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Long-term Results of Iliac Aneurysm Repair with Iliac Branched Endograft: A 5-Year Experience on 100 Consecutive Cases $\stackrel{\mbox{\tiny\sc true}}{\sim}$

G. Parlani^a, F. Verzini^a, P. De Rango^{a,*}, D. Brambilla^a, C. Coscarella^b, C. Ferrer^b, P. Cao^b

^a Unit of Vascular and Endovascular Surgery, Hospital S. Maria della Misericordia, Perugia, Italy ^b Unit of Vascular Surgery, Hospital S. Camillo-Forlanini, Rome, Italy

WHAT THIS PAPER ADDS

• The study provides further insight on the use of iliac branch device (IBD) for endovascular treatment of iliac/aorto-iliac aneurysms. By reporting long-term results up to 5 years with 100 IBDs of current generation (data not yet largely available due to the relative novelty of the technique), the study supports the durability in addition to the feasibility and safety of this approach to iliac aneurysms.

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ABSTRACT

Background: Iliac branch device (IBD) technique has been introduced as an appealing and effective solution to avoid complications occurring during repair of aorto-iliac aneurysm with extensive iliac involvement. Nevertheless, no large series with long-term follow-up of IBD are available. The aim of this study was to analyse safety and long-term efficacy of IBD in a consecutive series of patients.

Methods: Between 2006 and 2011, 100 consecutive patients were enrolled in a prospective database on IBD. Indications included unilateral or bilateral common iliac artery aneurysms combined or not with abdominal aneurysms. Patients were routinely followed up with computed tomography. Data were reported according to the Kaplan–Meier method.

Results: There were 96 males, mean age 74.1 years. Preoperative median common iliac aneurysm diameter was 40 mm (interquartile range (IQR): 35-44 mm). Sixty-seven patients had abdominal aortic aneurysm >35 mm (IQR: 40–57 mm) associated with iliac aneurysm. Eleven patients presented hypogastric aneurysm. Twelve patients underwent isolated iliac repair with IBD and 88 patients received associated endovascular aortic repair. Periprocedural technical success rate was 95%, with no mortality. Two patients experienced external iliac occlusion in the first month. At a median follow-up of 21 months (range 1–60) aneurysm growth >3 mm was detected in four iliac (4%) arteries. Iliac endoleak (one type III and two distal type I) developed in three patients and buttock claudication in four patients. Estimated patency rate of internal iliac branch was 91.4% at 1 and 5 years. Freedom from any reintervention rate was 90% at 1 year and 81.4% at 5 years. No late ruptures occurred.

Conclusions: Long-term results show that IBD use can ensure persistent iliac aneurysm exclusion at 5 years, with low risk of reintervention. This technique can be considered as a first endovascular option in patients with extensive iliac aneurysm disease and favourable anatomy.

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The presence of common iliac artery aneurysm (CIA) preventing the achievement of an effective seal and distal fixation is one of the major anatomic challenges of conventional endovascular aneurysm repair (EVAR). Extensive iliac aneurysm repair exposes a twofold major safety issue: preservation of pelvic circulation to avoid ischaemic complications and durable effective exclusion of the aneurysm to prevent risk of rupture in the long term.¹ Iliac branch

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^{*} Corresponding author. Unit of Vascular and Endovascular Surgery, Università degli Studi di Perugia, Ospedale S. Maria della Misericordia, Loc. S. Andrea delle Fratte, 06134 Perugia, Italy. Tel.: +39 075 5786436; fax: +39 075 5786435.

E-mail addresses: plderango@gmail.com, pderango@unipg.it (P. De Rango).

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device (IBD) has been introduced as a valid new endovascular approach to deal with extensive aorto-iliac aneurysms allowing effective preservation of antegrade flow of internal iliac artery (IIA). In the last decade, a number of studies have assessed the feasibility and safety of this novel endovascular technique showing that IBD was effective in preventing complications such as buttock claudication, colon ischaemia and erectile dysfunction. Most of the information available on IBD reports on perioperative or mid-term outcomes^{2–6} often combining older- and new-generation devices^{7–10} while today there are no data on the performance of currently available IBD in the long term.

This study investigated the outcome of IBD up to 5 years after repair.

Methods

Consecutive patients who received IBD implantation from 2006 to 2011 at two tertiary vascular centres (Unit of Vascular Surgery and Endovascular, S. Maria della Misericordia Hospital, Perugia, Italy and Unit of Vascular Surgery, S. Camillo-Forlanini Hospital, Rome, Italy) were reviewed. Patients' characteristics as well as preoperative, intraoperative and follow-up clinical and imaging data were obtained from prospectively maintained computed databases since the first introduction of the technique in January 2006. Patients treated with other endovascular techniques, such as simple common iliac endograft, bell-bottom or hypogastric coiling embolisation/occlusion during the same period, were excluded from the present study. Pseudoaneurysms, symptomatic, and ruptured iliac aneurysms as well as iliac aneurysms managed with open repair were also excluded.

Indication for treatment was the presence of unilateral or bilateral CIA of >35 mm diameter or the occurrence of CIA of >25 mm diameter associated with abdominal aortic aneurysm (AAA) >50 mm diameter. The selection for treatment with IBD was based on anatomic characteristics of aorto-iliac vessels and severe co-morbidities. Co-morbidities were defined according to the Society of Vascular Surgeons/American Association for Vascular Surgery (SVS/AAVS) reporting standards.¹¹ Age of >80 years associated with one or more severe co-morbidities (graded ≥ 2) were usually indications for IBD repair if anatomical feasibility was allowed. The IBD procedure was applied when the CIAs extended distally to preclude appropriate distal landing zone with conventional endovascular stent graft. When abdominal aortic diameter was >35 mm or in the absence of suitable proximal CIA neck, IBD release was associated with deployment of a bifurcated EVAR graft. A patent lumen of the CIA of at least 18 mm in diameter, 40 mm in length and a distal landing zone of at least 10 mm length on the main IIA trunk was required for correct graft expansion. An adequate length of external iliac artery (EIA) for a distal landing of more than 15 mm and EIA diameter <12 mm were also required. Exclusion criteria for IBD were severe IIA atherosclerosis, small CIA diameter (<18 mm) at the level of bifurcation, severe kinking and calcifications of EIA and wide angle of IIA off-sparing.

In case of bilateral CIA aneurysmal involvement, the side with the most proximal healthy segment, with richer distal arterial bed, without extensive calcification or tortuosity was chosen for IBD placement. The other side was usually excluded with coil or plug embolisation of IIA and overstenting into the EIA.

Contrast-enhanced computed tomographic (CT) aorto-iliac imaging was obtained in all patients and used for preoperative planning and then stored in a prospective computed data set.

IBD procedure

All patients received the Zenith straight version of the Zenith iliac branch device (Cook, Bloomington, IN, USA), a second-

generation IBD consisting in a bifurcated vessel graft including a main iliac limb with an additional reinforced stump for the IIA side branch. The Zenith IBD has a fixed proximal diameter of 12 mm and a distal diameter of 10, 12 or 16 mm, a common iliac segment length of 45 or 61 mm and an EIA segment length of 41 or 58 mm. The IBD was fitted within an indwelling catheter preloaded with a 0.035" guidewire and introduced through femoral access either percutaneously or by small surgical cut down over a stiff guidewire (Lunderquist, Cook Inc., Bloomington, IN, USA) and oriented under fluoroscopic guidance. The delivery sheath was withdrawn, exposing the tip of the preloaded catheter, and the preloaded 0.035" guidewire was then snared from the contralateral side to create a through-and-through access used to guide the introduction of a sheath that entered the main body of the device and exited through the IIA side branch. Through this sheath, the IIA was catheterised with a hydrophilic guidewire and a bridging covered stent (Advanta, Atrium Medical, Hudson, NH, USA or Fluency, C.R. Bard Peripheral Vascular Inc., Murray Hill, NJ, USA) was deployed to fill the gap between the side branch of the IBD and the IIA, to ensure adequate sealing and patency.

In the absence of suitable proximal CIA neck for landing or in the presence of abdominal aortic diameter >35 mm, the procedure was completed by deployment of the main bifurcated Zenith body from the contralateral side and subsequent bridging the gap into the proximal portion of the IBD with a Zenith iliac limb.

In the presence of IIA, landing of the internal branch was achieved on the IIA distal common trunk when available. Otherwise, landing was reached on the largest and the most straight of the two IIA distal division branches (anterior or posterior), while plug/coil embolisation was reserved for the other smaller branch to avoid distal type I endoleak.

Completion angiography was routinely performed to assess accuracy of deployment, patency of IBD, aneurysm exclusion and endoleak presence. The adequacy of external branch landing was assessed with multiple views in double projection. If external iliac angulation was caused or accentuated by the stent graft, an additional stent was deployed to straighten the external iliac artery at the end of the procedure.

Follow-up protocol

A similar follow-up protocol was applied after repair in the two centres. Abdominal ultrasound was performed in all patients before discharge to evaluate patency and endoleak occurrence. Clinical and ultrasound evaluations were repeated at 1 month and every 6 months. The imaging protocols included aorto-iliac CT imaging within the first month after implantation and yearly thereafter, and a plain X-ray at 6 months and yearly thereafter. A vascular dedicated digital workstation (TeraRecon Aquarius Workstation, Terarecon, Foster City, CA, USA) was used for CT-scan imaging analysis and three-dimensional (3D) reconstructions (Fig. 1). Arterial diameters were measured as the shortest outside transverse diameter of the artery on CT scans by the same observer. AAA and iliac diameter changes were considered significant when exceeding 3 mm. Arterial length was measured with centreline of flow from the CT scan.

Study end points and definitions

Primary outcomes were mortality, pelvic ischaemia (bowel, spinal cord or nerve ischaemia, erectile dysfunction, buttock or thigh claudication and buttock necrosis) and failure to exclude iliac aneurysm (growth >3 mm in maximum diameter, endoleak or rupture) up to 5 years after repair. Secondary outcomes were technical success, defined as successful implantation of the IBD in

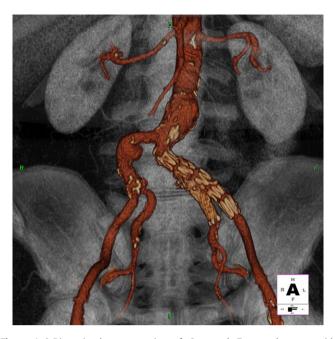


Figure 1. 3-Dimensional reconstruction of Computed Tomography scan with TeraRecon Aquarius Workstation in a patient with iliac side-branch repair for isolated left iliac aneurysm.

the intended iliac vessels with preservation of antegrade flow to the internal iliac tributaries, iliac patency (iliac branch or CIA patency; EIA patency) and need for reintervention.

Statistical analysis

Measured values are reported as percentages and means \pm standard deviations (SDs) or medians + inter-quartile ranges (IQRs). Change in aneurysm diameter over time was assessed using analysis of variance (ANOVA) with Levene's test for equality of variance. Cox regression analysis with backward stepwise method was used to analyse independent associations between the risk of reintervention at 5 years and six covariates (age, gender, iliac aneurysm >4 cm diameter, IIA aneurysm, associated aortic repair and AAA >5.5 cm). Kaplan–Meier survival estimates were calculated to assess long-term outcomes (survival, reintervention and patency); curves are displayed up to a value of standard error (SE) < 0.10.

A value of p < 0.05 was considered statistically significant for all measurements. All analyses were performed using SPSS package, 13.0 version (SPSS Inc, Chicago, IL, USA).

Results

Between January 2006 and March 2011, 120 patients with CIA were consecutively treated by endovascular route at two Italian vascular centres. Twenty CIAs (16.6%) were excluded because repaired by overstenting into external iliac artery with internal iliac embolisation (n = 18) or with Cardiatis SA (Isnes, Belgium) multilayer stent (n = 2) leading to 100 IBD procedures representing the present study population. Demographics, co-morbidities and morphology characteristics of patients with CIA and IBD procedure at baseline are shown in Table 1.

Most of the patients were males (n = 96) and the mean age was 74.1 \pm 7.4 years (54–89 years). Baseline median diameter of treated CIA was 40 mm (IQR, 35–44 mm). Eleven patients had an IIA aneurysm (diameter >20 mm), 67 had AAA \geq 35 mm associated with iliac aneurysm and one had a thoraco-abdominal aneurysm

Table 1

Characteristics in 100 patients undergoing endovascular repair with Iliac branch device (IBD).

	Ν
Male gender	96
Mean age (yrs)	74.1 ± 7.4
CIA diameter (median + IQR)	40 (35-44)
Internal iliac aneurysm	11
Bilateral iliac aneurysm	9
AAA	67
AAA diameter (median + IQR)	50 (40-57)
Smoking	24
Hypertension	84
Diabetes	10
Coronary artery disease	38
Renal insufficiency ^a	18
On dialysis	1
Previous aortic surgery	10
Endovascular AAA repair	3
Open AAA repair	7
COPD ^b	48

Co-morbidities were defined according to SVS standards as graded \geq 1. AAA: Abdominal Aortic Aneurysm; CIA: Common Iliac Aneurysm; IQR: Inter Quartile Range.

^a Renal insufficiency: elevated creatinine level, >1.5 mg/dl or on dialysis or with kidney transplant.

^b Chronic obstructive pulmonary disease: dyspnoea on exertion, chronic parenchymal X-ray changes, pulmonary function tests <65% of predicted.

requiring branched aortic stent graft. Associated aortic aneurysms showed diameter ranging from 35 to 68 mm (median 50 mm, IQR 40–57 mm). Twelve patients with suitable proximal iliac neck and no AAA received isolated iliac repair with IBD and 88 underwent IBD associated with endovascular aortic repair (EVAR). In nine patients bilateral CIA was concurrently treated: in all cases IBD was applied on one side and plug embolisation on the other side.

Perioperative results

Perioperative data are detailed in Table 2. Eighty-two procedures were performed under local anaesthesia and in 35 percutaneous approach and closure devices were used.

Technical success was 95% due to five intra-operative IBD occlusions. Four internal side branches occluded after long procedures where difficulties were experienced in advancing the contralateral sheath into the branch leading to thrombus shift into the IIA during catheter and guidewire manipulations inside the iliac aneurysm. The remaining occlusion was due to impossibility to correctly deploy the covered stent into the distal internal iliac landing zone for excessive vessel tortuosity.

There were no perioperative deaths, myocardial infarctions, strokes, conversions to open repair, mesenteric or spinal cord infarcts or buttock necrosis. Major morbidity occurred in seven patients, one had an episode of atrial fibrillation requiring medical treatment, one patient had asymptomatic pulmonary embolism detected at postoperative CT control, another had congestive heart failure 7 days after discharge and another, with preoperative renal failure, had a worsening of renal dysfunction requiring chronic

Table 2

Perioperative results (30 days).

	Ν
Mortality/Rupture	0
Mean procedure time (min)	135 ± 17
Mean fluoro time (min)	39 ± 21
Mean contrast (mL)	172 ± 35
Technical failure	5
External iliac limb occlusion	2
Endoleak	2

dialysis. In addition, three local complications occurred due to failure of closure device requiring surgical repair of the femoral artery used for access.

During the first 30 postoperative days, two external iliac limb occlusions occurred. Patency was restored in both by thrombectomy and stenting.

Long-term follow-up

Median follow-up was 17 months (range 1–60; IQR 6–37). Only one patient was lost after 2 years. All-cause survival at 5 years was 70.4% (Fig. 2). Thirteen patients died: only one death was aneurysm related due to stent-graft infection detected 3 months after repair and followed by sudden death. No autopsy was performed. Late deaths were mainly related to cardiac disease (n = 5 myocardial infarction and n = 4 congestive heart failure) or cancer (n = 2). Finally, one death occurred for liver failure. No aneurysm rupture occurred. Four patients developed buttock claudication. Three developed early after repair: two after intra-operative failure with internal iliac side-branch occlusion and another in a case of bilateral CIA successfully treated with IBD (patent) on one side and contralateral IIA embolisation. The fourth buttock claudication occurred after late occlusion of IIA branch 3 months from a procedure of unilateral IBD repair for isolated CIA aneurysm.

AAA and CIA diameter

No AAA expanded in diameter, while iliac aneurysm growth >3 mm was detected in four patients (4%). Seventy-two CIA showed aneurysm shrinkage >3 mm during follow-up.

Compared to preoperative values, median iliac aneurysm diameter significantly decreased during follow-up: from 40 (IQR, 35-44 mm) to 32 mm (IQR, 27-36), p < 0.0001 (by ANOVA).

Patency

Overall, seven occlusions of internal limb of IBD occurred. Five were intra-operative as described above. In addition, one internal iliac side-branch occlusion was recorded after 3 months and another after 5 months. According to Kaplan—Meier estimates, IBD patency rate was 91.4% at 1 year and 91.4% at 5 years (Fig. 3).

During follow-up two external iliac limbs occluded. Both occlusions occurred within 3 months of the procedure and were successfully restored, surgical cross-over femoro-femoral by-pass was performed in one case and thrombectomy and stenting in the other.

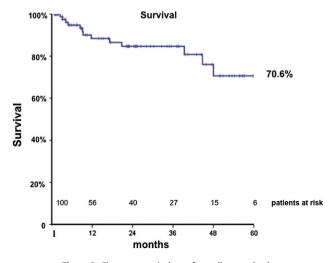


Figure 2. Five-year survival rate from all-cause death.

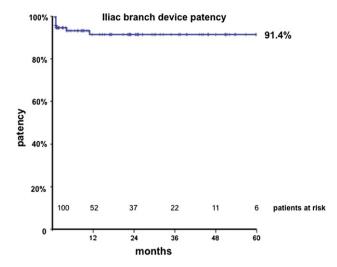


Figure 3. Kaplan-Meier estimates of internal iliac side-branch patency rate.

Endoleak

Iliac endoleaks were recorded in three patients: two were distal type I due to distal refilling from IIA branches occurring within the first month and after 15 months and another was a type III due to IIA stent disconnection from IIA side branch occurring during the first month. All endoleaks were successfully corrected with extension or interposition covered stent through brachial access.

Freedom from persisting iliac endoleak rate at 5 years was 100%.

Reinterventions

Nine reinterventions were performed during the follow-up period for multiple reasons. Causes and types of reinterventions are detailed in Table 3. Freedom from reintervention rate was 90% at 1 year and 81.3% at 5 years (Fig. 4). Most reinterventions (7/9) were performed for complications detected during the first 3 months and related to intra-operative technical defects as detailed in Table 3. Cox regression analysis found, among six potential predictors of outcome, that only the presence of an IIA aneurysm was a significant predictor of reintervention after 5 years from IBD repair hazard ratio (HR) 5.9; 95% confidence interval (CI) 1.57-22.08, p = 0.008.

Table 3
Details of reinterventions.

	Time (months)	Indication	Reintervention type
Patient 1	1	External iliac occlusion	Thrombectomy + stent implantation
Patient 2	1	External iliac occlusion	Thrombectomy + stent implantation
Patient 3	3	External iliac occlusion	Thrombectomy + stent implantation
Patient 4	3	External iliac occlusion	Fem—fem by-pass
Patient 5	1	Distal Type I, endoleak	Covered stent implantation
Patient 6	15	Distal Type I, endoleak	Covered stent implantation
Patient 7	1	Type III endoleak due to Internal iliac side-branch disconnection	Covered stent implantation
Patient 8	47	lliac aneurysm growth ^a	Aortobi-iliac stent graft
Patient 9	1	Femoral pseudoaneurysm	Femoral patch

^a This patient was originally treated with iliac branch device for isolated common iliac aneurysm associated with ectatic but not aneurysmal aorta (diameter <35 mm). After 47 months due to persisting growth of iliac aneurysm and due to the presence of short proximal landing the repair was extended to apply a bifurcated aortobi-iliac graft.

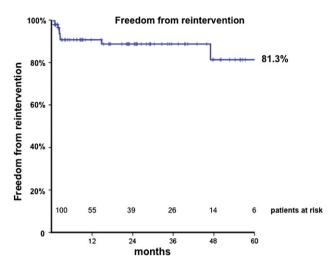


Figure 4. Kaplan–Meier estimates of reintervention rate after iliac side-branch device repair.

Discussion

To date, studies detailing IBD outcomes and patency over time are lacking and long-term durability and efficacy are still unsolved issues limiting the generalisation of the procedure. The present analysis shows that IBD could be used as an independent procedure or an EVAR adjunct for successful treatment of aortic aneurysms with extensive iliac involvement ensuring both safety and durability of the repair up to 5 years.

Indeed, IBD was performed with no perioperative mortality, no pelvic or colon ischaemia and 4% buttock claudication at 5 years. The durability of iliac repair was confirmed by 91.4% IBD patency and 81.3% freedom from reintervention rates at 5 years. Furthermore, >3 mm iliac aneurysm growth occurred only in four cases suggesting the efficacy of the treatment. Nevertheless, our data are based on a two-centre experience, limited numbers and no controlled randomised design and could not be generalised in many other settings.

The use of newer-generation IBDs as well as an improved understanding of these devices may have played an important role in achieving valuable side-branch patency rates reported to be over 80% in most of the recent series on IBD. Ferreira et al. published secondary patency rate of 87.3% and primary patency rate of 85.4% at 22 months over 47 IBDs in 37 patients.³ Pua et al. reported an excellent 100% side-branch patency rate even though they analysed a small group of 14 IBDs with a maximum of 35 months (mean 18.7 months) of follow-up.⁵ Donas et al. recently showed patency rate of 98.4% at a mean follow-up of 30.5 months in their group of 64 IBD compared to 54 iliac aneurysms receiving open repair.⁶ Our iliac patency rates in literature also due to the longer time estimation.

Of relevance, data support that the use of IBD is effective in preserving pelvic circulation and avoiding the risk of buttock claudication occurring in about 30% of patients after endovascular repair of CIA with embolisation/coverage of the IIA.^{12–14} On the contrary, the risk of side-branch occlusion after IBD implantation is not related to severe clinical consequences. A large recent review of 196 IBD from nine literature series showed that only half of the patients with side-branch occlusion.¹⁰ Accordingly, in our series, buttock claudication was recorded only in three of the overall seven patients with internal iliac side-branch occlusion (43%). No other more serious pelvic ischaemia manifestations (mesenteric or spinal cord infarcts, or buttock necrosis) were recorded up to 5 years after repair.

Whether bilateral IIA coverage can further increase the risk of buttock claudication is a subject of debate.^{12,13} In the pooled analysis of Rayt et al. including 634 patients who had undergone either unilateral or bilateral IIA occlusions, buttock claudication occurred in 31% of unilateral embolisations (99 of 322) and in 35% of bilateral embolisations (34 of 98; p = 0.46 Fisher's exact test).¹³ The use of IBD can decrease the need for bilateral IIA occlusion in the presence of bilateral CIA disease. In our experience, nine patients were treated for bilateral CIA and in all the cases one IIA was preserved with IBD while the contralateral IIA was occluded with plug. Only one buttock claudication developed (on the side of occluded IIA) among bilateral cases.

The major disadvantage of IBD is the technical feasibility related to anatomical requirements. Our major reasons for technical failure were related to severe vessel tortuosity or iliac anatomies not totally fulfilling criteria for IBD application. Furthermore, four of the five technical failures occurred during the first year of experience with IBD (in each of the two centres) confirming an important role of initial experience and learning curve effect (including morphology selection) on IBD outcomes. Technical success is expected to improve with better understanding of the device, increased device familiarity and better patient selection in the future.

Today, there are no standardised morphologic criteria for IBD use, also because of the sparse and various experiences with small IBD numbers. Preoperative planning with the use of 3D imaging reconstructions to identify appropriate iliac artery lengths and diameters is an essential tool to provide persisting success of the IBD procedure. As with any endovascular procedure, IBD application presents unavoidable anatomical feasibility limitations. These mainly rely on EIA and IIA vessels suitable for distal landing. The presence of small or tortuous EIA or the concurrence of large IIA are main negative predictors of outcome. In our series the only independent predictor of the need for reintervention after IBD was the presence of IIA aneurysm (HR 5.8, p = 0.008). Furthermore, four external limbs occluded, all within the first 3 months after the procedure and related to the presence of external anatomy not best suited for stent-graft landing. Liberalisation of morphology indications may result in decreased efficacy and durability and increased endoleak/failure rates. Donas et al. noted high endoleak rate (12.5%) in 65 IBDs, even though all of these were successfully managed with reintervention.⁶ The authors used minimal anatomical characteristics for IBD application of CIA of >30 mm in diameter and >50 mm in length and iliac bifurcation diameter >15 mm. Furthermore, challenging internal iliac anatomies including aneurysms >11 mm, short and absent neck for distal landing, were also included.⁶ In our study, three endoleaks over 100 IBD procedures were recorded. The rate was comparable and also lower than those shown in other literature data reporting 0-8.5% endoleak rates after IBD.^{2,5,8-10} Our endoleaks were easily treated with successful reinterventions allowing a zero rate of persisting endoleak at 5 years. Furthermore, 2/3 endoleaks occurred early, during the first month after the procedure, as a consequence of an inappropriate length of distal landing, suggesting that better anatomical criteria selection could have avoided these complications.

Freedom reintervention rates (81.3% at 5 years) that we found after IBD compared well with reintervention data reported in the long term in other EVAR series without adjuncts. Unfortunately, poor meaningful comparisons in reintervention rates for our data can be drawn from an available series on IBD due to differences in measurements and time of assessment. In the experience of Dias et al. on 22 IBDs, crude reintervention rate was 18% at a mean follow-up of 20 months.² Karthikesalingam et al. noted that over nine series on 196 patients with IBD, 12 reinterventions were reported.¹⁰ As in conventional EVAR, long-life clinical and imaging surveillance remains important after implantation of IBD.

The overall low endoleak and reintervention rates up to 5 years after IBD may suggest the efficacy of the technique in aneurysm exclusion. This efficacy may be due also to the small rate of aneurysm growth after repair. In our series only for CIAs enlarged after IBD and no aneurysm ruptured. However, this efficacy end point needs to be corroborated by prospective and also randomised controlled studies.

Major limitations of this study include the lack of a randomised design with associated selection biases and the lack of a control group to compare the clinical relevance of our results. Indications for IBD were based on subjective criteria even though the series was consecutively collected. Furthermore, the study was based on a two-centre experience and data could not be generalised in other outside settings.

Conclusions

The use of IBD for treatment of extensive iliac aneurysms can allow durable aneurysm exclusion with low rates of iliac branch occlusion and reintervention at 5 years. Risk of pelvic ischaemia is low either during the procedure or in the long term. Positive outcomes after IBD are strongly related to anatomical feasibility and proper patient selection. IBD could be used as a primary choice for endovascular treatment of iliac aneurysms with extensive disease and favourable anatomy.

Conflict of Interest

No conflict of interest to declare.

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