




Results of Iliac Branch Devices in Octogenarians Within the pELVIS Registry

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 on behalf of the pELVIS Registry Collaborators

Abstract

Purpose: To evaluate if the elderly could benefit from the implantation of iliac branch devices (IBDs) to preserve the patency of the internal iliac artery (IIA) in aneurysms involving the iliac bifurcation. **Materials and Methods:** From January 2005 to April 2017, 804 patients enrolled in the pELVIS registry underwent endovascular aneurysm repair with 910 IBDs due to aneurysmal involvement of the iliac bifurcation. Among the 804 patients, 157 (19.5%) were octogenarians (mean age 82.9 ± 2.5 years; 157 men) with 171 target IIAs for preservation. Outcomes at 30 days included technical success, death, conversion to open surgery, and major complications. Outcomes evaluated in follow-up were patency of the IBD and target vessels, type I and type III endoleaks, aneurysm-related reinterventions, aneurysm-related death, and overall patient survival. Kaplan-Meier analyses were employed to evaluate the late outcome measures; the estimates are presented with the 95% confidence interval (CI). **Results:** Technical success was 99.4% with no intraoperative conversions or deaths (1 bridging stent could not be implanted, and the IIA was sacrificed). Perioperative mortality was 1.9%. The overall perioperative aneurysm-related complication rate was 8.9% (14/157), with an early reintervention rate of 5.1% (8/157). Median postoperative radiological and clinical follow-up were 21.8 months (range 1–127) and 29.3 months (range 1–127), respectively. Estimated rates of freedom from occlusion of the IBD, the IIA, and the external iliac artery at 60 months were 97.7% (95% CI 96.1% to 99.3%), 97.3% (95% CI 95.7% to 98.9%), and 98.6% (95% CI 97% to 99.9%), respectively. Estimated rates of freedom from type I and type III endoleaks and device migration at 60 months were 90.9% (95% CI 87% to 94.3%), 98.7% (95% CI 97.5% to 99.8%), and 98% (95% CI 96.4% to 99.6%), respectively. Freedom from all cause reintervention at 60 months was 87.4% (95% CI 82.6% to 92.2%). The estimated overall survival rate at 60 months was 59% (95% CI 52.4% to 65.6%). **Conclusion:** IBD implantation in octogenarians provided acceptable perioperative mortality and morbidity rates, with satisfying long-term freedom from IBD-related complications and should be considered a feasible repair option for selected elderly patients affected by aneurysms involving the iliac bifurcation.

Keywords

age, elderly, endoleak, endovascular aneurysm repair, iliac artery aneurysm, iliac bifurcation, iliac branch device, internal iliac artery, migration, octogenarians, reintervention

Introduction

Life expectancy has progressively risen; within the past decade, there was a 2.4% increase in the over-65 population in the European Union.¹ Consequently, the incidence of aneurysmal disease has gone up, as has the need to treat elderly and frail patients.^{2,3} Endovascular aneurysm repair (EVAR) is a less invasive treatment option compared with open repair, and a shift toward EVAR has already been observed in elderly patients.⁴ However, when performed in

octogenarians, EVAR has been related to significantly higher perioperative and midterm death rates vs younger patients.⁵

Iliac branch devices (IBDs) are a repair option in patients with aneurysmal involvement of the iliac bifurcation. These devices can preserve antegrade flow to the internal iliac artery (IIA) and reduce the non-negligible complication rates related to pelvic ischemia, such as buttock and/or thigh claudication, erectile dysfunction, bowel or spinal cord ischemia, and buttock necrosis.^{6,7} The aim of this study was

to investigate the safety and midterm efficacy of IBD implantation in the elderly population to preserve IIA patency in aneurysms involving the iliac bifurcation.

Materials and Methods

Study Design

The pELVIS registry (pErformance of iLiac branch deVices for aneurysmS involving the iliac bifurcation) is a retrospective, multicenter, post-market study evaluating the outcomes of IBD repair of aneurysms involving the iliac bifurcation in surgical-high-risk patients. All consecutive IBDs performed in each participating center were originally captured in the institution's database; the anonymized data were retrospectively added to the database for the multicenter registry. Inclusion criteria for the registry followed the standards of the Society for Vascular Surgery (SVS) and have been discussed previously in the initial report of the pELVIS registry, which at the time included 575 patients undergoing 650 implants performed in 6 European vascular centers.⁸ During 2017, 3 additional centers joined the registry. Consequently, data in the present study were collected from 9 high-volume European endovascular centers (Appendix 1). The registry was conducted based on the Declaration of Helsinki; informed consent for the IBD procedures was obtained from all the patients per local regulations, and each institution's ethics committee approved participation in the registry.

The use of an IBD was the first-line endovascular treatment for a >24-mm-diameter aneurysm involving the iliac bifurcation. Stand-alone IBD implantation was applicable when there was a suitable neck ≥ 10 mm in the common iliac artery (CIA) and a maximum aortic diameter ≤ 35 mm, avoiding coverage of the healthy infrarenal aorta when not necessary. The choice of whether or not to perform a proximal aortic extension was at the discretion of the physicians.⁹ Two different iliac branch devices were used in the octogenarian cohort: Cook ZBIS (Cook Medical, Bloomington, IN, USA) and Gore IBE (W.L. Gore & Associates, Flagstaff, AZ, USA). Bridging devices included the Atrium Advanta V12 (Maquet Getinge Group, Mijdrecht, the Netherlands), Viabahn (W.L. Gore & Associates), Fluency (BD/Bard Peripheral Vascular, Crawley, UK), and Begraft (Bentley Innomed, Hechingen, Germany). For the purposes of this

analysis, patients who were ≥ 80 years of age at the time of the IBD procedure and had at least 1 postoperative imaging study were selected from the registry database.

Patient Sample

The pELVIS registry enrolled 804 patients who were treated with 910 IBDs for aneurysmal involvement of the iliac bifurcation from January 2005 to April 2017.⁹ Among the 804 patients, 157 (19.5%) were octogenarians (mean age 82.9 ± 2.5 years; 157 men) and form the basis of this analysis. Baseline characteristics and aneurysm morphology of the cohort are described in Table 1. The majority of patients (135, 86%) were considered high risk for surgery as defined by an American Society of Anesthesiologists (ASA) classification $\geq III$; the remaining 22 patients had a hostile abdomen or a specific comorbidity that made them poor surgical candidates. Fourteen patients (8.9%) required bilateral treatment for a total of 171 target implantations. The majority of the repairs (130, 76.0%) were for aortoiliac aneurysms; 39 (22.8%) were isolated CIA aneurysms, and 2 (1.2%) were isolated IIA aneurysms. In 24 cases (15.3%), isolated iliac aneurysms were treated without proximal extension in the abdominal aorta. More than a third of the 171 target IIAs 62 (36.3%) were ectatic preoperatively, with diameters > 11 mm.

Follow-up Imaging

Though follow-up protocols varied by center, computed tomography angiography (CTA) or magnetic resonance angiography (MRA) was done within the first postoperative month, again at 12 months, and yearly thereafter. MRA was preferentially used to follow patients with renal impairment or if significant aneurysm sac growth was detected by CT or duplex ultrasound. In patients with renal insufficiency or a contraindication to MRA, duplex ultrasound was performed prior to discharge, within 30 days, and every 6 months. If the postoperative control imaging showed a type II endoleak, no changes were made in the follow-up protocol.

Outcome Measures and Definitions

Outcomes at 30 days included technical success, death, conversion to open surgery, and major complications. Outcomes evaluated in follow-up were patency of the IBD

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Table 1. Demographics, Comorbidities, and Aneurysm Characteristics of the 157 Patients in the Study.^a

Demographics	
Age, y	82.9±2.5
Men	144/157 (91.7)
Comorbidities	
Diabetes mellitus	24/157 (15.3)
Hyperlipidemia	72/157 (45.9)
Hypertension	131/157 (83.4)
Cardiac insufficiency	75/157 (47.8)
COPD	52/157 (33.1)
Smoking history	79/157 (51.3)
Chronic renal insufficiency	9/157 (5.7)
Hemodialysis	1/157 (0.6)
ASA ≥III	135/157 (85.9)
Lesion characteristics	
Aortoiliac aneurysm	130/171 (76.0)
CIA aneurysm	39/171 (22.8)
Isolated IIA aneurysm	2/171 (1.2)
Ectatic IIAs (>11 mm)	62/171 (36.3)
Aneurysm diameter, mm	
Abdominal aorta	46.1±15.8
CIA on treated side	37.7±11.8
IIA on treated side	16.4±10.4

Abbreviations: ASA, American Society of Anesthesiologists; CIA, common iliac artery; COPD, chronic obstructive pulmonary disease; IIA, internal iliac artery.

^aContinuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).

and target vessels, freedom from type I and III endoleaks, aneurysm-related reintervention, aneurysm-related death, and overall patient survival.

Technical success was defined as correct deployment of the graft, patency of the target IIA, and no type I or III endoleak at the end of the procedure. Complications were categorized according to the SVS reporting standards.¹⁰ IBD occlusion referred to occlusion of the main body into the CIA. Reinterventions related to the IBD were those caused by occlusion or severe stenosis (peak systolic velocity ratio >2.5 or stenosis >70% detected with CTA) of the IBD and/or target iliac vessels, type I/III endoleak, migration of the device, or aneurysm sac rupture. The radiological follow-up index reflected the completeness of follow-up at the study end date as a ratio between the investigated and the potential follow-up examinations.

Statistical Analysis

Continuous data are presented as means ± standard deviation; categorical data are presented as the number/sample (percentage). The Kaplan-Meier method was used to evaluate overall patient survival and freedom from IBD occlusion, IIA occlusion, external iliac artery (EIA) occlusion,

Table 2. Perioperative Outcomes for Iliac Branch Devices (IBD) Implanted in the 157 Patients.^a

Technical success (per IBD)	170/171 (99.4)
General anesthesia	132/157 (84.1)
Intraoperative conversion	0
Procedure time, min	164.5±63.7
Fluoroscopy time, min	45.8±18.7
Contrast volume, mL	141.4±51.9
Major complications	12/157 (7.6)
IBD-related complications	14/157 (8.9)
Type I or III endoleak	7/171 (4.1)
IBD-related reinterventions	7/157 (4.5)
Mortality	3/157 (1.9)

^aContinuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).

type I and III endoleaks, device migration, and all-cause reintervention. Estimates are presented with the 95% confidence interval (CI). Statistical significance was set at $p < 0.05$. Analyses were performed using SPSS software (version 23; IBM Corporation, Armonk, NY, USA).

Results

Thirty-nine (22.8%) implantations were performed under local anesthesia (Table 2). The Cook ZBIS IBD device was implanted 163 IIAs (95.3%); 8 patients (4.7%) received a Gore IBE device. Technical success was achieved in 170 of 171 target sites (99.4%). The only technical failure was an uncrossable IIA that prevented bridging stent placement; the IIA was occluded intraoperatively with coils and the lateral branch overstented with an additional graft limb. Apart from Gore IBEs, which have a dedicated graft limb to achieve sealing in the IIA, 111 Atrium Advanta V12, 30 Viabahn, 39 Fluency, and 5 Begraft devices were used singly or in combination to secure the IBD in the IIA. Mean procedure and fluoroscopy times and contrast volume were 164.5±63.7 minutes, 45.8±18.7 minutes, and 141.4±51.9 mL, respectively. No intraoperative conversion or death occurred.

The 30-day major clinical complication rate was 7.6% [12/157: 2 myocardial infarctions, 3 strokes (one in a previous EVAR patient requiring a proximal brachial access to implant the IBD), 3 cases of pneumonia, 2 cases of acute renal failure, 1 multiorgan failure, and 1 spinal cord ischemia in a patient with a type IV thoracoabdominal aneurysm and concomitant implantation of a custom-made 4 fenestrated device]. Three of these patients (1.9%) died during hospitalization due to multiorgan failure, major stroke, and pneumonia.

The perioperative aneurysm-related complication rate was 8.9% (14/157), and the early reintervention rate was 5.1% (8/157). Six type I endoleaks (2 type Ia, 4 type Ib)

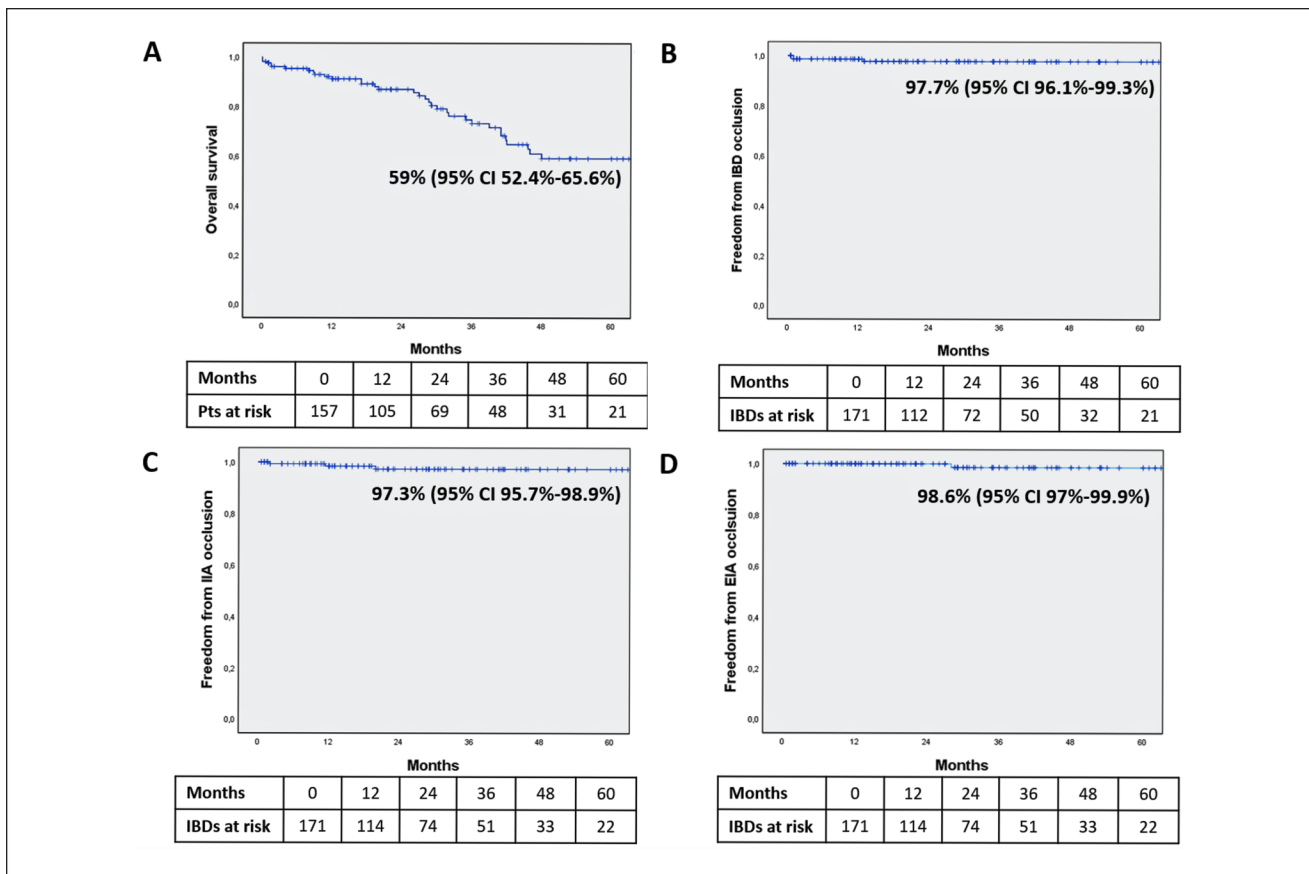


Figure 1. Kaplan-Meier curves of (A) overall survival of patients having iliac branch devices (IBD) and freedom from (B) IBD occlusions, (C) internal iliac artery (IIA) occlusions, and (D) external iliac artery (EIA) occlusions. CI, confidence interval.

and 1 type III endoleak were detected perioperatively (7 type I/III, 4.1%). All the type Ib endoleaks (2 from the target IIA and 2 from the ipsilateral EIA) and 1 of the 2 type Ia leaks were detected by duplex examination prior to discharge. They were categorized as slow flow due to their ultrasonographic appearance (nidus of the leak <1 cm in diameter and monophasic, low-velocity flow). Among these 5 leaks, the type Ia endoleak (in an IBD implant with a proximal bifurcated component) and 3 of 4 type Ib leaks (2 from the IIA and 1 from the EIA) showed complete resolution at the first postoperative CTA, while the type Ib leak from the EIA was treated by distal extension within the first month. The other type Ia endoleak was identified on the first postoperative CTA in a patient with an isolated IBD implant; the patient had a proximal extension with a bifurcated graft. The type III endoleak was due to dislocation of the bridging stent and required relining with an additional covered stent.

In addition, 3 other aneurysm-related early reinterventions were required during the hospital stay. One patient developed ipsilateral EIA occlusion that was treated by surgical thrombectomy, and 2 patients underwent thrombectomy due to

peripheral embolization in the lower limb. Within the first month, 2 patients suffered from early occlusion of the bridging stent but were left untreated due to the development of mild buttock claudication. Finally, 2 patients underwent surgical groin revision during hospitalization to treat access-site false aneurysms.

Outcomes in Follow-up

Median radiological and clinical follow-up periods were 21.8 months (range 1–127) and 29.3 months (range 1–127), respectively. The mean radiological follow-up index was 0.4±0.3. Only 1 aneurysm-related death occurred during follow-up due to sepsis consequent to a graft infection (see below). The estimated overall survival rate at 60 months was 59% (95% CI 52.4% to 65.6%, Figure 1A).

During follow-up, 3 additional IBDs (1.7%) occluded. Two patients were left untreated due to their poor general condition; the other patient was treated with a femorofemoral crossover bypass. The estimated freedom from IBD occlusion at 60 months was 97.7% (95% CI 96.1% to 99.3%;

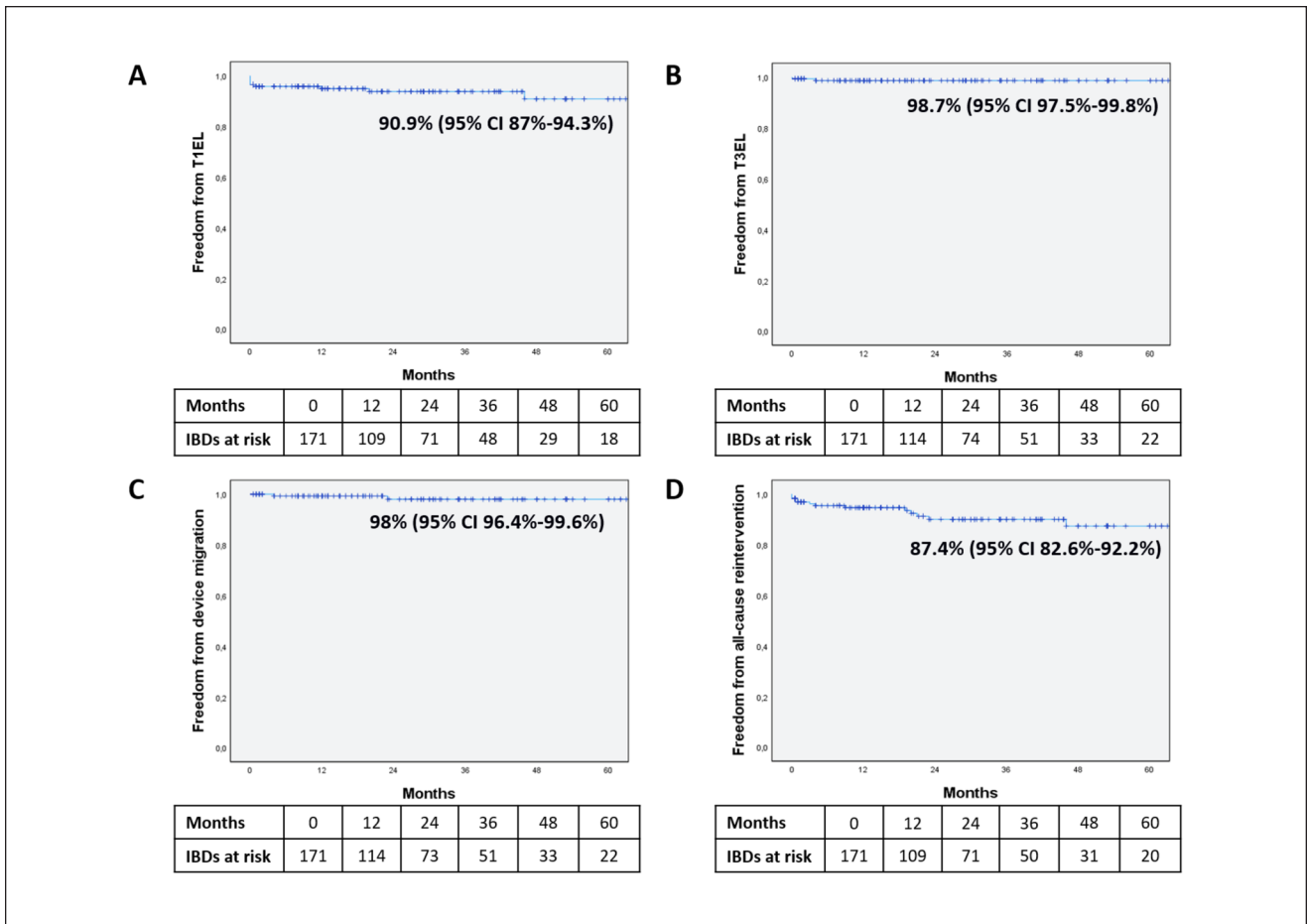


Figure 2. Kaplan-Meier curves for freedom from (A) type I endoleak (T1EL), (B) type III endoleak (T3EL), (C) device migration, and (D) all-cause reintervention during follow-up. CI, confidence interval; IBDs, iliac branch devices.

Figure 1B). Four target IIAs (2.4%) occluded. In 3, the occlusion was asymptomatic and was left untreated; the other patient underwent an endovascular reintervention with transaxillary covered stent implantation in the occluded IIA. However, graft infection developed, and the patient died from sepsis during hospitalization. The estimated rate of freedom from IIA occlusion at 60 months was 97.3% (95% CI 95.7% to 98.9%; Figure 1C). Two EIAs distal to the IBD occluded. One patient was left untreated due to poor general condition; the other occlusion was recanalized and an additional bare metal stent was implanted distally to the IBD. The estimated rate of freedom from EIA occlusion at 60 months was 98.6% (95% CI 97% to 99.9%, Figure 1D).

Two patients (1.2%) developed a type Ia endoleak during follow-up. The first was diagnosed by CTA 12 months after the procedure; he refused reintervention and was lost to follow-up. The second endoleak was detected by a duplex scan 46 months after the implantation of an isolated IBD in the right CIA; it was treated by proximal extension with a bifurcated endograft.

Two patients (1.2%) developed a type Ib endoleak from the target IIA. The first was detected 40 days after IBD placement and was treated by distal extension in the main trunk of the IIA. The other was diagnosed at the 12-month CTA; the covered stent into the IIA was flared with balloon angioplasty to seal the leak. One patient required an additional covered bridging stent due to dislocation of the initial stent into the target IIA, leading to a type III endoleak (0.7%). Estimated rates of freedom from type I/III endoleaks at 60 months (Figure 2A and B) were 90.9% (95% CI 87% to 94.3%) and 98.7% (95% CI 97.5% to 99.8%), respectively.

Two patients (1.2%) with an isolated IBD developed distal device migration without an endoleak; both were converted to a complete bifurcated graft. The estimated rate of freedom from device migration at 60 months (Figure 2C) was 98% (95% CI 96.4% to 99.6%). The overall estimated freedom from all-cause reintervention at 60 months (Figure 2D) was 87.4% (95% CI 82.6% to 92.2%).

Discussion

IBDs are a reliable endovascular treatment option for aneurysms involving the iliac bifurcation when proper anatomical requirements are met. Several studies have focused on the performance of the 3 commercially available IBD platforms. Jongsma et al¹¹ analyzed the results of 162 Cook ZBIS implants, reporting 96.9% technical success (157/162), with low rates of postoperative mortality (1.4%) and an estimated 75.9% rate of freedom from reintervention at 60 months. Schneider et al¹² investigated the results of the US investigational device exemption trial of the IBE endoprosthesis (98 implants) and of the global GREAT registry (92 implants). The target IIA patency rate was 93.5% (with 6-month follow-up for the IDE trial and 2 years for the GREAT registry), with a low rate of thrombotic events during the first 6 months. The PLIANT study documented the performance of the Jotec E-Iliac endograft in 45 patients; clinical success at 12 months was 90%.¹³ In the pELVIS registry of over 900 IBD implants,⁹ IBDs provided satisfying estimated rates of 8-year freedom from IBD and IIA occlusion (87% and 95.1%, respectively) and freedom from reintervention (85.7%) due to occlusion and/or type I endoleak.

However, there is a lack of data about the safety and efficacy of IBD implants in octogenarians. The findings reported in the present study suggest that IBD repair carries perioperative and long-term results similar to standard EVAR in patients older than 80 years. The results of standard EVAR in high-risk patients have been discussed in the literature.¹⁴ Focusing on octogenarians, a systematic review by Biancari et al¹⁵ based on 13,419 patients suggested that elective EVAR is a safer option in the elderly compared with open repair, providing lower rates of postoperative mortality (2.3% vs 8.6%; relative risk 3.87, $p < 0.001$). A single-center experience by Geisbüsch et al¹⁶ involving 279 patients > 80 years old undergoing EVAR found a 2.8% perioperative mortality rate (2.9% in high-risk patients) and a 10.3% perioperative morbidity rate. Midterm survival rates in the elderly were 87% after 1 year from the intervention, 70% at 3 years, and 52% at 5 years.

A recent meta-analysis by Han et al⁵ including 9 observational studies and $> 25,000$ patients reported higher but still acceptable rates of 30-day [3.7% vs 1.7%; odds ratio (OR) 2.37, $p < 0.001$] and 1-year mortality (9.2% vs 4.5%; OR 2.16, $p < 0.001$) in patients aged ≥ 80 years compared to younger patients, respectively, with similar rates of perioperative complications (14.5% vs 10.2%; OR 1.1, $p = 0.79$) and midterm reinterventions (hazard ratio 1.1, $p = 0.41$).

A clinical study by Giles et al¹⁷ reported slightly higher reintervention rates in patients aged > 80 years old undergoing elective EVAR compared with younger patients, perhaps due to the challenging anatomies found in elderly

patients. On the contrary, in our series, the estimated rate of reinterventions at 5 years from the procedure was lower than expected. One possible explanation of this finding could be a more restrictive preoperative anatomical selection of elderly candidates for IBD repair. Branched devices increase the total cost of aortoiliac endovascular repair vs standard EVAR. Their use and, therefore, the higher cost of the procedure in patients with poor life expectancy have to be justified by an aortoiliac anatomy ideal for IBD implantation. However, no data concerning the preoperative selection criteria for elderly patients from the participating centers were included in the registry, and this hypothesis cannot be verified with certainty.

Furthermore, old patients are less prone to undergo periodic testing, as reflected in the radiological follow-up index of this series, and when not bedridden, they usually adopt a less active lifestyle than younger patients. All these conditions can make it difficult to detect a postoperative defect in the implant.

Octogenarians usually have a higher rate of comorbidities and a poorer clinical status than younger patients, and their frailty should be considered when evaluating the results of endovascular repair for aortoiliac aneurysmal disease. In our series of 171 IBD implants in an elderly population, 86% of patients had an ASA score $\geq III$, defining a surgical-high-risk cohort of patients. The remaining 14% had specific comorbidities or hostile abdomen that made them unsuitable for open surgical repair. However, this pELVIS octogenarian series had the same perioperative mortality rate as the entire registry (1.9% vs 1.9%).⁸ On the other hand, the 30-day major complication rate was not negligible (7.6%) even if the procedure was performed in highly experienced centers, reflecting the frailty of elderly patients and the impact of longer procedure and fluoroscopy times and higher amounts of contrast during IBD implantation compared to standard EVAR. The perioperative reintervention rate was also higher in the elderly cohort than in younger patients (4.5% vs 1.6%).⁸

The 5-year 40% estimated mortality is likely due to advanced age at the index procedure. However, even if significantly higher than in younger patients, this rate is aligned with rates found in the literature for standard EVAR. Moreover, only 1 aneurysm-related death was recorded in this series during 30-day follow-up. In our opinion, these results are acceptable for a frail cohort of patients, and IBD use should not be excluded as a repair option in anatomically suitable octogenarians.

Limitations

This study has several limitations. This was a retrospective, nonrandomized study including patients from 9 different European centers, each one with different regulatory rules. Each center reviewed their data after its

transfer to the registry, and an additional critical review was than performed by the authors of this paper to avoid major inconsistencies. However, even if all possible efforts were made to report reliable data and results, the analysis was based on self-reported data without core laboratory adjudication, which should be considered as a possible limitation.

Furthermore, selection bias due to the different intraoperative strategies and technical issues was unavoidable, and such differences can be relevant to the clinical outcomes. An analysis of the patient-centered outcomes deriving from IBD implantation was not performed in this study, mainly due to the difficulty in obtaining reliable data regarding sexual impotence and gluteal claudication in this cohort of patients. This is probably a consequence of the heterogeneous follow-up methods of the different institutions, possibly causing a further bias in the evaluation of the follow-up results. Finally, a cost-effectiveness analysis was not undertaken due to the different reimbursement policies of the participating countries, with significant differences in the costs of the devices based on the geographical location.

Conclusion

In the pELVIS registry, IBD implantation in a high-risk cohort of patients such as octogenarians provided acceptable perioperative results and midterm freedom from IBD-related complications. It should be considered a feasible repair option for aneurysms involving the iliac bifurcation in selected elderly patients who have suitable aortoiliac anatomy.

Appendix I

Additional pELVIS registry collaborators: Münster, Germany: Martin Austermann, Mirjam Inchingolo, Theodosios Bisdas, Georgios A. Pitoulis, and Gergana T. Taneva; Florence, Italy: Walter Dorigo; Tor Vergata, Rome, Italy: Arnaldo Ippoliti and Matteo Barbante; San Camillo Forlanini, Rome, Italy: Piergiorgio Cao and Ciro Ferrer; Perugia, Italy: Fabio Verzini, Gianbattista Parlani, and Gioele Simonte; Hamburg, Germany: Tilo Kölbel and Nikolaos Tsilimparis; Lille Chru, France: Stephan Haulon; Leipzig, Germany: Daniela Branzan, Andrej Schmidt, and Dirk Scheinert.

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Declaration of Conflicting Interests

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