

Surgical versus endovascular repair by iliac branch device of aneurysms involving the iliac bifurcation

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Objective: To evaluate early and late results of open (OR) and endovascular aneurysm repair by iliac side branch device (EVRISB) for aneurysms involving the iliac bifurcation (AIB).

Methods: Between January 2004 and March 2010, 118 patients were diagnosed with AIBs and underwent OR or EVRISB at two European vascular centers. Particularly, 64 (54.2%) patients were treated by EVRISB and 54 (45.8%) by OR. In one center, 24 consecutive patients were treated by surgery because this was the standard therapeutic approach until January 2005. For the rest of the study period until March 2010, 64 consecutive patients with AIB suitable for EVRISB underwent placement of branched devices. In the other center, 30 consecutive patients with AIBs were treated by OR because advanced endovascular imaging was not available during the study period.

Results: No significant differences in demographics, anatomical characteristics, or comorbidities of the patients were recorded between the two groups. Early (30-day) mortality was 0% for EVRISB versus 5.5% for the OR group ($P < .001$). Major morbidity occurred in 4.6% versus 9.3% of the patient subgroups, respectively ($P < .001$). Buttock claudication and colonic ischemia were recorded in 5.9% and 2% of OR patients compared with 3.1% and 0% of EVRISB cases ($P > .05$). Primary patency rates were 98.4% for EVRISB and 100% for OR patients. Primary and secondary endoleak rates of the EVRISB group were 12.5% and 6.3%, respectively.

Conclusions: Endovascular repair by iliac branch device of aneurysms involving the iliac bifurcation can be accomplished with very low morbidity and mortality rates. Especially for young active patients or in cases of contralateral occlusion, the preservation of hypogastric artery seems to be a strong argument for use of EVRISB as a preferable therapy option. (*J Vasc Surg* 2011;53:1223-9.)

Abdominal aortic aneurysms (AAA) present with involvement of the iliac arteries in more than 20% of the cases.¹ In some patients, the aneurysm might involve the iliac bifurcation or might be extended in the iliac arteries. The deep pelvic location of these lesions makes the open surgical treatment challenging and technically demanding. Open repair (OR) has an increased risk of ureteric or iliac vein injury, especially in obese patients or in case of previous abdominal operations.¹

Current technological advances led to a shift toward endovascular repair. In particular, for isolated iliac artery aneurysms, the endovascular approach is widely accepted as first line treatment modality.²⁻⁴ Recently, Cochennec et al⁵ compared the OR versus hypogastric occlusion and graft extension into the external iliac artery (EIA) for AAA involving the iliac bifurcation and showed a trend toward

higher in-hospital mortality and higher risk of systemic complications for patients who were treated surgically. On the other hand, one-third of the endovascular group of patients developed severe buttock claudication postoperatively, caused by coil embolization of the internal iliac artery (IIA).

Iliac side branch devices (IBDs) extend from a conventional endovascular repair (EVAR) stent-graft into the EIA while preserving the flow into the ipsilateral IIA using a side branch. The reported experience with the outcomes of IBDs is limited, and the current literature provides scant information about their utility. The aim of the present study was to evaluate the role of IBDs for aneurysms involving the iliac bifurcation (AIBs) and to compare this treatment modality with open repair in a large series of patients.

METHODS

Retrospective data analysis from a prospectively maintained database was performed for patients with AIBs treated by OR or by endovascular aneurysm repair using iliac side branch device (EVRISB).

Patients with AIB with diameter <30 mm who were treated by other endovascular techniques, such as bell-bottom technique or hypogastric artery coils occlusion ($n = 32$), were excluded from the study. Moreover, patients with ruptured or infected and inflammatory aneurysms were not included in the study.

Standardized published⁶ morphologic criteria for the use of IBD have not been already defined or validated.

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Table I. Demographics and clinical characteristics

	Open (n = 54)	Endovascular (n = 64)	P
Age (years; mean \pm SD)	71 \pm 6.8	70.3 \pm 7.6	.578
Male gender (n; %)	52; 94.5%	60; 93.8%	.855
Coronary disease (n; %)	26; 47.3%	29; 45.3%	.988
Chronic obstructive pulmonary disease (n; %)	19; 34.5%	24; 37.5%	.739
Chronic renal insufficiency (n; %)	6; 10.9%	8; 12.5%	.789
Diabetes (n; %)	11; 20%	12; 18.8%	.864
Hypertension (n; %)	39; 70.9%	45; 70.3%	.943
Dyslipidemia (n; %)	37; 67.3%	42; 65.6%	.850
Smoking (n; %)	30; 54.5%	32; 50%	.622
Anatomical characteristics			
Localization			.778
Aortobiliac (n; %)	22; 40%	25; 39.1%	
Aortouniliac (n; %)	27; 49.1%	30; 46.9%	
Isolated iliac ^a (n; %)	6; 10.9%	9; 14%	
Diameters (mean \pm SD in mm)			
Infrarenal aorta	52.3 \pm 11.1	52.9 \pm 11.5	.793
Right iliac	27.7 \pm 10.9	27 \pm 10.3	.264
Left iliac	29 \pm 12.1	30 \pm 10.6	.317

All statistical differences were not significant ($P > .05$).

^aOne patient of the open group and two of the endovascular group had bilateral isolated iliac aneurysms involving the iliac bifurcation.

Objective criteria required for patients to receive an IBD include 1) the presence of a common iliac aneurysm (CIA) with diameter more than 24 mm, 2) the presence of a patent CIA lumen >18 mm, 3) an adequate length of EIA for distal landing of more than 20 mm or 15 mm, and finally, 4) sufficient length of IIA of more than 10 mm.⁴ Regarding the IIA, it has been stated that the IIA must be of "normal diameter" or up to 11 mm in diameter.⁴

In our institution, the following criteria were necessary for treatment by branched devices: CIA diameter more than 30 mm, length more than 50 mm, CIA diameter more than 24 mm, and iliac artery bifurcation diameter more than 15 mm. Challenging anatomies of the IIA, including aneurysms and diameter more than 11 mm but also short or absent sufficient neck of IIA for distal landing, were also tackled in our study.

In cases of bilateral AIBs, our strategy consisted of flow preservation in at least one hypogastric artery either by IBD or by open revascularization. The contralateral aneurysm was treated by coil embolization of the IIA and overstenting into the EIA or by open hypogastric artery ligation.

Reconstruction technique

Endovascular group. All patients were operated under loco-regional anesthesia and received a straight Zenith Bifurcated Iliac Side device (Cook Inc, Bloomington, Ind). The deployment of the IBDs started with preloaded indwelling catheter and guidewire through the side branch. The guidewire was snared from a contralateral or brachial approach and guided the introduction of a sheath that entered the main body of the device and exited through the side branch. The IIA was catheterized and a bridging covered stent; in all cases Advanta V12 (Atrium Medical, Hudson, NH) was deployed, uniting the side branch to the IIA. Based on our extensive clinical experience with the percutaneous endovascular approach for abdominal and

thoracic aortic aneurysms,⁶ all interventions were performed by the preclose technique with a single Prostar XL 10-F (Abbott Vascular, Santa Clara, Calif) vascular closure device.

Open repair group. All patients were operated under general endotracheal anesthesia with the transperitoneal approach. Four types of surgical reconstruction were used: 1) Bifurcated prosthesis and revascularization of both hypogastric arteries (n = 45). The hypogastric revascularization was performed either by end-to-end anastomosis at the iliac bifurcation or by end-to-end anastomosis at the IIA and reimplantation of the EIA; 2) Bifurcated graft and additional ligation of one of the hypogastric arteries (n = 6) and graft limb extension at the ipsilateral common femoral artery; 3) Trifurcated (custom tailored on-table) prosthesis for unilateral hypogastric artery revascularization with contralateral IIA ligation (n = 2); and 4) Bifurcated prosthesis plus hypogastric artery aneurysm resection (n = 1) with ligation of IIA's distal branches. All laparotomies were closed by running polydioxanone suture and patients were transferred routinely to the intensive care unit (ICU) for proper resuscitation.

Follow-up after endovascular therapy by EVRISB consisted of physical examination, computed tomography (CT) scan at discharge, duplex scan at 3 months, CT scan at 6 months, and annually thereafter. Follow-up after OR consisted of physical examination and duplex scan at first month and yearly thereafter. A CT scan was performed only in cases with clinical deterioration of the patients and possible procedure-related reason. Table I summarizes patients' demographics. The mean follow-up was 49.5 ± 22.6 months for the OR group and 30.5 ± 20.9 months for the EVRISB group.

Complications were classified and graded according to the reporting standards of the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery; In-

Table II. Results

	Open (n = 54)	Endovascular (n = 64)	P
30-day severe morbidity (n; %)	5; 9.3%	3; 4.6%	<.001
30-day mortality (n; %)	3; 5.5%	0; 0%	<.001
30-day vascular complications (n; %)	1; 2%	2; 3.1%	.698
30-day non-vascular complications (n; %)	9; 16.7%	3; 6.3%	.025
Intensive care unit stay (mean ± SD in days)	2.5 ± 1.2	1.2 ± 0.4	NP
Postoperative stay (mean ± SD in days)	9.7 ± 4.1	4.1 ± 1.5	<.001
Operative blood loss (mean ± SD in mL)	669 ± 460	89 ± 30	<.001
Transfusion (mean ± SD in units of packed red cells) ^a	1.6 ± 2.0	— ^a	NP ^b
Operative duration (mean ± SD in min)	197 ± 23	89 ± 24	.234
Related death during follow-up ^c	1; 2% ^d	—	NP ^b
Primary endoleak (n; %)	—	8; 12.5%	NP ^b
Primary patency (n; %)	51; 100% ^d	63; 98.4%	.358
Buttock claudication (n; %)	3; 5.9% ^d	2; 3.1%	.473
Colonic ischemia (n; %)	1; 2% ^d	0; 0%	.263
Postoperative hernia	16; 31.4% ^d	—	NP ^b

P < .05 considered statistically significant and appears bold-faced.

^aOne patient of the endovascular group suffered from groin hematoma requiring surgical exploration and transfusion of ten units of packed red cells.

^bSingle arm values; statistical analysis was not performed (NP).

^cOne patient of the open group had graft infection at the 6th postoperative month.

^dIn 51 patients of the open group (excluded the patients with early mortality).

ternational Society for Cardiovascular Surgery.³ Three classes of complications (systemic, local non-vascular, and local vascular or implant-related) and three grades of severity (mild, moderate, and severe) were used. Diagnosis of myocardial infarction was established based on electrocardiogram changes and troponin values. Acute renal insufficiency was defined as an increase of serum creatinine levels >50% of the patient's baseline. Colonic ischemia was documented by colonoscopy and/or by operational findings. Pulmonary complications were defined as any pulmonary abnormality that was clinically significant, such as infection or embolization. Hemorrhagic complications were defined as any postoperative bleeding related to OR surgery or access vessels for EVRISB cases.

Statistical analysis

Statistical analysis was performed with SPSS 13.0 (SPSS Inc, Chicago, Ill). Continuous data were compared using Student's *t* test and categorical variables with the non-parametric Mann-Whitney test as appropriate. A *P* value <.05 was considered to indicate statistical significance. The primary and secondary patency rates for both groups and primary and secondary endoleak rates for the EVRISB group were estimated by the Kaplan-Meier life-table analysis and compared using the log-rank test.

RESULTS

Between January 2004 and March 2010, 118 patients with AIB were treated at two European vascular centers. Particularly, 64 (54.2%) patients underwent IBD placement and 54 (45.8%) were treated by OR. Five (7.8%) patients of the IBD group and nine (16.6%) of the OR group were treated emergently. In one center (Münster, Germany), 24 consecutive patients with AIB were treated by surgery because this was the standard approach until January 2005. For the remaining study period until March

2010, 64 consecutive patients with suitable morphology of their aneurysm for treatment using IBD underwent EVRISB. In the second center (Thessaloniki, Greece), 31 consecutive patients were diagnosed with AIB and 30 of them (one patient denied the OR) were treated by conventional surgical techniques because advanced endovascular imaging allowing treatment with branch devices was not available during the entire study period. Twenty-five (39%) patients were diagnosed with bilateral AIBs. Eleven patients (17.2%) had had concomitant aneurysmal IIA.

Table II summarizes the results of both groups of patients. Early (<30 day) death was recorded in 5.5% (n = 3) versus 0% for the OR and EVRISB patients' groups, respectively (*P* < .001). Intravascular disseminated coagulopathy with consecutive multi-organ failure caused by perioperative bleeding and massive blood transfusion was the underlying etiology of death in the OR patients' group.

Morbidity

Severe systemic morbidity, including respiratory and cardiac complications, were more common in the OR group of patients (5 vs 3, *P* < .001). Particularly, in the OR group, pulmonary infection in four patients and myocardial infarction in one patient were noted compared with three patients with myocardial infarction in the EVRISB group.

Vascular complications

Two patients of the EVRISB group developed early local vascular complications. One of them underwent urgent surgical repair of the common femoral artery due to bleeding and shock. The patient received 10 units of red packed cells and had an uneventful further postoperative course. This patient was the only one with the need of blood transfusion in the EVRISB group. The other patient presented with an acute limb ischemia caused by subtotal

thrombotic occlusion of the iliac side branch device. The patient was treated by hybrid repair, including transfemoral thrombectomy and subsequent stent placement in the ipsilateral iliac axis due to residual stenosis. Especially, a Palmaz Genesis stent (Cordis Corp, Bridgewater, NJ) of 8 mm diameter and 24 mm length was placed in the IIA, and two additional covered stents (Luminexx; Bard, Phoenix, Ariz [14 mm diameter and 40 mm length] and Fluency, Bard [12 mm diameter and 40 mm length]) were deployed in the common iliac artery and EIA, respectively.

In the OR group one patient (with left aortouniliac AIB), despite the successful revascularization of both hypogastric arteries, developed sigmoid nonocclusive ischemia on the 20th postoperative day. The duplex ultrasound showed patency of the proximal left internal iliac artery, but the patency of distal branches was questionable. The colonoscopy revealed mild left colon ischemia, and the patient was set initially in conservative treatment with double antibiotic intravenous administration and total parenteral nutrition. CT 7 days later revealed a left paracolic abscess collection, and a second colonoscopy confirmed the sigmoid necrosis. The patient underwent left hemicolectomy with no further complications.

Non-vascular or minor local complications. Early minor local complications included nine (16.7%) patients of the OR group with wound infection and three (6.3%) of the EVRISB group with groin hematoma at the puncture site ($P < .025$). During follow-up, a postoperative incisional abdominal wall hernia was recorded in 16 patients of the surgical group (31.4%; single arm value analysis was not performed).

Midterm complications. Midterm severe complications occurred in both subgroups of the patients. One patient of the endovascular group suffered from fistula with the rectum caused by rupture of a coexisting internal iliac aneurysm of 6 cm diameter, 23 months after the IBD placement. The covered stent (Advanta, 8 mm diameter, 38 mm length) of the IIA was dislocated (Fig 1). The patient underwent an overstenting of the IIA and placement of Endurant limb (Medtronic, Minneapolis, Minn) (16 mm diameter and 95 mm length) into the EIA due to failed recanalization attempt of the dislocated endograft in the IIA. The further postoperative course was uneventful. However, the patient died 2 months postoperatively due to a non-procedure related cause.

On the other hand, one patient of the OR group presented with abscess of the groin and graft infection; he denied any further treatment and died from septic complications in the 6th postoperative month.

Buttock claudication occurred in three (5.9%) patients of the OR versus two (3.1%) of the EVRISB group ($P = .473$). In one OR case, the ipsilateral IIA was ligated (1/9 patients; 11%) while in the other two cases, both IIAs were revascularized (2/45 patients; 4.4%). In both EVRISB patients, the buttock claudication was due to restenosis of the IIAs branch and unrelated to coil embolization.



Fig 1. Dislocation of the covered bridging stent graft, which resulted in the rupture of a 6 mm in diameter internal iliac aneurysm and fistula with the rectum.

Endoleak

Regarding the endoleak rates, eight patients of the EVRISB group were diagnosed with endoleak during follow-up. The patient with the dislocated covered stent and rupture of the aneurysmal IIA has been described elsewhere. Two patients developed late type Ib endoleak and required reintervention. In particular, two patients presented with buttock claudication and were treated successfully by placement of an additional covered stent (Advanta in both cases, 8 mm \times 59 mm) in the IIA. The other one showed dislocation of the external and internal branch of the device, and the recanalization of the IIA was hazardous (endoleak type III). Using a through-and-through wire from brachial and transfemoral access, the recanalization of the iliac axis and the placement of coils in the IIA were achieved. The reintervention was completed by placement of an Endurant limb of 16 mm in diameter and 120 mm in length, which was extended from the CIA to the EIA. No further evidence of endoleak has been seen. The remaining four patients diagnosed with type II endoleak were treated conservatively with radiological surveillance and no need for repeat intervention. The primary and secondary endoleak rates of the EVRISB group were 12.5% and 6.3%, respectively (Fig 2).

Patency

Moreover, the primary patency of the EVRISB and OR groups were 98.4% and 100%, respectively (Fig 3). The primary patency of the OR group based on duplex scan was 100%.

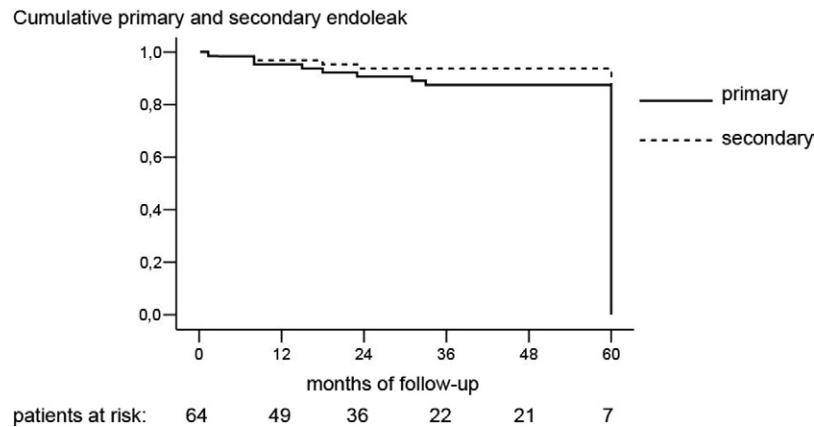


Fig 2. Primary and secondary endoleak of the endovascular group of patients.

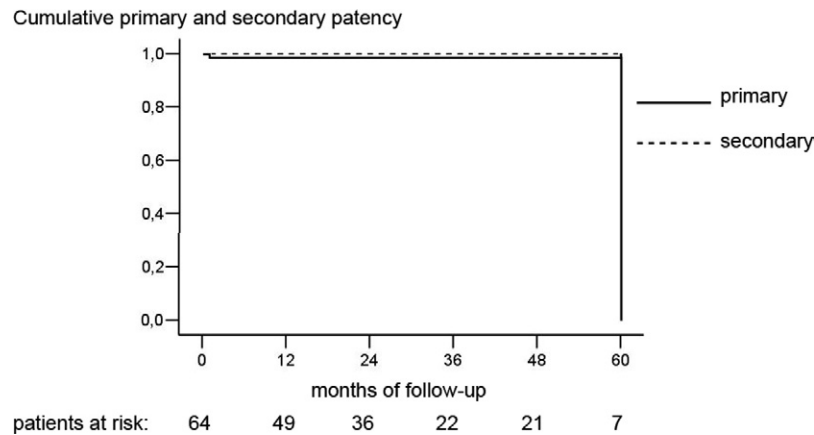


Fig 3. Primary and secondary patency of endovascular group of patients.

DISCUSSION

To our knowledge, the present article reports for the first time in the literature on the outcome of EVRISB compared with OR for AIBs. The endovascular group had better intraoperative and early postoperative results. In particular, a significant difference was recorded between the two modalities regarding length of hospital stay of the patients and perioperative blood loss with need for transfusion. Despite the excellent durability of the surgical reconstruction, several additional issues such as the frequency of postoperative incisional wall hernias in 31.4% of the patients, the length of stay in the ICU, and also the possibility of graft infection highlight the utility of endovascular means. Additionally, the infrequent onset of buttock claudication or colonic and pelvic ischemia represents another strong argument for the use of IBDs in cases of suitable anatomy, especially in younger, active patients or in patients with occluded contralateral IIA.

The high incidence of incisional hernias in our OR patients is consistent with previously published reports.⁷ The abnormal homeostasis between proteolytic and anti-proteolytic activity and increased blood proteolytic activity

may play a role in the development of aneurysm and incisional hernia.⁸ A constitutive and systemic increase in type III collagen synthesis is associated with reduced collagen fibril assembly in trauma healing, eventually leading to the development of hernia. Furthermore, the incision's closure option by non- or absorbable running suture did not affect the incidence of incisional hernias after aortic aneurysm open repair.⁸ An additional concern of the open subgroup of the patients is the relatively high incidence of wound infection rate in nine (16.7%) patients. Several factors might influence the healing process after aortic aneurysm OR such as diabetes mellitus, obesity, immunosuppressant medication, and trauma contamination with in-hospital "resistant" microorganisms, as well as duration and operative technique (ie, extensive use of monopolar diathermy). Several endovascular techniques, such as the bell-bottom technique³ and the hypogastric coil embolization with stenting of EIA² play an important role in the treatment of iliac aneurysms. Recently, Cochenec et al⁵ reported on the outcome of open versus EVAR by coil embolization of IIA for abdominal aortic aneurysms involving the iliac bifurcation. The study showed a similar with our study higher in-hospital mortality and risk of systemic

complications in the OR group. In contrast with our results, the onset of buttock claudication was more common in the EVAR group; it occurred in one-third of patients with EVAR, and 54% of these patients were still suffering debilitating symptoms after 1 year.

Additionally, severe morbidity, including colonic and pelvic ischemia, and gluteal compartment syndrome but also lower limb neurological events, are already described as a result of coil embolization of the hypogastric artery.³ Therefore, alternatives such as IBD placement are very attractive and have to be further evaluated.

Only one study in the current literature has been conducted to directly compare EVAR in patients with AIBs undergoing IIA embolization with those undergoing IIA revascularization with IBD.⁹ Despite the similar technical success and reintervention rates, endoleak and buttock claudication were different in the two subgroups. In particular, patients with hypogastric exclusion more frequently suffered from buttock claudication and showed endoleak, while these were uncommon in those with hypogastric revascularization.⁹ Moreover, Karthikesalingam et al¹⁰ published a review article of nine series in the literature that have reported the use of IBD of 196 patients in total. Claudication developed in 6.1% of the patients due to IBD occlusion. In context with the conclusion of Verzini et al⁹ and Karthikesalingam et al,¹⁰ the present study also reflects the crucial benefit of hypogastric revascularization regarding buttock claudication compared with the open repair.

Standardized morphologic criteria for the use of IBDs have not been defined. There is a paucity of the current literature regarding the proportion of patients with AIBs who are anatomically suitable for treatment by IBD. Recently, the St. George's Vascular Institute¹¹ conducted a study to assess the population of patients with aortoiliac aneurysms who have the morphologic applicability of a commercially available IBD. The authors found that patients' anatomical suitability represents one remarkable limitation of EVRISB.

Therefore, we liberalized the inclusion criteria for IBD placement in order to draw robust conclusions about whether the morphology of the aneurysms represents a significant drawback for the use of IBDs, as Karthikesalingam et al¹¹ suggest. In detail, patients with aneurysmal IIA or patients with diameter of the iliac bifurcation <20 mm were also included in our study. The minimal anatomical characteristics for the use of ISB devices of our patients with AIBs were AIB diameter more than 30 mm, length more than 50 mm, and iliac artery bifurcation diameter up to 15 mm. The described liberalization of inclusion criteria for ISB probably reflects the higher percentage of endoleaks in our EVRISB group of patients compared with the review analysis of Karthikesalingam.¹⁰ In particular, we note that 12.5% of our patients were diagnosed with endoleak, which is higher compared with 1.5% of the reported series.⁵ However, the successful treatment in all cases that required repeat intervention illustrates the safety of the procedure and justifies our management for patients with AIBs.

Based on our reported experience with the EVRISB of AIBs of 64 patients, coexisting aneurysmal IIA seems to be a remarkable limitation of ISB devices. One of our patients of the endovascular group with concomitant IIA aneurysm suffered from acute enteric fistula caused by aneurysm's rupture and dislocation of the covered stent in the IIA. However, further studies are needed in order to evaluate if this may be a contraindication for IBD placement.

Regarding the type of IBD stent graft, there are no data to compare the outcomes of self-expanding endografts such as Fluency and balloon expandable covered stents such as Advanta as bridging stent grafts of the IIA. Despite the fact that the majority of the articles in the current literature⁵ recommend the use of self-expanding stents due to better flexibility and conformability, our impression is in contrast with this conclusion.

Our extensive experience with the use of the Advanta stent graft in fenestrated endografting led us to the use of the Advanta stent graft as our first line bridging stent graft. The balloon expandable covered stent is characterized by high radial force and excellent fluoroscopic visibility, which allows precise placement. Additionally, it is possible that the postdeployment dilatation with oversized balloons allows better flaring of the stent in the branch. The excellent patency rate of our series legitimizes the use of balloon expandable stent grafts. Nevertheless, this issue has to be also addressed in future studies.

A limitation of our study is the lack of prospective randomized data analysis. On the other hand, the two study arms represent consecutive series of patients with similar demographic and anatomical data. The patients were treated by prearranged unified diagnostic, therapeutic, and surveillance study protocol between the two vascular centers. Additionally, it remains unknown what the influence is of different anesthesia in outcome between the two subgroups of patients. Another issue which is important to point out remains the fact that patients with short landing zones and poor internal iliac run-off have been treated with open surgery, and this might explain the worse results with open surgery.

CONCLUSIONS

To our knowledge, the present study represents the first in the literature of a comparative analysis of endovascular by iliac side branch and open repair of AIBs and the largest single center experience with EVRISB. The less invasive procedure and better intraoperative and postoperative outcomes justify the use of IBD for patients with suitable anatomy. The infrequent onset of buttock claudication or colonic and pelvic ischemia represents a strong argument for the use of IBDs, especially in younger, active patients or in patients with occluded contralateral IIA. Long-term results and larger numbers of patients are needed in order to prove if aneurysmal IIA represent the most important limitation to IBD use.

AUTHOR CONTRIBUTIONS

Conception and design: KD, GT, GP

Analysis and interpretation: KD, GP, GT, MA, DP

Data collection: KD, GP, MA

Writing the article: KD, GP

Critical revision of the article: KD, GT, GP, MA, DP

Final approval of the article: KD, GT, GP, MA, DP

Statistical analysis: GP

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Overall responsibility: KD

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