Eur J Vasc Endovasc Surg (2017) 54, 95—103

Lesson Learned with the Use of Iliac Branch Devices: Single Centre 10 Year Experience in 157 Consecutive Procedures☆

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WHAT THIS PAPER ADDS

The present study provides further insight on the use of iliac branch devices (IBD) for endovascular treatment of iliac/aorto-iliac aneurysms. Although IBD have been introduced as a valid endovascular approach to deal with extensive aorto-iliac aneurysms allowing preservation of antegrade flow to the hypogastric artery, few data are reported on the long-term outcome of these grafts. Presented here is the largest available experience both in terms of number of procedures and follow-up, analyzing factors influencing peri-operative and long-term failures.

Objective/Background: Absence of an adequate iliac seal rarely represents an absolute contraindication to endovascular abdominal aortic aneurysm repair. Iliac branch devices (IBD) are increasingly used in patients with extensive aorto-iliac aneurysmal disease, but few data are available on the long-term results of these procedures.
Methods: Between 2006 and 2016, 157 consecutive IBD procedures performed at a single centre were entered into a prospective database. Indications included unilateral or bilateral common iliac artery aneurysms combined or not with abdominal aortic aneurysms. Long-term results were reported according to the Kaplan—Meier method.
Results: During the study period 149 patients were treated with an iliac branched endograft. Isolated IBD was implanted in 17.8% of the cases; technical success rate was 97.5%. Peri-operative procedure failure occurred in seven patients, four during surgery and three within 30 days of the procedure. Presence of ipsilateral hypogastric aneurysm ($p = .031$; Exp [B] = 6.72) and intervention performed during the initial study period ($p = .006$; Exp [B] = 10.40) were predictive of early failure on multivariate analysis. After a mean follow-up of 44.2 months actuarial freedom from IBD related re-intervention was 97.4%, 95.6%, 94.0%, and 91.8% at 1, 3, 5, and 9 years, respectively. Hypogastric artery patency was 94.7%, 92.6%, and 90.4% at 1, 3, and 10 years, respectively. Presence of a hypogastric aneurysm was an independent predictor of target artery occlusion during follow-up on multivariate analysis ($p = .007$; Exp [B] = 5.93).
Conclusion: Iliac branched endografting can now be performed with a high technical success rate; long-term freedom from re-intervention is comparable with patients treated with standard aortic endografting. IBD should be considered a first-option treatment in patients with adequate vascular anatomy unsuitable for standard endovascular aortic repair.

Article history: Received 9 November 2016, Accepted 31 March 2017, Available online 7 May 2017
Keywords: Branched endograft, EVAR, Hypogastric, Iliac aneurysm, Iliac endograft, Long term

INTRODUCTION

While the often disabling and potentially catastrophic consequences of hypogastric occlusion are widely acknowledged,[1—5] absence of an adequate common iliac sealing zone seldom represents a contraindication to endovascular aorto-iliac aneurysm repair.

A variety of endovascular techniques can be used as preferred methods for the current treatment of extensive iliac artery aneurysms, especially when the hypogastric arteries are involved.[6]

The recent availability of dedicated devices for internal iliac flow preservation, the widely used iliac side branched endografts, allows minimally invasive treatment options for complex aorto-iliac and bilateral iliac aneurysms.

Few data are yet available on the long-term outcomes of these treatments, especially regarding patency rates and

☆ This paper was presented at the XXX Annual ESVS Vascular Meeting held in Copenhagen, September 28—30, 2016.

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http://dx.doi.org/10.1016/j.ejvs.2017.03.026

incidence of distal aneurysm refilling; most of the studies are limited to peri-operative or mid-term outcomes.[7–17]

The aim of the present study was to investigate the results achieved during 10 years of experience in a single high volume centre with iliac branch devices (IBD).

METHODS

Data from consecutive patients undergoing aorto-iliac aneurysm repair with endovascular IBDs from June 2006 to June 2016 at a single centre were reviewed.

Patient characteristics, pre-operative and intra-operative data, clinical events, and follow-up data were retrieved from a prospective electronic database at the time of the intervention and afterwards at any scheduled examination or new hospitalisation.

Indications for intervention included the following: presence of aortic aneurysm >50 mm in axial diameter with common iliac aneurysm >25 mm; isolated common iliac aneurysm (>30 mm); hypogastric aneurysm (>30 mm); iliac growth (>35 mm) after previous endovascular or surgical aorto-iliac repair; and distal type I endoleak without a suitable common iliac sealing length (>10 mm).

IBD implantation was planned in all cases after evaluation of the pre-operative computed tomography (CT) angiogram with a dedicated workstation (Aquarius Terarecon, Foster City, CA, USA).

Except in cases of severe concomitant pathologies, particularly in patients with limited walking capacity, hypogastric preservation was always considered mandatory and when technically feasible, IBD implant was the treatment of choice. Comorbidities were defined according to the Society of Vascular Surgeons/American Association for Vascular Surgery reporting standards.[18]

When there was an adequate proximal iliac neck, and in the absence of a concomitant AAA needing treatment, the IBD was deployed in isolation or in association with a proximal straight iliac endograft[19]; in any other case it was associated with aorto bi-iliac endografting.

Severe iliac axis kinking, common iliac lumen <16 mm, and high grade calcification or thrombosis with embolisation risk were considered exclusion criteria for IBD.

All procedures were performed in a hybrid operating room equipped with a fixed, ceiling mounted X-ray imaging system with flat panel detector (Axiom Artis; Siemens, Erlangen, Germany) by a dedicated team of vascular surgeons under local or general anaesthesia. Though the team expanded over time, operator experience and technological advancements were progressively incorporated in a team based institutional approach that guided the selection of patients, materials, and techniques shared by all team members.

Until November 2013 the only graft used was the straight version of the Zenith Iliac Branch Device (Cook Inc., Bloomington, IN, USA), coupled with Advanta (MAQUET Holding B.V. & Co., Rastatt, Germany), Fluency (BARD Peripheral Vascular, Tempe, AZ, USA), or Viabhan (Gore & Associates, Inc., Flagstaff, AZ, USA) for hypogastric stent grafting. After November 2013 the Gore Excluder Iliac Branch Endoprosthesis (IBE; Gore & Associates, Inc.) became available and was selectively implanted; in these cases the hypogastric stent graft used was the Gore hypogastric stent graft, extended distally with Viabahn when needed. The choice of the endograft type was determined by the operating surgeon at the time of planning, taking account of different anatomical features. Without a rigid predetermined protocol, the Gore IBE was the preferred graft in tortuous iliac anatomy because the continuous metallic stent support was deemed more kink resistant in cases of large hypogastric arteries, owing to the availability of hypogastric graft diameters up to 14.5 mm, or when an infrarenal aortic fixation endograft was preferred. The Cook device was chosen for shorter renal to iliac bifurcation lengths, owing to wider graft length options when a bifurcated aorto-iliac graft was already in place, for easier access from above (brachial or axillary) for the hypogastric component delivery, for smaller proximal common iliac diameters, for smaller diameter of the IBD, or when a suprarenal aortic fixation endograft was preferred.[10,20]

For hypogastric aneurysms with no suitable distal landing zone, the internal iliac component was deployed to seal in the gluteal artery, following visceral branch embolisation.

At the end of the procedure a completion angiogram was always performed to evaluate stent graft patency and aneurysm exclusion.

The follow-up protocol consisted of a duplex examination at discharge and contrast enhanced CT within 30 days after surgery. Plain abdomen Xray and duplex examination were scheduled at 6 months and contrast CT scan at 1 year. Duplex scan and clinical examination were performed yearly thereafter, except in cases requiring CT (i.e., persistent endoleak, short landing zone, aneurysm growth >5 mm).

Arterial diameters were measured as the shortest outer transverse diameter of the vessel on axial scans by the same observer. Arterial length was measured with centreline of flow from the CT.

Patients missing follow-up visits for >12 months were interviewed by telephone, while causes of death were obtained from family, primary care physicians, or death certificates.

Considering the retrospective nature of the study and the fact that all patients provided written consent for anonymous use of clinical data for scientific purposes, institutional review board approval was waived.

Statistical analysis

Data are presented as *n* (%) for qualitative variables and mean ± SD for quantitative variables.

The chi-square test was used to assess association between potential predictive factors (sex, bilateral procedure, IBD manufacturer, axial/brachial access, hypertension, ischaemic heart disease, chronic obstructive pulmonary disease, diabetes, chronic renal failure, ipsilateral hypogastric aneurysm, isolated side branch procedure, type and number of bridging stents used) and outcomes.

A p value of <.05 was considered significant for all the analyses. Kaplan–Meier survival estimates were calculated to assess long-term outcomes (survival, re-intervention, and patency); curves are displayed up to a value of SE <.10. The Hosmer–Lemeshow method was used to decide which variables to include in the regression evaluation using bivariate outcomes. Logistic regression analysis with backward stepwise method was used to test independent associations between the risk of early procedure failure and hypogastric occlusion and possible influencing factors.

To establish the learning curve effect on peri-procedural outcome, the threshold of 25 implants was set to divide the early period from the acquired experience phase. This limit was chosen by applying the individual recommended minimum number of endovascular procedures for credentialing.[21,22]

Statistical analysis was performed with SPSS (version 20; IBM, Armonk, NY, USA).

RESULTS

From June 2006 to June 2016, 157 bifurcated iliac grafts were implanted in 149 patients. Of the eight cases with bilateral iliac branched grafts, five were simultaneous, while three cases accounted for re-interventions on the contralateral iliac artery during follow-up after initial single IBD.

Patients were mostly male (95.5%) with a mean age of 74.0 ± 7.3 years. The target common iliac artery mean diameter was 37.0 ± 8.1 mm; a concomitant aortic aneurysm measuring >35 mm was present in 61.1% of the cases. Mean axial aortic transverse diameter was 47.1 ± 14.1 mm. Twenty-three patients (14.6%) had an ipsilateral hypogastric aneurysm; nine of them required visceral branch embolisation and distal landing in the gluteal artery to achieve adequate sealing. Population characteristics and indication for each intervention are reported in Tables 1 and 2, respectively.

The most used IBD was the ZBIS Cook straight configuration, used in 134 procedures (85.4%); the remaining cases were treated with the Gore IBE endograft.

In 122 cases (77.7%) a self expandable stent was used as a bridge component between the iliac bifurcated module and the hypogastric artery. In the remaining cases a balloon expandable stent graft (17.2%) or a combination of the two types (n = 7; 4.5%) was used. In one case, where hypogastric artery catherisation proved impossible no component was deployed and the iliac branch was internally relined with a straight iliac endograft. The total number of hypogastric graft segments was 180 (1.15 ± 0.45 per patient). In 28 cases an isolated IBD was implanted: the main indication was treatment of an isolated common or hypogastric aneurysm.[19] In all the other procedures an adjunctive aortic bifurcated endograft was deployed. The aortic prosthesis used was Cook Zenith in the majority of the cases (n = 100; 63.7%); other devices included Gore C3 (n = 22; 14.0%), Medtronic Endurant (Medtronic Vascular, Santa Rosa, CA, USA; n = 4 [2.5%]), and Cook custom made branched or fenestrated endograft (n = 3; 1.9%).

Table 1. Baseline patient characteristics.

Characteristic	
Mean ± SD age (y)	74.0 ± 7.3
AAA diameter > 50 mm	57 (36.3)
AAA diameter > 35 mm	96 (61.1)
Ipsilateral hypogastric aneurysm	23 (14.6)
Mean ± SD target common iliac diameter (mm)	37.0 ± 8.1
Mean ± SD aortic transverse diameter (mm)	47.1 ± 14.1
Male	150 (95.5)
Hypertension	129 (82.2)
Chronic obstructive pulmonary disease	78 (49.7)
Ischaemic heart disease	67 (42.7)
Diabetes	20 (12.7)
Chronic renal failure	22 (14.0)

Note. Data are n (%) unless otherwise indicated.

The hypogastric component was introduced with axillary or brachial access in 8.9% of the procedures because of the presence of a bifurcated aortic graft already in place or, in one case because of a longstanding contralateral external iliac artery occlusion.[20]

Most of the procedures were performed under local anaesthesia (61.1%) with surgical common femoral artery exposure (73.9%). In nine cases the intervention was performed under epidural anaesthesia; the remaining cases

Table 2. Indication for intervention.

Indication	
Common iliac aneurysm > 30 mm	146 (93.0)
Isolated	54 (34.4)
AAA > 50 mm associated	41 (26.1)
Bilateral	17 (10.8)
Bilateral and AAA > 50 mm associated	8 (5.1)
Hypogastric aneurysm > 30 mm associated	1 (0.6)
Bilateral and associated hypogastric aneurysm > 30 mm	7 (4.5)
Recurrent after previous aorto-aortic reconstruction	3 (1.9)
Recurrent after previous aorto-bi-iliac reconstruction	12 (7.6)
Pararenal AAA > 55 mm associated	1 (0.6)
Type IV thoraco-abdominal aortic aneurysm > 60 mm associated	1 (0.6)
Type III thoraco-abdominal aortic aneurysm > 60 mm associated	1 (0.6)
AAA > 50 mm + iliac ectasia	5 (3.2)
Hypogastric aneurysm > 30 mm	2 (1.3)
AAA > 50 mm + hypogastric aneurysm > 30 mm	2 (1.3)
AAA > 50 mm + short common iliac landing	1 (0.6)
Distal pseudoaneurysm on previous aorto-aortic reconstruction	1 (0.6)

Note. Data are n (%). AAA = abdominal aortic aneurysm.

employed general anaesthesia, 49 as initial approach and three after failed local anaesthesia.

Operative features are reported in Table 3.

Peri-procedural outcomes

Technical success, defined as effective aneurysm sealing maintaining direct hypogastric flow, was 97.5% (153/157). Intra-operative technical failures were due to one distal hypogastric endoleak (corrected 3 months later), one type III endoleak from hypogastric stent disconnection (corrected after 3 days), one IBD occlusion treated by thrombectomy (resulting in hypogastric occlusion), and one case of intra-operative hypogastric dissection leading to hypogastric thrombosis.

Early procedure failure occurred in three patients within 30 days. In one patient asymptomatic target hypogastric artery occlusion was detected at routine duplex scan performed on post-operative day 3 before discharge. In another patient hypogastric occlusion resulted after thrombectomy performed for side branch thrombosis on post-operative day 1. In the last case new onset of non-disabling claudication occurred at 30 days, and complete occlusion of the IBD was found on CT and duplex.

No peri-operative or in hospital death was recorded. In no case was early (or late) surgical conversion needed. There was no myocardial infarction, stroke, mesenteric or spinal cord infarct, or buttock necrosis. Major morbidity occurred in three patients: one had an episode of atrial fibrillation requiring medical treatment, the second patient had acute congestive heart failure 7 days after discharge, and the third patient, with pre-operative renal failure, had worsening of renal dysfunction requiring chronic dialysis 1 month after the procedure.

Considering the first 25 cases performed during the learning time interval (covering an 18 month period), the peri-operative success rate was significantly different between the two study periods: 21/25 (84.0%) versus 129/132 (97.7%) ($p = .013$; hazard ratio 8.2, 95% confidence interval 1.7—39.2) in favour of the acquired experience period.

No other risk factor was predictive of early failure on bivariate analysis among the 13 tested.

A binary logistic regression model was then generated, including potential predictive factors of procedural failure whose p value on bivariate analysis was $<.25$ (initial experience, ipsilateral hypogastric aneurysm [$p = .065$] and stent type [$p = .185$]). With backward stepwise variable selection, both hypogastric aneurysm ($p = .031$; Exp [B] $= 6.72$) and initial study experience ($p = .006$; Exp [B] $= 10.40$) were significant predictors of early failure.

Table 3. Operative features.

Characteristic	
ZBIS Cook	134 (85.4)
IBE Gore	23 (14.6)
Balloon expandable stent	27 (17.2)
Self expandable stent	122 (77.7)
Isolated IBD	28 (17.8)
Brachial access	14 (8.9)
Local anaesthesia	96 (61.1)
Percutaneous access	41 (26.1)
Contralateral hypogastric embolisation	19 (12.1)
Visceral branch embolisation and distal landing in gluteal branch	9 (5.7)
Mean ± SD procedure time (min)	158 ± 58
Mean ± SD fluoroscopy time (min)	43 ± 25
Mean ± SD contrast (mL)	145 ± 49
Peri-operative death	0
Type I endoleak	2 (1.3)
Type II endoleak	25 (15.9)
Type III endoleak	1 (0.6)

Note. Data are *n* (%) unless otherwise indicated. IBD = iliac branch device.

Long-term results

Median follow-up was 34.0 months (range 1—121; interquartile range 12.5—73.5; mean 44.2 ± 35.1 months). During this period 39 late deaths were recorded, none attributable to aneurysm presence or endovascular aorto-iliac repair.

Actuarial overall survival rate estimate was 93.9% at 1 year, 73.4% at 5 years, and 53.9% 10 years after IBD implantation (Fig. 1).

During the study, 36 re-interventions were needed in 25 patients. Freedom from re-intervention risk with Kaplan—Meier estimate was 94.8%, 88.7%, 79.6%, and 64.4% at 1, 3, 5, and 9 years, respectively (Fig. 2). Details regarding each single new procedure are reported in Table 4. As explained in detail, the need for re-intervention specifically related to the IBD device occurred in only eight patients (5.4%). Freedom from IBD related re-intervention was 97.4%, 95.6%, 94.0%, and 91.8% at 1, 3, 5, and 9 years of follow-up, respectively (Fig. 3).

Overall, 11 hypogastric branch occlusions were observed: five occurred peri-operatively and the remaining six during follow-up. Late hypogastric artery thrombosis occurred in

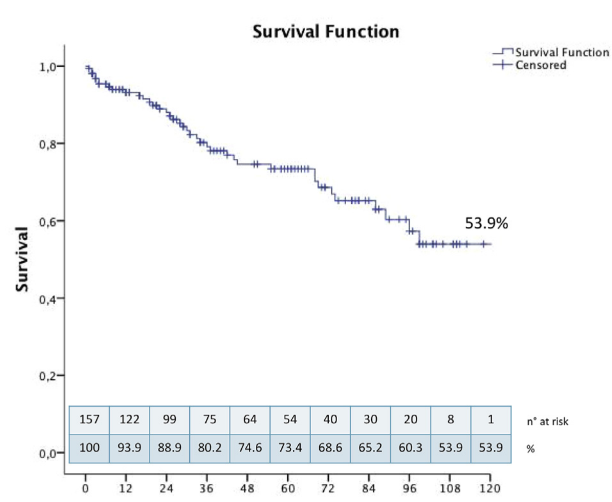

Figure 1. Ten year overall survival estimate calculated by Kaplan—Meier method.

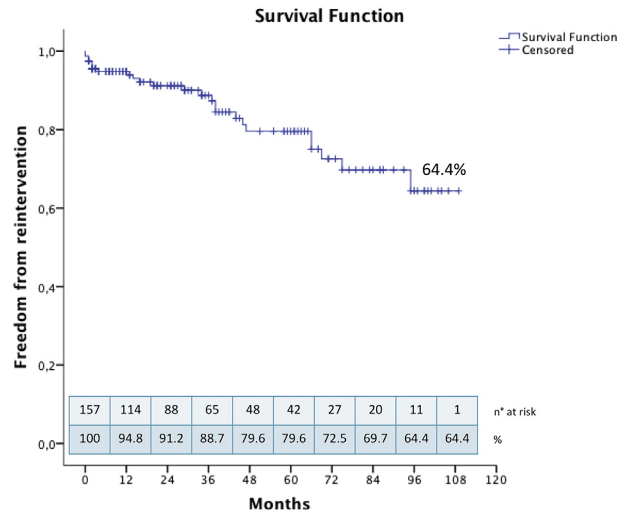

Figure 2. Nine year freedom from any re-intervention calculated by Kaplan—Meier method.

five cases: at 48 days, 75 days, 7 months, 14 months, and 32 months after implantation, respectively.

In the remaining case, the IBD was deliberately occluded as a re-intervention in order to seal a distal type IB hypogastric endoleak after 66 months in a patient without a suitable neck in distal hypogastric artery. Primary hypogastric patency is shown in Fig. 4. The actuarial patency rate was 94.7%, 92.6%, and 90.4% at 1, 3, and 10 years, respectively. In most cases (7/11), hypogastric occlusion caused persisting gluteal claudication; the remaining four patients did not experience symptoms from arterial thrombosis.

The same variables analysed as potential predictors of early procedure failure were considered as possibly implicated in determining hypogastric occlusion. In this context target hypogastric aneurysm was significantly associated with anytime hypogastric artery occlusion ($p = .011$; hazard ratio 5.9; 95% confidence interval 1.6—21.4). A multivariate model was constructed again with the same criteria used for early procedure failure. Among considered variables (hypogastric aneurysm and number of bridge hypogastric stents ($p = .149$), aneurysmal hypogastric artery was again predictive of bridge stent occlusion ($p = .007$; Exp [B] $= 5.93$).

DISCUSSION

Preserving pelvic perfusion during EVAR is advocated whenever possible to minimise the risk of ischaemic complications that may occur in up to 40—45% of acute unilateral hypogastric occlusion,[7,8,23—31] with probably increasing proportions after bilateral occlusion.[8,31]

Different endovascular options have been proposed for this purpose, but, except for IBD implantation, only experiences reporting anecdotal success without consistent follow-up are available.

IBDs have been used for more than a decade with commercially available devices; nevertheless, studies detailing the use of IBDs and their late complications are limited. In the last few years there have been reports of larger series of IBD from multiple centres.[7,11,12] Furthermore, reports on bilateral iliac aneurysm repair are also available.

In 2010 a systematic review by Karthikesalingam *et al.* collected data from seven published series, including 196 patients with commercially available IBD.[3,32—39] Since then, at least 13 other series have been published collecting results from other IBD in approximately 500 patients.[7—18,39] Furthermore, some data achieved follow-up lengths of up to 30—32 months to assess late outcomes after IBD.[7,12,13,17,40]

The rate of technical success with current grafts is reported to be high, with rates ranging from 86% to 100% in most series published after 2009.

The present study provides additional information especially on long-term outcomes, confirming the low risk of endograft late failures up to 10 years, the longest follow-up available in published literature.

Like most of the series on IBD, the present experience showed that most of the hypogastric branch occlusions occurred within the first 30 days of the primary procedure.[3,9,32—34,38] Technical mistakes during patient selection (underestimation of excessive iliac tortuosity, fragile thrombus burden in the iliac lumen) or intra-operatively (graft maldeployment, graft angulation left untreated, inappropriate landing, embolisation of thrombus during catheter manipulations) are paramount in affecting long-term patency. If the device is satisfactorily deployed and hypogastric arterial flow is well preserved without graft kinks, long-term patency may be expected and buttock claudication averted.

As already demonstrated for other endovascular procedures,[41—43] the present study underlines the importance of an adequate learning curve to decrease early complications and ensure long-term efficacy. In the first period of experience a 16.0% failure rate was incurred versus 2.3% after the first 25 cases. It was learned that landing zone length, both between hypogastric stents and in the distal hypogastric artery, are crucial for stable fixation; in fact, two of the four early failures in the early experience resulted from short landing zones. Another lesson learned was about patient selection for IBD: iliac tortuosity, especially at the level of the external iliac artery, is a critical risk factor for early occlusion. Arterial tortuosity (i.e., with a ratio between the straight and centreline distance between aortic bifurcation and external iliac landing point) was not measured specifically; however, two immediate IBD occlusions were experienced in patients with acute angulation at the origin of the external iliac artery, where the graft limbs kinked without the help of a relining stent.

The actuarial estimate of re-intervention rate in patients treated with IBD in the present experience does not differ significantly from previous reports with shorter follow-up times.

Five large studies, each including >40 IBD, published outcomes with a mean follow-up after implantation of >20 months.[7,12,13,17,40] The longest follow-up available (mean

Table 4. Schematic review of any re-intervention performed during follow-up.

Patient no.	Indication	Timing	IBD related	Surgery description
1	Acute limb occlusion (contralateral)	1 mo	No	Limb thrombectomy and bare stent implant
	Type I distal endoleak (hypogastric)	3 mo	Yes	Distal covered stent implant
3	Type III endoleak (between IBD and hypogastric covered stent)	3 d	Yes	Additional covered stent implant
	Type I distal endoleak (hypogastric) with recurrent aneurysm	66 mo	Yes	Side branch embolisation
5	Type I proximal endoleak (isolated IBD)	46 mo	Yes	Bifurcated aortic endograft implant
7	Type I proximal and distal (external) endoleak (isolated IBD) + type III endoleak (hypogastric stent fracture)	66 mo	Yes	Bifurcated aortic endograft + external covered stent + hypogastric covered stent implant
	Type III endoleak (external covered stent disconnection)	70 mo	Yes	Iliac cuff implant (external)
	Type III endoleak (IBD proximal disconnection)	76 mo	Yes	Common iliac cuff implant
8	Acute occlusion of IBD external branch (internal iliac patency)	2 mo	Yes	Femoro-femoral crossover bypass
11	Type II endoleak with growth	37 mo	No	Angiography and embolisation attempt
	Type II endoleak with growth	70 mo	No	Lumbar artery embolisation
	Type II endoleak with growth	85 mo	No	Aneurysmal sac embolisation
13	Common femoral artery pseudoaneurysm (percutaneous access)	2 mo	No	Pseudoaneurysm repair
14	Common femoral artery pseudoaneurysm (percutaneous access)	66 mo	No	Pseudoaneurysm repair
	Type III endoleak (contralateral limb disconnection)	79 mo	No	Common iliac cuff implant
	Type I proximal and distal (contralateral) endoleak	102 mo	No	Proximal and distal cuff implant (contralateral hypogastric embolisation)
15	Common femoral artery pseudoaneurysm (percutaneous access)	4 mo	No	Pseudoaneurysm repair
17	Acute IBD occlusion	1 d	Yes	Limb thrombectomy and covered stent implant
21	Recurrent contralateral common iliac aneurysm	95 mo	No	Common iliac cuff implant
27	Type II endoleak with growth	38 mo	No	Diagnostic angiography
	Type II endoleak with growth	51 mo	No	CT guided type II endoleak embolisation
29	Type I distal endoleak (hypogastric)	14 mo	Yes	Distal covered stent implant
33	Recurrent contralateral common iliac aneurysm	69 mo	No	Contralateral IBD implant
49	Acute limb occlusion (contralateral)	2 mo	No	Thrombolysis and covered stent implant
52	Type Ib endoleak and recurrent contralateral common iliac aneurysm	47 mo	No	Contralateral IBD implant
53	Type II endoleak with growth	38 mo	No	Lumbar artery and inferior mesenteric embolisation
	Type II endoleak with growth	51 mo	No	Sacotomy
57	AAA growth (isolated IBD)	75 mo	No	Bifurcated aortic endograft implant
61	Common femoral artery pseudoaneurysm (percutaneous access)	34 mo	No	Pseudoaneurysm repair with covered stent
67	Type I distal endoleak (hypogastric)	16 mo	Yes	Distal covered stent implant
80	Type Ib endoleak (contralateral)	29 mo	No	Contralateral IBD implant
81	Type II endoleak with growth	13 mo	No	Inferior mesenteric artery embolisation
	Type II endoleak with growth	24 mo	No	Lumbar arteries and aneurysmal sac embolisation
83	Suspect type I vs. III endoleak	4 mo	No	Diagnostic angiography
85	Groin infection	1 mo	No	Surgical wound toilet
99	Type II endoleak with growth and recurrent contralateral common iliac aneurysm	20 mo	No	Lumbar artery embolisation + contralateral hypogastric embolisation and iliac cuff implant

Note. IBD = iliac branch device; CT = computed tomography; AAA = abdominal aortic aneurysm.

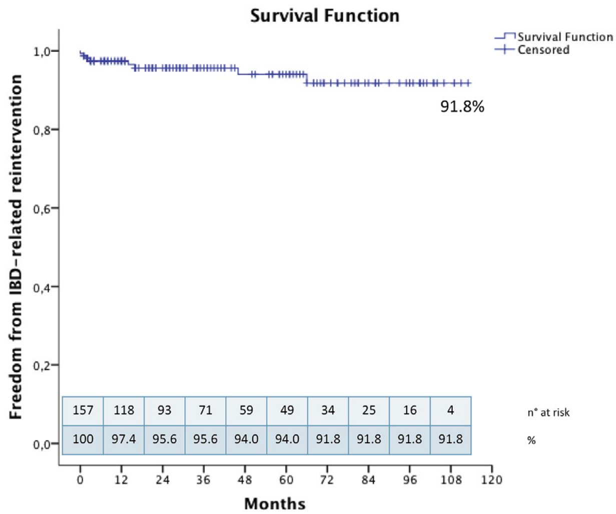

Figure 3. Nine year freedom from iliac branch device related re-intervention calculated by Kaplan—Meier method.

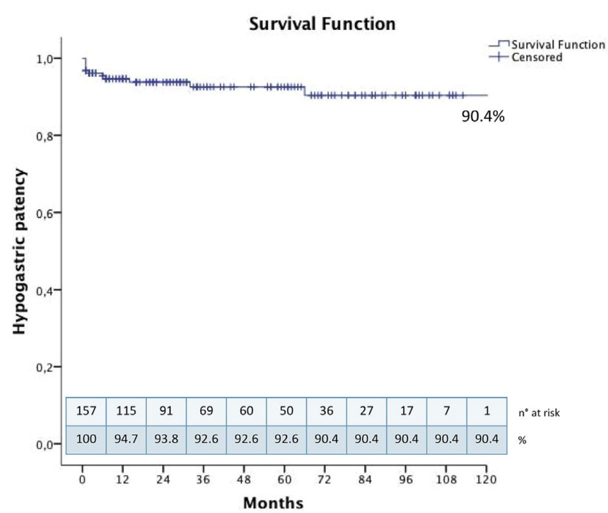

Figure 4. Ten year hypogastric patency rate calculated by Kaplan—Meier method.

32 $\pm$ 27 months, up to 109 months) comes from Frankfurt, with 45 IBD implants. The authors reported an actuarial hypogastric artery patency rate of 81%, freedom from iliac related endoleak rate of 83%, and freedom from any endoleak of 76% at 109 months.[13] Most re-interventions occurred within the first 18 months, with an overall freedom rate of 83%. Nevertheless, only a few patients reached the longer follow-up time. No patients reported symptoms of pelvic ischaemia or permanent buttock claudication.[13] The Cleveland Clinic reported the largest series available in the literature, with 138 IBDs in 130 patients, with a median follow-up of 20.3 months (range 1—72 months) and an estimated patency at 5 years of 81.8%.[12] Of the overall 18 occlusions, 11 occurred within 30 days of implantation and seven between 1 and 26 months: 71% developed permanent buttock claudication. Freedom from IBD related endoleak was 96% at 5 years and all were due to loss of distal sealing in the hypogastric artery. The authors performed 12 re-interventions, mainly for endoleak and occluded vessel correction. No stent fractures or component separations of IBD or mating stents were noted at follow-up. No aneurysm growth was found; all aneurysms remained stable or shrank.[12]

Predictors of failure after IBD implantation were searched to help selection of the patient pre-operatively. In a previous paper the present authors' group analysed the results of 100 consecutive patients treated with IBD at two high volume centres. The effect of six potential adverse features for risk of re-intervention were considered, (age, sex, iliac aneurysm diameter $>$ 4 cm, hypogastric aneurysm, associated aortic repair, and AAA $>$ 5.5 cm). The presence of a hypogastric aneurysm was the only predictor of re-intervention with a hazard ratio of 5.9 (95% confidence interval 1.57—22.08; p = .008).[40] This finding was confirmed after a further 5 years of experience in the present study, where risks of late type Ib and type III endoleak persisted in the long term. With experience, the present authors now tend to avoid short distal necks, with more extensive distal landing into gluteal artery in case of extensive hypogastric aneurysmal involvement.

A similar experience was reported by Donas *et al.*,[7] who reported primary patency rates after IBD of 98.4% and primary and secondary endoleak rates of 12.5% and 6.3%. One case of dislocated covered internal iliac stent with persistence of hypogastric perfusion and rupture was reported 23 months after endograft deployment.

Study limitations

This study was limited by its single centre design and by the absence of a control group. Because of the high variability of clinical and anatomical presentation, it was not possible to apply a standardised approach to patient selection. Patient and material selection for intervention derived from team discussion about the single case instead of rigid protocols as it might be for prospective studies.

Furthermore, after 2013 two different endograft models were used as IBDs. It is possible that differences in peri-operative or late performances between the grafts, may exist but are impossible to evaluate now for differences in numbers and follow-up lengths.

CONCLUSIONS

Iliac branched endografting can now be performed with a high rate of technical success. Mid-term and late patency rates are high, especially after acquiring confidence and experience following the learning phase. The presence of hypogastric aneurysm still represents a risk factor for adverse peri-operative and late outcome. These findings suggest that the need for careful pre-implant assessment and patient selection, remain paramount to preclude technical failure.

According to the present findings, IBD grafts should be considered as a first option in the treatment of patients with adequate vascular anatomy unsuitable for standard EVAR.

ACKNOWLEDGMENTS

Authors would like to thank Ms. Francesca Zannetti for editing and language support.

CONFLICT OF INTEREST

None.

FUNDING

None.

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