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Use of Bilateral Cook Zenith Iliac Branch Devices to Preserve Internal Iliac Artery Flow During Endovascular Aneurysm Repair

Pablo Marques de Marino, Balazs Botos, George Kouvelos, Eric L.G. Verhoeven *, Athanasios Katsargyris

Department of Vascular and Endovascular Surgery, Klinikum Nuremberg, Paracelsus Medical University Nuremberg, Nuremberg, Germany

WHAT THIS PAPER ADDS

This paper describes the use of bilateral iliac branch devices (IBD) for patients in whom a dilated common iliac artery precludes appropriate distal landing in that artery. Although IBD implantation has become a validated option to preserve antegrade flow to the internal iliac artery (IIA), reported data on the bilateral use of this device are missing. This single centre experience provides further insight on indication, technical options, and outcomes of this procedure. The study suggests that bilateral IBDs can be safely used to preserve IIA flow in well selected patients.

Objectives: Iliac branch devices (IBD) have become a widespread option to preserve antegrade internal iliac artery (IIA) flow during endovascular aneurysm repair (EVAR). Reported experience with bilateral implantation of IBDs is limited. This study aimed to describe the indications, technical options, and outcomes with the use of bilateral IBDs.

Methods: All patients undergoing elective implantation of bilateral Cook Zenith IBD between January 2010 and September 2017 in a single centre were included. Bilateral IBD was indicated in physically active, anatomically suitable patients and those with previous or concomitant surgery for a thoraco-abdominal aortic aneurysm or impaired collateral circulation to the IIA. Data were collected prospectively.

Results: Twenty-nine patients (29 male, mean age 64.1 ± 10 years) were included. Of the 58 IBDs, 48 (83%) were implanted in one procedure and 10 (17%) in two procedures (mean time between procedures 30.4 ± 9 months). Nineteen patients (65%) had a previous or simultaneous EVAR and the remaining 10 (35%) a previous or simultaneous complex aortic repair. Mean CIA diameter was 35.2 ± 8 mm. Technical success was achieved in 55 of the 58 IBDs (95%) with no mortality. Axillary artery access was used in 13 (38%) procedures. During follow up, four (7%) IIA branches occluded (1 bilateral occlusion and 2 unilateral). Estimated IIA branch patency at one and three years was 97.8% ± 2% and 88.5% ± 7%, respectively. All patients with late IIA occlusion remained asymptomatic. Re-intervention was needed in four patients (14%): two bridging stent graft extensions for type Ib endoleak, one relining of the external iliac artery because of mural in-stent thrombus and one femoro-femoral crossover bypass to treat an external iliac limb occlusion.

Conclusions: Bilateral implantation of IBDs is a safe and effective technique to preserve IIA flow in selected patients with suitable anatomy, showing similar technical success and mid-term outcomes to the unilateral use of the device.

Keywords: Hypogastric, Internal iliac artery, Branched stent graft, Iliac branch device, Iliac aneurysm, Endovascular aneurysm repair
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INTRODUCTION

Endovascular aneurysm repair (EVAR) in patients with absence of an adequate distal landing zone because of an ectatic or aneurysmal common iliac artery (CIA) remains a challenge.

For many years, occlusion of the internal iliac artery (IIA) with extension of the stent graft to the external iliac artery (EIA) was the strategy most commonly used to treat these patients. This option has been associated with buttock claudication, as well as other more infrequent complications such as impotence, ischaemic colitis, spinal cord ischaemia, and gluteal necrosis.[1–4] To prevent such complications, alternative techniques have been used aiming to preserve the IIA. These options include bell bottom stent grafts, sandwich/snorkel techniques, and transposition/bypass to the IIA.[5–8] In more recent years, iliac branch

* Corresponding author. Department of Vascular and Endovascular Surgery, Klinikum Nuremberg, Breslauer Strasse 201. 90471, Nürnberg, Germany.
E-mail address: eric.verhoeven@klinikum-nuernberg.de (Eric L.G. Verhoeven).

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devices (IBD) have become an increasingly popular option to preserve antegrade IIA flow and avoid ischaemic complications.[9,10]

Data from different studies show that in 18%—40% of the patients treated by EVAR, the aneurysm extends into at least one CIA.[11—13] In up to 12% of the cases both CIAs are affected.[14] Most authors advocate preservation of one IIA with an IBD and embolisation of the contralateral IIA. Preservation of both IIA by the use of bilateral IBDs is not frequently reported.[15] However, risks of ischaemic complications seem to appear in 30—55% of the patients after unilateral IIA occlusion.[4,9] Therefore, based on the good initial outcomes of bilateral IBD implantation at the study centre, the aim was bilateral IIA preservation whenever possible. The present study summarises experience of bilateral IIA implantation at a single centre, focusing on the indications, technique, and outcomes.

METHODS

A retrospective single centre study was conducted including all patients undergoing elective implantation of a bilateral IBD between January 2010 and September 2017. Data used for the analysis were taken from a prospectively maintained database. Ethical committee approval was waived in view of the design of the study with anonymised retrospective data analysis.

Patients

During the study period, all patients with a thoraco-abdominal, pararenal, infrarenal, or CIA aneurysm planned for an endovascular repair in which dilation of the CIA precluded appropriate distal landing zone with a conventional stent graft were evaluated for an IBD. Bilateral IBD was considered in young physically and sexually active patients, those with a previous or concomitant surgery for a thoraco-abdominal aortic aneurysm, and those with impaired collateral circulation to the IIA, with suitable anatomy. Collateral blood flow was assessed by the senior author (EV) according to the collateral vessels from the inferior mesenteric artery, ipsilateral femoral arterial system, and contralateral IIA seen in the pre-operative CTA. Patients with a previous endovascular repair and progressive dilation of the CIA $\geq$3 cm or type Ib endoleak during follow up in which a bilateral IBD was implanted in two procedures were also included. Criteria for IBD suitability according to the instructions for use (IFU) include: CIA diameter $\geq$16 mm and CIA length $\geq$50 mm ($\geq$55 mm preferred); adequate EIA for distal landing with length $\geq$20 mm and diameter measured outer wall to outer wall of 8—11 mm; a suitable landing in the IIA with length $\geq$10 mm (20—30 mm preferred) and diameter acceptable for proper sealing; and implantation of the device using a through-and-through crossover technique via contralateral femoral artery access.

The physical status of all patients was assessed pre-operatively with the American Society of Anaesthesiologists (ASA) Physical Status Classification score and the aneurysm morphology was assessed by thin slice ($\leq$1.5 mm) spiral computed tomography angiography (CTA) with axial, coronal, and sagittal reconstructions.

Baseline and comorbidity characteristics as well as intra-operative data were analysed. Primary endpoints of the study included technical success and 30 day mortality. Technical success was defined as successful implantation of the IBD in the iliac vessels with preservation of antegrade flow to the internal and external iliac arteries and absence of type I or III endoleak at the first post-operative CTA. Secondary endpoints included patency and re-intervention rates during follow up. To ensure complete follow up, all patients/relatives were successfully phoned by the investigators.

Procedure

Procedures were performed in a hybrid operating room with a fixed imaging system. All stent grafts were implanted under general anaesthesia. Patients were usually admitted one day before the procedure. Surgical access was performed with a bilateral femoral cutdown and an additional left axillary artery cutdown via a longitudinal incision in the axilla when needed. Double purse string sutures of 4—0 Prolene (Ethicon, Somerville, NJ, USA) fitted with a snugger were used to allow removal of the delivery system to restore blood flow to the ipsilateral limb as early as possible.

All patients received the second generation Zenith IBD device (CE Mark 2006; Cook, Bloomington, IN, USA), which consists of a bifurcated graft with a main iliac limb and a side branch for the IIA. IBDs were implanted via contralateral femoral access unless the patient had a previous abdominal or thoraco-abdominal endovascular repair, a short CIA or a sharp aortic bifurcation, when left axillary access was used instead.

The IBD was inserted through the femoral access and deployed partially. The preloaded guidewire was then snared from a contralateral or left axillary approach to create a through-and-through access. Over this through-and-through wire a 12 F ANL-1 sheath (Cook Inc.) was introduced into the main body of the IBD device. A second 7/8 F ANL-1 sheath (Cook Inc.) was then inserted through the 12 F sheath with the coaxial technique and was advanced through the iliac side branch of the device. After advancing a Berenstein (Angiodynamics Inc., Queensbury, NY, USA) catheter over the through-and-through wire to the distal end of the iliac side branch, the preloaded wire was removed and the IIA was catheterised. Once the IIA was catheterised, the guidewire was exchanged to an Amplatz Super Stiff guidewire (Boston Scientific Corp, Natick, MA, USA), the 7/8 F ANL-1 sheath was advanced inside the IIA and the IBD pulled down to reduce the gap to the hypogastric artery and deployed completely. Finally, a bridging covered stent (Advanta V12, Atrium Medical, Hudson, NH, USA; Fluency, C.R. Bard Peripheral Vascular Inc., Murray Hill, NJ, USA; Begraft, Bentley Innomed, Hechingen, Germany or Lifestream, C.R. Bard Peripheral Vascular Inc.) was deployed

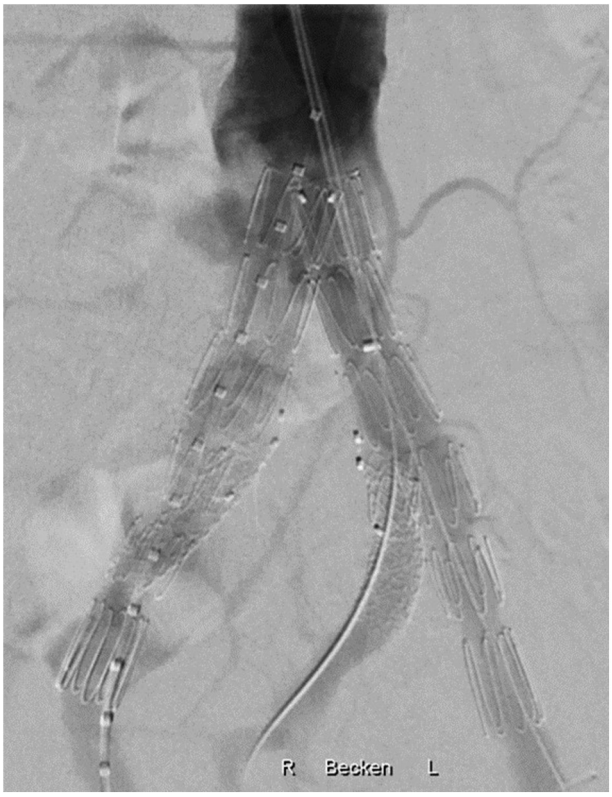

Figure 1. Bilateral iliac branch device implantation from axillary artery access.

into the IIA. Completion angiography was performed in all patients to assess IBD patency, antegrade flow to the iliac vessels, aneurysm exclusion, and endoleak presence (Fig. 1).

Post-operative management

All patients underwent post-operative reference abdominal X-ray imaging in four antero-posterior and oblique standardised views before discharge. Surveillance with CTA imaging (Fig. 2) was performed at one month, one year, and thereafter ultrasound or CTA imaging depending on each patient's characteristics after discussion in the department. Upon suspicion of endoleak or branch stenosis/occlusion, additional digital subtraction angiography for further evaluation and possible re-intervention was performed.

Statistical analysis

Continuous data were presented as mean ± standard deviation in normally distributed variables and median and range if non-normally distributed. Qualitative variables were presented as total number and percentage. Patient survival, target vessel patency, and re-intervention during follow up were subjected to Kaplan—Meier life table analysis. Data processing and analysis were performed using the SPSS statistical package for Windows, version 20.0 (SPSS, Chicago, IL, USA), and $p < .05$ was considered statistically significant.

Figure 2. 3D reconstruction of a completed repair with bilateral iliac branch device.

RESULTS

Patients

During the study period, 149 patients required unilateral or bilateral IBD and/or IIA embolisation. Twenty-nine (20%) patients (29 male; mean age 64.1 ± 10 years) were treated with bilateral IBD and were included in this study, 49 (33%) had a unilateral IBD with contralateral limb landing in the CIA, 17 (11%) had a unilateral IBD with embolisation of the contralateral IIA, and 54 (36%) had a unilateral embolisation with contralateral landing in the CIA.

Forty-eight (83%) IBDs were implanted bilaterally in one procedure, and 10 (17%) were implanted in two procedures, for a total of 34 procedures. The mean time between the two procedures was 30.4 ± 9 months. Demographic characteristics and co-morbidities of the patients included in this study are shown in Table 1 and anatomical characteristics in Table 2.

Nineteen (65%) patients had a previous or simultaneous EVAR (three of them in two separate procedures) and 10 (35%) a previous or simultaneous complex aortic repair by FEVAR/BEVAR (two of them in two separated procedures). The indication for treatment was an AAA in eight (23.5%) of the 34 procedures, CIA aneurysm in 12 (35.3%), concomitant AAA and CIA aneurysm in six (17.6%), CIA aneurysm after previous EVAR in four (11.8%), and type Ib endoleak in four (11.8%). Thirteen patients (44.8%) fell outside the previously described IFU. Reasons were i) a CIA length <50 mm in four patients (procedure performed via a left axillary access in three of them) and ii) use of a left axillary access in nine patients with a previous EVAR/FEVAR or a sharp aortic bifurcation.

Table 1. Baseline and comorbidity characteristics in 29 patients with bilateral iliac branch devices

	Total (n = 29)
Mean age (SD)	64.1 (10)
Male sex	29 (100%)
Hypertension	20 (69%)
Hypercholesterolemia	9 (31%)
Diabetes mellitus	7 (24%)
Smoking, current or past	15 (52%)
Peripheral artery disease	7 (24%)
Coronary artery disease	15 (52%)
COPD	9 (31%)
Cerebrovascular disease	1 (3.5%)
Serum creatinine > 1.13 mg/dL	5 (17%)
ASA physical status ≥ III	9 (31%)

Data expressed in absolute numbers (percentage), except where indicated: Mean (SD). ASA = American Society of Anesthesiologists; COPD = chronic obstructive pulmonary disease; SD = standard deviation.

Table 2. Anatomical characteristics

Aortic diameter, mm	
Mean (SD)	46.1 (14.2)
Range	20–79
CIA diameter, mm	
Mean (SD)	35.2 (8.2)
Range	20–54
EIA diameter, mm	
Mean (SD)	10.4 (0.7)
Range	9–11
IIA diameter, mm	
Mean (SD)	9.2 (1.3)
Range	7–11
CIA length, mm	
Mean (SD)	61.5 (18.5)
Range	25–103
IIA length, mm	
Mean (SD)	33.2 (7.6)
Range	19–45

CIA = common iliac artery; EIA = external iliac artery; IIA = internal iliac artery; SD = standard deviation.

Technical success

Primary technical success was achieved in 55 of the 58 IBDs (95%). There were two failures to catheterise the IIA in two patients with a calcified and stenosed IIA origin. In both cases the IIA was overstented without signs of endoleak. The third patient had an intra-operative IIA branch occlusion. This patient had a previous EVAR in which an IBD and two bridging limbs were implanted. The old iliac limb was also relined with a bare stent because of kinking. The patient suffered a CIA and EIA intra-operative thrombosis, which was treated by thrombectomy. This resulted in occlusion of the IIA side branch of the IBD. Of these three patients with IIA occlusion, one suffered mild buttock claudication after the intervention that persisted during follow up.

Operative data

Median operation time was 180 min (range 100–320) with a median fluoroscopy time of 43 min (range 16–113). Median estimated blood loss was 200 mL (range 120–300) and mean iodinated contrast volume used 120 ml (range 60–180). An axillary artery access was performed in 13 (38%) of 34 procedures: five patients had previous EVAR and unilateral IBD, three patients previous FEVAR, two patients a short CIA, two patients a sharp aortic bifurcation, and one patient in which the crossover wire was lost during the procedure and the access changed to the axillary artery.

The bridging stent graft used for the IIA was an Advanta V12 (Atrium Medical) in 52 IBDs, a Fluency (C.R. Bard Peripheral Vascular Inc.) in two IBDs, and a Begraft Plus (Bentley Innomed) and a Lifestream (C.R. Bard Peripheral Vascular Inc.) in one IBD each. In the last two IBDs, no bridging stent graft was implanted because of technical failure as mentioned above. Relining of the bridging stent graft with a self expandable stent was performed in nine (16.1%) cases (SMART, Cordis, Miami Lakes, FL, USA n = 8, Zilver Flex, Cook, n = 1).

Peri-operative results

There was no early (30 days) death, open conversion, spinal cord or mesenteric ischaemia, myocardial infarction, stroke, need for haemodialysis, or buttock necrosis. Mean total hospital stay, including the pre-operative admission day, was 6 ± 2 days. Four patients (14%) with complex aortic repairs spent the first 24 h in the intensive care unit.

Follow up

Median follow up was 11 months (range 1–79). One patient died during follow up, 20 months after the intervention, because of a myocardial infarction. Four IIA branches occluded (1 bilateral and 2 unilateral) in three patients who presented with extensive calcification with stenosis at the origin of the IIA. Estimated IIA branch patency at one and three years was 97.8% ± 2% and 88.5% ± 7%, respectively (Fig. 3). All three patients with late IIA occlusion remained asymptomatic.

Re-intervention was needed in four (14%) patients. Two patients with a type Ib endoleak were treated by extension of the IIA stent graft via axillary access. In one of these patients the stent graft was extended to the larger IIA branch and the smaller branch occluded with coils (Fig. 4). One patient had relining of the left EIA for mural thrombus on the follow up CTA, and another patient underwent a femoro-femoral crossover bypass after EIA limb occlusion.

DISCUSSION

In the last decade, several studies have shown that IBD is a safe and effective alternative to preserve antegrade flow to the IIA in the absence of a suitable landing zone in the CIA.[9,10,16–18] However, the subset of patients that may benefit from bilateral hypogastric preservation is not well defined.[19]

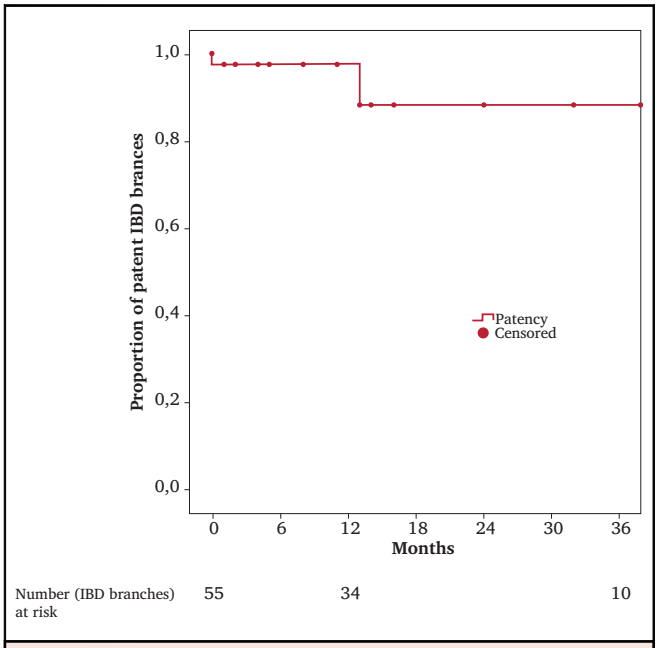

Figure 3. Kaplan–Meier analysis of iliac branch device (IBD) patency during follow up.

Data on bilateral IBD are scarce, so the benefits of preserving both IIAs must be extrapolated from the unilateral IBD studies where the risks of ischaemic complications seem to appear in 30–55% of the patients with embolisation or coverage of one IIA.[20,21] In a study by Rayt et al., 31% of the patients with unilateral and 35% of bilateral embolisation presented with post-operative buttock claudication. New erectile dysfunction occurred in 17% of unilateral and 24% of bilateral embolisations.[4] A recent review comparing the outcomes of interruption versus preservation of IIA flow during EVAR showed that patients undergoing bilateral IIA interruption had a higher incidence of buttock claudication than patients with unilateral IIA interruption (36.5% vs. 27.2%).[9] Other ischaemic events such as mesenteric or spinal cord infarcts and buttock necrosis were rare in these patients but may lead to serious complications when they occur.

It seems reasonable to preserve IIA antegrade flow when possible, especially in young, physically and sexually active patients, in those with surgery for a thoraco-abdominal aortic aneurysm, and those with impaired collateral circulation from the inferior mesenteric artery, ipsilateral femoral arterial system, or contralateral IIA. Given that even unilateral interruption of an IIA involves a certain risk of ischaemic events, attempts gradually became more liberal aiming to preserve bilateral IIA flow with IBDs where possible.

Some published IBD series include patients who have been treated with bilateral IBDs.[16–18,22–30] Patients with bilateral IBD were not separately reported in these studies. To date, only two case reports,[31,32] one small series of six patients,[15] and a series from an international multicentre experience,[33] have analysed the use of bilateral IBDs. For Huilgol et al.[15] technical success was achieved in all six cases and one patient suffered a branch occlusion at week eight. There was no peri-operative morbidity or mortality and no type I endoleak during follow up. The authors concluded that bilateral IBD procedures were feasible and presented good mid-term outcomes in selected cases. Selection criteria for implanting a bilateral IBD were not reported. Maldonado et al. recently reported outcomes of 47 patients treated with bilateral Gore Excluder Iliac Branch Endoprosthesis (IBE; W. L. Gore & Associates, Flagstaff, AZ, USA) between 2006 and 2013 in 24 centres (16 U.S., 8 European).[33] Technical success was achieved in 46 patients (97.9%), there was no significant peri-operative morbidity or mortality, and two of 80 (2.5%) IIA branches occluded on CTA during a mean follow up of 6.5 months. The authors concluded that preservation of bilateral IIAs during repair of bilateral CIA aneurysms could be performed safely with

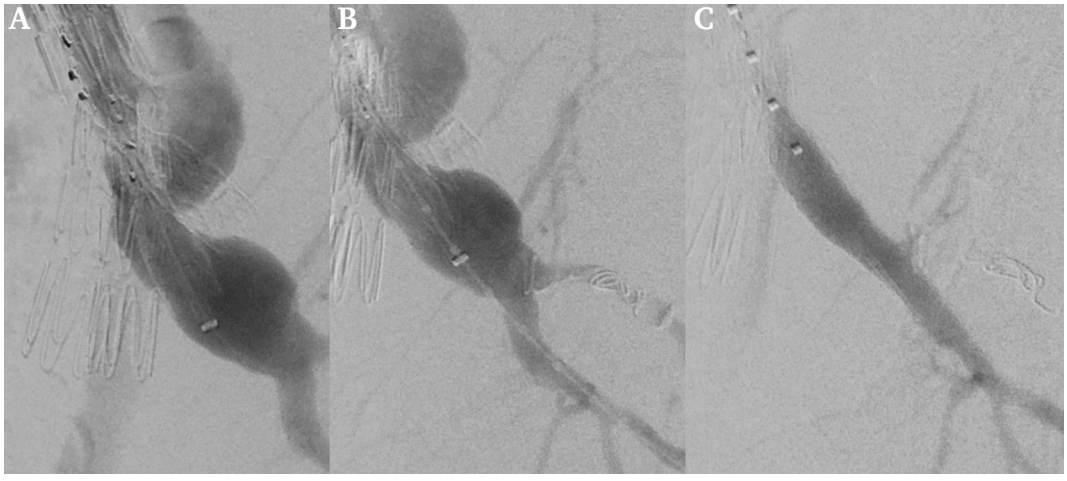

Figure 4. Re-intervention for a type Ib endoleak. (A) Sheath advanced through the iliac side branch of the iliac branch device (IBD). (B) Occlusion of the smaller internal iliac artery (IIA) branch with coils. (C) Extension of the stent graft to the larger IIA branch.

excellent technical success and short-term patency rates using the Gore IBE device.

The results of the present study are in line with those of Maldonado et al.,[33] and with those reported in the unilateral IBD studies[9,10,16,28] for technical success, mortality, morbidity, IBD patency, and re-intervention. EIA limb patency was also good, with only one (1.8%) occlusion registered during follow up. This suggests that adding a second IBD does not increase operative risks in anatomically suitable cases. Considering that all three patients with initial IBD occlusion (technical failure) in the present series presented extensive calcification with stenosis at the origin of the IIA, special caution must be taken in patients with this anatomy to select those suitable for this therapeutic strategy. The patient who presented with a bilateral IBD occlusion suffered two additional thrombotic episodes during follow up (superficial femoral artery occlusion and popliteal-crural thrombosis), suggesting a coagulation disorder or insensitivity to antiplatelet agents.

Interestingly, the three patients in the present series who suffered an IBD occlusion during follow up remained asymptomatic without buttock claudication or any other ischaemic symptom. These results are consistent with the outcomes of previous series in which the majority of late IBD occlusions were asymptomatic.[18] In a review of IBD implantations by Karthikesalingam et al., only 50% of the IBD occlusions caused buttock claudication.[3]

Some studies have cited relative contraindications for the use of IBDs, such as the presence of a previous EVAR or thoraco-abdominal endovascular repair, a short CIA, or a sharp aortic bifurcation.[28] The use of upper limb access (e.g. axillary artery) overcomes these limitations, allowing extension of the indications for IBDs to a larger number of patients. Additionally, it is mandatory for implantation of a second IBD in patients that have already a previous EVAR with unilateral IBD. Upper limb access is used routinely for branched stent graft repair and now belongs to the standard armamentarium in modern endovascular surgery. A short or ectatic main IIA is a relative contraindication for IBD. In selected cases, however, the distal landing zone can be extended to a larger IIA branch with coiling of the smaller branch if necessary. This can be decided at primary intervention or to treat a type Ib endoleak from the bridging stent graft (Fig. 4).

The potential benefits of bilateral antegrade IIA flow should be weighed against the disadvantages of the procedure: longer operating and fluoroscopy times, higher iodinated contrast volumes, and higher procedural costs.

The main limitations of this study include a potential bias in the selection of patients who were considered for a bilateral IBD, as this process is highly individualised and subjective (patients selected at the discretion of the senior author, EV) and a heterogenous group of procedures (e.g. EVAR, FEVAR, BEVAR, procedure in one or two stages). The extra costs of the bilateral procedure were not taken into account directly in the present series. Furthermore, this study was conducted in a centre experienced in complex aneurysm endovascular repair and therefore outcomes may not be generalizable.

In conclusion, bilateral implantation of IBDs appears to be a safe and effective technique to preserve antegrade IIA flow in selected patients with suitable anatomical characteristics, showing similar technical success and mid-term outcomes to unilateral iliac branched grafting. This procedure should be considered in patients with bilateral CIA dilation who undergo endovascular procedures.

CONFLICTS OF INTEREST

None.

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