Results of iliac branch devices for hypogastric salvage after previous aortic repair

Davide Mastrorilli, MD,[a] Luca Mezzetto, MD,[a] Michele Antonello, PhD,[b] Mario D'Oria, MD,[c] Gioele Simonte, MD,[d] Giacomo Isernia, MD,[d] Emiliano Chisci, MD,[e] Mattia Migliari, MD,[f] Stefano Bonvini, MD,[g] *and* Gian Franco Veraldi, MD,[a] on behalf of the RESCUE study collaborative group, *Verona, Padua, Trieste, Perugia, Florence, Baggiovara and Trento, Italy*

ABSTRACT

Objective: The aim of this multicentric study was to assess the "REsults of iliac branch deviceS for hypogastriC salvage after previoUs aortic rEpair (RESCUE)."

Methods: All consecutive patients who underwent implantation of iliac branch devices (IBDs) after previous open aortic repair (OAR) or endovascular aortic repair (EVAR) at seven centers were captured. The study cohort was divided into two groups according to the type of repair originally performed. Early outcomes included immediate technical success and perioperative adverse events. Late outcomes included survival, side branch (SB) primary patency, SB instability, and new onset buttock claudication.

Results: A total of 94 patients (82 male) were included in the study, 10 of them received bilateral implantation of IBDs. This resulted in a total of 104 devices included in the final analysis. Indication for treatment were endoleak 1b or progressive iliac aneurysmal degeneration or distal para-anastomotic aortic aneurysms; 73 were implanted after previous EVAR and 31 after previous OAR. Technical success was 100% in both groups. The 3-year rate of freedom from SB instability was 90.1% after previous EVAR and 85.4% after previous OAR, respectively ($P = .05$). The 3-year estimates of SB primary patency were significantly lower in patients who had received OAR as compared with those that had received EVAR (89.8% vs 94.9%; $P = .05$).

Conclusions: Endovascular treatment with IBDs following previous OAR or EVAR is safe and effective up to 3 years. Freedom from SB instability during follow-up was lower in patients who had previously undergone OAR than EVAR.

Keywords: Aortoiliac disease; Endovascular repair; Iliac branch device; Internal iliac artery

When endovascular aortic repair (EVAR) is performed in a patient with an enlarged common iliac artery (CIA), continued vessel expansion remains a concern eventually resulting in failure of the distal sealing and type Ib endoleak.[1,2] Nevertheless, distal para-anastomotic aortic aneurysms or progressive CIA aneurysmal degeneration below a previous OAR are encountered with increasing frequency, owing to the improved survival of this

From the Department of Vascular Surgery, University of Verona School of Medicine, University Hospital of Verona, Verona[a]; the Division of Vascular and Endovascular Surgery, Department of Cardiac, Thoracic, Vascular Sciences and Public Health, School of Medicine, University of Padua, Padua[b]; the Division of Vascular and Endovascular Surgery, Cardiovascular Department, University Hospital of Trieste ASUGI, Trieste[c]; the Unit of Vascular and Endovascular Surgery, Santa Maria della Misericordia Hospital, Perugia[d]; the Department of Surgery, Vascular and Endovascular Surgery Unit, Usl Toscana Centro, "San Giovanni di Dio" Hospital, Florence[e]; the Division of Vascular Surgery, University Hospital of Modena and Reggio Emilia, Baggiovara[f]; and the Department of Vascular Surgery, Santa Chiara Hospital, Trento.[g]

Author conflict of interest: none.

RESCUE study collaborative group: Elda Chiara Colacchio (Division of Vascular and Endovascular Surgery, Department of Cardiac, Thoracic, Vascular Sciences and Public Health, School of Medicine, University of Padua, Padua, Italy), Salvatore Bruno (Department of Vascular Surgery, University of Verona School of Medicine, University Hospital of Verona, Verona, Italy), Massimo Lenti (Unit of Vascular and Endovascular Surgery, Santa Maria della Misericordia Hospital, Perugia, Italy), Sandro Lepidi (Division of Vascular and Endovascular Surgery, Cardiovascular Department, University Hospital of Trieste ASUGI, Trieste, Italy), Nicola Leone (Division of Vascular Surgery, University Hospital of Modena and Reggio Emilia, Baggiovara, Italy), Stefano Michelagnoli (Department of Surgery, Vascular and Endovascular Surgery Unit, Usl Toscana Centro, "San Giovanni di Dio" Hospital, Florence, Italy), Mattia Migliara (Division of Vascular Surgery, University Hospital of Modena and Reggio Emilia, Baggiovara, Italy), Gianbattista Parlani (Unit of Vascular and Endovascular Surgery, Santa Maria della Misericordia Hospital, Perugia, Italy), Francesca Rossi (Division of Vascular Surgery, University Hospital of Modena and Reggio Emilia, Baggiovara, Italy), Nicola Spadoni (Department of Vascular Surgery, Santa Chiara Hospital, Trento, Italy), Jacopo Taglialavoro (Division of Vascular and Endovascular Surgery, Cardiovascular Department, University Hospital of Trieste ASUGI, Trieste, Italy), Edoardo Veraldi (Department of Vascular Surgery, University of Verona School of Medicine, University Hospital of Verona, Verona, Italy), Elisa Zanetti (Department of Vascular Surgery, University of Verona School of Medicine, University Hospital of Verona, Verona, Italy).

population.[3] The development of iliac branch devices (IBDs) has allowed total endovascular incorporation of one or both internal iliac arteries (IIAs) in most cases using an on-label option as they are specifically designed for this purpose.[4-6]

The use of IBDs as treatment for the iliac disease is associated with favorable perioperative outcomes and a lower rate of major complications compared with OAR.[7] The technique has been performed with high technical success and low morbidity and mortality. It has also decreased rates of pelvic ischemic complications compared with historical results of IIA exclusion.[8,9] In patients who previously underwent abdominal aortic repair, iliac branch devices have been used through an upper extremity approach for placement of the IIA bridging stent,[10] through femoral access with steerable sheaths,[11] or through an up-and-over technique.[12] Only one single-center series has reported on the safety and feasibility of IBDs after previous aortic repair.[13] Other cases remains anecdotal and are reported in studies with de novo iliac aneurysm repair. For these reasons, outcomes of IBDs after previous aortic repair are still limited, and there are uncertainties about which technique is best to use and whether an implant after endovascular treatment or open surgery affects procedural and long-term results.

The aim of this multicentric registry was to assess the "REsults of iliac branch deviceS for hypogastriC sparing after previoUs aortic rEpair (RESCUE)."

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter retrospective single-arm analysis
- **Key Findings:** Iliac branch devices in 31 patients with previous open aortic repair and in 63 patients with previous endovascular aortic repair resulted in excellent perioperative safety and technical success, with very low side branch instability rate up to 3 years.
- **Take Home Message:** Our results support the safety and efficacy of iliac branch devices for revascularization of the hypogastric artery in patients with previous open aortic repair or endovascular aortic repair.

METHODS

Study design. This was a voluntary, observational, multicenter retrospective study. Between January 2011 and December 2021, all patients with previous open or endovascular abdominal aortic repair undergoing IBDs at seven tertiary Italian vascular surgery centers were prospectively collected in local databases. All surgical interventions and subsequent follow-up protocols were carried out according to local policy endorsed at each of the participating institutions. Each center used its own internal rules, and approval from the Institutional Ethics Committee as well as patient informed consent was not needed because of the observational design of the study. The included patients provided written informed consent.

Patients treated during the same period with other endovascular techniques, such as simple common iliac endograft, bell-bottom, hypogastric coiling embolization/occlusion, or chimney/sandwich technique, were excluded from this study. Symptomatic and ruptured iliac aneurysms as well as iliac aneurysms treated with open repair were also excluded. Preoperative clinical/anatomical/endograft features, and procedural and postoperative data were analyzed retrospectively. The indication for treatment was the presence of a unilateral or bilateral CIA of ≥35 mm in diameter or the presence of IAA aneurysm, endoleak type Ib in case of previous endovascular repair and the presence of an anastomotic pseudoaneurysm in case of previous OAR.

In case of bilateral CIA aneurysmal involvement, a simultaneous IBD implantation was performed.

In patients treated for endoleak (EL) type 1b, the previously placed iliac limb was a bell bottom graft. In these cases, the IBDs were secured in place via a new iliac extension that anchored the proximal part of the main body with the flow divider of the previous EVAR. Different techniques have been employed in the various centers including the use of brachial access,[10] femoral access with steerable sheaths,[11] or an up-and-over technique,[12] depending on the operator preference and anatomical feasibility. If available, the use of a cone-beam computed tomography allowed for immediate assessment and revision of eventual technical problems.[14]

Different devices have been used in the various centers depending on operators' preference, local availability and anatomical feasibility according to manufacturers' instructions for use (IFU). The reason for not using Cook ZBIS was a short length CIA (manufacturer's IFU ≥50 mm), and narrow bifurcation diameter CIA (manufacturer's IFU ≥16 mm). For the Gore IBE, a narrow common iliac origin diameter (manufacturer's IFU ≥17 mm) and a short length from renal to the IIA artery (manufacturer's IFU ≥165 mm) were the reasons of non-compliance. For the JOTEC E-Iliac device, the most common cause for the non-compliance was an angle between the EIA and the IIA more than 50° and a narrow CIA bifurcation diameter (manufacturer's IFU ≥18 mm). Given the real-world retrospective nature of the study, indications for placement of different devices were not restricted by study protocol and made by experienced physicians on a case-by-case basis.

Outcomes were compared for patients who had IBD after prior endograft and who had IBD after surgical graft.

Follow-up protocols. The study did not interfere with the clinical routine practices at participating centers; follow-up was conducted according to the local institutional protocols and included computed tomography angiography (CTA) before discharge or within 30 days from the index procedure, followed by at least yearly imaging assessment with either CTA or duplex ultrasound (DUS) at the treating physician's discretion.

Outcomes and definitions. Technical success, acute myocardial infarction, stroke, spinal cord ischemia, acute kidney injury, bowel ischemia, acute respiratory failure, and 30-day mortality were assessed as early outcomes.

Double iliac sign was present when any portion of the iliac vessel is tortuous enough to be duplicated in a single cut of an axial computed tomography slice, briefly, whenever parts of the iliac vessel (within the landing zone of the graft limb) were visually doubled or more on an axial CTA slice, an angulation of >90 was depicted as a sign of severe tortuosity. The double iliac sign was recorded as present or not present, but no other quantitative measurements were taken.[15,16] CIA index (centerline length of the CIA divided by the shortest straight-line distance between the CIA origin and iliac bifurcation) and total iliac index (centerline length of the CIA plus centerline length of the external iliac artery, divided by the shortest straight-line distance between the CIA origin and terminal external iliac artery).[17] All the measurements were made according to the preoperative anatomy.

Survival, side branch (SB) patency, freedom from reinterventions (FFRs), SB instability, and freedom from new onset buttock claudication were evaluated during follow-up. Technical success was defined as deployment of the IBD and SB component. SB instability was a composite end point, defined according to Mastracci et al[18] as the presence of at least one among branch occlusion, device migration effecting a branch, branch related growth, or the need for any secondary intervention.

Statistical analysis. Outcomes were compared for patients who had a prior endovascular aortic repair vs those who had a prior surgical aortic repair. Differences between the study groups were analyzed using the Fisher exact test for categorical variables and the Mann-Whitney *U* test for continuous variables. Categorical variables are expressed as frequencies and proportions and continuous variables as the mean ± standard deviation or median and interquartile range (IQR), as appropriate. P values $<$ .05 were considered statistically significant. All variables with a P value $<$ .05 at univariable analysis were included in the multivariate Cox regression model using backward stepwise method to evaluate the association between covariates and SB instability, and the results are expressed as hazard ratios (HRs) with 95% confidence intervals (CIs).

Survival was estimated by Kaplan-Meier analysis based on the number of patients; consequently bilateral IBDs were evaluated as a single patient, whereas FFR, freedom from new onset buttock claudication, and SB patency were estimated by Kaplan-Meier analysis based on vessels number, and differences were determined by the log-rank test. Statistical analysis was performed by MedCalc Statistical Software version 19.2.6 (MedCalc Software bv; https://www.medcalc.org; 2020).

RESULTS

Study cohort

A total of 104 IBDs were used to treat 84 unilateral and 10 bilateral iliac artery diseases. Of the 31 patients who underwent previous OAR, 27 were straight surgical graft and 4 were aorto-bisiliac; whereas over 63 patients underwent previous EVAR: 56 had standard EVAR, 5 EVAR + IBD and the remaining two fenestrated EVAR.

There were 94 patients overall, 82 males, with mean age of 76 ± 8 years. Patients in the previous endovascular and open surgery group had similar demographics, cardiovascular risk factors, and Society for Vascular Surgery comorbidity scores (Table I).

Anatomical and procedural details

Pre- and operative data are reported in Table II. The mean time between the previous aortic repair and IBD reintervention was 108 ± 60 months with no difference between the two groups (previous endovascular: 8 ± 6, previous OAR: 10 ± 6, $P = .23$). Fifty-eight (55.8%) branch devices were implanted in patients with type Ib endoleak in previous EVAR, 39 (37.5%) were deployed for new CIA aneurysm (previous EVAR, 15; previous OAR, 24; $P \leq .001$) and only three (2.9%) for new IIA aneurysm (previous EVAR, 2; previous OAR, 1; $P \leq .001$). Four patients had a para-anastomotic aneurysm after aortoiliac reconstruction. In the OAR group, the 27 patients with a straight graft underwent IBD implantation with concomitant EVAR, whereas isolated IBD was implanted in the four patients with perianastomotic degeneration. On the other side, all patients with prior EVAR underwent isolated IBD implantation.

The mean length of CIA was 60 ± 28 mm, IIA stenosis or calcification >50% of the lumen was present in nine (8.7%) and five (4.8%) cases respectively. The mean size for the CIA where the IBD landed proximally was 21 mm, with no statistically significant difference between the two groups. A double iliac sign was present in 28 IBDs (38.4%) in the previous EVAR group and in eight (25.8%) in the previous OAR group ($P = .26$). Among 104 IBDs implanted, 12 (11.5%) were Gore IBE (W. L. Gore & Associates), 69 (66.3%) were Cook Zenith IBD device (CE Mark 2006; Cook), and 23 (22.1%) were the E-liac stent graft system from Jotec GmbH, with no statistical distributions between the two groups ($P = .37$). All procedures were performed under general anesthesia through percutaneous access at femoral level. In 55 patients (52.9), the IBD was placed on the right, with no significant difference between the two groups. A brachial/axillary access was obtained in 62 cases (59.6%) from left and

Table I. Demographics, pre-operative cardiovascular risk factors, and comorbidities of the 94 patients treated by iliac branch devices (IBDs) after previous endovascular (n = 63) or open repair (n = 31)

Variable	Overall (n = 94)	Previous EVAR (n = 63)	Previous OAR (n = 31)	*P* value
Baseline				
Age, years	76 ± 8	76 ± 7	73 ± 9	.10
Age >80 years	38 (40.4)	27 (42.9)	11 (35.5)	.46
Male gender	82 (87.2)	54 (85.7)	28 (90.3)	.39
Hypertension	86 (91.5)	60 (95.2)	26 (83.9)	.06
Smoke	34 (36.2)	20 (31.7)	14 (45.2)	.20
Diabetes	13 (13.8)	9 (14.3)	4 (12.9)	.85
Coronary artery disease	37 (39.4)	28 (44.4)	9 (29)	.13
Chronic obstructive pulmonary disease	32 (34)	20 (31.7)	12 (38.7)	.50
Chronic kidney disease III-V	25 (26.6)	19 (30.2)	6 (19.4)	.26
Congestive heart failure	12 (12.8)	9 (14.3)	3 (9.7)	.54
Cerebrovascular disease	4 (3.8)	4 (5.5)	0 (0)	.31
SVS score	0.7 ± 0.4	0.7 ± 0.4	0.6 ± 0.4	.22

EVAR, Endovascular aortic repair; *OAR*, open aortic repair; *SVS*, Society for Vascular Surgery.
Data are presented as number (%) or mean ± standard deviation.

in seven cases (6.7%) from right. The up-and-over technique was used especially in the previous OAR group (19 [61.3%] vs 16 [21.9%]; *P* ≤ .001). A contralateral approach with steerable catheter was used in three patients (4.1%) with previous endovascular repair and in one patient (1.0%) with previous OAR.

Procedure time, iodine contrast media volume, and total fluoroscopy time averaged 187 ± 78 minutes, 118 ± 37 mL, and 46 ± 22 minutes for the entire cohort. The only difference in procedure metrics between the groups was in fluoroscopy time (50 ± 24 minutes in the previous EVAR group vs 38 ± 14 minutes in the previous OAR group; *P* = .02).

Different types of bridging stent grafts (BSGs) were used (Fig 1). Subjects with previous endovascular repair were more likely to receive balloon-expanding BSG (68.5% vs 45.2%), but less likely to receive a combination of different BSG (2.7% vs 4.8%; *P* = .002). Embolization of IIA side branches was done in 11.5% of the entire cohort (previous EVAR, 7 [9.6%]; previous OAR, 5 [16.1%]; *P* = .33).

Perioperative outcomes

Technical success was 100% in both study groups. Occurrence of any adverse event had no significant difference between the groups, as shown in Table III.

Outcomes during follow-up

The median follow up was 28 months (IQR, 13-39 months), with no significant differences between study groups (prior EVAR, 24 ± 28 vs prior OAR, 30 ± 33; *P* = .35).

Survival. The estimates of patient survival at 3 years were 82.3% vs 84.9% (Fig 2, log-rank test = .71) for prior EVAR and OAR, respectively. All deaths were due to non-aortic related causes.

SB instability. The rate of composite SB instability showed significant differences between previous EVAR and previous OAR group (8.2% vs 25.8%; *P* = .02) (Table III), with 3-year rates of freedom from SB instability of 90.1% and 85.4% (log-rank test = .05), respectively (Fig 3). Branch-related intervention (9.6%) and branch-related endoleak (3.8%) showed no significant differences between previous EVAR and previous OAR (6.8% vs 16.1%; *P* = .15; and 1.4% vs 9.7%; *P* = .07, respectively). Branch occlusion or stenosis (7.7%) was significantly different (previous EVAR, 4.1% vs 16.1%; *P* = .05). Using univariate and multivariate Cox proportional hazards model (Supplementary Table I, online only), the use of balloon expandable BSG was independently associated with lower risk for IBD branch instability (HR, 0.1; 95% CI, .0.1-0.7; *P* = .02).

SB primary patency. The 3-year estimates of IBD patency were significantly lower in patients who received previous OAR when compared with those who received previous EVAR graft (primary patency, 89.8% vs 94.9%; log-rank test = .05) (Fig 3). No significant differences could be found in the 3-year rates of freedom from IBD-related reinterventions (previous EVAR, 91.6% vs previous OAR, 88.1%; log-rank test = .29) (Fig 3). Ten reinterventions were registered, of which only five occurred after the first year of follow-up, and all were managed by endovascular means (Supplementary Table II, online only).

New-onset buttock claudication. Also, the 3-year estimates of freedom from new onset buttock claudication were not significantly different between study groups (previous EVAR, 94.7% vs previous OAR, 100%; log-rank test = .87) (Fig 2).

Table II. Procedural details and anatomical characteristics of 104 iliac branch devices (IBDs) implanted below a previous endovascular (*EVAR*) (n = 73) or open repair (OAR) (n = 31)

Variable	Overall (n = 104)	Previous EVAR (n = 73)	Previous OAR (n = 31)	*P* value
Anatomy				
Iliac branch device indication				<.001
Endoleak 1b	58 (55.8)	58 (78.8)	0 (0)	
New CIA aneurysm	39 (37.5)	15 (20.5)	24 (77.4)	
New IIA aneurysm	3 (2.9)	2 (2.7)	1 (3.2)	
Pseudoaneurysm	4 (3.8)	0 (0)	4 (12.9)	
Maximum diameter common iliac artery	32 ± 9	31.3 ± 9.9	36.9±6.9	.05
Mean diameter common iliac artery	21 ± 1.9	23 ± 1.7	19 ± 2.1	.05
Length of common iliac artery	60 ± 28	56.7 ± 30	68.2± 21	.05
Length of IIA	44 ± 15	47.7 ±15	38 ± 12	.04
Maximum diameter IIA	13 ± 8	12.4 ± 7	17.5 ± 10	.02
IIA stenosis >50%	9 (8.7)	4 (5.5)	5 (16.1)	.12
IIA calcification >50%	5 (4.8)	1 (1.4)	4 (12.9)	.03
Length from the lowest RA to aortic bifurcation	112 ± 30	115 ± 29	103 ± 31	.06
Double iliac sign	36 (34.6)	28 (38.4)	8 (25.8)	.26
Total iliac index	1.4 ± 0.2	1.4 ± 0.2	1.4 ± 0.2	.91
Common iliac index	1.0 ± 0.3	1.1 ±0.3	1.1 ± 0.3	.57
Procedural				
Device				.37
Gore	12 (11.5)	10 (13.7)	2 (6.5)	
Cook	69 (66.3)	49 (67.1)	20 (64.5)	
Jotec	23 (22.1)	14 (19.2)	9 (8.7)	
Left side	55 (52.9)	39 (53.4)	16 (51.6)	.86
Bilateral side branch	10 (10.4)	10 (7.3)	0 (0)	<.001
Amount of contrast, mL	118 ± 37	114.5 ± 33	126.6±43	.13
Total operating time, minutes	187 ± 78	194 ± 80	170 ± 74	.15
Total fluoroscopy time, minutes	46 ± 22	50 ±24	38 ± 14	.02
Brachial or axillary access				<.001
No	35 (33.7)	16 (21.9)	19 (61.3)	
Right	7 (6.7)	6 (8.2)	1 (3.2)	
Left	62 (59.6)	51 (69.9)	11 (35.5)	
Steerable use	4 (3.8)	3 (4.1)	1 (1.0)	.99
Bridging characteristic				
Bridging stent				.002
Iliac branch endoprosthesis	3 (2.9)	0 (0)	3 (9.7)	
Self-expanding stent	30 (28.8)	21 (28.8)	9 (29)	
Balloon exp stent	64 (61.5)	50 (68.5)	14 (45.2)	
Combination of different stent	7 (6.7)	2 (2.7)	5 (4.8)	
Bridging stent diameter	9 ± 1.6	9 ± 1.5	9 ± 1.7	.39
Bridging stent length	58 ± 13	56 ±12	63 ± 13	.02
Embolization of branches	12 (11.5)	7 (9.6)	5 (16.1)	.33
Seal zone of IIA				.06
Main trunk	91 (87.5)	67 (91.8)	24 (77.4)	
Posterior branch	12 (11.5)	5 (6.8)	7 (22.6)	
Anterior branch	1 (1.0)	1 (1.4)	0 (0)	
Relining with bare metal stent	12 (11.1)	7 (9.6)	5 (13.4)	.26

CIA, Common iliac artery; *IIA*, internal iliac artery; *RA*, renal artery.
Data are presented as number (%) or mean ± standard deviation.

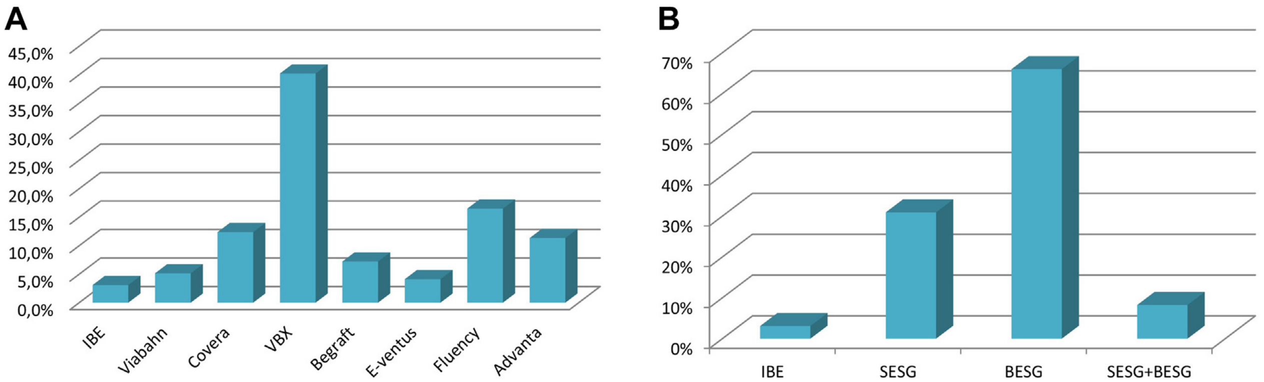


Fig 1. Name **(A)** and type **(B)** of bridging stent used in 104 iliac branch devices (IBDs). *BESG*, Balloon-expandable stent graft; *IBE*, iliac branch endoprosthesis; *SESG*, self-expandable stent graft.

Different devices. The 3-year estimates of SB instability were significantly different depending on the devices used (IBE Gore, 100% vs Cook Zenith IBD, 93.5% vs E-liac Jotec, 58.2%; log-rank test = .03) (Supplementary Fig, online only). However, no significant differences could be found in the 3-year rates of IBD patency (IBE Gore, 100% vs Cook Zenith IBD, 94.9% vs E-liac Jotec, 86.7%; log-rank test = .26) (Supplementary Fig, online only).

DISCUSSION

The present study analyses a series of 104 IBD implants performed in patients with previous EVAR or OAR in seven Italian vascular facilities over a 10-year period.

A technical success rate of 100%, associated with a 9.6% reintervention rate, should be considered satisfactory, also if compared with similar studies.[19,20] As reported in Supplementary Table II (online only), about one-half of the reintervention occurred in the first year after index surgery, and in most cases, occurred in patients with a new CIA aneurysm. A hypothesis that can explain these reinterventions is that the progression of the disease after a previous corrective intervention could alter the anatomy, and therefore it is more complex and less safe to intervene later. Also, the rates of postoperative cardiac (0%), pulmonary (3.8%), and renal complications (1.9%) were low.

Although there are no statistically significant differences between the two groups, it is possible to recognize a higher percentage of comorbidities and a higher SVS score in the previous endovascular group. This finding is not unexpected, as it is possible that patients undergoing OAR were more fit for surgery and had fewer comorbidities. However, the greater frailty of the previous EVAR group did not appear to have influenced the IBD instability outcomes.

IBDs are designed for the purpose of preserving IIA flow; these devices also take advantage of excellent safety profiles, satisfactory mid-term durability, and have shown significant benefits as compared with both OAR[21] or flared iliac limbs[22] (ie, bellbottom technique). Other benefits include high technical success, low mortality, and exceptionally low rates of pelvic ischemic complications. The medical performance of IBDs in aneurysms involving the iliac bifurcation is registered in an international multicenter database including over 900 implants reported the long-term results of the first 650 IBD procedures (617 Cook ZBIS, 33 Gore IBE), reporting good estimated rates of an 8-year period of freedom from occlusion (87% and 95.1%, respectively) and freedom from reintervention due to occlusion or type I endoleak (85.7%).[23]

Although only very few studies have dealt with IIA preservation in patients with prior bifurcated endografts to treat iliac aneurysm degeneration or type IB endoleaks,[13,24] current literature so far has not addressed outcomes of IBDs after previous OAR.

Therefore, the focus of this study was the comparison of clinical and technical outcomes of IBDs that were implanted after an OAR or EVAR, regardless of the chosen technique. In the current series, despite the excellent feasibility demonstrated by all three devices currently available, the outcome of SB instability had an overall rate of 13.5%. A significant difference between the study groups at a 3-year follow up (89.5% vs 72.5%; $P = .04$) the branch occlusion/stenosis rate showed a trend that seemed to favor the previous EVAR group. This can be explained keeping in mind the vascular anatomical variations of the cohort; in patients with previous OAR, the IIA was significantly shorter and more calcified. Moreover, the BSGs of this group are significantly longer, despite the IIA length being shorter. It is probable that in patients with a previous OAR, it was necessary to lengthen the sealing zone in the IIA branches, increasing the procedure complexity[8] or to position the IBDs higher than the bifurcation to reach better diameter in which to open the side gate, affecting the SB instability. Taking this into account, the patency remains similar with what others report in which the IIA branch ranges from 82% to 94% at 1 years to 5 years.[25-28]

Table III. Periprocedural, early, and late outcomes of 104 iliac branch devices (IBDs) implanted below a previous endovascular (*EVAR*) (n = 73) or open repair (*OAR*) (n = 31)

Variable	Overall (n = 104)	Previous EVAR (n = 73)	Previous OAR (n = 31)	*P* Value
Periprocedural and early outcomes				
Technical success	104 (100)	73 (100)	31 (100)	NA
Early death	0	0	0	NA
Acute myocardial infarction	0	0	0	NA
Stroke	0	0	0	NA
Spinal cord ischemia	0	0	0	NA
Acute kidney injury	2 (1.9)	2 (2.7)	0 (0)	.99
Bowel ischemia	0	0	0	NA
Acute respiratory failure	4 (3.8)	4 (5.5)	0 (0)	.31
Return to operating room	9 (8.7)	6 (8.2)	3 (9.7)	.99
Late outcomes				
Death	16 (15.4)	11 (15.1)	5 (16.1)	.99
Any branch instability	14 (13.5)	6 (8.2)	8 (25.8)	.02
Branch-related intervention	10 (9.6)	5 (6.8)	5 (16.1)	.15
Branch occlusion or stenosis/kink	8 (7.7)	3 (4.1)	5 (16.1)	.05
Branch disconnection	0	0	0	NA
Branch-related endoleak	4 (3.8)	1 (1.4)	3 (9.7)	.07
Branch-related rupture	0	0	0	NA
Branch-related death	0	0	0	NA
New-onset buttock claudication	3 (2.9)	2 (2.7)	1 (3.2)	99

Data are presented as number (%).

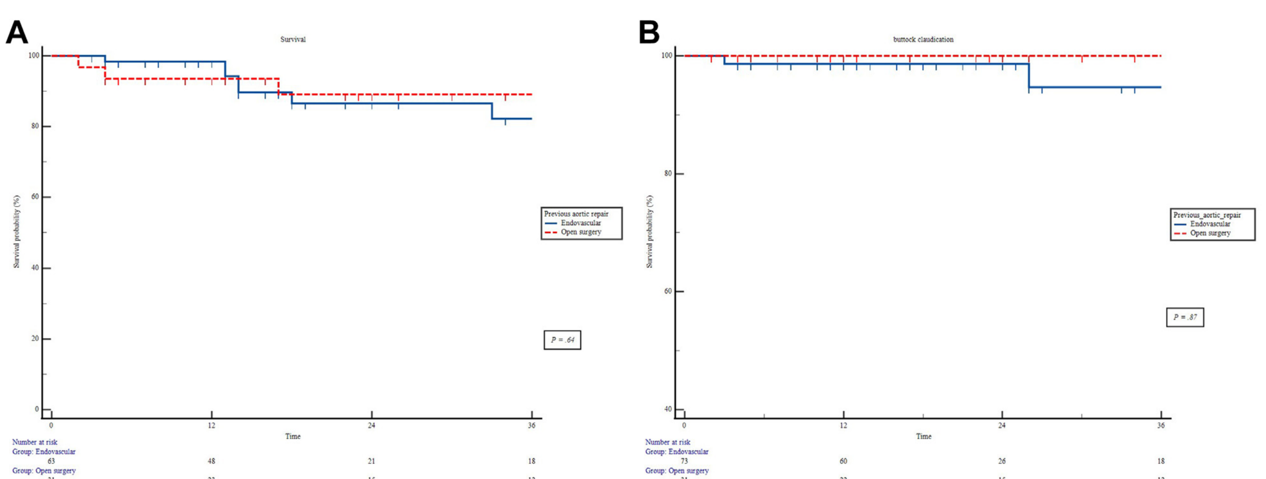


Fig 2. Kaplan-Meier curves for 3-year survival **(A)** and new onset buttock claudication **(B)**.

Even if the treatment was technically the same in the two groups (specifically IBD) it would probably be necessary to plan the cases differently according to the indication and to follow them differently over time. Vessel expansion may occur after OAR due to disease progression, whereas after EVAR, graft failure itself may cause complications. Furthermore, after EVAR, there may be greater technical difficulties responsible for different outcomes, especially on endoleaks, because the patency is identical. Further studies on the feasibility of different devices in these types of patients would be necessary to be able to perform a treatment that is as tailored as possible to the patient and therefore more durable.

Occurrence of buttock claudication is nearly related to an intentional embolization or to late branch occlusion. Schneider et al[29] reported the results of the United

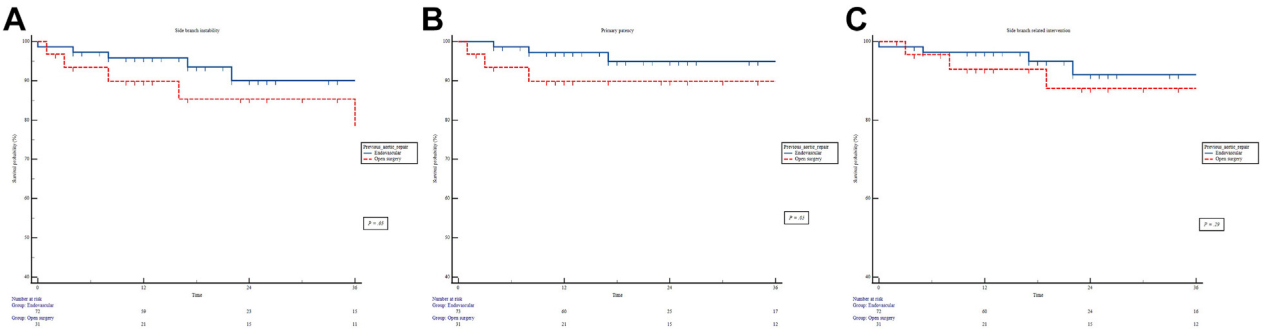


Fig 3. Kaplan-Meier curves for 3-year side branch (SB) instability **(A)**. Kaplan-Meier curves for 3-year side branch (SB) primary patency **(B)**. Kaplan-Meier curves for 3-year reintervention **(C)**.

States prospective pivotal study, which included 95% branch patency and 100% from free buttock claudication at 6 months. Simonte et al[30] reported similar results of 149 patients, including branch patency of 94.7% at 1 year. Exclusion of IIA flow due to embolization has been widely used but carries a definitive risk of pelvic ischemic complications, most notably, buttock claudication and erectile dysfunction but also colonic ischemia, spinal cord injury, and gluteal muscle necrosis in a few patients.[31] Indeed, patent side branches may contribute to type 2 endoleak and aneurysmal sac increase during follow-up.[32] Therefore, it is common practice to embolize these branches at time of index operation, when this adjunctive maneuver is relatively straightforward rather than at later times when it would prove extremely challenging if not unfeasible.

In this series, coil embolization of IIA distal branches was needed just in 11.5% of IBDs because distal sealing zone was mostly in IIA main trunk. Notably, there was no bowel ischemia or spinal cord ischemia, and buttock claudication occurred in 2.9% (3/104) of implanted IBDs, confirming that iliac preservation with branch devices effectively avoids these ischemic complications. Moreover, all the patients who developed buttock claudication had undergone left IBD implantation; however, it is not possible to establish a true correlation between the two events due to the small number of this complication. Further studies will be needed to establish whether the implant side could be a risk factor.

The choice of bridging covered stent included self-expanding (SECS), balloon-expandable (BECS), or a combination of them. Furthermore, there might be other technical issues such as local availability of different BSG lengths that could affect the real-world use of endovascular devices. In the univariate analysis, branch instability was less frequent when BECS were used (HR, 0.4; $P = .007$), this association was confirmed in the multivariate analysis. Recently, Verzini et al[33] analyzed the outcomes of different types of BSGs in 747 IBD implants in the PELVIS registry and did not find any significant differences at a mean follow-up of 5 years in primary patency rates (99% SESG vs 91% BESG at 62 months) nor FFR (83% SESG vs 80% BESG).

In a recent study, Lima et al[34] shows similar outcomes for BESGs and SESGs compared with primary patency and reinterventions, but a trend towards more IIA-related endoleaks and lower branch instability has begun with BSGs. This was explained when it was given the indication of BSGs to treat IIA aneurysms, which often require multiple stent components and may increase the risk of endoleak or stent disconnections.

As can be seen from the Supplementary Fig (online only), the most used bridging stent in the 104 IBDs was the Viabahn balloon expandable (VBX). This is probably due to the characteristics of this BSG, which allows with its crimping good pushability and trackability even beyond the 12 Fr sheath.

Selection of the ideal bridging stent and intraoperative technical assessment with cone-beam CT are important pitfalls to avoid unnecessary reinterventions for stent-related endoleak, kinks, or disconnections.[14]

In this study, all three available devices were used, using different techniques. It is interesting to note how the up-and-over technique was used in previous surgically treated aneurysms, whereas in the patients' group with previous EVAR, the technique of choice was the axillary or brachial approach. The use of these techniques has made it possible to extend the IFU of the devices despite the anatomical complexity of the cases; in addition to the great anatomical adaptability, the iliac branch proved to be safe even when positioned bilaterally, or when used in off-label rescue techniques.[35-39] The broad feasibility reported in this patients group is not surprising; according to Gouveia and Melo et al,[40] the use of IBDs using liberal criteria, the feasibility increased significantly, for the JOTEC E-Iliac device (26.9% to 90.8%) and the Cook ZBIS (52.9% to 93.3%), but also for the Gore IBE device (33.6% to 53.8%). In our series, only 8 (7.6%) patients were treated with IBD outside the devices' IFU with a mean diameter of the CIA at the proximal landing zone of 16.7 mm.

Of these patients, only one had SB instability, namely a branch-related endoleak. Although it seems intuitive that placing the devices outside their IFU might lead to worse durability outcomes, future studies are needed to assess this issue. Although different authors argue brachial access is limited by potential risk of cerebral embolization and arterial or peripheral nerve injury.[41] In this cohort, no patient experienced a postoperative cerebrovascular accident or upper limb nerve injury. This technique is useful in selected patients with prior fenestrated endograft because it avoids compression of the renal side stents while advancing the sheath up and over the bifurcation and permits a quick engagement of IIA.

Study limitations. The present study has a series of limitations. In the first time, it is a retrospective analysis of cases performed at seven centers during a 10-year timeframe, thus the limitations of a shared experience with different settings, technical approaches, and expertise must be added to the constraints of all retrospective analyses. Furthermore, although the sample size was relatively large and extracted from a contemporary multicenter data set, coupled with a reasonable long follow-up duration, it is possible that absence of statistically significant differences in some of the reported outcomes could reflect a type II error. Also, buttock claudication, although assessed in the present study, is difficult to extrapolate without a prospective study design.

It was not possible to perform any comparison between the techniques used, as any computation would have been complicated by the confounding due to the association of deployment technique with indication.

In addition, most of the patients who underwent OAR had straight grafts. Only four patients underwent IBD for perianastomotic degeneration. For this reason, the success of the placement of IBDs in this subgroup of patients cannot be thoroughly evaluated. Finally, although we tried to account for known confounders such as different indications for treatment and technique used, using multivariate analyses, it is still possible that some unmeasured confounders have remained.

CONCLUSIONS

According to the present experience, the use of IBDs following previous OAR or EVAR is safe and feasible with high technical success rates, no perioperative mortality, and low complication rates.

An alternative therapeutic option to IBD is hypogastric artery embolization with stenting of the external iliac artery even if theoretically at greater risk of ischemic complications, especially if the contralateral hypogastric artery is occluded. Further comparative studies are needed to establish which technique is best in this particular cohort of patients. Although mid-term durability was overall favorable, IBD patency at 3 years was lower when implanted in patients who had previously undergone OAR rather than EVAR. Moreover, the use of BSGs seemed to be associated with preservation of SB stability.

REFERENCES

1. Richards T, Dharmadasa A, Davies R, Murphy M, Perera R, Walton J. Natural history of the common iliac artery in the presence of an abdominal aortic aneurysm. J Vasc Surg 2009;49:881-5.
2. Falkensammer J, Hakaim AG, Andrew Oldenburg W, et al. Natural history of the iliac arteries after endovascular abdominal aortic aneurysm repair and suitability of ectatic iliac arteries as a distal sealing zone. J Endovasc Ther 2007;14:619-24.
3. Dube B, Ünlü Ç, de Vries JP. Fate of enlarged iliac arteries after endovascular or open abdominal aortic aneurysm repair. J Endovasc Ther 2016;23:803-8.
4. Chaikof EL, Dalman RL, Eskandari MK, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. J Vasc Surg 2018;67:2-77.e2.
5. Wanhainen A, Verzini F, Van Herzeele I, et al. Editor's choice - European society for vascular surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. Eur J Vasc Endovasc Surg 2019;57:8-93. Erratum in: Eur J Vasc Endovasc Surg. 2020 Mar;59(3):494.
6. D'Oria M, Mastrorilli D, DeMartino R, Lepidi S. Current status of endovascular preservation of the internal iliac artery with iliac branch devices (IBD). Cardiovasc Intervent Radiol 2019;42:935-48.
7. D'Oria M, Mendes BC, Bews K, et al. Perioperative outcomes after use of iliac branch devices compared with hypogastric occlusion or open surgery for elective treatment of aortoiliac aneurysms in the NSQIP database. Ann Vasc Surg 2020;62:35-44.
8. Farivar BS, Abbasi MN, Dias AP, et al. Durability of iliac artery preservation associated with endovascular repair of infrarenal aortoiliac aneurysms. J Vasc Surg 2017;66:1028-36.e18.
9. Cao Z, Zhu R, Ghaffarian A, et al. A systematic review and meta-analysis of the clinical effectiveness and safety of unilateral versus bilateral iliac branch devices for aortoiliac and iliac artery aneurysms. J Vasc Surg 2022;76:1089-98.e8.
10. Bellandi G, Ventoruzzo G. Endovascular bilateral evolutive common iliac artery aneurysm repair using a Zenith branch graft through a combined femoro brachial approach in a patient with previous EVAR. Eur J Vasc Endovasc Surg 2010;40:596-8.
11. Oberhuber A, Duran M, Ertaş N, Simon F, Schelzig H. Implantation of an iliac branch device after EVAR via a femoral approach using a steerable sheath. J Endovasc Ther 2015;22:610-2.
12. Dawson DL, Sandri GA, Tenorio E, Oderich GS. Up-and-over technique for implantation of iliac branch devices after prior aortic endograft repair. J Endovasc Ther 2018;25:21-7.
13. Tenorio ER, Oderich GS, Sandri GA, et al. Outcomes of an iliac branch endoprosthesis using an "up-and-over" technique for endovascular repair of failed bifurcated grafts. J Vasc Surg 2019;70:497-508.e1.
14. Mezzetto L, Mastrorilli D, Abatucci G, et al. Impact of cone beam computed tomography in advanced endovascular aortic aneurysm repair using last generation 3D C-arm. Ann Vasc Surg 2022;78:132-40.
15. Taudorf M, Jensen LP, Vogt KC, Grønvall J, Schroeder TV, Lönn L. Endograft limb occlusion in EVAR: iliac tortuosity quantified by three

different indices on the basis of preoperative CTA. Eur J Vasc Endovasc Surg 2014;48:527-33.
16. Fenelli C, Gargiulo M, Prendes CF, et al. Effect of iliac tortuosity on outcomes after iliac branch procedures. J Vasc Surg 2022;76:714-23.e1.
17. Chaikof EL, Fillinger MF, Matsumura JS, et al. Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair. J Vasc Surg 2002;35:1061-6.
18. Giosdekos A, Antonopoulos CN, Sfyroeras GS, et al. The use of iliac branch devices for preservation of flow in internal iliac artery during endovascular aortic aneurysm repair. J Vasc Surg 2020;71:2133-44.
19. Austermann M, Bisdas T, Torsello G, Bosiers MJ, Lazaridis K, Donas KP. Outcomes of a novel technique of endovascular repair of aneurysmal internal iliac arteries using iliac branch devices. J Vasc Surg 2013;58:1186-91.
20. Mendes BC, Oderich GS, Sandri GA, et al. Comparison of perioperative outcomes of patients with iliac aneurysms treated by open surgery or endovascular repair with iliac branch endoprosthesis. Ann Vasc Surg 2019;60:76-84.e1.
21. Pini R, Faggioli G, Indelicato G, et al. Early and late outcome of common iliac aneurysms treated by flared limbs or iliac branch devices during endovascular aortic repair. J Vasc Interv Radiol 2019;30:503-10.
22. Donas KP, Inchingolo M, Cao P, et al. Secondary procedures following iliac branch device treatment of aneurysms involving the iliac bifurcation: the pELVIS registry. J Endovasc Ther 2017;24:405-10.
23. Bisdas T, Weiss K, Donas KP, Schwindt A, Torsello G, Austermann M. Use of iliac branch devices for endovascular repair of aneurysmal distal seal zones after EVAR. J Endovasc Ther 2014;21:579-86.
24. D'Oria M, Lima GBB, Dias N, et al; R3OYAL Registry collaborators, R3OYAL Registry Collaborators. Outcomes of "anterior versus posterior divisional branches of the hypogastric artery as distal landing zone for iliac branch devices": the international multicentric R3OYAL registry. J Endovasc Ther 2022:15266028221120513.
25. Parlani G, Verzini F, De Rango P, et al. Long-term results of iliac aneurysm repair with iliac branched endograft: a 5-year experience on 100 consecutive cases. Eur J Vasc Endovasc Surg 2012;43:287-92.
26. Kouvelos GN, Katsargyris A, Antoniou GA, Oikonomou K, Verhoeven EL. Outcome after interruption or preservation of internal iliac artery flow during endovascular repair of abdominal aorto-iliac aneurysms. Eur J Vasc Endovasc Surg 2016;52:621-34.
27. Wong S, Greenberg RK, Brown CR, Mastracci TM, Bena J, Eagleton MJ. Endovascular repair of aortoiliac aneurysmal disease with the helical iliac bifurcation device and the bifurcated-bifurcated iliac bifurcation device. J Vasc Surg 2013;58:861-9.
28. Schneider DB, Matsumura JS, Lee JT, Peterson BG, Chaer RA, Oderich GS. Prospective, multicenter study of endovascular repair of aortoiliac and iliac aneurysms using the Gore Iliac Branch Endoprosthesis. J Vasc Surg 2017;66:775-85.
29. Simonte G, Parlani G, Farchioni L, et al. Lesson learned with the use of iliac branch devices: single centre 10 year experience in 157 consecutive procedures. Eur J Vasc Endovasc Surg 2017;54:95-103.
30. Chitragari G, Schlosser FJ, Chaar CIO, Sumpio BE. Consequences of hypogastric artery ligation, embolization, or coverage. J Vasc Surg 2015;62:1340-7.e1.
31. D'Oria M, Mastrorilli D, Ziani B. Natural history, diagnosis, and management of type II endoleaks after endovascular aortic repair: review and update. Ann Vasc Surg 2020;62:420-31.
32. Verzini F, Parlani G, Varetto G, et al; pELVIS Investigators. Late outcomes of different hypogastric stent grafts in aortoiliac endografting with iliac branch device: results from the pELVIS Registry. J Vasc Surg 2020;72:549-55.e1.
33. Lima GB, Tenorio ER, Marcondes GB, et al. Outcomes of balloon-expandable versus self-expandable stent graft for endovascular repair of iliac aneurysms using iliac branch endoprosthesis. J Vasc Surg 2022;75:1616-23.e2.
34. D'Oria M, Tenorio ER, Oderich GS, et al. Outcomes of unilateral versus bilateral use of the iliac branch endoprosthesis for elective endovascular treatment of aorto-iliac aneurysms. Cardiovasc Intervent Radiol 2022;45:939-49.
35. D'Oria M, Pitoulias GA, Torsello GF, et al; pELVIS registry investigators. Bilateral use of iliac branch devices for aortoiliac aneurysms is safe and feasible, and procedural volume does not seem to affect technical or clinical effectiveness: early and midterm results from the pELVIS international multicentric registry. J Endovasc Ther 2021:15266028211016439.
36. D'Oria M, Pipitone M, Riccitelli F, et al. Successful off-label use of an iliac branch device to rescue an occluded aortofemoral bypass graft. J Endovasc Ther 2019;26:128-32.
37. D'Oria M, Chiarandini S, Pipitone M, et al. Urgent use of Gore excluder iliac branch endoprosthesis with left transaxillary approach for preservation of the residual hypogastric artery: a case series. Ann Vasc Surg 2018;51:326.e17-21.
38. Simonte G, Isernia G, Fino G, et al. The effect of manufacturer's instructions for use compliance on Cook ZBIS iliac-branched endograft long-term outcomes. Ann Vasc Surg 2021;72:454-63.
39. Gouveia E Melo R, Fenelli C, Fernández Prendes C, et al. A cross-sectional study on the anatomic feasibility of iliac side branch grafts in a real-world setting. J Vasc Surg 2022;76:724-32.
40. Ahn SS, Feldtman RW, Hays FA. Thoracic aorta aneurysm repair using the right axillary approach. J Vasc Surg 2011;54:1201-4.
41. Probst C, Esmailzadeh B, Schiller W, Wilhelm K. Emergent antegrade endovascular stent placement in a patient with perforated Stanford B dissection via right axillary artery. Eur J Cardio Thorac Surg 2008;33:1148-9.

Supplementary Table I (online only). Cox regression univariable and multivariable analysis for the identification of independent risk factors for the side branch instability in 104 iliac branch devices (*IBDs*)

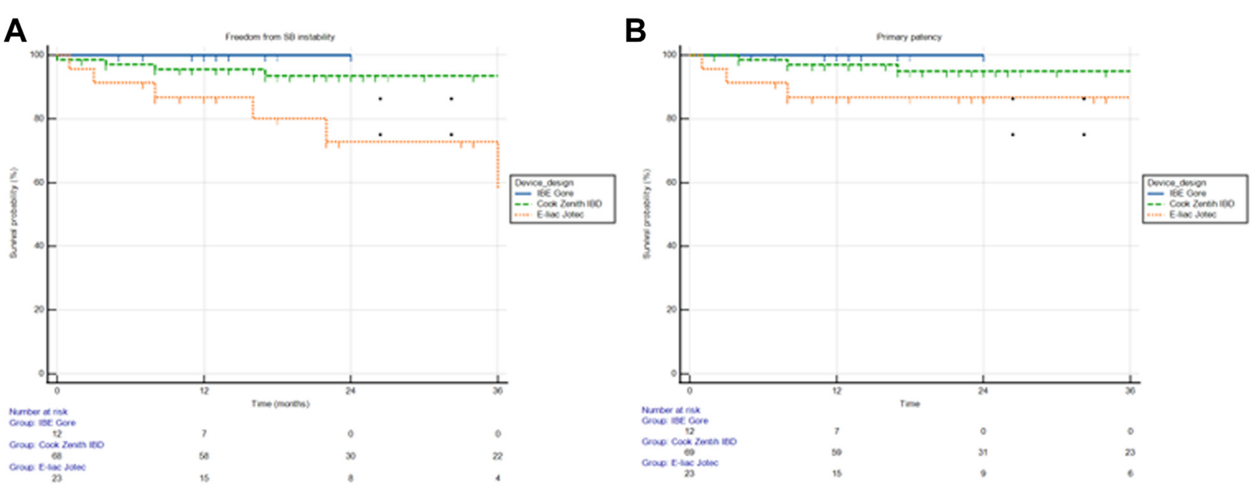
	Univariable analysis		Multivariable analysis	
	HR (95% CI)	*P*	HR (95% CI)	*P*
IBD indication				
Endoleak 1b	Reference			
New CIA aneurysm	.72 (0.7-6.7)	.77		
New IIA aneurysm	1.9 (0.2-9.1)	.54		
Pseudoaneurysm	3.6 (0.2-17.4)	.37		
Maximum CIA diameter	1.1 (0.9-1.06)	.94		
Length of CIA	.99 (0.9-1.01)	.84		
Length of IIA	.98 (0.9-1.1)	.56		
Maximum diameter of IIA	1.1 (0.9-1.1)	.55		
IIA calcification >50	1.5 (1.6-8.2)	.45		
Up-and-over technique	0.8 (0.2-2.4)	.73		
Prior aortic repair				
Endovascular	Reference			
Open surgery	2.8 (0.9-8.2)	.04	2.5 (0.7-8.6)	.14
Bridging stent type				
IBE	Reference			
SESG	1.1 (1.1-5.6)	.98	1.2 (1.4-6.3)	.97
BESG	0.4 (0.01 - .04)	.007	1.1 (0.1-0.7)	.02
Combination	0.5 (0.1-1.5)	.21	0.7 (0.1 -3.5)	.68

BESG, Balloon-expandable stent graft; *CI*, confidence interval; *CIA*, common iliac artery; *HR*, hazard ratio; *IBE*, iliac branch endoprosthesis; *IIA*, internal iliac artery; *SESG*, self-expandable stent graft.

Supplementary Table II (online only). Description of timing and procedure of patients who underwent reintervention

Pt	Priori aortic repair	Indication	Time to reintervention (months)	Bridging stent	Reason of reintervention	Type of reintervention
1	Endovascular	Endoleak 1B	1	VBX 39 * 8	Occlusion	Fogarty thromboembolectomy and relining of the external iliac artery sealing zone with BMS
2	Open surgery	CIA aneurysm	8	Advanta-V12 10*38	Occlusion	Fibrinolysis, PTA and relining of EIA
3	Open surgery	CIA aneurysm	3	VBX 59*8	Occlusion	Fibrinolysis, PTA and relining of EIA
4	Open surgery	Pseudoaneurysm	67	advanta 10*38	Endoleak	Relining
5	Open surgery	CIA aneurysm	47	advanta 9*59	Endoleak	Relining
6	Open surgery	CIA aneurysm	19	BeGraft 9-27	Endoleak	Relining
7	Endovascular	CIA aneurysm	5	BeGraft 9-37	Occlusion	Fogarty thromboembolectomy and relining of the external iliac artery
8	Endovascular	Endoleak 1B	1	Fluency 13.5-40	Endoleak	Relining
9	Endovascular	CIA aneurysm	44	Fluency 13.5-40	Occlusion	Fogarty thromboembolectomy and relining of the external iliac artery sealing zone with BESG
10	Endovascular	Endoleak 1B	22	Be-Graft 8-57	Occlusion	Fibrinolysis, PTA and relining of IIA

BESG, Balloon-expandable stent graft; *BMS*, bare metal stent; *CIA*, common iliac artery; *EIA*, external iliac artery; *IIA*, internal iliac artery; *PTA*, percutaneous transluminal angioplasty.



Supplementary Fig (online only). Kaplan-Meier curves for 3-year side branch (SB) instability **(A)** and SB primary patency **(B)**, stratified for device design.