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Clinical Outcomes of the GORE VIABAHN VBX Balloon-expandable Covered Stent in Aortoiliac Occlusive Disease and Acute Limb Ischemia

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Abstract **Objectives:** This study examined the short-term outcomes of endovascular therapy (EVT) with the GORE VIABAHN VBX (VBX) which is a balloon-expandable covered stent in patients with aortoiliac occlusive disease (AIOD) and acute limb ischemia (ALI). **Methods:** This was a single-center retrospective review of patients with AIOD and ALI who underwent EVT with the VBX between December 2018 and January 2021. Primary, assisted, and secondary patency rates were assessed, along with 30-day mortality rates. **Results:** Twenty-two patients underwent EVT with the VBX; 18 patients had AIOD, whereas 4 had ALI. The incidence of TransAtlantic Intersociety Classification II D lesions was 50% (n=9). Technical success was 100%. One patient with unilateral common iliac artery stenosis developed an intraoperative dissection of the distal edge of the VBX, which required an additional self-expanding VIABAHN stent on the distal edge of the VBX. The primary patency rate at 24 months was 100%. No patients required additional target vessel treatment at a median follow-up of 10 months (range, 1-27). EVT was also successful in the four patients with ALI, who had no complications of the target vessel. **Conclusion:** The present study demonstrated that EVT with the VBX is effective for AIOD and ALI.

Key words: aortoiliac occlusive disease, acute limb ischemia, balloon-expandable covered stent, VIABAHN VBX

Objectives

In the last few decades, endovascular therapy (EVT) has become the preferred treatment for mild to moderate aortoiliac occlusive disease (AIOD).[1] EVT provides excellent outcomes in short lesions and is associated with low complication rates and short hospital stays.[2,3] However, severe calcification and long occlusions increase a risk of arterial rupture and technical failure in EVT.[4] For TransAtlantic Intersociety Consensus (TASC) C and D lesions, which show long stenosis or occlusion, stenting is inferior to surgical bypass because the former provides less patency rate.[5-7] The most recent guidelines recommend an endovascular-first approach for patients with TASC/D lesions and severe comorbidities.[8,9] However, these recommendations are not based on strong-high-quality evidence, and other reports have demonstrated that a secondary patency rate in patients with TASC C/D is approximately same between stenting and surgical bypass.[10-12] We theorized

that the clinical outcomes of EVT for TASC C/D lesions can be improved by refining the stenting technique and devices.

The Covered Versus Expanded Balloon Stent (COBEST) trial recommends balloon-expandable covered stents for TASC C/D lesions.[13-15] The Society of Vascular Surgery (SVS) also recommends the use of covered stents for the treatment of AIOD with severe calcification, because dilatation using uncovered stents increases the risk of rupture.[8] The GORE VIABAHN VBX balloon-expandable endoprosthesis (VBX) (W. L. Gore & Associates, Flagstaff, Arizona, USA) is the first balloon-expandable covered stent that has been available for AIOD in Japan since 2018. The VBX has good clinical outcomes, with a nine-month primary patency rate of 96.7%.[16]

The VBX has also been successfully utilized in acute limb ischemia (ALI), despite the standard of treatment being surgical thrombectomy or catheter-directed thrombolysis.[17]

Reports on utilizing the VBX in patients with AIOD continue to increase; however, real-world studies are still needed, especially in Japan.[18-22] To our knowledge, there is no reports on the outcomes of the VBX in a Japanese population in a single center. This study examined the clinical outcomes of performing EVT with the VBX in patients with AIOD and ALI.

Design

This study was approved by the institutional review board (H2019-062) of the medical safety committee at our institution about the off-label use of the VBX. All study participants provided informed consent and this study was conducted in accordance with the Declaration of Helsinki. An approval of the ethics committee is not required for retrospective data collection in our institution.

Material and Methods

Population

Consecutive patients with AIOD or ALI who underwent EVT with the VBX at Yamaguchi University Hospital between December 2018 and January 2021 were included in this study. Data were retrospectively collected from medical records.

The surgical indications for AIOD included symptomatic claudication, pain at rest, or tissue loss (Rutherford category ≥1).[9] We treated restenosis target lesion/s in the common iliac artery (CIA) and/or external iliac artery (EIA), as well as de novo lesion/s in target vessels that demonstrated stenosis ≥50%. In contrast, the surgical indications for ALI included thrombi in the terminal aorta or origin of CIA or plaque protrusion.

The surgical plan for each patient was designed based on a preoperative contrast-enhanced computed tomography (CT) scan.

Surgical technique

All procedures were performed in a hybrid surgical room with a fixed C-arm fluoroscope.

Ipsilateral retrograde femoral access was secured under ultrasound guidance. The occluded segment was also accessed in an antegrade direction from the contralateral femoral or brachial arteries. After the target lesion was successfully crossed with a 0.035-inch wire, the guidewire was then exchanged for an Amplatzer Stiff guidewire (Cook Medical, Bloomington, Indiana, USA) to allow covered stent advancement and deployment. The VBX was deployed into the occluded or stenosed lesion. A self-expanding bare metal stent was also deployed into the distal EIA if the VBX was extended to the distal EIA. After deployment, we performed postconditioning with the VBX balloon or a MAXI LD balloon catheter (Cordis Corporation/Johnson & Johnson, Bridgewater, New Jersey, USA). Completion angiography was performed to assess the final procedural results.

Upon discharge, patients were basically initiated on at least one month of double antiplatelet therapy with clopidogrel (75 mg daily) and aspirin (100 mg daily). Patients were subsequently shifted to single antiplatelet therapy.

Postoperative management

Patients were evaluated through clinical visits and ankle-brachial index (ABI) measurements every 3-6 months. Loss of patency was suspected in the presence of ABI drop

greater than 0.1, absent femoral pulses, or symptom recurrence.[3] Loss of patency was confirmed by Doppler ultrasonography.[3] Stenosis >50% was defined as a >100% increase in the peak systolic velocity in the involved segment relative to the adjacent segments, and stenosis >70% was defined as a peak systolic velocity ratio >3.5.[3,23] All patients with stenosis >70% were planned to be undergone CT angiography for further evaluation. If stenosis >70% was confirmed on CT angiography, percutaneous angioplasty or distal stent prolongation was to be advised to prevent acute thrombosis.

Endpoint

All clinical, anatomical, and surgical data were collected and analyzed retroactively from the hospital database. The primary endpoints of the study were technical success rate and primary patency rate. Primary patency was defined as uninterrupted patency that did not require procedures performed at or near the edges of the treated segment. Secondary endpoints included 30-day mortality, assisted patency rate, and secondary patency rate; these were defined according to the SVS guidelines.[8] Technical success was defined as less than 30% residual stenosis on angiography.

Statistical analysis

Statistical analyses were performed using the Stata/IC 15.1 (StataCorp, College Station, Texas, USA). Due to the small number of patients, we did not select a control group in this study. The data was presented using a descriptive analysis method. Kaplan-Meier survival estimates were made for patency rate and mortality. The categorical data was described using absolute numbers and prevalence percentages (%), while continuous variables were represented as median (range).

Results

During our study period, 22 patients underwent EVT with the VBX; 18 patients had AIOD, whereas 4 patients had ALI. Tables 1-2 present data on the patients with AIOD. As shown in Table 1, 12 (67%) of the patients with AIOD were male. The median age was 75-years (range, 57-94). The anatomic characteristics of the aortoiliac lesions in our patients are presented in Table 1. 95% of the patients had primary lesions, except for one patient who received a bare metal stent for an iliac artery stenosis one year prior. 50% of the patients had TASC II D lesions, and almost all of the AIOD lesions had severe calcifications or were long lesions.

All patients received the VBX and 13 (76%) patients required deployment using the kissing stent technique in Table 2, because they did not have adequate landing zones in the proximal occluded CIA (Fig. 1).[24] Among these patients, three underwent covered endovascular reconstruction of the aortic bifurcation (CERAB).

Technical success was achieved in 100% of the cases. Intraoperative dissection of the distal edge of the VBX was occurred in one patient with unilateral CIA stenosis. Therefore, additional placement of a self-expandable covered stent VIABAHN (W. L. Gore & Associates, Flagstaff, Arizona, USA) needed to be performed as it covered the tear of the distal edge of the VBX in a single operation (Fig. 2A). The time required for the patients to be discharged after surgery was 5 days (range, 1-10).

No death was observed during 30 days after surgery; however, four patients died during a median follow-up of 10 months (range, 1-27) due to non-disease-related causes (hemorrhage from a cervical abscess, postoperative hemorrhage from colon cancer, pneumonia, and unknown). The two-year survival rate was 74% (Fig. 2B).

We followed all the patients. The primary patency rate at 24 months was 100% (Fig. 2C). No limb amputation was required during the follow-up period.

Table 3 presents the data on the patients with ALI. Two patients complained of acute pain at rest, whereas two patients had foot cyanosis without any pain. Case 1 was symptomatic for nine days, and circulation via collateral flow in the involved extremity was very poor upon consultation. Three patients had occlusions in the proximal CIA, whereas one patient with an existing bare metal stent presented with plaque protrusion. All four patients underwent acute stent

Table 1 Patient and anatomic characteristics of the aortoiliac occlusive disease group

Variable	No. of patients (%) or median (range) (N=18)
Sex (male)	12 (67)
Age (years)	75 (57-94)
Body mass index (kg/cm^2)	19.6 (15.5-24.4)
Smoking	15 (83)
Hypertension	17 (94)
Diabetes mellitus	8 (44)
Dyslipidemia	11 (61)
Coronary vessel disease	3 (17)
Chronic renal disease (≥ stage III)	8 (44)
Hemolytic dialysis	3 (17)
Hostile abdomen	9 (50)
Rutherford's ischemia degree	
1 (mild claudication)	2 (11)
2 (moderate claudication)	3 (17)
3 (severe claudication)	12 (67)
6 (major tissue loss)	1 (5)
TASC II classification	
A	3 (17)
B	3 (17)
C	3 (17)
D	9 (50)
Target vessel	
Aorta	3 (17)
Aorta - CIA	2 (11)
CIA - EIA	2 (11)
CIA	8 (44)
EIA	3 (17)
Disease characterization	
Stenosis	11 (61)
Occlusion	7 (39)
Calcification	13 (76)
Lesion length (mm)	36 (11-129)
Pre-operative ABI	0.46 (0.13-0.75)

TASC: TransAtlantic Inter-Society Consensus, CIA: common iliac artery, EIA: external iliac artery, ABI: ankle brachial index.

Table 2 Operative characteristics of the aortoiliac occlusive group

Variable	No. of patients (%) or median (range) (N=18)
Operative time (minute)	125 (55-280)
Blood loss (g)	75 (18-466)
Contrast media usage (mL)	41 (20-90)
Fluoroscopic time (minute)	34 (13-95)
Treated vessel	
Aorta	1 (5)
Aorta - bilateral CIA	10 (56)
Aorta - CIA, EIA	3 (17)
Unilateral CIA	1 (5)
Unilateral EIA	3 (17)
Number of deployed GORE VIABAHN VBX stents	2 (1-4)
Stented diameter (mm)	8 (7-10)
Stented length (mm)	59 (29-79)
Kissing technique	13 (76)
CERAB technique	3 (17)
Technical success	18 (100)
Operative death	0
Operative complication	
Dissection at the GORE VIABAHN VBX distal edge	1 (5)
Dissection at area of CFA patch plasty	1 (5)
Post-operative hospital stay (day)	5 (1-10)
Post-operative ABI	0.89 (0.43-1.43)

CIA: common iliac artery, EIA: external iliac artery, CERAB: covered endovascular reconstruction of the aortic bifurcation, CFA: common femoral artery, ABI: ankle brachial index.

Table 3 Characteristics of cases with acute limb ischemia.

Pt	Age (years)	Time from onset to operation (hour)	Symptoms	Occluded lesion	Treated vessel of the VIABAHN VBX	Additional procedure	Operative complication	Follow-up period (month)	Event
1	74	216	Rt.foot rest pain	Aorta-rt. EIA, lt.CIA Rt.BKp-foot arteries	Aorta-rt. EIA, lt.CIA	Rt.BKp-ATA thrombectomy		24	
2	70	6	Lt.foot cyanosis	Lt.CIA-foot arteries	Aorta-bil. CIA	Lt.CIA-EIA, lt.DFA, lt.SFA-BKp thrombectomy	Compartment syndrome	2	Death from MOF due to septic shock from gastric perforation at 2 months
3	85	24	Lt.foot rest pain	Lt.EIA Lt.BKp-trifurcation	Lt.EIA	Lt.BKp-peroneal artery thrombectomy		13	
4	81	12	Lt.foot cyanosis	Lt.CIA-CFA lt.BKp-foot arteries	Aorta-rt. CIA, lt.EIA	Lt.CFA, lt.BKp-peroneal artery thrombectomy		6	

EIA: external iliac artery, CIA: common iliac artery, BKp: below knee popliteal artery, ATA: anterior tibial artery, DFA: deep femoral artery, SFA: superficial femoral artery, MOF: multiple organ failure, CFA: common femoral artery.

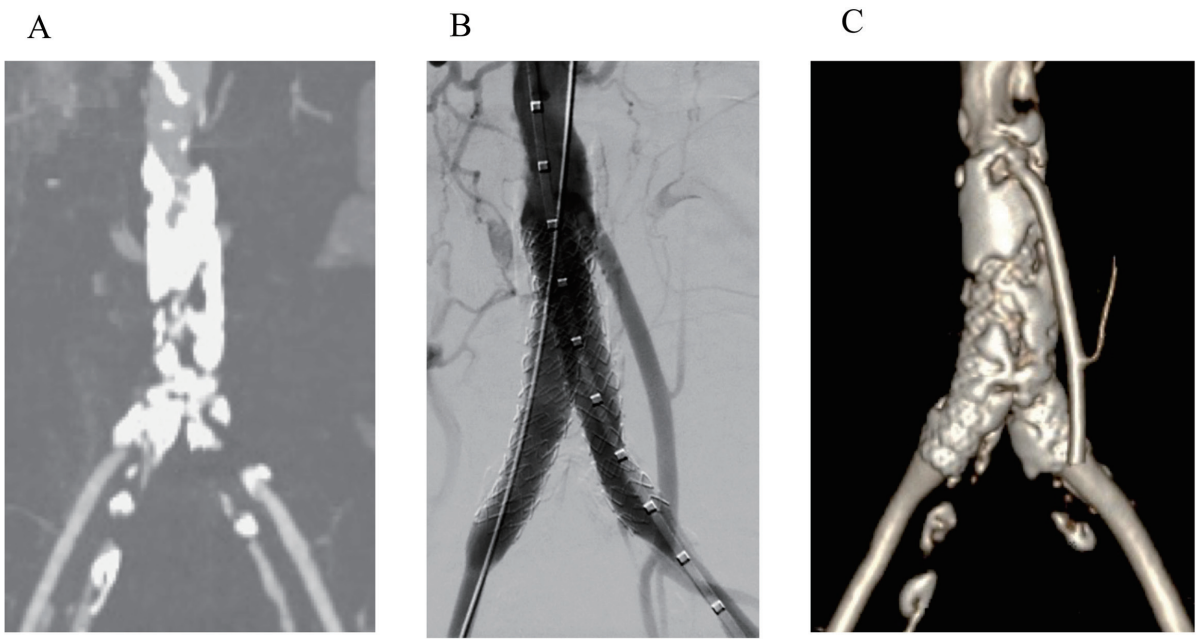

Fig. 1

Angiography showing successful endovascular treatment using the GORE VIABAHN VBX stent in a patient with aortoiliac occlusive disease of both common iliac arteries (A) Preoperative computed tomography (CT) angiography scan showing bilateral common iliac artery occlusion. (B) Completion angiography showing good dilatation using the kissing stent technique with the VBX. Each band on the inserted sizing catheter is spaced 1 cm apart. (C) Postoperative CT angiography scan showing perfect alignment of the stents with the aortic wall.

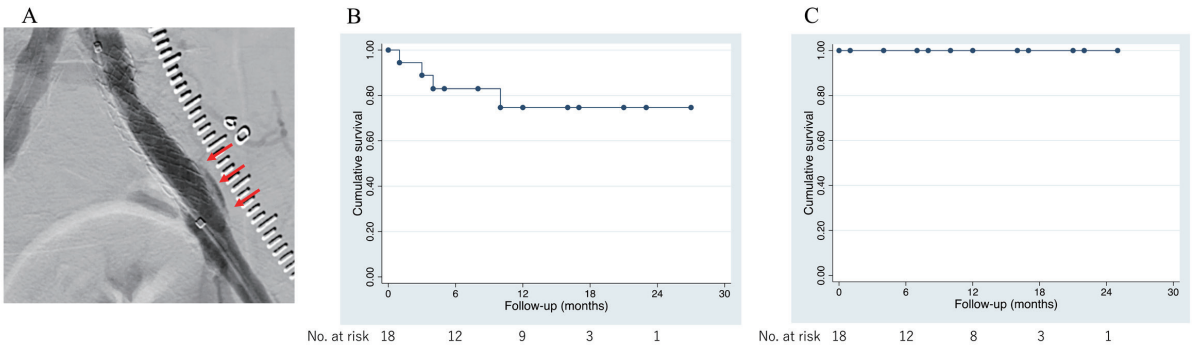

Fig. 2

(A) Completion angiography showing the endovascular treatment with the GORE VIABAHN VBX stent in a patient with aortoiliac occlusive disease of the left common iliac artery. The red arrows indicate stent dissection in the distal edge of the VBX. One scale of the radiopaque ruler in the angiographic image is 2 mm. (B) Kaplan-Meier graph of survival estimates on follow-up. (C) Kaplan-Meier graph of primary patency rate.

placement with thrombectomy of the distal arteries from common femoral artery (CFA) and subsequent angioplasty. The kissing-stenting technique was performed in three patients, whereas the CERAB technique was performed in one patient. Distal embolization was not observed in any of the cases. The procedures were technically successful in all cases. All symptoms improved following revascularization.

Case 2 required a fasciotomy because of compartment syndrome. This patient was a 70-year-old male who died due to multiple organ failure from septic shock secondary to gastric perforation.

Discussion

The treatment for AIOD has evolved in recent years, because endovascular techniques and covered stents are increasingly being used for challenging cases. Data from a multicenter registry in Europe has confirmed this shift by demonstrating that complex aortoiliac lesions were predominantly treated with covered stents.[25] The worldwide shift in technique appears reasonable from a clinical standpoint, because the secondary patency rates following EVT for TASC C/D lesions approximately equal the rates following surgical bypass. EVT is superior to surgical bypass, because it is associated with minimal perioperative complications.[10-12] Covered stents also provide a safety margin against rupture among patients with calcified lesions.[8] Moreover, balloon-expandable covered stents seemed superior to self-expanding stents for patients with AIOD and TASC C/D lesions and/or significant calcification because the former can provide stronger radial force. The VBX is the first balloon-expandable covered stent that has been available for AIOD in Japan since 2018. Reports on utilizing the VBX in patients with AIOD continue to increase; however, real-world studies are still needed.[18-21] To our knowledge, there is only one report on the outcomes of the VBX in a Japanese population.[22] Our study showed no restenosis or occlusion after a median 10 months (range, 1-27), which corresponded well with the results of the VBX-FLEX trial.[26]

ALI is conventionally treated with surgical thrombectomy or catheter-directed thrombolysis;[17] however, some reports have shown that EVT without thrombolytic agents, such as stenting or balloon angioplasty, is equally effective.[27,28] We performed EVT with the VBX in patients with ALI with thrombi in the terminal aorta or origin of the CIA. These patients were at an increased risk for clot dislodgement, contralateral embolization, and plaque protrusion; however, we believed that a covered stent could push the thrombus against the arterial wall and provide more reliable support than bare metal stent placement or balloon dilatation. However, we think EVT using the VBX is at risk of distal embolization. Therefore, the CFA sheaths must be suctioned well during stent deployment and balloon dilatation.

Conclusion

This study demonstrated that EVT with the VBX is effective for AIOD and ALI, particularly in patients with TASC C/D lesions, severe calcification, and limb ischemia secondary to iliac thrombosis.

Conflict of Interest

The authors declare no conflict of interest.

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