

Bilateral Use of Iliac Branch Devices for Aortoiliac Aneurysms Is Safe and Feasible, and Procedural Volume Does Not Seem to Affect Technical or Clinical Effectiveness: Early and Midterm Results From the pELVIS International Multicentric Registry

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Abstract

Objective: To evaluate early and follow-up outcomes following bilateral use of iliac branch devices (IBD) for aortoiliac endografting and assess the impact of center volume. We used data from the pELVIS international multicentric registry. **Methods:** For the purpose of this study, only those patients receiving concomitant bilateral IBD implantation were analyzed. To assess the impact that procedural volume of bilateral IBD implantation could have on early and follow-up outcomes, participating institutions were classified as Site(s) A if they had performed >10 and/or >20% concomitant bilateral IBD procedure, otherwise they were classified as Site(s) B. Endpoints of the analysis included early (ie, 30-day) mortality and morbidity, as well as all-cause and aneurysm-related mortality during follow-up. Additional endpoints that were evaluated included IBD-related reinterventions, IBD occlusion or stenosis requiring reintervention (ie, loss of primary patency), and IBD-related type I endoleak. **Results:** Overall, 96 patients received bilateral IBD implantation (out of 910 procedures collected in the whole pELVIS cohort), of whom 65 were treated at Site A (ie, Group A) and 31 were treated at Site(s) B (ie, Group B). In total, only 1 death occurred within 30 days from bilateral IBD implantation, and 9 patients experienced at least 1 major complication without any significant difference between subjects in Group A versus those in Group B (10.8% vs 6.5%, $p=0.714$). In the overall cohort, the 2-year freedom from IBD-related type I endoleaks and IBD primary patency were 96% and 92%, respectively; no significant differences were seen in those rates between Group A or Group B (95% vs 100%, $p=0.335$; 93% vs 88%, $p=0.470$). Freedom from any IBD-related reinterventions was 83% at 2 years, with similar rates between study groups (85% vs 83%, $p=0.904$). **Conclusions:** Within the pELVIS registry, concomitant bilateral IBD implantation is a safe and feasible technique for management of aortoiliac aneurysms in patients with suitable anatomy. Despite increased technical complexity, effectiveness of the repair is satisfactory with low rates of IBD-related adverse events at mid-term follow-up. Procedural volume does not seem to affect technical or clinical outcomes after bilateral use of IBD, which remains a favorable treatment option in selected patients.

Keywords

abdominal aortic aneurysm, aortoiliac disease, iliac branch device, center volume

Introduction

Although hypogastric artery sacrifice was previously reported to be relatively safe, pelvic ischemic complication may actually occur and they can significantly affect patients’ function and quality of life. Systematic reviews have showed that buttock/thigh claudication will develop in nearly one-third of subjects undergoing hypogastric

exclusion and about 10% of men can experience a new onset erectile dysfunction.^{1,2} Iliac branch devices (IBD) currently represent the first-line endovascular option to preserve antegrade flow to the hypogastric artery, when anatomically feasible, in patients with aortoiliac aneurysms. This has revolutionized endovascular aortic repair (EVAR) for abdominal aortic aneurysms (AAA), now allowing totally endovascular preservation of the hypogastric artery

in most cases.³ However, bilateral IBD implantation procedures are challenging, and published outcomes are still limited and only in a few highly specialized centers. The aim of this study was to evaluate early and follow-up outcomes following bilateral use of IBD for aortoiliac endografting and assess the impact of center volume. We used the largest worldwide collected cohort of patients treated with IBD, the pELVIS registry of iliac branch deVices for aneurysmS involving the iliac bifurcation (pELVIS) registry.

Methods

Data Sources

The pELVIS registry is a multicenter project that prospectively collected data of 8 European vascular centers from 2005 to 2017. In brief, institutions were selected on the basis of an experience with at least 30 IBD procedures. All information on consecutive patients treated with IBD, including clinical and anatomic characteristics, intraoperative data, in-hospital outcomes, and postoperative follow-up was collected. The study was approved by the local ethical committee of the participating centers as required. Main indications for IBD repair of common iliac artery aneurysm (CIAA) were as follows: (a) CIAA extending to the bifurcation, having a diameter ≥ 30 mm and (b) CIAA > 24 mm, with an associated AAA meeting the threshold for EVAR. All patients underwent imaging follow-up with computed tomography angiography within 1 month from the intervention and yearly thereafter. However, this could be replaced by magnetic resonance arteriography or duplex ultrasound at the investigators' discretion on the basis of patients' characteristics.

Study Design

For the purpose of this study, only those patients receiving concomitant bilateral IBD implantation were analyzed. To

assess the impact that procedural volume of bilateral IBD implantation could have on early and follow-up outcomes, participating institutions were classified as Site(s) A if they had performed > 10 and $> 10\%$ concomitant bilateral IBD procedure, otherwise they were classified as Site(s) B. Based on the aforementioned criteria, only 1 center could be named as Site A, while all remaining institutions were included as Site(s) B (Supplementary Table 1). Patients treated at the aforementioned institution were therefore characterized as either Group A or Group B, respectively.

Immediate technical success was defined as correct deployment of IBD without any type I or III endoleaks, and preservation of antegrade flow to the internal and external iliac arteries at completion angiography. Endpoints of the analysis included early (ie, 30-day/in-hospital) mortality and morbidity, as well as all-cause and aneurysm-related mortality during follow-up. Additional endpoints that were evaluated included IBD-related reinterventions, IBD occlusion or stenosis requiring reintervention (i.e. loss of primary patency), and IBD-related type I or III endoleaks. Sac size changes were also assessed comparing preoperative measurements with longest individual available imaging examination, in those subjects who had at least 6 months imaging follow-up available.

Statistical Analysis

Distribution of continuous variables was explored by the Shapiro-Wilk test. Variables with normal distribution were presented as mean \pm standard deviation and compared with Student's *t* test. Variables with skewed distribution were presented as median and interquartile range (IQR) and compared by Wilcoxon signed rank test for related samples or Mann-Whitney *U* test for independent samples. Categorical variables were presented as numbers with percentage and compared with Pearson's chi-square or Fisher's exact test. Time-to-event analysis was carried out by Kaplan Meier

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Table 1. Baseline Characteristics of the 96 Patients Who Received Concomitant Bilateral IBD Implantation in the pELVIS Registry.^a

	Total Series (n=96)	Group A ^b (n=65)	Group B ^b (n=31)	p ^c
Demographics				
Age, y, mean ± SD	69.2±10.4	69.4±10.1	66.5±11.7	0.936
Male gender, n (%)	95 (99)	64 (98.5)	31 (100)	1.0
Risk factors, n (%)				
Hypertension	82 (85.4)	54 (83.1)	28 (90.3)	0.347
Diabetes mellitus	14 (14.6)	9 (13.8)	5 (16.1)	0.317
Obesity	25 (26)	15 (23.1)	10 (32.3)	0.338
Dyslipidemia	52 (54.2)	35 (53.8)	17 (54.8)	0.927
Chronic respiratory insufficiency	23 (24)	8 (12.3)	15 (48.4)	<0.001
Smoking (current or past)	44 (45.9)	21 (32.3)	23 (64.4)	<0.001
Coronary disease	42 (43.8)	27 (41.5)	15 (48.4)	0.527
Myocardial infarction (<6 mo)	1 (1)	1 (1.5)	0 (0)	0.488
Creatinine, mg/dL, median/IQR	1.0/0.3	1.0/0.3	1.0/0.4	0.620
Dialysis	0 (0)	0 (0)	0 (0)	NA
Peripheral arterial disease	7 (7.3)	5 (7.7)	2 (6.5)	0.827
Previous EVAR	10 (10.4)	9 (13.8)	1 (3.2)	0.111
Previous laparotomy	18 (18.8)	12 (18.5)	6 (19.4)	0.916
Anatomical data				
AAA maximum diameter, mm, mean ± SD	42.3±13.2	43.1±13.8	40.1±12.0	0.929
RCIA maximum diameter, mm, median/IQR	31.0/13.0	30.5/12.0	34.0/14.0	0.083
LCIA maximum diameter, mm, median/IQR	31.0/9.0	30.0/7.8	35.0/11.0	0.836
Aorto-bi-iliac, n (%)	67 (70.8)	41 (63.1)	26 (83.9)	0.038
Isolated bi-iliac, n (%)	27 (28.1)	22 (33.8)	5 (16.1)	
At least 1 hypogastric involvement, n (%)	52 (54.2)	40 (61.5)	12 (38.7)	0.036
Hypogastric artery diameter >12 mm, n (%)	50 (52.1)	38 (58.5)	12 (38.7)	0.070
Operative data				
Locoregional anesthesia, n (%)	28 (29.2)	20 (30.7)	8 (25.8)	0.270
Fluoroscopy time, min, median/IQR	56/25	60/23	48/29	0.135
Contrast medium, mL, median/IQR	150/53	155/55	150/70	0.334
Duration, min, median/IQR	180/72	176/77	180/62	0.352
Hospital stay, d, median/IQR	7/3	8/3	6/4	0.031
Type of bridging stent-grafts, n (%)				
Balloon-expandable	120 (62.5)	86 (66.1)	34 (64.9)	0.108
Self-expanding	28 (14.6)	2 (1.5)	26 (42.0)	<0.001
Combined grafts	44 (22.9)	42 (32.3)	2 (3.2)	<0.001

Abbreviations: AAA, abdominal aortic aneurysm; IBD, iliac branch device; IQR, interquartile range; LCIA, left common iliac artery; NA, not applicable; RCIA, right common iliac artery.

^aNormal distribution variables presented as mean ± SD and skewed distribution variables as median/IQR.

^bGroup A “Muenster” and Group B “other centers.”

^cStatistical significance set at level of p<0.05 and significant correlations appear in boldface.

method and reported with standard error <0.10, with the log rank test used to compare groups. All analyses were performed using IBM SPSS Statistics for Macintosh, Version 25.0 (IBM Corp, Armonk, NY) Statistical significance was defined as p<0.05.

Results

Study Population

Overall, 96 patients received bilateral IBD implantation (out of 910 procedures collected in the whole pELVIS cohort), of

which 65 were treated at Site A (ie, Group A) and 31 were treated at Site(s) B (ie, Group B). The incidence of bilateral IBD implantation in the remaining 8 Group B varied from 3.2% to 9.4%. Analysis of distribution of bilateral IBD cases during the study timeframe revealed a more pronounced increase in performance of such procedures for Site A as compared with Site(s) B (Supplementary Figure 1).

At baseline, the mean age of the study population was 69.2±10.4 years and 95 subjects were males, without significant differences between Group A and Group B (Table 1). Patients in Group A and Group B were also similar regarding prior medical conditions but for chronic obstructive

pulmonary disease and history of (current or past) smoking, which were significantly less frequent in Group A as compared with Group B (12.3% vs 48.4% and 32.3% vs 64.4, respectively; $p < .001$ for both).

Aorto-bi-iliac aneurysm was present in 67 subjects (Group A 63.1% vs Group B 83.9%) while isolated bilateral iliac aneurysm was present in 27 subjects (Group A 33.8% vs Group B 16.1%; $p = 0.038$). Additionally, patients in Group A had more frequently aneurysmal involvement of at least 1 hypogastric artery as compared with those in Group B (61.5% vs 38.7%, $p = 0.036$).

Procedure Details and Early Outcomes

The immediate technical success rate was 100%. No significant differences were noted between study groups in terms of procedural metrics, including use of locoregional anesthesia, fluoroscopy, or operative times, and contrast medium volume. The overall procedure-related mortality was 1.0% (1 patient died within 30 days due to acute myocardial infarction). Other 7 patients experienced at least 1 major complication without any significant difference between subjects in Group A vs those in Group B (7.7% vs 6.5%, $p = 0.714$; Table 2). These included 1 case of peripheral embolization that required surgical thrombectomy and 2 cases of graft thrombosis that necessitated endovascular thrombectomy with secondary relining and femoral-femoral crossover bypass, respectively. All perioperative thromboembolic events occurred within the external iliac axis and were successfully resolved with aforementioned reinterventions, with patients remaining free from recurring symptoms.

Follow-up Outcomes

The median duration of follow-up for the study cohort was 22.7 months (21.4 vs 24.0 months, $p = 0.057$), with an estimated 2-year survival rate of 92% (Figure 1). Only 1 instance of aneurysm-related mortality was reported in the study cohort.

In the overall cohort, the 2-year freedom from IBD-related type I endoleaks and IBD primary patency were 96% (Figure 2) and 92% (Figure 3), respectively; no significant differences were seen in those rates between Group A or Group B (95% vs 100%, $p = 0.335$; 93% vs 88%, $p = 0.470$). Seventeen persistent type II endoleaks were seen in the overall cohort (Group A, $n = 14$; Group B, $n = 3$; $p = 0.155$), all from the AAA sac; of these, 5 were associated with AAA sac increase > 5 mm and required secondary embolization during follow-up, while in 11 the AAA sac remained stable. In 1 patient, a type Ia endoleak with aortic stent-graft migration was detected with concomitant type II endoleak and treated with proximal aortic cuff placement and onyx embolization of inferior mesenteric artery

(Supplementary Table 2). A total of 7 pelvic ischemic events were recorded in the study cohort (5 cases of buttock claudication, 2 cases of erectile dysfunction, 0 cases of colonic ischemia), without any significant differences between study groups (7.7% vs 6.5%, $p = 0.827$).

Freedom from any IBD-related reinterventions was 83% at 2 years (Figure 4), with similar rates between study groups (85% vs 83%, $p = 0.904$). In the restricted cohort of 84 patients who completed > 6 months of follow-up, the median diameter of the right and left CIA decreased significantly (31.0 vs 30.0 mm, $p < 0.001$; and 31.0 vs 28.0 mm, $p = 0.035$, respectively). Results are summarized in Supplementary Table 3.

Discussion

Long-term durability of EVAR strictly depends on stable and durable stent-graft fixation and sealing at both the proximal and distal landing zones. Presence of ectatic (or frankly aneurysmal) CIA may pose high risk for long-term reinterventions owing to loss of sealing and subsequent development of type Ib endoleaks.⁴ Extension of repair beyond the iliac bifurcation was traditionally carried out with embolization of the hypogastric artery and overstenting of its ostium. However, clinical practice guidelines from the Society for Vascular Surgery and the European Society for Vascular Surgery recommend preservation of blood flow to the hypogastric artery at least on one side strongly, if it does not compromise aneurysm exclusion.^{5,6}

Currently, IBDs represent the first dedicated totally endovascular option to preserve antegrade flow to the hypogastric artery, and have shown excellent technical success,⁷ lower periprocedural morbidity and mortality rates as compared with open surgery,⁸ as well as superior outcomes to the bell-bottom technique in the midterm.⁹ Main findings from this analysis of the pELVIS dataset showed bilateral implantation of IBD in 96 patients was safe and feasible, with extremely low rates of periprocedural morbidity and mortality. Midterm effectiveness of treatment was also highly satisfactory, with 2-year rates of freedom from type I endoleaks and IBD primary patency $> 90\%$. Reinterventions might still be required during follow-up; however, most of them will be performed endovascularly, without compromising the intention to remain minimally invasive.¹⁰ Therefore, bilateral use of IBD provides a valid treatment option in the context of suitable patients.

Experience with bilateral implantation of IBD is still rarely reported in the literature. In the pivotal Gore Iliac Branch Endoprosthesis (IBE) prospective trial, 25 of 64 patients had bilateral CIA aneurysms, yet only 4 out of these 25 were treated with bilateral IBE devices while the remaining 21 underwent unilateral IBE implantation with embolization of contralateral hypogastric artery and extension in

Table 2. Early and Follow-up Outcomes in the 96 Patients Who Received Concomitant Bilateral IBD Implantation in the pELVIS Registry.^a

	Total Series (n=96)	Group A ^b (n=65)	Group B ^b (n=31)	p ^c
Follow-up, mo, median (IQR)	22.7 (30.4)	21.4 (32.0)	24.0 (25.0)	0.057
Mortality				
Early	1 ^d (1)	1 ^d (1.5)	0 (0)	1.0
Midterm	9 (9.4)	7 (10.8)	2 (6.5)	0.714
Total follow-up	10 ^d (10.4)	8 ^d (12.3)	2 (6.5)	0.292
Total procedure related	1 ^d (1)	1 ^d (1.5)	0 (0)	1.0
Morbidity and complications				
Early				
Total complications	7 (7.3)	5 (7.7)	2 (6.5)	0.827
Acute myocardial infarction	3 ^d (3.1)	2 ^d (3.1)	1 (3.2)	1.0
Respiratory insufficiency	1 (1)	1 (1.5)	0 (0)	1.0
Peripheral embolization	1 (1)	1 (1.5)	0 (0)	1.0
Graft thrombosis	2 (2.1)	1 (1.5)	1 (3.2)	0.588
Midterm				
Claudication (all types ^e)	11 ^e (11.5)	7 ^e (10.8)	4 ^e (12.9)	0.759
Pelvic ischemia	7 (7.3)	5 (7.7)	2 (6.5)	0.827
Colon ischemia	0 (0)	0 (0)	0 (0)	NA
Buttock claudication ^e	5 ^e (5.2)	3 ^e (4.6)	2 ^e (6.5)	0.705
Erectile dysfunction	2 (2.1)	2 (3.1)	0 (0)	0.324
Persistent endoleaks (all types)	18 ^f (18.8)	15 ^f (23.1)	3 (9.7)	0.116
Type Ia-Ib endoleaks	2 ^f (2.1)	2 ^f (3.1)	0 (0)	0.324
Type II endoleaks	17 ^f (17.7)	14 ^f (21.5)	3 (9.7)	0.155
Types III, IV, and V endoleaks	0 (0)	0 (0)	0 (0)	NA
Migrations	0 (0)	0 (0)	0 (0)	NA
IBD occlusion/>70% stenosis	10 (10.4)	6 (9.2)	4 (12.9)	0.582
Common iliac	4 (4.2)	0 (0)	4 (10.9)	0.003
External iliac	4 (4.2)	4 (6.2)	0 (0)	0.158
Internal iliac	2 (2.1)	2 (3.1)	0 (0)	0.324
Entire internal iliac	2 (2.1)	2 (3.1)	0 (0)	0.324
Bridging stent only	0 (0)	0 (0)	0 (0)	NA
Total early and midterm reinterventions				
Endovascular reinterventions	18 (18.7)	12 (18.5)	6 (19.4)	0.941
IBD related	13 (13.5)	9 (13.7)	4 (12.9)	0.805
Non-IBD related	5 (5.2)	3 (4.6)	2 (6.5)	0.705
Open reinterventions	2 (2.1)	1 (1.5)	1 (3.2)	0.588

Abbreviations: IBD, iliac branch device; IQR, interquartile range; NA, not applicable.

^aData presented as number (percentage) unless indicated otherwise.

^bGroup A "Muenster" and Group B "other centers."

^cStatistical significance set at level of p<0.05 and significant correlations appear in boldface.

^dOne patient of Group A subgroup underwent an early acute myocardial infarction and died.

^eButtock claudication cases are included in pelvic ischemia and in claudication (all types).

^fOne patient of Group A had 2 endoleaks (type Ia-Ib and type II).

the external iliac artery on the contralateral side.¹¹ In the study of de Marino et al,¹² 29 patients underwent bilateral implantation of the Cook Zenith IBD during a 7-year period. Out of these 58 IBDs, only 48 (83%) were implanted in 1 procedure, with similar technical success and midterm outcomes to the unilateral use of the device. Our study results also parallel the recent reports by Maldonado et al¹³ with the Gore Excluder IBE, thereby showing that IBD are versatile devices and can be implanted bilaterally with high

rates of technical success without compromising immediate safety and midterm effectiveness.

As expected, differences were noted in the intercenter distribution of bilateral IBD procedures. In this study, only 1 center (therefore classified as Site A) showed a linear increase in the prevalence of those procedures over time, while the remaining centers (therefore collectively named Site(s) B) showed a stable prevalence of bilateral IBD cases despite an increase in the overall number of IBD

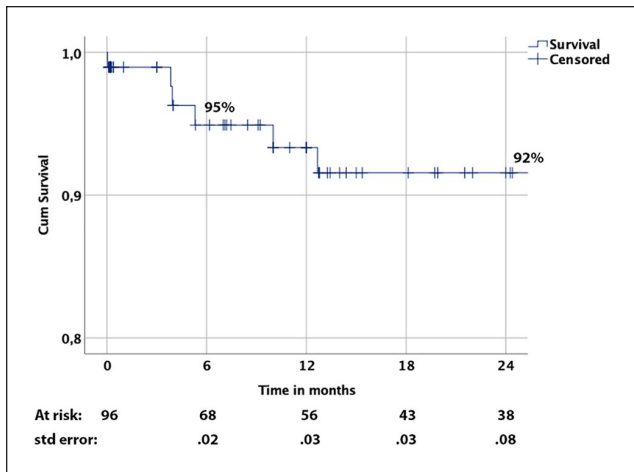


Figure 1. Kaplan-Meier estimates of overall survival at 2 years.

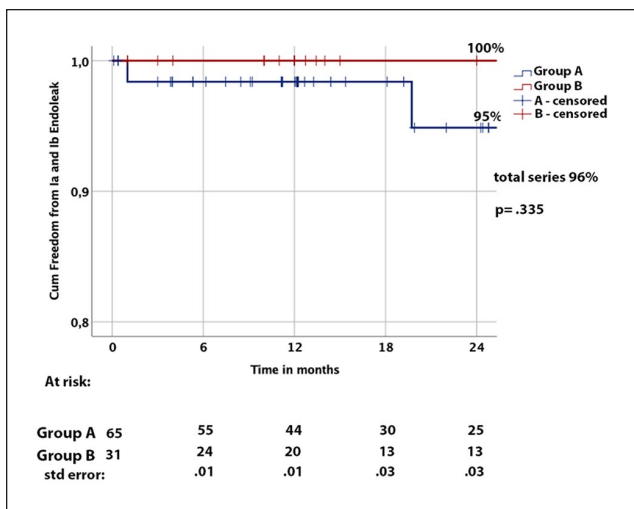


Figure 2. Kaplan-Meier estimates of freedom from iliac branch device (IBD)-related type I endoleak at 2 years.

implantations during the study timeframe. Although unable to comment on the actual reasons beyond such differences in clinical practice, the decision to attempt bilateral IBD implantation can be influenced by the perceived risk of increased complexity and costs vs the benefit of maximizing pelvic circulation. This may explain why many would remain hesitant to be aggressive in preserving both hypogastric arteries when confronted with bilateral iliac aneurysmal disease.

Despite these considerations, no significant differences were found between Group A and Group B up to 2 years of follow-up for any of the endpoints analyzed. The volume-outcome relationship after AAA surgery is well documented and a strong argument in favor of centralization of aortic care to high-volume institutions.¹⁴ However, it still attracts some debate, especially after minimally invasive

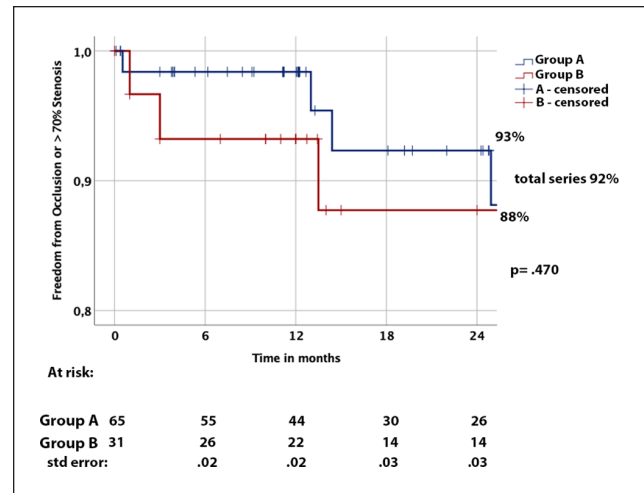


Figure 3. Kaplan-Meier estimates of iliac branch device (IBD) primary patency at 2 years.

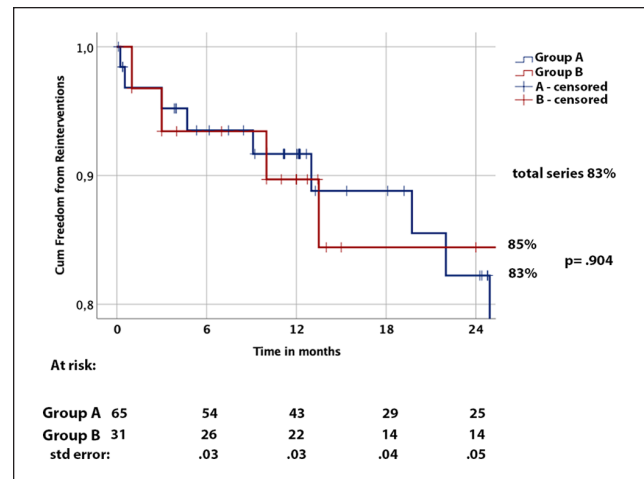


Figure 4. Kaplan-Meier estimates of freedom from iliac branch device (IBD)-related reinterventions at 2 years.

endovascular interventions for which standard quality metrics, as in-hospital mortality, might not represent the optimal performance indicators. Indeed, improved outcomes after EVAR in the modern endovascular era should be evaluated in the context of long-term repair durability,¹⁵ and benefits of endovascular procedures (even more so for complex repairs as with use of IBD) when performed in high-volume institutions may extend well beyond the immediate postoperative period.¹⁶ In that sense, it must be borne in mind that all pELVIS centers could be defined as “highly experienced” as they were required a prior experience with at least 30 IBD procedures before they could be selected for the registry. This could have attenuated some of the differences reported.

One common limitation with IBD applicability is inadequacy of the distal landing zone, because of coexisting

aneurysm or poor quality of the hypogastric main trunk, which is a known factor that can lead to worse outcomes.¹⁷ However, it is still possible to create a suitable landing zone within one of its divisional branches with satisfactory results as shown by recent clinical series.¹⁸ In the present series, patients treated with bilateral IBD in Group A had higher prevalence of aneurysmal hypogastric involvement), which might reflect the fact that physicians will likely expand treatment boundaries as their confidence with techniques and devices increase. In case of large hypogastric aneurysms with numerous side branches, others have advocated excluding all of them using coil embolization or vascular plugs since stent oversizing alone may not be sufficient to reliably prevent type 2 endoleaks.¹⁹ Although data in the literature are scarce to assess the long-term clinical relevance of these type 2 endoleaks, some might actually lead to aneurysm sac expansion as also shown in this study, alike to what can be observed after standard or fenestrated-branched EVAR.^{20,21} Furthermore, one should consider that embolization of hypogastric side branches when a stent-graft has already been deployed across a hypogastric aneurysm would be an extremely challenging (if not unfeasible) procedure. Therefore, it might be a better option to embolize those branches when it is relatively straightforward at the time of first intervention.

Although direct comparison of bilateral implantations against unilateral procedures was not the primary focus of this article, immediate postoperative results as well as mid-term outcomes in this series seem largely similar to those achieved in the whole pELVIS cohort as reported in prior publications,^{22,23} although procedural metrics would indicate an expected higher complexity of repair. In light of these findings, it is the authors' opinion that when IBD are employed by well-trained physicians in adequately selected patients, procedural complexity should not be the only reason to deny bilateral repair other reasons might ultimately affect the decision-making process. For instance, costs may remain the most significant impediment to treating bilateral disease or bilateral hypogastric preservation could be sought in those patients with extensive aortic disease that will undergo complex fenestrated-branched endovascular repair. Thus, bilateral IBD devices should be employed judiciously in the context of a comprehensive risk to benefit evaluation to such patients. Ideally, preservation of both hypogastric arteries could be advisable especially for young physically and sexually active individuals or for those with previous, concomitant or planned extensive aortic repair to minimize the risks of spinal cord ischemia.²⁴

Study Limitations

Findings from this analysis must be interpreted within the context of its inherent limitations. Collected data are

based on experience of well-experienced centers, not necessarily reflecting the results of less experienced teams. Variability in indications, outcomes reporting, and follow-up schedules could have increased heterogeneity between different groups. The retrospective nature of the analysis might have introduced unknown biases, and the absence of statistical significance could reflect a type II error given the relatively small sample size. Furthermore, some outcomes (eg, buttock claudication and erectile dysfunction) may be difficult to capture without a prospective design. Procedural volume of bilateral procedures did not seem to affect study outcomes, but it must be noted that all interventions were performed at centers with proven high-volume of IBD procedures; therefore, whether the findings could be translated to less experienced operators remains unproven. Although the study aim was to assess the impact of procedural volume with bilateral IBD implantation procedures could have on subsequent outcomes, we compared one center vs all others in the registry; however, the overwhelming difference in the number of such procedures among participating pELVIS sites was clinically meaningful to justify our approach. As no data were made available regarding the manufacturers of devices implanted in the study cohort. Last, absence of core-lab imaging assessment could have introduced inaccuracy in evaluation of relevant outcomes. Despite the statistical significance of observed diameter changes, most were relatively small and could fall within the measurement margin of error; nevertheless, the absence of significant differences in terms of net sac increase >5 mm between groups would provide further proof of similar treatment effectiveness.

Conclusions

Within the pELVIS registry, concomitant bilateral IBD implantation is a safe and feasible technique for management of aortoiliac aneurysms in patients with suitable anatomy. Despite increased technical complexity, effectiveness of the repair is satisfactory with low rates of IBD-related adverse events at midterm follow-up. Procedural volume does not seem to affect technical or clinical outcomes after bilateral use of IBD, which remains a favorable treatment option in selected patients.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Supplemental Material

Supplemental material for this article is available online.

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