Increasing efficacy of endovascular recanalization with covered stent graft for TransAtlantic Inter-Society Consensus II D aortoiliac complex occlusion

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Objective: **We compared the outcomes and the durability of endovascular recanalization (EVR) with the Viabahn (W. L. Gore and Associates, Flagstaff, Ariz) covered stent graft vs traditional aortobifemoral or aortofemoral bypass grafting for complex aortoiliac occlusions.**

Methods: **Between 2008 and 2014, 11 unilateral iliac occlusions and 11 aortobiiliac occlusions were treated by EVR. Also collected were data from the last 21 consecutive patients treated in the same period by aortofemoral (n = 6) or aortobifemoral (n = 15) bypass grafting. In accordance with the TransAtlantic Inter-Society Consensus II (TASC II) document, only patients with type D lesions were considered. Kaplan-Meier estimates for patency were calculated, and Cox proportional hazard modeling was performed.**

Results: **The difference in risk factors between the groups was not significant. General anesthesia was required in 100% of the surgical group, and local or locoregional anesthesia was used for EVR. Suprarenal aortic cross-clamping was required in nine of the open surgical procedures (41%). A brachial percutaneous approach was performed in all patients undergoing EVR, and technical success was 100% in both groups. All of the attempts at EVR were successful. At the 2-year follow-up, primary patency did not differ significantly between the endovascular (91%) and surgical (95%) groups. This was seen in the univariate model (hazard ratio [HR], 0.27; 95% confidence interval [CI], 0.02-2.95; $P = .28$) and in the multivariate model (HR, 0.77; 95% CI, 0.06-10.07; $P = .84$) for group (HR, 0.58; 95% CI, 0.04-7.72; $P = .68$), age (HR, 0.89; 95% CI, 0.73-1.08; $P = .24$), symptoms (HR, 1.98; 95% CI, 0.42-9.46; $P = .39$), and occlusion (HR, 3.22; 95% CI, 0.51-20.35; $P = .21$). The average hospital length of stay was shorter for patients treated with ERV than for those treated with open surgery (3.9 ± 2.2 vs 5.8 ± 3.1 days, respectively; $P = .03$). The complication rate was 4% for EVR vs 18% in the surgical group ($P = .32$).**

Conclusions: **At 2 years of follow-up, the results of endoluminal bypass grafting with the Viabahn stent to treat complex aortoiliac disease are promising. Longer-term results are needed to fully evaluate the potential benefits and longer-term patency. (J Vasc Surg 2015;62:1219-26.)**

The TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) consensus document classifies bilateral and unilateral iliac occlusions as D lesions, with open surgical repair (OSR) as the treatment of choice.[1] Aortobifemoral bypass (ABF) grafting is traditionally considered the standard treatment for aortoiliac complex occlusions, with a primary patency rate of >90% after 5 years. However, ABF carries significant mortality (3.3%) and morbidity (8.3%); therefore, high-risk patients are not always candidates for what remains major surgery.[2] Extra-anatomic bypass grafting (axillofemoral bypass) is a potential alternative treatment for high-risk patients; however, longer-term patency is poorer, with a primary patency rate of 63% after 5 years.[3]

With the advent of endovascular therapy, several different techniques with a number of suitable devices are reported for the treatment of this complex pathology.[4-7] Endovascular recanalization (EVR) using the Viabahn covered stent graft (W. L. Gore and Associates, Flagstaff, Ariz) has been reported in some series but has never been the subject of a focused study.[6,8,9] The results of this device in aortoiliac segment have never been compared with the surgical standard treatment for this pathology. Thus, the aim of this study was to evaluate our experience

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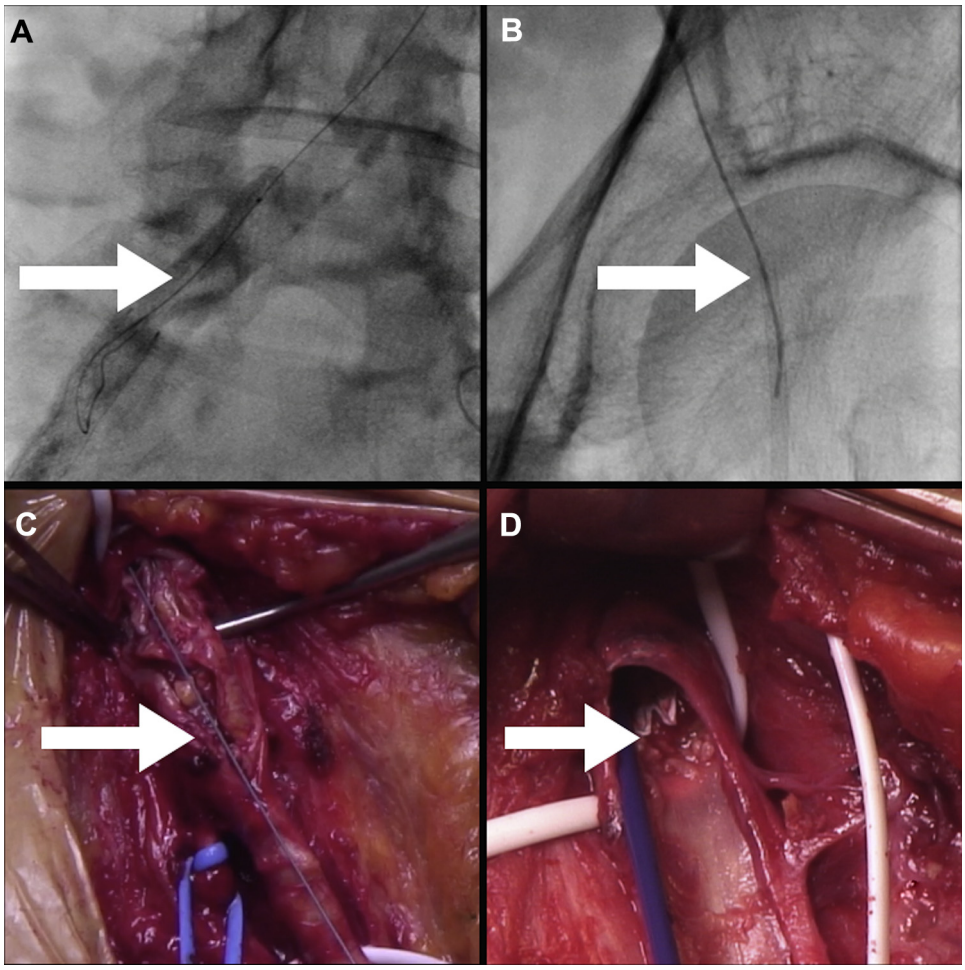

Fig 1. A, Endoluminal recanalization from the brachial access with a 0.018-inch guidewire (*arrow*). In this case, an occluded stent was crossed in the left iliac artery. **B,** The guidewire that comes from the brachial access has crossed the occluded aortoiliac segment and is recovered into a 6F introducer sheet (*arrow*) positioned in the common femoral artery. **C,** The guidewire (*arrow*) is directly recovered through the femoral artery exposure while endarterectomy with profundoplasty is performed. **D,** Distal edge of a Viabahn (W. L. Gore and Assoc, Flagstaff, Ariz) stent graft (*arrow*) positioned in the proximal segment of the femoral artery, crossing the inguinal ligament.

of EVR with the Viabahn stent for complex aortoiliac occlusions compared with OSR.

METHODS

Patient selection criteria. Between January 2008 and December 2014, 658 procedures for aortoiliac occlusive disease were performed in our center. Forty-three patients were treated for abdominal aorta or iliofemoral chronic total occlusion (CTO). Aortoiliac CTO is defined as a proximal or distal aortic occlusion, or both, in addition to unilateral or bilateral iliac occlusion. Iliofemoral CTO is defined as a unilateral common and external iliac occlusion. Data relating to these interventions were obtained from our dedicated database, consisting of demographic data, preoperative risk factors, clinical and diagnostic assessments, symptoms at presentation (Rutherford scale), intraoperative features, and early and middle-term follow-up results.[10]

Patients were grouped according to treatment with OSR or EVR. The EVR group also included patients undergoing hybrid repair. Hybrid repairs consisted of an endovascular intervention as well as surgical exposure of the femoral arteries with common or profunda femoris endarterectomy, or both. The treatment decision was made by the referral physician, after multidisciplinary team discussion.

The caseload in this study consisted of 18 patients presenting with proximal aortoiliac occlusions (juxtarenal or infrarenal), 8 with distal aortoiliac occlusions (below the origin of the inferior mesenteric artery or intramesenteric), and 17 with unilateral iliac occlusions. We also included patients with CTO involving the common femoral artery. Aortic or iliac artery stenoses, without total occlusion,

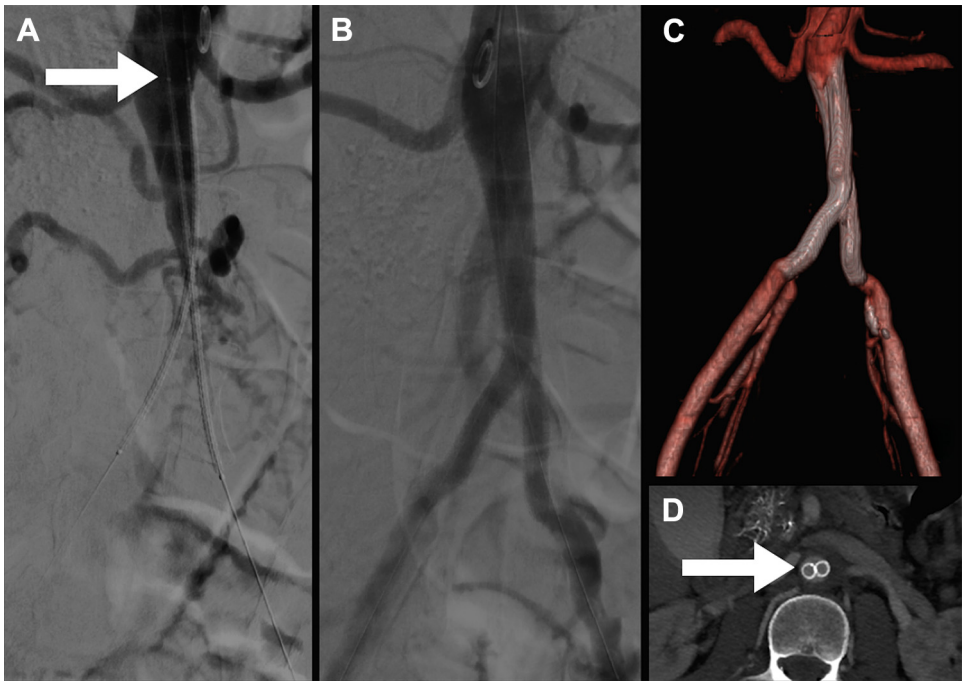

Fig 2. A, Proximal edge of two Viabahn (W. L. Gore and Assoc, Flagstaff, Ariz) covered stents (*arrow*) positioned immediately inferior to the renal arteries. **B,** Completion angiography after endovascular recanalization (EVR). **C,** A three-dimensional computed tomography scan reconstruction after 6 months from the procedure shows a good result of the procedure. **D,** Computed tomography image shows the proximal position of the two Viabahn covered stents (*arrow*).

were considered as exclusion criteria. Iliac artery stenosis is often treated with a bare-metal stent, hence the exclusion of these lesions. Also excluded were patients who underwent thrombolysis at any stage.

All patients who met the study criteria gave written informed consent to undergo the proposed treatment, and the protocol was locally approved from an ethics perspective after review by a nominated committee.

Preoperative study. All patients underwent preoperative diagnostic imaging with digital subtraction angiography or computed tomography scan in addition to duplex ultrasound imaging. All preoperative imaging was reviewed to confirm the diagnosis, and patency of the femoropopliteal and tibial vessels was evaluated. Patients with stenosis or occlusion of the common femoral or profunda femoral artery, or both, were eligible for a hybrid procedure. After the primary intervention, patients were considered to have "poor outflow" if they had occlusions of one or both of their superficial femoral arteries.

Treatment techniques. OSR consisted of a conventional aortobifemoral Dacron (DuPont, Wilmington, Del) bypass grafting for aortoiliac CTO and aortofemoral disease and iliofemoral Dacron bypass grafting for unilateral iliac CTO. Endovascular treatment consisted of EVR with the Viabahn for aortoiliac or unilateral iliac CTO.

EVR technique. The EVR procedures were performed in a hybrid operating theater using an Artis Zeego system (Siemens AG, Forchheim, Germany) under local or epidural anesthesia. Percutaneous brachial access was performed with a 6F hydrophilic introducer sheath. Brachial arterial puncture was routinely performed 1 to 2 cm above the antecubital crease. Percutaneous femoral access was obtained with a 6F hydrophilic introducer sheath. When the occlusion also involved the common femoral artery, surgical exposure of the common femoral artery was performed and a hybrid procedure performed.

The occluded aortoiliac segments were crossed with a 0.018-inch guidewire by a brachial approach. Guidewire position was determined to be transluminal or subintimal, and then a 0.018-inch guidewire was recovered through a femoral introducer or through the femoral artery surgical exposure (Fig 1). Marked pigtail catheters were routinely used to ensure correct selection of endograft length.

Appropriate Viabahn diameter was selected based on preoperative digital subtraction angiography images using the diameter of an arterial segment on the ipsilateral side. For unilateral occlusions, the contralateral side was used for diameter evaluation and selection. For aortoiliac CTO, the standard diameter was 8 mm proximal (in the aorta) and 7 mm in the distal iliac artery. Viabahn stent grafts were deployed simultaneously via the femoral access to cover the entire arterial occlusion (Fig 2).

For juxtarenal occlusions, the proximal edge of the Viabahn stent graft was positioned immediately inferior to the renal arteries. If the occlusion involved the common femoral artery, the distal edge of the Viabahn stent graft was positioned near the proximal segment of the femoral artery, crossing the inguinal ligament. In all cases the Viabahn stent

Table I. Preoperative demographic variables for patients undergoing endovascular and hybrid recanalization (*EVR*) or open surgical repair (*OSR*) with aortobifemoral or aortofemoral bypass for extensive aortoiliac occlusive disease

Variable	*EVR group (n = 22)*	*OSR group (n = 21)*	P *value*
Age, mean ± SD years	64.2 ± 8.1	67 ± 6.4	.27
Gender, No.			
Male	15	15	.40
Female	7	6	.40
Hypertension, No.	19	19	.99
Diabetes, No.	8	2	.07
Coronary artery disease, No.	5	2	.41
Renal failure,[a] No.	1	2	.96
Hyperlipidemia,[b] No.	12	7	.16
Smoking, No.	15	18	.17
Rutherford stage, No.			
III	13	15	.29
IV	7	5	.40
V	2	1	.29
Occlusion, No.			
Proximal aortoiliac	7	11	.14
Distal aortoiliac	4	4	.35
Common and external unilateral iliac	11	6	.13
Poor out flow (SFA occlusion)	8	9	.66

SD, Standard deviation; *SFA,* superficial femoral artery.
[a]Defined as patients with elevated serum creatinine concentration >1.5 mg/dL.
[b]Defined as patients with elevated plasma lipids or under medical treatment.

grafts were balloon-dilated for their full length. Technical success of the EVR was defined as successfully crossing the occlusion and correctly deploying the stent graft, with no measurable hemodynamic pressure gradient across the lesion.

All patients received unfractionated heparin (50 U/kg) during the procedure and were discharged with dual-antiplatelet therapy (aspirin, 100 mg; clopidogrel, 75 mg) and a statin.

OSR technique. All ABFs were performed under general anesthesia via a conventional transperitoneal approach. A suprarenal cross-clamp was performed for juxtarenal occlusions. In all cases, a Dacron bifurcated graft was used to perform end-to-side proximal and distal anastomoses. For unilateral iliac occlusions, the site of proximal cross-clamping was the distal aorta or the proximal common iliac artery. An end-to-end proximal anastomosis was used, with an end-to-side distal anastomosis. Technical success of OSR was defined as successful bypass of the occluded segment with a prosthetic graft in the absence of graft thrombosis.

All patients received unfractionated heparin (50 U/Kg) during the intervention and were discharged on single-antiplatelet therapy and a statin.

Follow-up. All patients underwent duplex ultrasound scans 6 months after the procedure and then every 12 months. The median length of follow-up was 28 months. Primary and secondary patency rates were determined according to the Society for Vascular Surgery guidelines.[10] Loss of patency and other complications were determined by duplex ultrasound imaging and confirmed with formal angiography.

Statistical analysis. Data are presented as frequency and percentage for qualitative variables and means and standard deviation for quantitative variables. Baseline comparisons for qualitative variables were conducted using χ^2 and Fisher exact tests. Baseline comparisons for quantitative variables were conducted using the Wilcoxon sum rank test. Patency was analyzed with univariate and multivariate Cox proportional hazard models adjusted for age, symptoms, and type of occlusion. Analyses were performed using SAS 9.3 (SAS Institute Inc, Cary, NC) and Stata 10.1 (StataCorp LP, College Station Tex) software. All tests were two-tailed, and an overall $P = .05$ was considered significant.

RESULTS

Of the 43 patients who met the inclusion criteria for the study, 22 were treated by EVR and 21 by OSR. All patients had TASC II D lesions, and the two groups had similar risk factors, symptoms at presentation, runoff status, and level of arterial occlusion, as reported in Table I.

EVR group. The 22 patients in the EVR group underwent 14 endovascular procedures and eight hybrid procedures. Local anesthesia was used in 10 procedures and locoregional anesthesia in 12. Technical success was achieved in all cases. Four patients required a subintimal recanalization, and the recanalization for the remaining 18 patients was performed via an endoluminal approach. Endarterectomy with profundoplasty was performed in 36% (8 of 22) of ERV patients. No stent compression or fracture was seen, including cases crossing the inguinal ligament, and there were no instances of distal artery embolization. No patients in this group required concomitant lower extremity bypass. Manual compression was used for hemostasis, although conversion to surgical closure was performed in one patient.

No patient experienced nerve sheath hematoma, brachial occlusion, hematoma, arm ischemia, or stroke. Acute renal failure (serum creatinine >2 mg/dL) developed in two patients in the EVR group, with spontaneous resolution. No patient experienced renal or visceral artery embolization.

At 2 years of follow-up, cumulative primary for the EVR group was 94% (31 of 33 limbs) and secondary patency was 97% (32 of 33 limbs). Two unilateral occlusions occurred in patients who underwent aortoiliac bilateral EVR recanalization with a purely endovascular procedure. The first occurred at 19 months with critical limb ischemia and was treated with thrombolysis and distal external iliac artery relining with a Viabahn stent. The occlusion was deemed to be due to external iliac artery tortuosity just below the distal edge of the Viabahn. The second patient had a unilateral occlusion at a similar time with mild to moderate claudication. The patient chose conservative management given his mild symptoms and after discussion of the treatment options.

OSR group. All surgical procedures were performed under general anesthesia. Technical success was achieved

in all cases. Nine patients (43%) required suprarenal aortic cross-clamping. Transitory renal failure (serum creatinine >2 mg/dL) developed in two patients, with spontaneous resolution. Nine of the 21 surgical repairs (43%) were associated with endarterectomy and profundoplasty (3 unilateral and 6 bilateral).

The 2-year primary patency rate for the OSR group was 97% (35 of 36 limbs) and secondary patency was 100% (36 of 36 limbs). One unilateral and one bilateral occlusion occurred after 19 and 33 months. The first (19 months) was due to poor runoff and treated with thrombectomy and femoropopliteal jump bypass grafting. The second patient (33 months) presented with moderate claudication and was managed conservatively. There were four major complications in this group: 1 patient had pneumonia on the second postoperative day, 2 patients with double-antiplatelet therapy for a recent percutaneous transluminal coronary angioplasty underwent surgical revision for hemoperitoneum (on the third and fifth postoperative days, respectively), and 1 patient underwent surgical revision after 18 months for an incisional hernia.

Group comparison. Median follow-up time was 28 ± 21.5 months (range, 5-112 months) for the entire cohort. Primary occlusion rate was 0.58/100 person-years in the EVR group and 0.31 in the OSR group. No significant difference was found between primary patency by limb at 2 years (94% [33 of 31 limbs) in the EVR group vs 97% [35 of 36 limbs]) in the OSR group ($P = .50$). At the 2-year follow-up, the difference in overall primary patency between the EVR and OSR group was not significant in the univariate model (hazard ratio [HR], 0.27; 95% confidence interval [CI], 0.02-2.95; $P = .28$; Fig 3) and the multivariate model (HR, 0.77; 95% CI, 0.06-10.07; $P = .84$). A multivariate analysis to test the possible effects of other variables, such as group (HR, 0.58; 95% CI, 0.04-7.72; $P = .68$), age (HR, 0.89; 95% CI, 0.73-1.08; $P = .24$), symptom (HR, 1.98; 95% CI, 0.42-9.46; $P = .39$), and occlusion (HR, 3.22; 95% CI, 0.51-20.35; $P = .21$) found no significant differences between the groups.

The average hospital length of stay was shorter for patients treated with EVR (3.9 ± 2.2 days) vs OSR (5.8 ± 3.1 days; $P = .03$). The complication rate was 4% for ERV vs 18% for OSR ($P = .32$).

DISCUSSION

Endovascular treatment with bare-metal stents for aortoiliac disease in TASC II A and B lesions has demonstrated excellent results, with 1-year primary patency of 95%.[11] Recent studies are currently extending the endovascular treatment recommendations for TASC II C and D lesions, traditionally the preserve of OSR.[5,6,12]

However, despite the technologic improvement of the devices, there is a relative paucity of endovascular devices specifically designed for aortoiliac occlusive diseases. Bare-metal stents, balloon-expandable stents, and self-expandable covered stents and endografts have been used for the treatment of this pathology.[4-9] The self-expanding Viabahn covered stent graft is the only device approved by the U.S. Food and Drug Administration for use in iliac arteries, but not in the distal or proximal aorta. The Advanta V12 (Atrium Medical Corp, Hudson, NH) is also approved for iliac artery occlusive disease, but in Europe only. Covered stents that have been approved for other indications are used off label for treating aortoiliac diseases.

Bare-metal stents. Early reports of recanalization of this pathology report angioplasty and bare-metal stenting as the most commonly used technique to treat iliac stenosis and occlusion.[13] Some studies have advocated the advantage of primary stenting over percutaneous transluminal angioplasty alone for the treatment of iliac artery occlusion.[6-14] Patients with occlusive lesions of the proximal common iliac artery represent a complex subgroup, and the results associated with the use of iliac artery kissing bare-metal stents have been less encouraging when the stents extend into the aorta.[7] This is most likely caused by the hemodynamic effect or lack of neoendothelialization of the free end of the bare stents within the aortic lumen, which could increase thrombogenicity. Moreover, iliac arterial rupture after angioplasty and bare-metal stent placement is a potential risk of the procedure.[14]

Covered stents. Some studies suggest the use of covered balloon-expandable stents confer the advantage of decreased thrombogenicity, with less chance of plaque prolapse through a covered stent and less ingrowth of hyperplastic tissue compared with bare-metal stents.[7-9]

In general, most studies focusing on the use of covered stents in iliac artery occlusion report superiority over uncovered stents.[7] Conversely, recent studies claim the superiority of bare-metal stents compared with covered balloon-expandable stents for treatment of aortoiliac occlusive disease. Humphries et al[15] recently reported their experiences of recanalizing occluded iliac arteries treated by bare-metal stent vs covered stent and concluded that primary patency was significantly better in the bare-metal stent group (89% ± 3% vs 72% ± 6%; $P = .008$).[15] The debate is therefore still open, and this is reflected by ongoing trials.[16]

Stent grafts (component of endoprosthesis). Some studies have demonstrated the efficacy of using stent grafts for aortoiliac occlusive disease.[17] Zander et al[9] used a bifurcated aortic endovascular prosthesis in 14 patients, and reported a primary of 85.7% and secondary patency of 100% at a mean follow-up of 62 months. However, the use of stent grafts for aortic bifurcation occlusive disease requires large introducer sheath sizes in the face of potentially small access vessels and has higher associated treatment costs. Moreover, a decreased diameter of the aorta or iliac arteries makes the procedure technically challenging and carries the inevitable potential risk of graft occlusion.[18]

Other techniques have been described, such as covered endovascular reconstruction of the aortic bifurcation (CERAB). This technique describes the use of an aortic cuff that covers the proximal edge of the iliac covered stents in the distal aorta in an attempt to reconstruct the aortic bifurcation in a more anatomic fashion.[19] A recent study by Jebbink et al[20] analyzed, in vitro, the geometric consequences of CERAB compared with three alternatives:

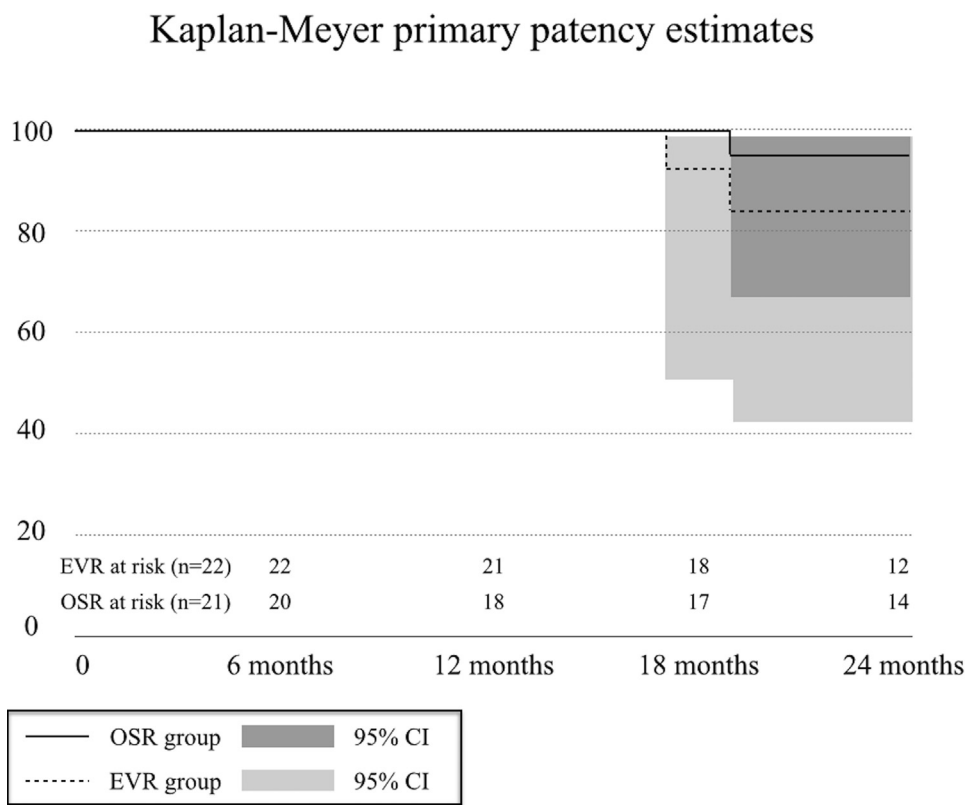

Fig 3. Kaplan-Meier and 95% confidence interval (*CI*) curve estimates for primary patency in patients undergoing endovascular recanalization (*EVR*) with a Viabahn (W. L. Gore and Assoc, Flagstaff, Ariz) covered stent vs an open surgical procedure (*OSR*). No significant difference was found between the EVR and OSR groups at 24 months (hazard ratio [HR], 0.27; 95% CI, 0.02-2.95; $P = .28$).

self-expandable nitinol kissing stent, balloon-expandable covered stent, and another variant of the CERAB technique. They reported that the CERAB configuration with the iliac legs positioned inside the tapered part of the aortic cuff has the lowest radial mismatch, which can minimize flow perturbations and thrombus formation. However, this remains an in vitro model and may not correlate to clinical outcome.

Viabahn covered stent. No previous study has focused solely on the use of Viabahn covered stents for aortoiliac CTO. Lammer et al,[21] in 2000, reported the results of the Hemobahn covered stent graft (W. L. Gore and Associates), but they included also iliac artery stenotic lesions, with a reported primary patency rate of 91% at 12 months. Other studies have reported experiences with the Viabahn device, but they usually analyzed its results in combination with other covered stents and typically also considered patients with TASC II B lesions (Table II).

We exclusively used the Viabahn covered stent, without an aortic cuff, to perform our EVRs. In our opinion, the Viabahn has three main advantages: (1) it is a covered stent, providing a direct barrier to the ingrowth of neointimal hyperplasia; (2) it is extremely flexible, minimizing the risk of occlusion due to kinking in the tortuous external iliac artery; and (3) it is low profile, allowing the 7-mm and 8-mm devices to be deployed via a 7F introducer sheath. In 2008, the Gore Viabahn received U.S. Food and Drug Administration indication for use in the treatment of iliac occlusive disease, although our use of these stents with extension in the aortic bifurcation is still out of the instruction for use.[24]

In our study, mean infrarenal aortic diameter was 18.8 ± 3.1 mm. No proximal stent compression was recorded in any patient. We can postulate that a proximal aortic diameter of <14 mm might increase the chances of stent compression. In this case, choosing a proximal stent diameter of 7 mm would probably be better.

Our results show no significant difference related to patency between OSR and EVR with the Viabahn covered stent. We reached a 100% technical success rate mainly thanks to the brachial access, which leads us to cross the occluded arterial tract in all cases, and also thanks to the high conformability of the endograft. Thanks to the endograft low profile, we did not have any access vessel injury. The fact that the Viabahn is a covered stent mitigates some of the potential risk of vessel rupture during the course of recanalization.

For patients with a juxtarenal occlusion, the only complication was an episode of acute renal failure in the EVR group. Notably, we also observed acute renal failure

Table II. Studies reporting the results of covered stents for the treatment of aortoiliac or iliac occlusive disease

First author	*TASC II lesion*	*Total iliac arteries treated, No.*	*Viabahn, No. (%)*	*Hemobahn, No. (%)*	*Advanta-V12*	*Icast, No. (%)*	*Fluency, No. (%)*	*Wallgraft, No. (%)*	*Cordis, No. (%)*	*Overall primary patency*
Lammer,[21] 2000	B, C, D	61	–	61 (100)	–				–	91% at 12 months
Chang,[8] 2008	C, D	193	9 (5)	–	–	6 (3)	52 (27)	–	–	87% at 5 years
Ali,[6] 2003	C, D	22	2 (9)					20 (91)		84% at 24 months
Rzucidlo,[9] 2003	B, C, D	34	4 (12)	–	–	–	–	30 (88)	–	70% at 12 months
Sabri,[7] 2010	A, B, C, D	26	–	–	–	26 (100)	–	–	–	92% at 24 months
Bosiers,[11] 2013	C, D	91	–	–	91 (100)	–	–	–	–	91.1% at 12 months
Wiesinger,[22] 2005	A, B, C, D	60	–	–	–	–	–	–	60 (100)	90.7% at 12 months
Mwipatayi,[23] 2011	B, C, D	81			81 (100)					92% at 18 months
Humphries,[15] 2014	A, B, C, D	64	–	–	–	64 (100)	–	–	–	72% at 3 years
This study	D	33	33 (100)	–	–	–	–	–	–	90.9% at 24 months

TASC II, TransAtlantic Inter-Society Consensus.
All these studies report treatment of TASC C and D and some of them even TASC B lesions. The covered stents considered are Viabahn and Hemobahn (W. L. Gore and Assoc, Flagstaff, Ariz), Advanta-V12 and Icast (Atrium Medical Corp, Hudson, NH), Fluency (Bard, Lowell, Mass), Wallgraft (Boston Scientific, Natick, Mass), Cordis polytetrafluoroethylene-covered nitinol stents (Johnson & Johnson, Waterloo, Belgium).

in a patient with unilateral iliac occlusion; both cases resolved spontaneously after appropriate management, with no evidence of renal artery occlusion or embolism.

When the distance between the lowest renal artery and the aortic occlusion is <2 cm, some authors suggest the use of renal protection devices such as guidewires, filters, or balloons.[25] In our experience, seven of the described cases had proximal aortic occlusions, and our patients experienced no complications despite not using a renal protection device. A possible explanation for this is that all of our recanalizations were done via a brachial approach, although one must bear in mind that renal embolization can also occur during predilatation and deployment of the endograft. The limited numbers in this series make it difficult to draw a meaningful conclusion on this.

In terms of runoff vessels, common femoral artery occlusion was quite common among these patients. We performed femoral endarterectomy in almost one-third of the cases in both groups, which reflects the advanced level of disease; however, this had no significant effect on the patency of the endografts. Although at potential risk of stent compression or fracture, covered stenting crossing the inguinal ligament was safe and effective in this series, as reported by other series.[26] Patients with superficial femoral artery occlusion, even if affected by Rutherford 4 lesions, did not undergo concomitant lower limb bypass or revascularization. We adopted a policy of performing aortoiliac recanalization first to see if the restored inflow was sufficient.

For OSR, although aortounifemoral bypasses have been reported to have poorer outcomes than aortobifemoral grafting, we did not observe this phenomenon. At 2 years, the only limb occlusion recorded occurred in a patient treated with an ABF graft.

Study limitations. This study is limited by the small sample size, the lack of prospective randomization, and by the relatively short follow-up. However, we believe the comparison is still a valid one.

CONCLUSIONS

EVR with the Viabahn stent graft for complex aortoiliac occlusion is a safe and effective treatment, which seems a valid alternative to OSR for its comparable outcome at 2 years. A prospective trial with longer follow-up might be able to clarify if these encouraging results will be result in similarly promising long-term outcomes.

AUTHOR CONTRIBUTIONS

Conception and design: DP, MF, FN
Analysis and interpretation: DP, FR, FN
Data collection: DP, AV, AT
Writing the article: DP, EF, SB
Critical revision of the article: EF, MF, SB
Final approval of the article: DP, EF, FN
Statistical analysis: FR
Obtained funding: Not applicable
Overall responsibility: FN

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