Hybrid Viabahn-Assisted Bypass for Long Femoro-Popliteal Occlusive Disease — Midterm Results —

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Background: Endovascular therapy has become the first-line treatment for most peripheral artery diseases, but re-entry into the true lumen is not always possible, particularly in some cases of chronic total occlusion (CTO). We previously reported a novel hybrid Viabahn-assisted bypass (VAB) technique to facilitate revascularization of the femoro-popliteal CTO. This study assessed the mid-term results of VAB technique.

Methods and Results: Between January 2013 and April 2017, 440 patients received femoro-popliteal intervention and 17 of them (mean age, 76.2 years; 11 male patients) were treated using the VAB technique. The technical success was 100%. The mean follow-up period was 27.4 ± 14.4 months (range, 6–50 months). Two patients underwent major amputation at 6 and 11 months postoperatively, but they died of acute myocardial infarction and of sepsis, respectively. Another 3 patients received re-intervention because of edge stenosis of the Viabahn stent graft. Another patient had acute Viabahn thrombosis and was treated using open thrombectomy. The primary and secondary patency rates at 12 months were both 88.2%, and at 24 months they were 69.2% and 84.6%, respectively.

Conclusions: The VAB technique could be a safe and feasible alternative treatment for long femoro-popliteal CTO when conventional treatments fail. The technical success is high, and the midterm patency rates are acceptable.

Key Words: Endovascular therapy; Femoro-popliteal artery; Peripheral arterial disease; Viabahn-assisted bypass

Owing to advancements in technology and improved outcomes in recent years, endovascular therapy (EVT) is now widely used as a first-line treatment for complex peripheral artery disease (PAD) instead of traditional open bypass surgery.^{1–3} The use of the Viabahn (W.L. Gore, Flagstaff, AZ, USA) covered stent, 1 possible EVT, has shown favorable long-term results for treatment of TransAtlantic Inter-Society Consensus II (TASC II)⁴ C or D femoropopliteal (FP) steno-occlusive disease,^{1,2,5–7} and the results are similar to those of surgical revascularization using the conventional femoral-to-above-knee popliteal artery bypass method with a synthetic graft.^{8,9}

Wiring through an entire FP chronic total occlusion (CTO) using intraluminal, subintimal, or subintimal arterial flossing with antegrade-retrograde intervention (SAFARI)¹⁰ is responsible for the success of EVT. In the case of severely calcified occlusive lesions, however, wiring may not be achievable despite the use of various endovascular techniques, thereby causing EVT failure. The hybrid Viabahn-assisted bypass (VAB) technique, which combines small open surgery and the SAFARI technique,¹¹ is designed for cases in which bypass surgery is unsuitable

and EVT failure is certain. The VAB technique improves the success rate of FP revascularization without requiring any special device.

The aim of the present study was therefore to report the midterm results of VAB for long superficial femoral artery (SFA) occlusive lesions at Taipei Veterans General Hospital, Taiwan.

Methods

Study Design

A retrospective review of 17 consecutive patients who underwent attempted recanalization of SFA CTO using the VAB technique between January 2013 and April 2017 was conducted. The institutional review board at Taipei Veterans General Hospital, Taiwan, approved this retrospective study, and the need for informed consent was waived because of the retrospective nature of this study. All patients had critical limb ischemia with rest pain or tissue loss (Rutherford categories 4–6), and all preoperative computed tomography angiography (CTA) showed long SFA CTO lesions (>15 cm). Vascular surgeons with a

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similar training background and a high level of consensus regarding treatment policies owing to routine periodical meetings performed all the revascularization procedures. EVT was considered the first-line treatment if the patients were not eligible for bypass surgery owing to high anesthesia-associated risk or the unavailability of great saphenous vein (GSV) graft. The hybrid VAB technique was used when endovascular wire cannulation of the SFA CTO could not be achieved.

VAB

A detailed description of the VAB technique has been provided previously.¹¹ The antegrade wire was directed from the common femoral artery either contralaterally or ipsilaterally. An intraluminal approach was attempted first, followed by subintimal recanalization. If the antegrade approach failed, we switched to a retrograde approach. Direct puncture of the distal SFA, popliteal artery, anterior tibial artery, or posterior tibial artery was performed using ultrasound or fluoroscopy guidance. Retrograde recanalization was attempted intraluminally or in combination with the SAFARI technique (**Figure 1A,B**). If the antegrade and retrograde approaches both failed, VAB was used. Using fluoroscopy guidance, a 3-cm incision was made immediately above the middle SFA where the antegrade and retrograde guidewires overlapped. A longitudinal or transverse arteriotomy was made without transection. Both the antegrade and retrograde guidewires were retrieved with the supporting catheter from the antegrade access (**Figures 1C,2A**). The antegrade guidewire was removed, and the retrograde guidewire was manually inserted into the antegrade supporting catheter (**Figure 2B**) and externalized from the antegrade access as the flossing wire (**Figures 1D,2C**). Predilatation was performed using the antegrade approach and then a Viabahn was deployed across the arteriotomy site (**Figures 1E,2D**). Postdilatation was performed, and the restoration of the blood flow was confirmed on angiography. After hemostasis was achieved, the wound was closed using the conventional method.

Medication and Follow-up Protocol

All patients received 75 mg clopidogrel per day for ≥ 1 year if it was not contraindicated. Follow-up included symptom evaluation every 3 months at an outpatient department, survey of the ankle-brachial index (ABI) every 6 months, and lower limb CTA postoperatively at 6 and 12 months and then once yearly.

Study Endpoint and Definition

Technical success was defined as the successful deployment of the Viabahn stent graft and restoration of distal blood flow. The primary outcomes included technical success, Viabahn patency, PAD-related death, major amputation (above- or below-knee amputation), and ABI.

Statistical Analysis

Parameters were analyzed using SPSS 18.0 (SPSS Inc. Chicago, IL, USA). Continuous variables are expressed as mean $\pm$ SD. Wilcoxon signed rank test was used to compare the postoperative and preoperative parameters. Patency rates were determined using Kaplan-Meier analysis.

Figure 1. Schematic diagram of Viabahn-assisted bypass. (**A**) TransAtlantic Inter-Society Consensus II C or D lesion of the superficial femoral artery (SFA). (**B**) The antegrade and retrograde guidewires do not meet on the same plane of the subintimal space. (**C**) A small skin incision and a longitudinal or transverse arteriotomy are made to retrieve the antegrade supporting catheter and retrograde guidewire. (**D**) Insertion of the retrograde guidewire into the antegrade supporting catheter and externalization as the flossing wire. (**E**) Deployment of the Viabahn from the antegrade access. A short segment of the stent graft is outside the SFA.

Results

Procedure Results

The demographic features and comorbidities of the 17 patients (mean age, 76.2 years; 11 male patients), are listed in **Table 1**. Technical success was achieved in all patients. Procedural data are listed in **Table 2**. All patients received 2 Viabahn stent grafts, except for 1 patient who received 3 stent grafts. Fourteen patients had 2 distal run-offs, and 3 had only 1 run-off. Thirteen patients received below-the-knee (BTK) interventions, and 5 patients received concomitant iliac stenting. One patient had a contralateral iliac artery rupture with a retroperitoneal hematoma caused by short-segment subintimal wire passage. The patient required iliac stent grafting to stop the bleeding. The other patients did not have intraoperative complications.

Midterm Results

All 17 patients were followed up according to the study protocol, and no patients were lost to follow-up. The mean follow-up was 27.4 ± 14.4 months (range, 6–50 months). All the endpoint outcomes are listed in **Table 3**. Procedure-

Figure 2. Viabahn-assisted bypass technique with open subintimal arterial flossing antegrade and retrograde intervention and covered stent implantation. **(A)** After a small incision is made to expose the middle of the superficial femoral artery (SFA) and longitudinal arteriotomy is performed, the guidewire and supporting catheter from the (white dotted arrow) antegrade and (white arrow) retrograde access are both retrieved. **(B)** White arrow, manual insertion of the retrograde guidewire into the antegrade catheter. **(C)** The flossing guidewire (white arrow) is established and spans the arteriotomy of the middle SFA. **(D)** A covered stent (white arrow) is then deployed to cover the lesion, and is positioned across the arteriotomy of the middle SFA.

Table 1. Patient Demographics

	Mean±SD or n
Age (years)	76.2±5.8
Male	11
Smoking	11
Hypertension	10
Diabetes mellitus	12
Hyperlipidemia	10
CAD	10
Carotid stenosis >70%	8
Stroke	4
Hemodialysis	9
Preoperative ABI	0.51±0.1
Rutherford class	4.7±0.8
SFA lesion length (cm)	19.7±4.0

ABI, ankle-brachial index; CAD, coronary artery disease; SFA, superficial femoral artery.

Table 2. Procedure Data

	Mean±SD or n
Contrast volume (mL)	64.7±18.6
Bleeding (mL)	410±218.1
No. stent grafts	
2	16
3	1
Technical success	17
No. distal run-offs	
2	14
1	3
BTK intervention	13
Iliac stenting	5

BTK, below the knee.

related mortality was not observed. One patient died of acute myocardial infarction 6 months postoperatively. That patient had newly developed renal failure and received hemodialysis. Another patient died of sepsis at 11 months postoperatively. Both patients received additional percutaneous transluminal angioplasty (PTA) for BTK

vessels because of poor wound healing and 1 of them received PTA for edge stenosis, but nonetheless they had to undergo amputation. Another 2 patients received re-intervention because of recurrence of PAD symptoms. One had recurrence of symptoms because of edge restenosis and received PTA using plain balloons. The other

patient had symptom recurrence because of thrombosis of the Viabahn stent graft, and open thrombectomy was performed on this patient. The ABI increased from 0.51 ± 0.10 preoperatively to 1.00 ± 0.34 at 12 months ($P=0.001$), and 1.00 ± 0.50 at 24 months ($P=0.003$) postoperatively. The primary (Figure 3A) and secondary patency rates (Figure 3B) at 12 months were both 88.2%, and at 24 months they were 69.2% and 84.6%, respectively.

Discussion

Surgical bypass is an effective treatment for severe atherosclerotic lower extremity arterial occlusive disease. This treatment, however, is not always possible because of an absence of suitable veins, lack of an appropriate distal target, or difficulty in providing vascular control or in clamping of the SFA for revascularization due to severe calcification. Because of recent advancements in technology and the favorable outcomes of EVT, an increasing number of physicians now use an endovascular-first strategy to treat challenging SFA occlusive lesions that were previously deemed unsuitable for EVT. The technical success rate in treating TASC C or D FP arterial occlusive disease is approximately 90–100%.^{1–3} The most common cause of failure is an inability to re-enter the distal true lumen. Some of these patients can be treated using the SAFARI technique or re-entry devices. SAFARI, however, does not necessarily work in difficult cases, and the re-entry device is expensive and not available in every country. VAB requires only a 3-cm-long skin incision and a small arteriotomy for retrieving both the antegrade and retrograde guidewires. The technical success was 100% in the present 17 patients. We believe that VAB is an alternative hybrid treatment for PAD when conventional EVT fails, and when patients are not eligible for bypass surgery.

The VIPER trial reported a 73% 12-month primary patency rate in patients with long FP steno-occlusive lesions treated using Viabahn endoprosthesis with heparin bioactive surfaces; 56% of the lesions were occlusions, the mean lesion length was 19 cm, and 60% of the enrolled

Table 3. Clinical Results

	VAB (n=17)
Procedure complication	1 (5.88)
Death	2 (11.76)
PAD-related death	1 (5.88)
Major amputation	2 (11.76)
Acute MI	3 (17.65)
Stroke	0 (0)
New hemodialysis	1 (5.88)
TLR	4 (23.53)
Edge stenosis	3 (17.65)
ABI	
12 months	1.00 ± 0.34
24 months	1.00 ± 0.50
1-year primary patency rate	88.2
1-year secondary patency rate	88.2
2-year primary patency rate	69.2
2-year secondary patency rate	84.6

Data given as mean $\pm$ SD, n (%) or %. ABI, ankle-brachial index; MI, myocardial infarction; PAD, peripheral arterial disease; TLR, target lesion revascularization; VAB, Viabahn-assisted bypass.

limbs had TASC II C or D lesions.⁶ The VIASTAR group also reported that the intention-to-treat primary patency rate at 12 months was 70.9% in patients with symptomatic FP steno-occlusive disease; the mean lesion length was 19.3 cm.⁵ In the present VAB group, the mean SFA occlusive length was 19.7 cm, and all the limbs had TASC II C or D lesions. The 12-month primary patency rate was 88.2%, which is superior to that reported from those studies. We believe that if a few rules – such as correct graft sizing; extending the device to relatively disease-free areas of the vessel; and not performing angioplasty beyond the area of planned stent coverage to avoid edge stenosis^{7,8} – are strictly followed, VAB is a feasible alternative treat-

ment for long SFA steno-occlusive lesions.

The use of GSV bypass remains the gold standard for surgical revascularization of PAD, when available. The alternative conduit is prosthetic polytetrafluoroethylene (PTFE). The primary patency rates at 12 and 24 months for above-the-knee FP bypass using GSV or PTFE graft are around 83%, 80% and 74%, 60% respectively.¹² The primary patency in the present VAB group was superior to the PTFE bypass graft. Also, VAB requires only a 3-cm incision above the middle SFA, which can be performed under local anesthesia. The avoidance of general anesthesia and multiple incision wounds may facilitate recovery and shorten the length of hospital stay.

Some technical steps should be followed when using the VAB technique. First, the arteriotomy (skin incision) site should be located away from the popliteal artery because it is deeper than the SFA and may require a relatively large incision for enabling exposure. The middle of the SFA is an ideal site for the arteriotomy to retrieve the antegrade and retrograde guidewires because it is relatively superficial and easily accessible. Second, the proximal and distal landing zones of the Viabahn stent graft should be longer than the normally used 1-cm zones because a short segment of the Viabahn is outside the native SFA. When the patient performs daily activities, the movement of the endoprosthesis may become more prominent than usual. Thus, we recommend that the landing zone be at least 3 cm away from the arteriotomy site in the disease-free SFA to prevent the stent graft from exiting the SFA. Third, while performing pre-dilatation from the antegrade access, finger compression of the arteriotomy site is necessary after deflation of the balloon to prevent bleeding. Most blood loss occurs at this stage. After deployment of the Viabahn stent graft, no further bleeding problems are encountered. Finally, skin incisions near pre-existing ulcers or infection of the medial thigh should be avoided because this increases the risk of wound complication.

Study Limitations

The limitations of this study were its single-center and retrospective design, in which treatment was allocated according to surgeon preference. We cannot draw conclusions regarding the superiority of VAB compared with other treatments. The small sample size might have introduced bias. Additional studies are warranted to evaluate the long-term outcomes of this novel technique.

Conclusions

VAB is a safe alternative procedure that does not require special or expensive devices; it requires only a small skin incision. The short-term and midterm results are acceptable for treating TASC II C or D FP occlusive lesions, but additional studies are warranted to evaluate the long-term outcomes.

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Disclosures

The authors declare no conflicts of interest.

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