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Original Article

Outcomes of Unibody Bifurcated Endograft and Aortobifemoral Bypass for Aortoiliac Occlusive Disease

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Purpose: We compared the outcomes between the total endovascular approach using a unibody bifurcated aortoiliac endograft and the gold standard aortobifemoral bypass (ABF) surgery for the management of extensive aortoiliac occlusive disease (AIOD).

Materials and Methods: This retrospective observational study compared the outcomes of endovascular technique with unibody bifurcated endograft (UBE) using the Endologix AFX unibody stent-graft and a standard surgical approach (ABF) in the management of AIOD based on patient records in Western Vascular Institute, Galway University Hospital, National University of Ireland. Procedural details and outcomes were documented to compare both groups.

Results: From January 2002 to December 2018, 67 patients underwent AIOD (20 UBE and 47 ABF). Both the ABF and UBE groups showed 100% immediate clinical and technical successes without 30-day mortality. There were no statistical differences in the overall survival and sustained clinical improvement between the bypass and the UBE groups; however, statistically significant differences were observed in 3-year freedom from re-intervention and amputation-free survival. Furthermore, the mean length of the intensive care unit (ICU) stay was significantly lower in the UBE group than that in the ABF group (0.75 days vs. 3.1 days, P=0.001).

Conclusion: Total endovascular reconstruction of AIOD is an alternative to invasive bypass procedures, with a shorter ICU stay.

Key Words: Arterial occlusive diseases, Endovascular procedures, Comparative study

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INTRODUCTION

Aortoiliac occlusive disease (AIOD) affects 7.2 million people in the United States alone, more commonly young patients [1]. The prevalence of AIOD in male patients under 60 years of age is approximately 112 per 100,000 person-years. Most patients with AIOD present with impotence and buttock and thigh claudication, which are distressing for young patients [1,2]. According to the Trans-Atlantic Inter-Society Consensus (TASC-II) document [3], surgical reconstruction with aorto-bi-iliac bypass grafting is the treatment of choice for extensive aortoiliac occlusive lesions

(TASC-II D), including bilateral occlusion of the common iliac arteries (TASC-II C) due to the favorable long-term patency rates following reconstruction. However, as open surgery is associated with considerable morbidity and mortality, especially in frail patients with significant comorbidities, there is a need for a safe alternative.

Multiple endovascular approaches have been utilized for the management of AIOD as an alternative, with varying levels of success. Kissing stents, first used in TASC II A and B lesions, have been increasingly being considered in TASC II C and D lesions. However, endovascular approaches are not devoid of complications and their association with higher restenosis rates and competitive flow between stents makes them challenging at times [4]. The covered endovascular reconstruction of the aortic bifurcation (CERAB) technique was developed in an attempt to overcome some of the anatomical and physiological disadvantages of kissing stents [5]. Alternatively, unibody bifurcated endograft (UBE) for the treatment of AIOD has several advantages as it can preserve the aortic bifurcation, avoid limb competition in the distal aorta, allow for future endovascular interventions, and protect against potentially fatal aortoiliac rupture in heavily calcified lesions [6].

This study compared the outcomes between the total endovascular approach using a UBE and the gold standard aorto-bi-femoral bypass (ABF) surgery in the management of extensive AIOD.

MATERIALS AND METHODS

1) Study design

This retrospective observational study compared the outcomes between endovascular treatments versus the standard surgical approach in the management of AIOD. We adhered to the guidelines for reporting on observational studies, as outlined by the Strengthening the Reporting of Observational Studies in Epidemiology statement [7].

2) Outcomes

Outcomes were reported according to the Society for Vascular Surgery (SVS) reporting standards for endovascular management of chronic lower extremity peripheral artery disease (PAD) [8].

Our primary endpoint was any major adverse limb event (MALE) and amputation-free survival. MALE included major amputation and reintervention and was defined as a revascularization intervention in patients, including major amputation above the ankle or any major vascular procedure and either reintervention or revision of the procedure in the index limb.

The secondary endpoints included: 1) immediate clinical, technical, and hemodynamic success rates; 2) 30-day morbidity, and any major adverse cardiovascular event (MACE), including myocardial infarction, stroke, and cardiovascular mortality; 3) 30-day all-cause mortality; 4) intensive care unit (ICU) and total hospital stays; 5) sustained clinical and hemodynamic improvement; 6) freedom from binary restenosis and re-intervention; and 7) overall survival, including amputee patients. MACE was defined as a composite of nonfatal stroke, nonfatal myocardial infarction, and cardiovascular death. Hemodynamic success was defined as an improvement in the ankle-brachial index (ABI) by more than 0.1. Clinical improvement was assessed using the Rutherford classification of chronic limb ischemia and defined as a Rutherford class reduction by one category [9].

3) Patients

All patients who underwent a procedure for AIOD from January 2002 to December 2018 at Western Vascular Institute, Galway University Hospital, National University of Ireland were reviewed. The diagnosis was confirmed with ABI and computed tomography angiography (CTA) scans. The patients were classified anatomically according to their TASC II classifications and clinically according to the Rutherford category [3]. Patients with concomitant abdominal aortic aneurysm (AAA) (defined as an aortic diameter >3 cm) were excluded from the study.

4) Data collection

Clinical, anatomical, and operative data were collected from a prospectively maintained database (Vascubase, Version 5.2; Consensus Medical Systems Inc., Richmond, BC, Canada). Any missing data were collected from our institutional patient administration system, picture archiving and communication system, and patients' clinical medical records.

5) Techniques

The patients were managed with either ABF or endovascular approach using the UBE; that is, Endologix AFX unibody stent-graft (EUSG) (Endologix LLC., Irvine, CA, USA). All ABF and UBE were performed under general anesthesia (GA).

The consulting vascular surgeon (SS) performed all the surgical and interventional procedures. This surgeon chose the intervention in consultation with multidisciplinary vascular teams after considering the patients' choice, associat-

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ed comorbidities, frailty, lesion location and characteristics, expected outcome, and quality of life.

6) Unibody bifurcated endograft

The unibody design avoids the need to cannulate the contralateral gate and allows for placement of the flow divider of the bifurcated component of the UBE system directly on the native aortic bifurcation. The techniques for delivery and deployment of the UBE device have been well described when treating AAAs [10]. For AIOD, we modified these steps to suit our objectives (Fig. 1). Preferentially, we inserted the device via the least-diseased iliac vessel, with or without pre-dilation. A French sheath was then advanced into the contralateral side to the level of the aortic bifurcation to protect the contralateral limb while being pulled down beyond the bifurcation and avoid snagging on the atheromatous and calcified plaque. In cases of crimping of the distal limb component, a balloon-mounted stent (Genesis stent; Cardinal Health, Dublin, OH, USA) was used to support the iliac limbs. In cases where the aortic atheroma extended above the level of the renal arteries, an uncovered Sinus-XL stent (OptiMed Medical Instruments GmbH, Ettlingen, Germany) was used for proximal aortic extension (Fig. 2).

7) Open procedures

All ABFs were performed according to surgical standards under GA [11], and using the transperitoneal approach in all

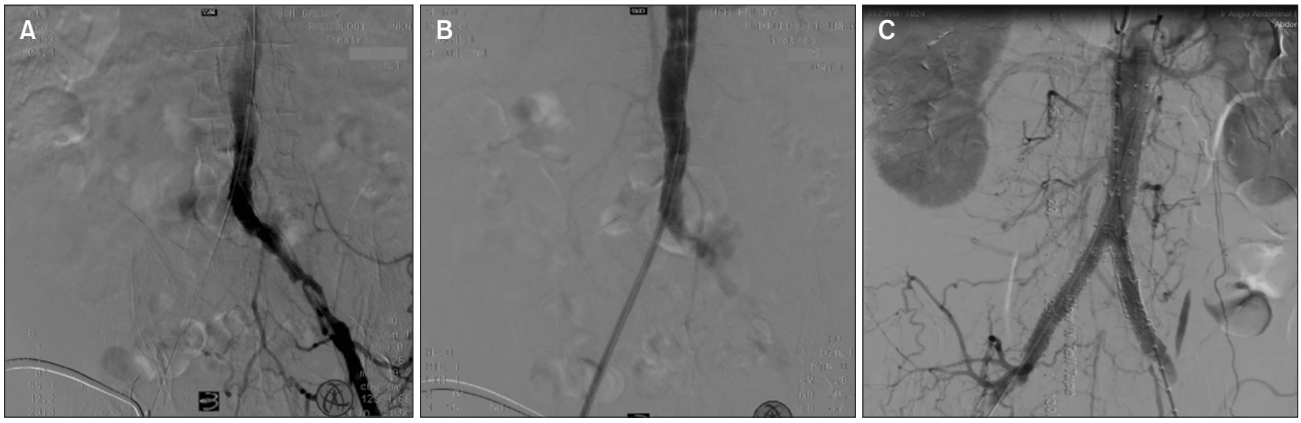

Fig. 1. Engage and protect for aortoiliac occlusive disease, showing preoperative angiogram (A), a 12-Fr sheath for protection of the contralateral limb during snaring (B), and a bilateral iliac balloon mounted 10×57 mm Palmaz Genesis stent (Cardinal Health) with a 26×40 mm Sinus-XL stent (OptiMed Medical Instruments GmbH) in the aorta (C).

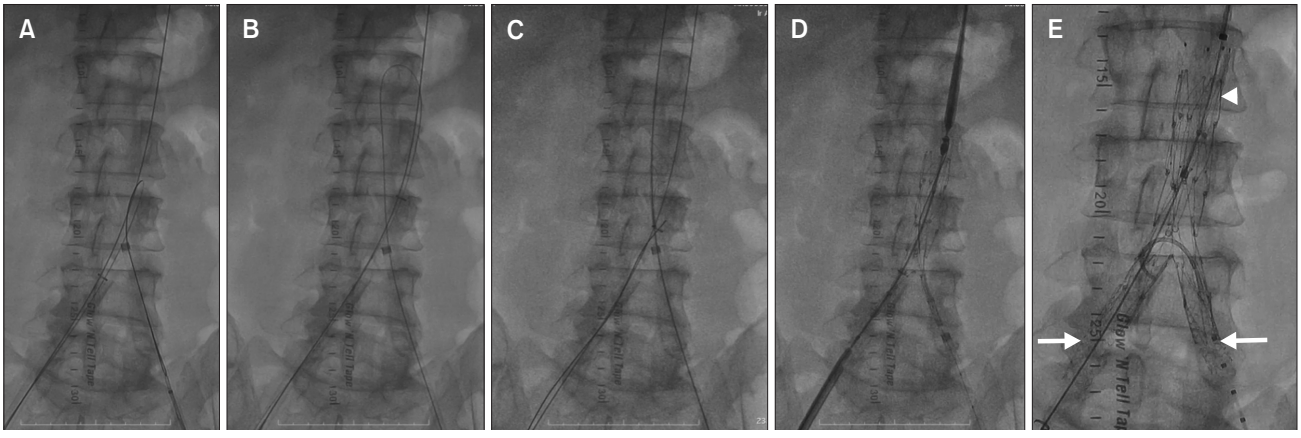

Fig. 2. Steps in the deployment, showing snaring of the wire of the contralateral limb (A), the introduction of the main body from the ipsilateral side (B), starting the graft deployment (C), final deployment (D), and Sinus-XL stent (OptiMed Medical Instruments GmbH) deployed in the aorta (arrow head) and Palmaz Genesis (Cardinal Health) peripheral balloon-expanding stent deployed in both common iliac arteries (arrows) (E).

cases using the Dacron graft.

8) Follow-up

All patients underwent an ABI assessment before discharge and were discharged on aspirin. They were followed up with an ABI and arterial duplex scan at 6 weeks and then every 6 months after that. If the ABI or duplex confirmed any abnormality or if the patient clinically complained of recurring symptoms, a CTA was performed.

9) Data analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA). Descriptive data were summarized as proportions or percentages for categorical variables and as means or medians for continuous variables. The univariate analyses were performed using a parametric test (Fisher's exact tests for discrete variables and Mann–Whitney U-tests for continuous variables) due to the limited numbers of samples. P-values<0.05 were considered statistically significant.

10) Ethical considerations

Ethical approval was sought and granted by Clinical Research Ethics Committee of Galway University Hospital (No. C.A. 1210).

RESULTS

Between 2002 and 2018, a total of 830 patients underwent revascularization for PAD. Among 67 (8.1%) with AIOD, 20 underwent an endovascular intervention using the UBE and 47 underwent open surgical repair in the form of an ABF (no aorto-bi-iliac-bypass). The baseline demographics, risk factors, and clinical presentation are shown in Table 1. The mean patient age was 68 years, with most patients being smokers and hypertensive. More than half of the patients (55.2%) had pain at rest (Rutherford IV) (Table 2).

All UBE cases were performed through surgical exposure of the main body side and a percutaneous approach for the contralateral limb. Six patients required endarterectomy of the common femoral artery and eight patients required additional self-expandable stents in the external iliac artery. The planned concomitant procedures included renal artery stenting and popliteal artery embolectomy due to preoperative distal embolization in one patient each. No other additional endograft or stenting was performed.

Six cases of superficial femoral artery (SFA) disease required intervention during the surgery, after UBE deployment; of these, five were treated endovascularly and one through the bypass. Similarly, 13 cases in the ABF group required extension of the ABF graft to the popliteal artery with silver Dacron due to concomitant TASC D SFA disease.

Table 1. Baseline demographics and comorbidities

Characteristic	UBE (n=20)	ABF (n=47)	P-value
Male	16	28	0.160
Mean age (y)	70.0±10.4	68.5±7.9	0.060
Hyperlipidemia	19	44	>0.999
Elevated without medication	11	43	
Elevated with diet control	1	0	
Statin use	7	1	
Diabetes mellitus	8	19	>0.999
Not requiring insulin	6	7	
Taking insulin	2	11	
Type I or not controlled	0	1	
Hypertension	19	47	0.299
Controlled on one drug	16	40	
Controlled on two drugs	3	5	
Controlled on three drugs	0	2	
Ischemic heart disease	3	10	0.529
Asymptomatic with >6-month MI	0	3	
Stable angina	3	4	
Unstable angina	0	3	
Atrial fibrillation	2	4	>0.999
GFR (mL/min)			–
>90	–2	–0	
60-89	0	1	
30-59	0	1	
Carotid disease	7	36	0.002
Asymptomatic	4	36	
TIA or stroke	3	0	
Smoker	20	47	–
Current smoker (<1 pack)	8	28	
Current smoker (>1 pack)	3	3	
Past smoker	9	16	
Respiratory impairment	1	3	0.819
Mild dyspnea	1	0	
Moderate dyspnea	0	3	
Requires oxygen	0	0	
Hypercoagulable status	1	1	0.511
Impaired functional status	2	1	0.263
Slightly impaired	2	0	
Requires some assistance	0	1	

Values are presented as number only or mean±standard deviation.
UBE, unibody bifurcated endograft; ABF, aorto-bi-femoral bypass; MI, myocardial infarction; GFR, glomerular filtration rate; TIA, transient ischemic attack; –, not available.

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There were three cases of infrapopliteal disease in the UBE group; two of which were treated simultaneously by an endovascular approach. However, there were no cases of infrapopliteal disease in the ABF group.

1) Procedural outcomes

Both the ABF and UBE groups had 100% immediate clinical and technical successes. Significant ABI improvement was observed following the procedure in both groups (Supplementary Table 1). There were no cases of macroembolization, ruptured iliac access, or device-related malfunction. There was no 30-day mortality in either group (Table 3).

Overall, seven patients developed wound hematoma, one of whom required surgical evacuation. Eight patients developed wound infection, one of whom required surgical evacuation. Six patients developed MACEs due to cardiac complications, five of whom required treatment in a high-dependency unit. However, there were no cases of cerebrovascular complications. While five patients developed acute kidney injury, only one progressed to permanent dialysis. Two patients developed deep vein thrombosis with pulmonary embolism but without hemodynamic instability. Two patients with ABF developed sexual dysfunction.

2) Clinical outcomes

The mean lengths of ICU stay were 3.1 and 0.75 days in the ABF and UBE groups, respectively (P=0.001). Similarly, the mean lengths of postoperative hospital stay were 12.5 and 7.8 days for the ABF and UBE groups, respectively (P=0.026).

The rate of immediate hemodynamic improvement was significantly higher in the ABF group than that in the UBE group (100% vs. 90%, P=0.001).

The mean duration of follow-up was 36 months (45.89 ABF and 16 UBE). At 3 years, 85% of patients in the bypass group and 95% in the UBE group showed sustained clinical improvements (P=0.232). The 3-year rates of freedom from binary restenosis were 88% in both the bypass and endovascular stenting groups (P=0.91). There were no statistical differences in overall survival between the bypass and the UBE groups (P=0.167; Supplementary Fig. 1); however, there were statistically significant differences in 3-year freedom from re-intervention (P=0.041; Fig. 3) and amputation-free survival (P=0.015; Fig. 4).

Table 2. Rutherford and TASC classifications

Classification	Total (n=67)	UBE group (n=20)	ABF group (n=47)
Rutherford category			
3	29	9	20
4	37	10	27
5	0	0	0
6	1	1	0
TASC-II			
A	1	1	0
B	6	6	0
C	25	5	20
D	35	8	27

UBE, unibody bifurcated endograft; ABF, aorto-bi-femoral bypass; TASC, Trans-Atlantic Inter-Society Consensus.

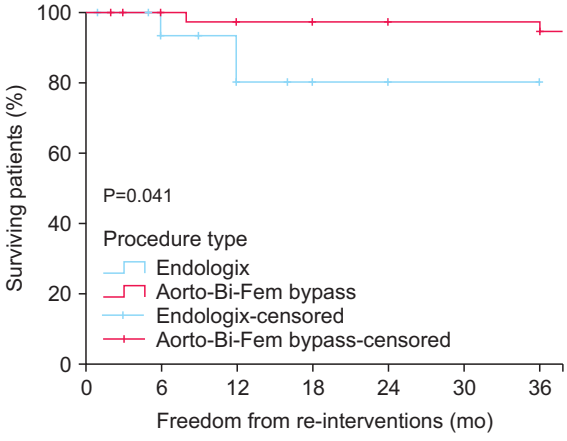
DISCUSSION

To date, the management of TASC-D AIODs remains challenging. The traditional therapy, ABF, is associated with 8% local and 12% systemic morbidity and 3% to 5%

Table 3. Postoperative complications

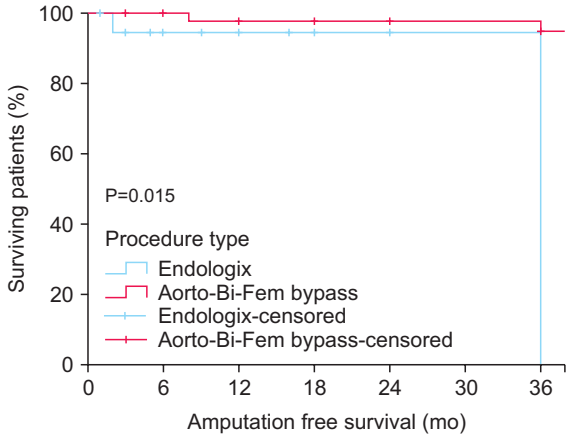
Total	Total cases (n=67)	UBE group (n=20)	ABF group (n=47)	P-value
30-day mortality	0	0	0	–
Hematoma	7	5	2	0.021
No intervention	5	3	2	
Surgical evacuation	1	1	0	
Arterial repair[a]	1	1	0	
Infection	8	4	4	0.226
Oral antibiotic	2	0	2	
Intravenous antibiotics	5	3	2	
Surgical treatment	1	1	0	
Cardiac complications	6	1	5	0.660
No hemodynamic effect	2	1	1	
Needed PCI or CABG	3	0	3	
With hemodynamic instability	1	0	1	
Respiratory complications	9	0	9	0.049
With good recovery	5	0	5	
Prolonged treatment	4	0	4	
Renal complications	5	1	4	>0.999
No dialysis	4	1	3	
Require dialysis	1	0	1	
Deep vein thrombosis	2	1	1	0.511
Pulmonary embolism	2	1	1	0.511
Sexual dysfunction	2	0	2	>0.999

UBE, unibody bifurcated endograft; ABF, aorto-bi-femoral bypass; PCI, percutaneous intervention; CABG, coronary artery bypass grafting; –, not available.
[a]The patient had dissection and disruption of atheroma by the introduction of a large sheath that was repaired by endarterectomy and patch.



No. at risk (mo)	0	6	12	18	24	30	36
Endologix	18	12	4	2	1	1	1
Aorto-Bi-Fem bypass	46	44	41	40	37	35	19

Fig. 3. Kaplan–Meier curve of three-year freedom from re-intervention showed a statistically significant difference between the groups.



No. at risk (mo)	0	6	12	18	24	30	36
Endologix	18	11	5	2	1	1	0
Aorto-Bi-Fem bypass	46	44	41	40	36	34	17

Fig. 4. Kaplan–Meier curve of amputation-free survival showed a statistically significant difference between the groups.

mortality rates [12]. To overcome these challenges, there has been an eight-fold increase in the endovascular treatment of AIOD in recent decades [13]. Despite the increase in overall endovascular interventions, traditional endovascular interventions for complex AIOD, such as kissing stents, pose technical challenges and higher chances of complications due to the complexity of the procedure, particularly in patients with heavily calcified aortic bifurcations or aortic thrombi. Moreover, patency may be compromised in more complex lesions due to a radial size mismatch between stents and certain stent configurations within the distal aorta [14].

There is a wide discrepancy in long-term patency rates of kissing stents, depending on the anatomy, indications, and patient risk factors. While some studies showed primary patency as low as 65% at 2 years (even after reintervention) [15-17], others showed higher patency rates of 82% and 68% at 5 and 10 years, respectively [18,19]. The presence of two crossed competitive lumens in a diseased distal aorta leads to compromised flow in the kissing stents [19,20]. Moreover, aortic bifurcations with heavy calcification, aortic thrombus, and high risk of rupture present challenges to successful treatment with kissing stents [15,20,21]. On the other hand, the CERAB technique shows superior patency rates compared to bare-metal stents, probably due to the graft fabric, which acts as a barrier to tissue in-growth from neo-intimal hyperplasia along with the avoidance of competitive flow in a narrowed distal aorta [22]. However, CERAB has several disadvantages that limit its application. For instance, a radial mismatch can occur in the absence of precise deployment. Additionally, future crossover interventions may be difficult with an irregularly shaped aortic bifurcation. Furthermore, CERAB is not preferred in dilated aortas (>20 mm) due to the creation of dead space outside the aortic stent [23].

We have used the UBE for complex AIOD as it provides advantages over CERAB in patients with TASC-D lesions. The unibody configuration allows the preservation of the aortic bifurcation. This minimizes the flow disturbance, especially in narrow aortas. Furthermore, it will enable easy access for future reintervention and has the advantage of using covered stents with minimal distal embolization and rupture risk, particularly in heavily diseased calcific aortas [23]. However, it is worth remembering that ABF is still considered the gold standard treatment for TASC-II-D AIOD, despite its association with considerable mortality and significant morbidity, especially in patients with multiple comorbidities [12,13].

Most ABF and UBE procedures in the current study were performed in TASC-D lesions. This makes the comparison between UBE and ABF more realistic, as both were done in the same complex anatomy. The minimally invasive approach allows for shorter postoperative ICU and hospital stays compared to ABF. Our UBE patients had a mean ICU and hospital stays of 0.75 and 7.8 days compared to 3.1 and 12.5 days, respectively, in the ABF patients. The ABF patients also had a higher incidence of cardiac, respiratory, and renal complications compared to those in the UBE

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group, although the difference was not significant. The endovascular stenting approach achieved this improved hospital stay with reduced morbidity.

As the EUSG was initially designed for aneurysmal disease, its behavior in occlusive disease was uncertain due to the lack of radial force. Maldonado et al. [6] overcame this limitation by using adjunctive stents in 59% of their cases. In our study, we deployed balloon-mounted stents in both limbs that did not extend into the body to preserve the aortic bifurcation. This subsequently increased the radial support of the limbs, especially in the calcified iliac. Our low binary restenosis and reintervention rates can be attributed to the augmented limb radial force.

Although we addressed the lack of radial force in the EUSG, there were concerns regarding the coverage of important collaterals and lumbar arteries, resulting in pelvic ischemia. Maldonado et al. [6] reported a 4% dissection rate and 3% thromboembolic complication rate without spinal cord ischemia and only one case of 30-day mortality secondary to intestinal ischemia. We did not observe gluteal claudication, intestinal ischemia, or spinal cord ischemia from coverage of the terminal aorta, which could be attributed to our use of the shortest body endovascular stent-graft to cover the diseased portion of the aorta rather than covering the whole infrarenal aorta. In cases where further proximal fixation was required, we used an uncovered Sinus-XL stent (OptiMed Medical Instruments GmbH) to support the plaque proximally.

Furthermore, access-related complications can be troublesome in patients with occluded iliac vessels. Maldonado et al. [6] reported a 22% overall procedure-related complication rate, including 4% due to ruptured iliac vessels. We did not experience any vascular access-related complications in the current study, as pre-dilatation for the main body entrance side was conducted in all our cases. Additionally, we used a 12-French sheath to safely pre-dilate the contralateral iliac to protect the contralateral limb and prevent it from snagging on the plaque during positioning of the device.

1) Study limitations

This retrospective study has some potential limitations. The number of study samples was limited due to the availability of the patient records and retrospective nature of the study, which may have led to selection bias. The small sample size can be explained by the novelty of the treatment and use of UBE in AIOD. Similarly, this was a single-center experience, which may affect the reproducibility of the results. In addition, the two comparative groups showed differences in TASC classifications and disease severity, which could have influenced the study outcomes. Furthermore, the usage of UBE is limited due to the associated cost, which was not addressed in this study.

CONCLUSION

Total endovascular repair of AIOD is an alternative to invasive bypass procedures with a shorter ICU stay.

SUPPLEMENTARY MATERIALS

Supplementary data can be found via https://doi.org/10.5758/vsi.200051.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHOR CONTRIBUTIONS

Concept and design: BG, WT, SS. Analysis and interpretation: BG, MES, MELS, YA, NH, WT, SS. Data collection: BG, MES, MELS, YA. Writing the article: BG, MES, MELS, YA, NH, WT, SS. Critical revision of the article: BG, MES, MELS, YA, NH, WT, SS. Final approval of the article: BG, MES, MELS, YA, NH, WT, SS. Statistical analysis: BG, MES, MELS, YA, WT. Obtained funding: none. Overall responsibility: BG, MES, MELS, YA, NH, WT, SS.

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