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Clinical Research

Contemporary Results of Endovascular Repair of Isolated Abdominal Aortic Dissection with Unibody Bifurcated Stent Grafts

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Objectives: To report the midterm safety and efficacy of the Aegis™-B (Microport, Shanghai, China) unibody bifurcated stent graft for endovascular treatment of isolated abdominal aortic dissection (IAAD).

Background: Isolated abdominal aorta dissection (IAAD) is a rare event. Endovascular stent grafts seem to offer an efficient therapeutic approach to treat IAAD. However, the relatively small diameter of the infrarenal aorta and aortic bifurcation remains the main anatomical limitation to endovascular repair.

Methods: Between 2008 and 2015, we retrospectively evaluated 32 IAAD patients (21 men; mean age 58 ± 18 years), who underwent endovascular repair using Aegis™-B unibody bifurcated stent graft. Narrow proximal landing zone and narrow distal aorta was present in 11 (34.4%) patients and 10 (31.3%) patients, respectively. In the follow-up period, aortic remodeling was observed with computed tomography angiography.

Results: All patients were treated by endovascular means, with a primary technical success rate of 100%. During a mean follow-up period of 30.71 ± 16.36 months (range, 8−56 months), no death, rupture, stent fracture, material failure, or device migration was observed. Complete false lumen thrombosis was observed in all patients at 1 year, and all patients were free from false lumen growth in the follow-up.

Conclusions: Endovascular treatment of IAAD using the Aegis™-B system appears to be safe and effective. Results from this study suggest this algorithm can provide stable, secure fixation for IAAD patients with narrow proximal landing zone, and distal aorta.

M.Z. and H.C. contributed to this work equally, shared first authorship.

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INTRODUCTION

Isolated abdominal aorta dissection (IAAD) is a rare event, usually related to spontaneous, traumatic, or iatrogenic causes. The clinical presentation of IAAD may be associated with abdominal pain, visceral ischemia, acute renal failure, and limb ischemia.[1–4] The advent and applicability of endovascular stent grafts for abdominal aorta aneurysms seem to offer an efficient therapeutic approach to treat IAAD. However, the relatively small diameter of the infrarenal aorta and aortic bifurcation remains the main anatomical limitation to endovascular repair.[5] As the experience with endovascular repair has matured, so have device design considerations. Unibody endograft with an endoskeleton and anatomical fixation was adopted to prevent device migration.[6–8] Especially, this approach was widely applied into abdominal aortic aneurysm (AAA) with hostile aortic necks or distal narrow aorta, which was considered as challenging anatomy for endovascular repair.[9]

The aim of this retrospective study was to assess the midterm safety and efficacy of endovascular IAAD repair using the Aegis™-B (Microport, Shanghai, China) unibody bifurcated stent graft.

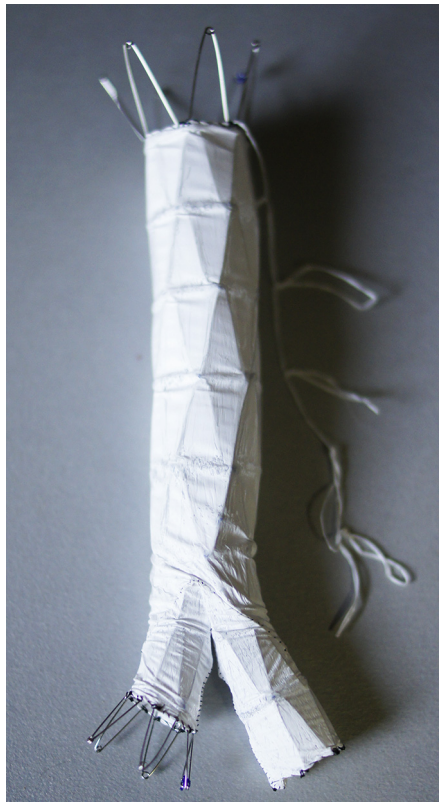


Fig. 1. Microport Aegis unibody bifurcated stent graft.

MATERIALS AND METHODS

Between January 2008 and October 2015, clinical data of 32 IAAD patients (21 men; mean age 58 ± 18 years, range 40–75) undergoing endovascular repair using Aegis™-B unibody bifurcated stent grafts (Microport, Shanghai, China, Fig. 1) were analyzed retrospectively. This study has been approved by the ethics committee of Nanjing Drum Tower Hospital, Medical School of Nanjing University. Each patient who was enrolled in this study has signed the informed consent.

In this IAAD study (Table I), the lesion was located at the level of the abdominal aorta without retrograde extension to the thoracic aorta (Fig. 2). Mean dissection length was 66 ± 28 mm (range 23–98). The mean distance between the proximal entry tear of the dissection and the lowest renal artery or the aortic bifurcation was 56 ± 28 mm and 41 ± 22 mm, respectively, and the maximal diameter of the aorta was 37 ± 8.6 mm. In 11 (34.4%) patients, the lesion retrograde extended to the renal arterial level, and 10 (31.3%) lesions involved the iliac arteries. In the remaining 11 (34.4%), the lesions were only detected between the renal arteries and the aortic bifurcation. The mean true lumen area at proximal landing zone and aortoiliac bifurcation was 3.8 ± 1.0 cm^2 and 2.9 ± 0.9 cm^2, respectively. The mean maximal abdominal aorta area was 6.3 ± 1.1 cm^2, the mean minimal true lumen area was 1.5 ± 0.8 cm^2, and the mean maximal false lumen area was 4.7 ± 1.4 cm^2.

The majority of IAAD occurred spontaneously ($n = 29$), while 3 dissections had an iatrogenic etiology (previous cardiac or hybrid interventions). Indications for operative interventions included signs of aortic rupture, limb ischemia, unremitting pain, and increase in aortic diameter >5 mm in 6 months.[2,10,11] Twenty-four patients suffered from acute ($n = 16$) or subacute ($n = 8$) lesions accompanied by abdominal pain ($n = 17$) or acute limb ischemia caused by flow restriction by the flap ($n = 7$). The other 8 patients had asymptomatic chronic dissections with an increase in aortic diameter >5 mm in 6 months based on computed tomographic angiography (CTA). All patients with acute symptoms underwent analgesic therapy and medical management of systolic blood pressure (target < 120 mm Hg) at first.

Implantation Procedures

One common femoral artery (CFA) was exposed for delivery access, and an 8-F sheath was inserted

Table I. Characteristics of 32 patients from the Aegis™-B study

Demographics	
Age, year	58 ± 18
Men	21 (65.6%)
Body mass index, kg/m^2	28.7 ± 5.8
Serum creatinine, mg/dL	0.89 ± 0.12
Risk factors	
Arrhythmia	8 (25%)
CAD	12 (44%)
CVD	5 (16%)
COPD	6 (19%)
Family history of AAD	8 (25%)
Hypertension	22 (69%)
Diabetes mellitus	14 (44%)
Myocardial infarction	2 (6.3%)
Renal insufficiency	2 (6.3%)
Hyperlipidemia	26 (81%)
Prior abdominal surgery	3 (9.4%)
Smoking	25 (78%)
Marfan syndrome	1 (3.1%)
Pregnancy	1 (3.1%)
Dissection characteristics	
Dissection length, mm	66 ± 28
Distance from the lowest renal artery, mm	56 ± 28
Maximum abdominal aorta diameter, mm	37 ± 8.6
Maximum abdominal aorta area, cm^2	6.3 ± 1.1
Maximal false lumen area, cm^2	4.7 ± 1.4
Minimal true lumen area, cm^2	1.5 ± 0.8
True lumen area at proximal landing zone, cm^2	3.8 ± 1.0
Longer diameter of the true lumen at proximal landing zone, mm	25 ± 3.1
True lumen area at aortoiliac bifurcation, cm^2	2.9 ± 0.9
Longer diameter of aortoiliac bifurcation, mm	22 ± 5.3
True lumen area at distal landing zone, cm^2	1.6 ± 0.3
Longer diameter of the true lumen at distal landing zone, mm	15 ± 2.7

Continuous data are presented as means ± standard deviation; categorical data are given as counts (percentages).
CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease.

percutaneously on the contralateral side to deploy the contralateral iliac limb. After angiogram and length measuring, the main body was brought up above the bifurcation level. Then, the whole stent graft was pulled down to the abdominal aortic bifurcation, and the bifurcated device was deployed following the sequence of main body, contralateral and ipsilateral limbs (Fig. 3).

Definitions

A narrow distal aorta was defined as the longer diameter of bifurcation <20 mm,[12] and a narrow proximal landing zone was defined as the longer diameter of the proximal landing zone <20 mm with the lesion retrograde extended to the renal arterial level.[13]

The largest abdominal aortic area of the affected aortic segment between the lowest renal artery and iliac bifurcation was measured and defined as the maximal abdominal aortic area (MAAA), the maximal false lumen area (MFLA) was defined as the area over the segment with maximal false lumen in the aorta between the lowest renal artery and iliac bifurcation. The minimal true lumen area (MTLA) was defined as the area over the segment with minimal true lumen in the aorta between the lowest renal artery and iliac bifurcation with dissection. All the measurements were conducted with an open source DICOM software OsiriX (OsiriX Foundation, Geneva, Switzerland).

Major adverse events (MAE) included all-cause death, dissection rupture, conversion to open repair, secondary procedure, coronary intervention, myocardial infarction, renal failure, respiratory failure, stroke, or transient ischemic attack.

Endoleak was defined as the presence of contrast material within the false lumen channel but outside of the graft material. Because of lacking reported standard of abdominal aortic dissection remodeling, MAAA, MFLA, and MTLA decrease or increase was defined as a change of 10% compared with baseline. Migration was defined as >10 mm movement of the proximal end of the graft from the baseline scan relative to the lowest renal artery.[14]

Follow-up

All patients underwent a postoperative surveillance protocol, which included physical examination, blood pressure measurement, and CTA at 3, 6, and 12 months, postoperatively and yearly thereafter. All the films were reviewed by the specified group including 2 endovascular specialists and 1 interventional radiologist to assess dissection changes, device position and integrity, migration, false lumen thrombosis, and endoleaks.

Statistical Analysis

Baseline and procedural continuous, ordinal, and categorical variables are presented descriptively, as are early (within 30 days) and late (>30 days) MAEs and aortic dissection size changes. Analysis

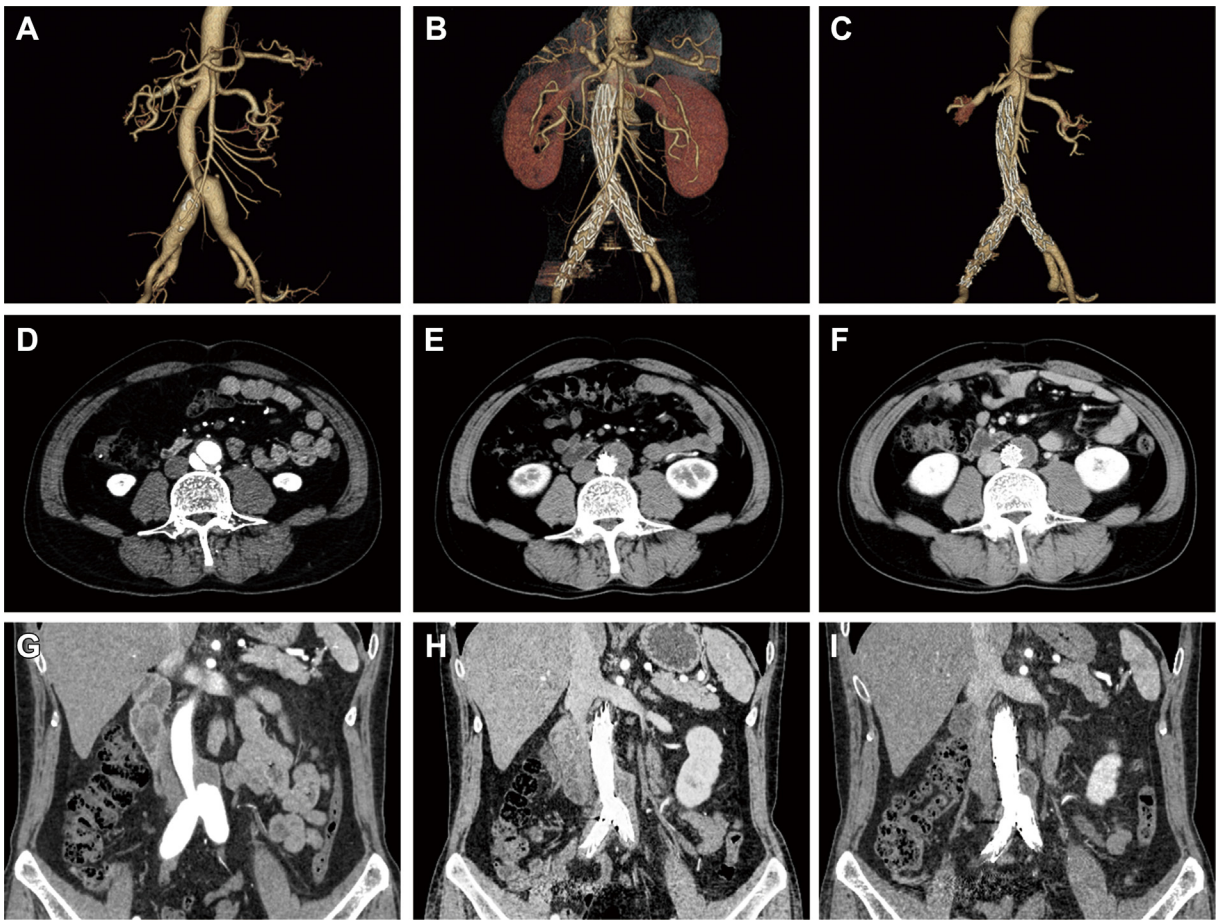


Fig. 2. Representitive computed tomography scans of the enrolled patients in this study. **(A, D,** and **G)** Before EVAR; **(B, E,** and **H)** at 3-month follow-up; and **(C, F,** and **I)**, at 1 year follow-up.

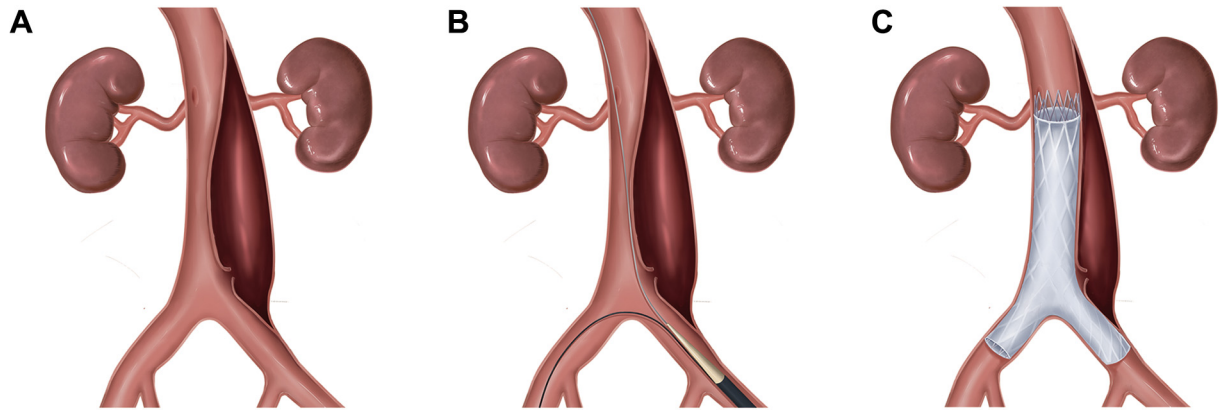


Fig. 3. (A) Thin wires are inserted into femoral arteries through a small cut (EVAR). **(B)** The delivery catheter is inserted and advanced over the wire into position in aorta. **(C)** The main body and limbs of the stent graft are in proper position, and the stent portion of the stent graft is allowed to expand.

of follow-up data was based on eligible patients available at each interval. Comparisons of continuous variables were analyzed with a paired *t* test; proportions were analyzed using the Fisher's exact test. Statistical significance was considered for $P < 0.05$. All statistical analyses were performed using SPSS 21.0 (IBM Corp., Armonk).

RESULTS

Technical success was achieved in 100% (32/32) of patients. Three proximal cuff extensions were used to ensure secure sealing at proximal landing zone because of the main bodies (usually 8 or 9 cm in length) were not long enough to cover the entry tears, which were close to the origin of renal artery. And 5 patients received iliac extensions (total 7 extensions). Among them, 3 patients presented leg ischemic symptom, and the low limb perfusion was not improved after deployment of the unibody stent graft; therefore, iliac extensions were deployed to expand the severely compressed iliac true lumen. The other 2 patients were given iliac extensions to cover the intimal tears located in the iliac bifurcations; obviously, the iliac extensions were extended to the external iliac arteries and internal iliac arteries, which were pre-embolized to prevent type II endoleak.

Complications and clinical utility outcomes were shown in Table II. In this study, all 32 patients were implanted with the device and completed 6-month follow-up with no deaths or loss to follow-up. One-year follow-up data were available for 30 patients. Long-term follow-up data were available from each subsequent annual visit to 3 years in 27 and 19 patients, respectively.

Mortality and Major Adverse Events

No death occurred within 3 months. Throughout the current follow-up, no dissection rupture, conversion to open repair, renal failure, or respiratory failure has occurred, 1 patient suffered myocardial infarction within 1 year after EVAR, 1 patient received coronary intervention 2 years after implantation, 1 patient suffered stroke 2 years after implantation, and limb occlusion occurred in 1 case 6 month after implantation. Mean serum creatinine level at 1 year was not significantly different than that measured preoperatively (0.90 ± 0.11 vs. 0.89 ± 0.12, $P = 0.73$).

Treatment Effectiveness

Device integrity. At each evaluation on period, no stent fracture, material failure, or loss of patency was found by the specified group. Moreover, no device migration was observed despite increased prevalence of narrow proximal landing zone and bifurcation anatomy.

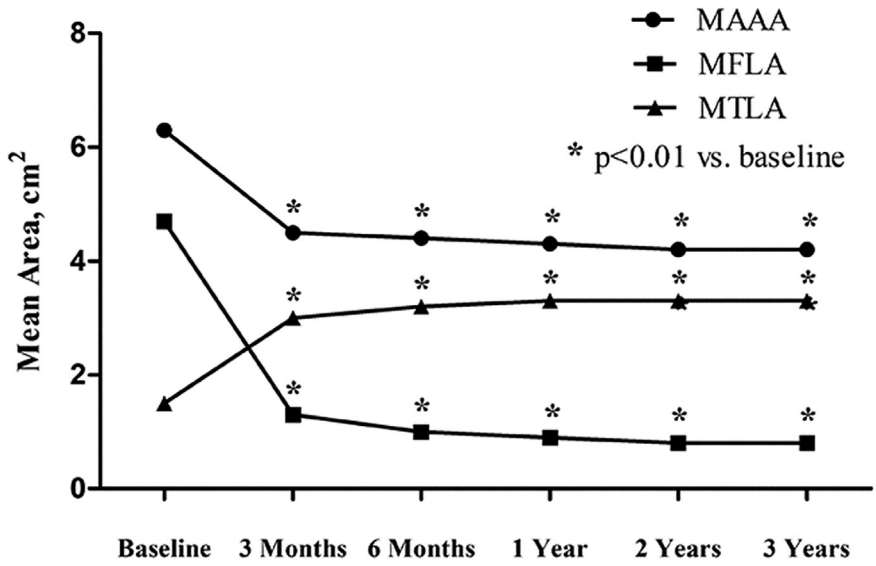
Table II. Procedural outcomes in 32 patients from the Aegis™-B study

Anesthesia types	
General	12 (37.5%)
Local	20 (62.5%)
Complications[a]	
Access site hematoma	2 (6.3%)
Access vessel laceration	2 (6.3%)
Access site pseudoaneurysm	1 (3.1%)
Access site lymphocele	1 (3.1%)
Device limb damage	0 (0%)
Clinical utility outcomes	
Procedure time, min	112 ± 37
Estimated blood loss, mL	240 ± 193
Contrast media, mL	126 ± 51
Fluoroscopy time, min	20 ± 13
Time to hospital discharge, d	5.4 ± 1.7

Continuous data are presented as means ± standard deviation; categorical data are given as counts (percentages).
[a]All complications were resolved endovascularly.

Endoleak and secondary interventions. There have been 2 type IV endoleaks identified throughout the study, and both type IV endoleaks required no treatment and disappeared during the follow-up. One patient received femoral crossover for left limb occlusion. The intervention was successful, and no aneurysm enlargement was noted.

Aortic remodeling. At each evaluation on period, significant reductions in mean MFLA were observed (Fig. 4); there was no growth in MFLA in all patients. Mean MTLA increased significantly throughout the follow-up, there was no decrease in MTLA in all patients at 3 months, and all patients were identified with an increase in MTLA thereafter. As to MAAA, the mean MAAA decreased significantly throughout the follow-up despite increased MAAA in 3 patients at 3 months. And there were 26 (81.3%), 31 (96.9%), 29 (96.7%), 26 (96.3%), and 19 (100%) patients identified with a decrease in aortic area at each evaluation on period, respectively. Moreover, CTAs were carried out using an arterial and a delayed phase to determine the status of the false lumen (patent/thrombosed). Of the 32 patients that completed a 6-month follow-up, complete false lumen thrombosis was noted in 28 (87.5%) patients, and the



N	32	32	32	30	27	19
MAAA, cm^2	6.3 ± 1.1	4.5 ± 1.2	4.4 ± 1.3	4.3 ± 0.9	4.2 ± 1.0	4.2 ± 1.1
MFLA, cm^2	4.7 ± 1.4	1.3 ± 1.4	1.0 ± 1.0	0.9 ± 1.0	0.8 ± 0.8	0.8 ± 0.8
MTLA, cm^2	1.5 ± 0.8	3.0 ± 0.6	3.2 ± 0.6	3.3 ± 0.7	3.3 ± 0.6	3.3 ± 0.7

Fig. 4. Abdominal aortic dissection remodeling throughout 3-year follow-up.

complete false lumen thrombosis rate reached 100% at 1, 2, and 3 years.

DISCUSSION

This study was conducted to evaluate the safety and feasibility of the Aegis™-B infrarenal unibody bifurcated stent graft in the treatment of isolated abdominal aortic dissection. Favorable aortic remodeling was noted over the follow-up interval. And we found all-cause mortality and the rate of major adverse events were low in this population having a variety of comorbidities, suggesting suitable application of this endovascular implantation algorithm even in patients with large false lumen area at proximal landing zone and/or aortoiliac bifurcation.

Mimicking the shape of the natural anatomy of the abdominal aorta, the Aegis™-B system can be directly placed on the aortoiliac bifurcation, which enables distal fixation of the main device independently from sealing at the proximal landing zone and provides support to counteract the downward force of pulsatile blood flow and prevent distal migration.[15] Device stability without migration is the most important element in constructing the endoluminal exclusion channel.[16] In this study, no distal migration was observed throughout the 3-year follow-up, which provided substantial reinforcement for the safety and midterm durability of this approach. Moreover, it has been recognized that the combined achievement of proximal and distal fixation and sealing is essential to ensure long-term modular stent-graft positional stability.[17,18]

The deployment procedure of unibody endograft is totally different from other endografts. In this procedure, more attention should be focused on the distance from the lowest renal artery to the abdominal aortic bifurcation and the distance from the aortic bifurcation to the hypogastric artery than the modular devices.[16] Graft length was determined by the lengths of the native abdominal aorta and the common iliac artery. In this study, the open source DICOM software OsiriX was applied to process all images to achieve precise measurement. Prudent assessment of the aortic anatomy and planning procedures preoperatively are the keystones for optimal outcomes in endovascular repair.[19] As a result, no renal arterial or hypogastric arterial ischemia or related symptom was found during the 3-year follow-up.

Device diameter selection before the procedure can be based on various measurement methods. In most cases, the main body graft size was selected according to longer diameter of the proximal landing zone with approximately 10% oversizing.[20] However, in this study, the lesion retrograde extended to the renal arterial level in 11 (34.4%) patients, and 9 (28.1%) of them were observed with a crescent true lumen compressed by the false lumen, which increased the difficulty in device diameter selection. Weng et al.[19] reported that the sensitivity of the method was most significant with oversizing discrepancy with area measurements. The unibody endograft had very poor radial force; as a result, insufficient oversizing was unable to provide proper anchoring adaptation for secure fixation and seal, resulting in proximal type I endoleak and distal migration.[21] It was also recommended that avoiding area oversizing of more than 4 times preoperatively although the unibody endograft had great tolerance to oversizing.[22] Therefore, 4 times oversizing of the true lumen area were used for graft diameter selection in these 9 cases. At 1 year after EVAR, the complete false thrombosis rate reached 100%, and no complication mentioned previously was observed, which probably implied the secure fixation and seal as a result of proper size selection of the device.

Although increasing numbers of dissection patients are being treated with EVAR, anatomical limitations including small access vessels and a narrow distal aorta prevent many patients from qualifying for EVAR.[23–25] Narrow distal aorta is a known challenge for endovascular repair. As endograft limbs usually measure 12–16 mm in diameter each, 20 mm of bifurcation diameter is generally required for implantation of a bifurcated device to reduce the risk of graft limb occlusion.[12] In this study, the average bifurcation true lumen diameter was 21.5 ± 5.3 mm, and there were 10 (31.3%) patients with narrow distal aorta, which increased the risk of endograft limb restriction or occlusion. Adam et al.[5] reported the successful use of an aortouniiliac stent graft in an IAAD patient with narrow distal aorta, whereas the change of the bifurcation anatomy might cause some complications.[26] In this study, all patients received EVAR with the Aegis™-B system, and only one suffered from left limb occlusion and received femoral crossover. We hypothesized that it was tortuous iliac artery that resulted in limb kinking and subsequent limb occlusion. No limb kinking or thrombosis was observed, and no limb or buttock claudication and limb-threatening ischemia occurred in other patients during the 3-year follow-up. This treatment algorithm was well tested with prevalent challenging aorta-iliac bifurcation anatomical features. Long-term results would be evaluated to assess the durability of this approach.

The best indication of success would be a gradual expansion of the true lumen, with a corresponding thrombosis[27,28] and shrinkage of the false lumen and total aortic volume.[29] By covering the proximal tear in acute dissections, we obtained increase in MTLA and reduction in MFLA and MAAA in all patients, which suggested shrinkage of the false lumen and a reduction in aneurysmal dilatation. Regarding to false lumen thrombosis, 28 (87.5%) patients achieved complete false thrombosis 6 months after implantation, and all patients achieved complete false lumen thrombosis at 1 year. The rationale for endovascular repair in abdominal aortic dissection is closure of the proximal entry to initiate a natural healing process that encourages false lumen thrombosis and eventual expansion of the true lumen.[29] Unfortunately, IVUS is currently not available in our center. Therefore, computed tomography (thin slice) and angiography before or during the procedure are employed to identify the entry tear and make sure it was covered. These findings may be important to endovascular durability and the avoidance of serious complications like aortic rapture due to ongoing aortic dilation.

For the other major adverse event, no conversion to open repair was necessary, and no stent or graft material failure was observed. High technical success rate and outstanding clinical outcome provided additional support for the safety and effectiveness of this treatment algorithm.

The promising results with a fully supported unibody stent graft placed at the aortoiliac bifurcation implied that patients might benefit substantially from this algorithm with challenging aortoiliac bifurcation, landing zone morphology, and other anatomies for modular proximal fixation treatment approaches. For example, the bifurcation is artificially elevated when using modular proximal fixation devices, which necessitates gate cannulation at some distance from the patient's aortoiliac bifurcation. In comparison, the Aegis™ device includes a precannulated contralateral limb appropriate for 8-F percutaneous access, anatomical fixation of the unibody device obviates the cannulation challenges associated with modular device (9).

CONCLUSION

Despite the small number of patients studied, our experience with endovascular treatment of IAAD using the Aegis™-B system appears to be safe and effective, even in the presence of narrow proximal

landing zone and distal aorta. The absence of death, conversion to open repair, migration, stent fracture, or graft fatigue during the follow-up emphasizes the significant clinical benefits of this device and endovascular treatment algorithm. Careful follow-up over the longer term is necessary to ensure the durability of these results.

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