTFE-covered, self-expandable nitinol stents and they yielded favorable patency outcomes. Only one patient experienced stent edge stenosis at 1 year after endovascular treatment, and was successfully treated with covered stent extension deployment over the lesion.

The other factor influencing patency outcomes is configuration of stent deployment. The parallel kissing stent configuration has been frequently used for the management of extensive AIOD since its introduction in 1991.[18] However, the Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB) technique was developed in 2013 to potentially provide improved long-term patency outcomes by overcoming the anatomical and physiological disadvantages of kissing stents.[19,20] Nevertheless, compared with the kissing stent configuration, the CERAB technique has a lower cost-effectiveness, demonstrates a higher failure rate of contralateral limb recanalization, and involves a major sacrifice of collateral circulation from the aorta, which is important for colono-rectal perfusion in TASC-II D AIOD lesions, after the deployment of aortic cuff stent grafts. Furthermore, compared with the CERAB technique, the kissing stent configuration is more straight forward, easier, cheaper, and more successful when executed using an antegrade or retrograde approach. In our study, all patients were treated using the parallel kissing stent configuration with

covered stents, and the patency results were not inferior to those reported in a retrospective study on the treatment of TASC II D lesions using the CERAB technique (1-year primary patency rate: 88.2% vs. 87.3%; 2-year primary patency rate: 88.2% vs. 82.3%).[21] However, long-term patency should be evaluated in future studies.

Our study has some limitations. First, because of the retrospective study design, the results are likely to be affected by selection bias. Second, some data were unavailable, and few patients were followed up for less than 2 years until the end of the study period. Third, because of the relatively rare cases of TASC-II D lesions in clinical practice, some statistical calculations were confined to a small number of patients and may be overestimated or underestimated. Nevertheless, this study provides real-world data for the clinical management of extensive AIOD lesions, which have been less commonly reported due to their rarity and higher surgical complication and failure rates.

CONCLUSIONS

In conclusion, the present study results show that endovascular and hybrid procedures are favorable treatment choices for patients with extensive AIOD. The endovascular approach had a high procedural success rate and low risk of surgical complications. However, in the patients with multilevel steno-occlusive and severely calcified lesions involving the common femoral artery, the hybrid approach was beneficial in ensuring a positive distal arterial runoff flow, reducing the complexity of endovascular stenting procedures, and eliminating the higher risk of open surgical reconstructions. To select an appropriate approach, adequate and careful preoperative evaluation and planning are necessary.

CONFLICT OF INTEREST

None.

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