Outcomes of "Anterior Versus Posterior Divisional Branches of the Hypogastric Artery as Distal Landing Zone for Iliac Branch Devices": The International Multicentric R3OYAL Registry

Mario D'Oria, MD[1*], Guilherme B. B. Lima, MD[2*], Nuno Dias, MD[3], Giambattista Parlani, MD[4], Mark Farber, MD[5], Nikolaos Tsilimparis, MD[6], Randall DeMartino, MD[7], Carlos Timaran, MD[8], Tilo Kolbel, MD[9], Mauro Gargiulo, MD[10], Ross Milner, MD[11], Germano Melissano, MD[12], Thomas Maldonado, MD[13], Kevin Mani, MD[14], Emanuel R. Tenorio, MD[2], Gustavo S. Oderich, MD[2], on behalf of the R3OYAL Registry collaborators, and R3OYAL Registry Collaborators (PubMed indexed list): Angelos Karelis[3], Bjorn Sonesson[3], Sandro Lepidi[1], Gioele Simonte[4], Giacomo Isernia[4], Fernando Motta[5], Tugce Öz[6], Jan Stana[6], Bernardo Mendes[7], Carla Scott[8], Kirsten Haack[9], Enrico Gallitto[10], Antonino Logiacco[10], Trissa Babrowski[11], Luca Bertoglio[12], Alessandro Grandi[12], and Anders Wanhainen[14]

Abstract

Objective: The aim of this multicentric registry was to assess the outcomes of "anteRior versus posteRior divisional bRanches Of the hYpogastric artery as distAl landing zone for iLiac branch devices (R3OYAL)."
Methods: The main exposure of interest for the purpose of this study was the internal iliac artery (IIA) divisional branch (anterior vs posterior) that was used as distal landing zone. Early endpoints included technical success and adverse events. Late endpoints included survival, primary/secondary IIA patency, and IIA branch instability.
Results: A total of 171 patients were included in the study, of which 50 received bilateral implantation of iliac branch devices (IBDs). This resulted in a total of 221 incorporated IIAs included in the final analysis, of which 40 were anterior divisional branches and 181 were posterior divisional branches. Technical success was high in both groups (anterior division: 98% vs posterior division: 100%, P = .18). Occurrence of any adverse event was noted in 14% of patients in both groups (P = 1.0). The overall rate of freedom from the composite IBD branch instability did not show significant differences between patients receiving distal landing in the anterior or posterior division of the IIA at 3 years (79% vs 87%, log-rank test = .215). The 3-year estimates of IBD patency were significantly lower in patients who received distal landing in the anterior divisional branch than those who received distal landing in the posterior divisional branch (primary patency: 81% vs 96%, log-rank test = .009; secondary patency: 81% vs 97%, log-rank test < .001).
Conclusions: The use of the anterior or posterior divisional branches of the IIA as distal landing zone for IBD implantation shows comparable profiles in terms of immediate technical success, perioperative safety, and side-branch instability up to 3 years. However, IBD patency at 3 years was higher when the distal landing zone was achieved within the posterior divisional branch of the IIA.

Clinical Impact

The results from this large multicentric registry confirm that use of the anterior or posterior divisional branches of the internal iliac artery (IIA) as distal landing zone for implantation of iliac branch devices (IBD) shows comparable profiles of safety and feasibility, thereby allowing to extend the indications for endovascular repair of aorto-iliac aneurysms to cases with unsuitable anatomy within the IIA main trunk. Although mid-term rates of device durability and branch instability seem to be similar, the rates of primary and secondary IBD patency at three years was favored when the distal landing zone was achieved in the posterior divisional branch of the IIA.

Keywords

aortoiliac disease, abdominal aortic aneurysm, endovascular repair, stent-graft, iliac branch, internal iliac artery

Introduction

Iliac branch devices (IBDs) represent the first-line treatment option to preserve internal iliac artery (IIA) perfusion when anatomically feasible, as endorsed by the current clinical practice guidelines.[1,2] The technique has expanded the indications of endovascular aortic repair (EVAR) for complex aortoiliac aneurysms,[3] now allowing totally endovascular incorporation of the IIA in most cases with excellent short-term[4] and mid-term[5] outcomes.

Despite improvements in stent-grafts design and increasing clinical experience, some anatomical limitations still restrict applicability of IBD. One common restriction to IBD feasibility is inadequacy of the IIA distal landing zone due to ectasia or aneurysm.[6–8] In these cases, the IIA bridging stent may be extended into one of its major divisional branches, whereas smaller branches are sacrificed.[9] Although some single-center series have reported on the safety and feasibility of this approach,[10–12] outcomes of this technique are still limited, and there is uncertainty whether obtaining the distal seal in the anterior or posterior divisional branch has comparable outcomes in terms of durability and rates of sexual dysfunction or buttock claudication.

The aim of this multicentric registry was to assess the outcomes of "anteRior versus posteRior divisional bRanches Of the hYpogastric artery as distAl landing zone for iLiac branch devices (R3OYAL)."

Materials and Methods

Study Design

The study was approved by the Institutional Review Board of the Mayo Clinic (Rochester MN). All 12 U.S. and European participating centers obtained approval or exemption from local institutional review board (IRB) or ethical committees as applicable (Supplementary Table I). Each center had advanced endovascular programs with an overall annual EVAR volumes >30 procedures/year and were required to had performed at least 15 IBD cases over the last 5 years (irrespective of distal landing zone) to be included in the study. Investigators at participating institutions identified all consecutive patients electively treated for aortoiliac or common iliac artery (CIA) aneurysms using commercially available IBD that had distal landing zone in a divisional branch of the IIA.

The main exposure of interest for the purpose of this study was the IIA divisional branch (anterior vs posterior) that was used as the distal landing zone, and study subjects were classified into 2 groups accordingly.

Data Collection

The study timeframe for data collection at each participating center was set between the first IBD case performed and June 30, 2020 (Supplementary Table 1). Patients without complete data on their in-hospital phase and/or lack of at least one available imaging follow-up study within the first year after index intervention were excluded (n = 15). Data were reported according to the Society for Vascular Surgery reporting standards for EVAR.[13] All surgical interventions and subsequent follow-up protocols were carried out according to local policy endorsed at each of participating institutions. Clinical and imaging data were reviewed for baseline demographics, comorbidities, and anatomical characteristics, as well as procedural details and outcomes by at least 2 experienced investigators at each center. One center was responsible of merging the data from each

[1]Division of Vascular and Endovascular Surgery, Cardiovascular Department, University Hospital of Trieste, ASUGI, Trieste, Italy
[2]Department of Cardiothoracic and Vascular Surgery, McGovern Medical School, The University of Texas Health Science Centre at Houston, Houston, TX, USA
[3]Department of Thoracic Surgery and Vascular Diseases, Vascular Centre, Skåne University Hospital, Malmö, Sweden
[4]Vascular and Endovascular Surgery Unit, S. Maria della Misericordia Hospital, University of Perugia, Perugia, Italy
[5]Division of Vascular Surgery, Department of Surgery, The University of North Carolina at Chapel Hill, Chapel Hill, NC, USA
[6]Department of Vascular Surgery, Ludwig Maximilians University Hospital, Munich, Germany
[7]Division of Vascular and Endovascular Surgery, Gonda Vascular Center, Mayo Clinic, Rochester, MN, USA
[8]Department of Surgery, University of Texas Southwestern Medical Center, Dallas, TX, USA
[9]Department of Vascular Medicine, German Aortic Centre, University Heart and Vascular Centre, Hamburg, Germany
[10]Vascular Surgery, IRCCS University Hospital, Policlinico S. Orsola and University of Bologna, Bologna, Italy
[11]Section of Vascular Surgery and Endovascular Therapy, Department of Surgery, Pritzker School of Medicine, University of Chicago, Chicago, IL, USA
[12]Division of Vascular Surgery, IRCCS San Raffaele Scientific Institute, Vita-Salute San Raffaele University, Milan, Italy
[13]Division of Vascular and Endovascular Surgery, NYU Langone Health, New York, NY, USA
[14]Division of Vascular Surgery, Department of Surgical Sciences, Uppsala University, Uppsala, Sweden

*Mario D'Oria, MD and Guilherme BB Lima, MD contributed equally to this work and should share 1[st] co-authorship

Corresponding Author:

Mario D'Oria, Division of Vascular and Endovascular Surgery, Cardiovascular Department, University Hospital of Trieste, ASUGI, Strada di Fiume 447, 34149 Trieste, Italy.
Email: mario.doria88@outlook.com

participating institution and assessing the quality of the imputed data. The follow-up schedule was assessed by the operating physicians on a single-center protocol basis.

Definitions and Endpoints

Early endpoints were assessed at 30 days and included technical success, mortality, and any adverse events, defined as composite cumulative endpoint of all-cause mortality, acute myocardial infarction, new-onset cardiac heart failure, stroke, spinal cord ischemia, acute kidney injury or new-onset dialysis, bowel ischemia, estimated blood loss ≥1 L, respiratory failure, access complications, and early reintervention. Major vascular access complications were defined as any complications occurring at vascular access sites leading to either reintervention or prolonged hospitalization or limb loss. Technical success was defined as correct deployment of all endografts with complete exclusion of the aneurysm sac(s), patent target vessels, and absence of type 1/III endoleak (EL) at completion angiography.

Late endpoints were assessed at the last available follow-up contact for each study individual and included overall survival and aneurysm-related mortality, primary/secondary IIA patency, IIA branch instability (defined as composite cumulative endpoint of any IIA branch-related complications leading to aneurysm rupture, death, occlusion or stenosis/kink, disconnection, type I/III EL, or reintervention to maintain branch patency or to treat a separation or EL), IIA branch-related reinterventions and type IC/IIIC EL, new-onset sexual dysfunction (in males) and buttock claudication, and aneurysm sac diameter changes (classified as reduction or increase if a change ≥5 mm from baseline was noted or otherwise as stable if a change <5 mm in either direction was observed).

Statistical Analysis

Technical success, mortality, adverse events, major vascular access complications, and sexual dysfunction/buttock claudication were analyzed per patient. Branch instability, patency, reinterventions, endoleaks, and sac changes were analyzed per vessel. Results were reported as absolute numbers (with frequencies) for categorical variables, and mean (standard deviation, SD) or median (interquartile range, IQR) for continuous variables according to normality of distribution. Pearson's chi-square or Fisher's exact test were used for analysis of categorical variables. Differences between means or medians were tested with 2-sided Student *t*-test, Wilcoxon rank-sum test, or Mann-Whitney *U*-test as appropriate. Statistical significance was defined as P value $< .05$. Statistical analysis was carried out using JMP 13 (SAS Institute). Univariate and multivariate Cox Proportional Hazards was used to assess independent predictors for IIA branch instability, with results reported as hazard ratio (HR) with 95% confidence intervals (CI). Covariates for these models were selected based on previously described risk factors or univariate screen of all available potential confounders, using backwards selection with a criterium of 0.25 to stay in the final models.

Time-dependent outcomes were reported using life tables with standard error <.10 and displayed as Kaplan-Meier curves with differences determined using the log-rank test.

Results

Baseline Characteristics

A total of 171 patients were included in the study, of which 29 received unilateral implantation in the anterior division, 92 received unilateral implantation in the posterior division, 39 received bilateral implantation in the posterior division, and 11 received bilateral implantation in both anterior and posterior divisions (Tables 1 and 2). Therefore, 50 patients received bilateral implantation of IBD. This resulted in a total of 221 incorporated IIAs included in the final analysis, of which 40 were anterior divisional and 181 were posterior divisional branches.

At baseline, no significant differences were seen in mean age (anterior division: 69 years vs posterior division: 72 years, $P = .07$), and most of patients were males in both study groups (93% vs 92%, $P = .62$). Distribution of major comorbidities was not significantly different across study groups, although patients who received distal landing in the anterior division were less likely to have significant renal dysfunction as compared to patients who received distal landing in the posterior division (10% vs 28%, $P = .04$). Also, patients in the anterior landing zone group had a higher cigarette smoking rate (97 vs 53%, $P \leq .001$). Patients selected for anterior division landing zone had less often unilateral (29% vs 68%, $P < .001$) IIA aneurysm.

Procedural Details and Perioperative Outcomes

Most of the procedures were performed electively (anterior division: 93% vs posterior division: 95%, $P = .64$), and patients who received distal landing in the anterior division were less likely to undergo concomitant fenestrated-branched EVAR as compared to patients who received distal landing in the posterior division (3% vs 21%, $P = .041$). Also, patients in the anterior division group required smaller volumes of contrast (mean 109 vs 165 mL, $P < .001$) and shorter fluoroscopy times (mean 45 vs 64 minutes, $P = .003$) than those in the posterior division group (Table 2). Notable differences were found in the type of bridging stent-grafts (BSGs) between study groups (Table 3). Subjects receiving distal landing in the anterior division were less likely to receive self-expanding BSG (10% vs 24%) or a combination of different BSG (15% vs 35%), but more likely to receive balloon-expandable BSG (45% vs 28%) ($p < .001$). Embolization

Table 1. Demographics, Clinical and Anatomical Characteristics of 171 Patients Treated With Iliac Branch Endoprosthesis (IBE) using Anterior Versus Posterior Divisional Branches as Leading Zone.

	All patients, n = 171	Anterior division, n = 29	Posterior division, n = 131	[a]Anterior and posterior (bilateral), n = 11	*P* value[b]
	n (percent) or mean ± SD (median, IQR)				
Demographics					
Mean age (years)	71±8.4 (71, 67-77)	68.6 ± 7.6 (68, 64-73)	71.5 ± 8.4 (72, 67-77)	73±9.4 (76, 66-81)	.07
Male gender	158 (92.4)	27 (93.1)	121 (92.4)	10 (90.9)	.62
BMI (kg/m^2)	27.9±4.2 (27, 25-31)	28.9 ± 5 (29, 25-32)	27.7 ± 4 (27, 25-31)	27.2±2.6 (27.2, 25-28)	.22
Cardiovascular Risk Factors					
Hypertension	144 (84)	25 (86.2)	108 (82.4)	11 (100)	.78
Hypercholesterolemia	105 (61)	20 (69)	81 (62)	4 (36)	.47
Cigarette smoking	103 (60)	28 (96.6)	70 (53.4)	5 (45)	<.001
Coronary artery disease	65 (38)	14 (48.3)	45 (34.4)	6 (54.5)	.16
Chronic obstructive pulmonary disease	45 (26)	10 (34.5)	33 (25.2)	2 (18.2)	.31
Chronic kidney disease III-V	44 (25.7)	3 (10.3)	37 (28.2)	4 (36.4)	.04
Congestive heart failure	32 (18.7)	3 (10.3)	28 (21.4)	1 (9)	.17
Peripheral artery disease	30 (17.5)	3 (10.3)	25 (19.1)	2 (18)	.26
Diabetes mellitus	25 (14.6)	5 (17.2)	18 (13.7)	2 (18.2)	.57
Stroke or TIA	9 (5)	2 (6.9)	7 (5.3)	0 (0)	.51
Preoperative Evaluation					
Creatinine (mg/dL)	1.1±0.7 (1.0, 0.9-1.2)	1.0±0.2 (1, 0.9-1.0)	1.2 ± 0.83 (1, 0.9-1.2	1.0±0.3 (1.0, 0.9-1.2)	.02
eGFR (ml/min/1.73 m^2)	70.5±20 (69, 58-82)	77.3 ± 19.3 (76.4, 65-86)	69.5 ± 20.4 (69, 58-81)	67.2 ± 25.4 (60, 56-74.5)	.064
Prior aortic repair					
Open aortic repair	15 (9)	2 (6.9)	12 (9.2)	1 (9)	1.0
Endovascular repair	19 (11)	3 (10.3)	14 (10.7)	2 (18.2)	0.96
Anatomic characteristics (mm)					
Largest aortic diameter	50.5 ± 17.6 (50, 36-60)	50 ± 14.6 (50, 41-55)	50.7 ± 18.5 (53, 35-63)	49.8 ± 14.3 (48.5, 40.5-55)	.61
Maximum diameter of the treated common iliac artery	35.1 ± 12 (33, 26-40)	37.2 ± 14.8 (34, 25.5-45.3)	34.5 ± 12.2 (33, 26-40)	30.9 ± 7 (30, 25.8-35)	.55
Length of the treated common iliac artery	60.5 ± 25 (58, 45-72)	77.9 ± 33 (69, 55-86)	57.5 ± 24 (58, 43-69)	61 ± 16.4 (55, 49.4-75.3)	.004
Length of the treated IIA	42 ± 18 (40, 32-49)	37 ± 16 (37, 23-46)	42 ± 16 (40, 34-49)	53 ± 42 (48.8, 18.5-68.8)	.12
Maximum diameter of the treated IIA	21.6 ± 12 (18, 11-31)	16.2 ± 12 (11, 9-17)	22 ± 12 (19, 12-32)	28.3 ± 16.8 (24.9, 16.6-37)	.005
Aortic bifurcation diameter	35.7 ± 14.7 (30, 26-43)	35 ± 15 (30, 24-40)	36 ± 15 (30, 26-43)	30 ± 9 (28.5, 24.8-33.8)	.71
Hypogastric aneurysm					
Ipsilateral internal iliac aneurysm	94 (55)	8 (29)	86 (68)	0	<.001
Bilateral internal iliac aneurysm	31 (19)	3 (11)	25 (20)	3 (27)	.26

Abbreviations: BMI, body mass index; eGFR, estimate glomerular filtration rate; IBE, iliac branch endoprosthesis; IIA, internal iliac artery; IQR, Interquartile range; TIA, transient ischemic attack.
[a]This group was excluded for comparison only between anterior and posterior landing zones.
[b]*P* values are comparisons between anterior versus posterior division landing zones only. We are not comparing these 2 groups with patients who had bilateral repair with anterior division landing zone in one side and posterior division landing zone in the other.

Table 2. Procedure Details of 171 Patients Treated With Iliac Branch Endoprosthesis (IBE) Using Anterior Versus Posterior Divisional Branches As Leading Zone.

	All patients, n = 171	Anterior division, n = 29	Posterior division, n = 131	[a]Anterior and Posterior (bilateral), n = 11	
	n (percent) or mean ± SD (median, IQR)				*P* value[b]
Unilateral IBE repair	121 (71)	29 (100)	92 (70)	0	<.001
Bilateral IBE repair	50 (29)	0 (0)	39 (30)	11 (100)	<.001
Elective procedure	163 (95)	27 (93)	125 (95)	11 (100)	.64
Device[c]					.005
Gore	61 (38)	18 (64)	41 (32)	2 (50)	
Cook	95 (59)	9 (32)	84 (65)	2 (50)	
Jotec	5 (3)	1 (4)	4 (3)	0	
Concomitant aortic repair					.041
EVAR	108 (63)	23 (79)	74 (57)	11 (100)	
F-BEVAR	28 (16)	1 (3)	27 (21)	0	
Isolated IBE	35 (20)	5 (17)	30 (23)	0	
Percutaneous femoral approach					.003
Unilateral	9 (5)	2 (8)	7 (5)	0	
Bilateral	122 (73)	14 (54)	101 (78)	7 (64)	
Brachial or axillary access	28 (16)	2 (7)	26 (20)	0	.1
Amount of contrast (ml)	155 ± 86 (131, 99-200)	109 ± 80 (83, 65-120)	165 ± 87 (149, 106-218)	149 ± 40 (145, 122-176)	<.001
Total operating time, min	216 ± 95 (193, 146-278)	213 ± 114 (188, 120-300	214 ± 92 (191, 142-272)	251 ± 72 (225, 201-288)	0.67
Total fluoroscopy time, min	62 ± 35 (53, 38-81)	45 ± 27(37, 26-52)	64 ± 38(57, 38-85)	66 ± 25(60, 51-73)	.003
Estimated blood loss, ml	313 ± 336 (200, 100-400)	253 ± 281 (200, 100-300)	346 ± 352 (275, 100-500)	100 ± 163 (0, 0-175)	0.11
Technical success per patient	170 (99.4)	28 (96.6)	131 (100)	11 (100)	.181

It is not possible to do radiation dose. The centers sent it in different units.

Abbreviations: EVAR, endovascular aneurysm repair; FBEVAR, Fenestrated-branched endovascular aortic repair; IBE, iliac branch endoprosthesis; IQR, interquartile range.

[a]This group was excluded for comparison only between anterior and posterior landing zones.

[b]*P* values are comparisons between anterior versus posterior division landing zones only. We are not comparing these 2 groups with patients who had bilateral repair with anterior division landing zone in one side and posterior division landing zone in the other.

[c]In 10 patients, the device was not recorded

Table 3. Procedure Details of 221 Iliac Arteries Treated With IBE Using Anterior Versus Posterior Divisional Branches as Leading Zone.

	All IBE, n = 221	Anterior division, n = 40	Posterior division, n = 181	*P* value
	n (percent)			
IBE				<.001
Gore	71 (32)	20 (50)	5 (28)	
Cook	125 (56.6)	11 (28)	114 (63)	
Jotec	5 (2)	1 (3)	4 (2)	
Combination (bilateral)	2 (1)	0	2 (1)	
Unknown	18 (8)	8 (20)	10 (6)	
Bridging stent				<0.001
Iliac branch endoprosthesis	34 (15)	12 (30)	22 (12)	
Self-expanding stent	48 (22)	4 (10)	44 (24)	
Balloon expandable stent	69 (31)	18 (45)	51 (28)	
Combination of different stents	70 (32)	6 (15)	64 (35)	
Bridging stent proximal diameter	10.1±3.2 (9, 8-10)	10.9±4.1 (10, 8-15)	10±3 (9, 8-10)	.34
Bridging stent distal diameter	9.4 ± 5.5 (8, 8-10)	9.2 ± 2.2 (10, 8-10)	9.4 ± 5.9 (8, 8-10)	.34
Length of stenting	83 ± 32 (80, 60-100)	64 ± 19.9 (60, 48-72)	86 ± 33 (80, 60-100)	<.001
Division diameter (distal)	7.4 ± 3.1 (6.5, 6-8)	7.3 ± 1.2 (7, 6.3-8.1)	7.4 ± 3.3 (6, 6-8)	.08
Embolization of branches	104 (47)	5 (13)	99 (55)	<.001
Embolization device				<.001
Coils	51 (23)	2 (5)	49 (27)	
Plug	48 (22)	3 (8)	45 (25)	
Both	5 (2)	0	5 (3)	
Technical success per vessel	220 (99.5)	39 (98)	181 (100)	.18

No IBE branch-related death or rupture.
Abberivation: IBE, iliac branch endoprosthesis.

of IIA side branches was done in 13% of patients who received distal landing in the anterior division as compared with 55% of those that received distal landing in the posterior division ($P < .001$). Technical success was similarly high in both study groups (anterior division: 98% vs posterior division: 100%, $P = .18$). Occurrence of any adverse event was noted in 14% of patients in both study groups ($P = 1.0$) and no significant differences were found in the rates of individual complications (Table 4).

Survival and Branch Instability

The median follow-up of the study was 28 months (IQR 12-47), with no significant differences between study groups (anterior division: median 27 months, IQR 12-47 vs posterior division: median 30 months, IQR 12-50; $P = .64$). The estimates of patient survival and freedom from aneurysm-related mortality at 3 years were 100% vs 87% (Figure 1, log-rank test = .173) and 100% vs 99% (Supplementary Figure 1, log-rank test = .651), for anterior and posterior landing zone, respectively.

The rate of composite IBD branch instability did not show significant differences between patients receiving distal landing in the anterior or posterior division of the IIA (18% vs 13%, $P = .49$) (Table 5), with 3-year rates of freedom from IBD branch instability of 79 and 87% (log-rank test = .215), respectively (Figure 2). On in-depth analysis of branch instability events, no instances of IBD branch disconnection or IBD branch-related rupture were noted (Table 5). Using multivariate Cox proportional hazards model (Supplementary Table 3), embolization of IIA side branches was independently associated with lower risk for IBD branch instability (HR .442, 95%CI .196-.995, $P = .049$), while any 5 mm increase in the aneurysm sac diameter was independently associated with higher risk for IBD branch instability (HR 1.478, 95% CI = [1.069, 2.043], $P = .018$).

The 3-year estimates of IBD patency were significantly lower in patients who received distal landing in the anterior divisional branch as compared to those that received distal landing in the posterior divisional branch (primary patency: 81% vs 96%, log-rank test = .009, Figure 3; secondary patency: 81% vs 97%, log-rank test <.001, Figure 4).

Table 4. 30-Day Outcomes of 171 Patients Treated With Iliac Branch Endoprosthesis (IBE) Using Anterior Versus Posterior Divisional Branches as Leading Zone.

	All patients, n = 171	Anterior division, n = 29	Posterior division, n = 131	[a]Anterior and posterior (bilateral), n = 11	
	n (percent) or mean ± SD (median, IQR)				*P* value[b]
Any complication	22 (13)	4 (14)	18 (14)	0	1.0
30-day or in-hospital mortality	0	0	0	0	—
EBL > 1000 mL	20 (11.7)	3 (10)	17 (13)	0	1.0
New-onset cardiac heart failure	1 (0.6)	0	1 (1)	0	1.0
Myocardial infarction	0	0	0	0	—
Respiratory failure[c]	2 (1.2)	0	2 (1.5)	0	.67
Stroke	0	0	0	0	—
Any spinal cord injury[d]	4 (2.3)	0	4 (3.1)	0	1.0
Paraparesis	2 (1.2)	0	2 (1.5)	0	.63
Paraplegia	2 (1.2)	0	2 (1.5)	0	.63
Acute kidney injury	6 (3.5)	2 (7)	4 (3)	0	.30
New-onset dialysis	2 (1.2)	0	2 (1.5)	0	1.0
Gluteal necrosis	0	0	0	0	—
Bowel ischemia requiring resection	2 (1.2)	0	2 (1.5)	0	1.0
Vascular/access complications	14 (8)	0	14 (11)	0	.065
Any early reintervention	9 (5)	0	8 (6)	1 (9)	.35
IBD-related early reintervention	2 (1)	0	1 (1)	1 (9)	1.0

Abbreviations: EBL, estimated blood loss; EVAR, endovascular aneurysm repair; FBEVAR, fenestrated-branched endovascular aortic repair; IBD, inflammatory bowel disease; IQR, interquartile range.

[a]This group was excluded for comparison only between anterior and posterior landing zones.

[b]p values are comparisons between anterior versus posterior division landing zones only. We are not comparing these 2 groups with patients who had bilateral repair with anterior division landing zone in one side and posterior division landing zone in the other.

[c]Reintubation or prolonged intubation >48 hours.

[d]Two patients with paraparesis had concomitant FBEVAR; 1 patient with paraplegia had concomitant FBEVAR, and 1 patient with paraplegia had concomitant EVAR.

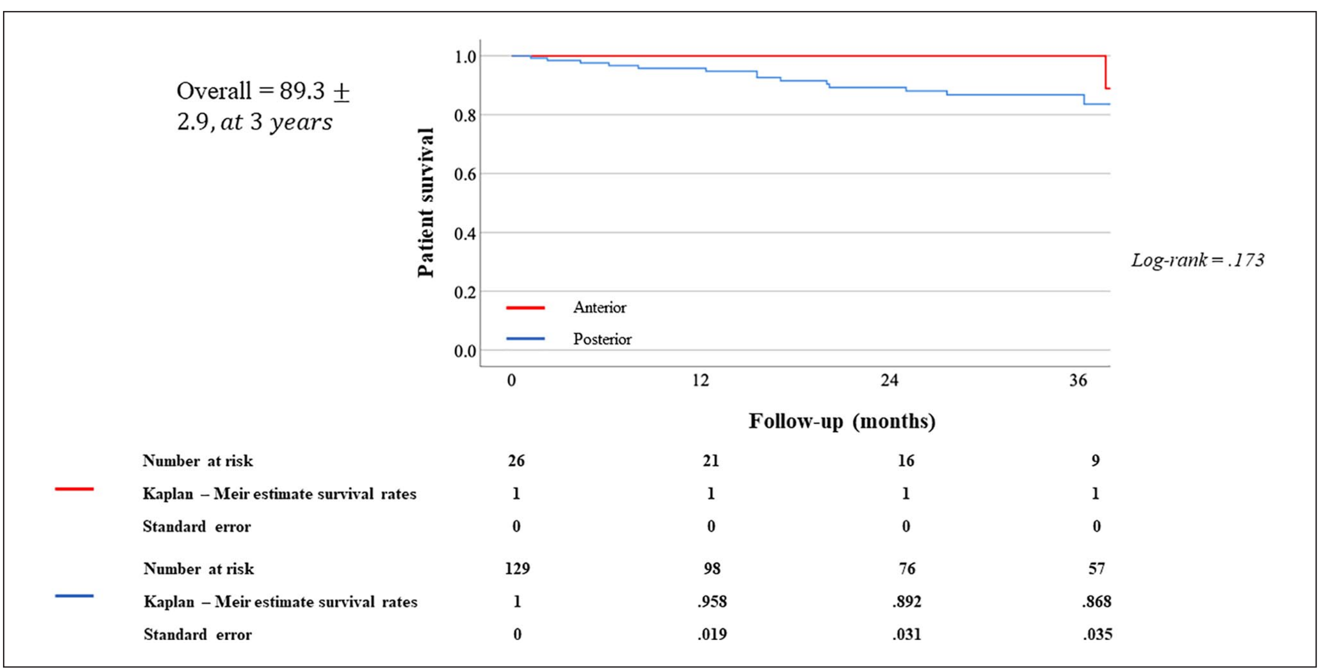


Figure 1. Kaplan-Meier estimates of overall survival (analysis per patient).

Table 5. Branch Instability in 221 Iliac Arteries Treated With Iliac Branch Endoprosthesis (IBE) Using Anterior Versus Posterior Divisional Branches as Leading Zone.

	All IBE, n = 221	Anterior division, n = 40	Posterior division, n = 181	
		n (percent)		*P* value
Any IBE branch instability	31 (14)	7 (18)	24 (13)	.49
IBE occlusion or stenosis	21 (10)	6 (15)	15 (8)	.23
IBE branch disconnection	0	0	0	—
IBE branch-related rupture	0	0	0	—
IBE-related reintervention	17 (8)	1 (3)	16 (9)	.32
IBE-related endoleak	10 (5)	1 (3)	9 (5)	.69
Ib	3 (1)	0	3 (2)	1.0
II	4 (2)	1 (2)	3 (2)	1.0
III	1 (1)	0	1 (1)	1.0
Indeterminate	2 (1)	0	2 (1)	1.0

Abbreviation: IBE, iliac branch endoprosthesis.

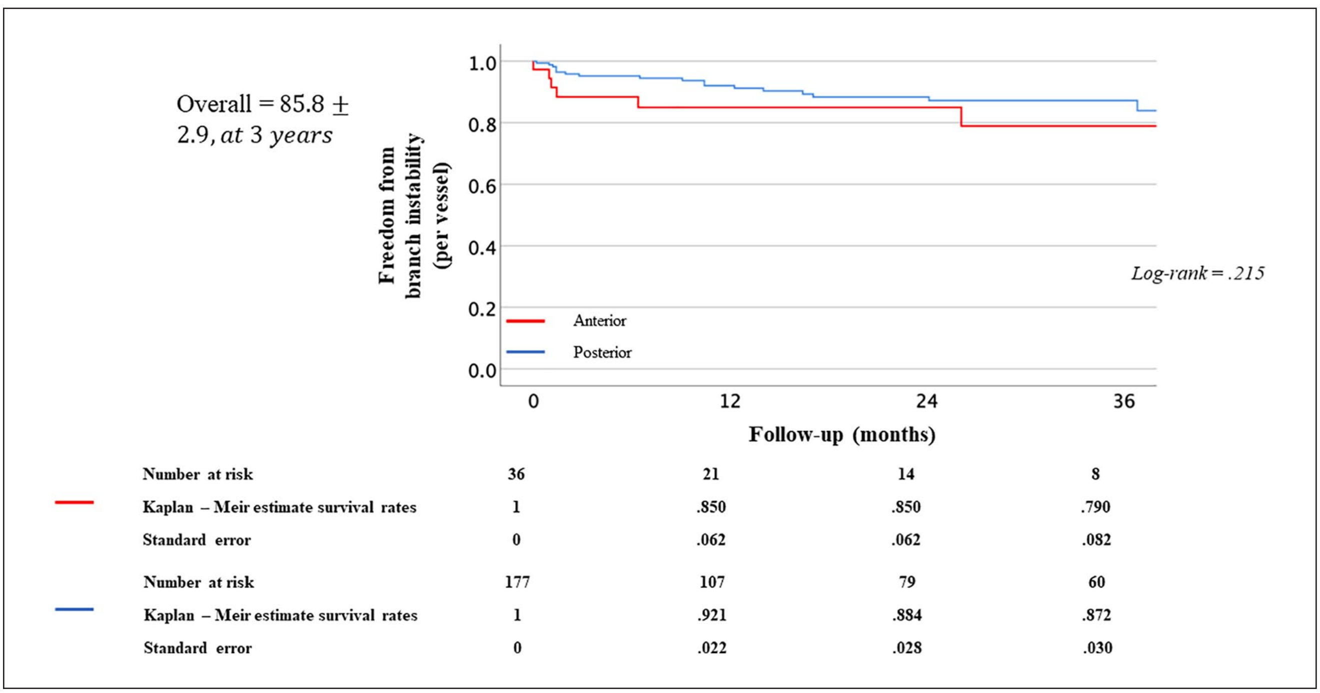


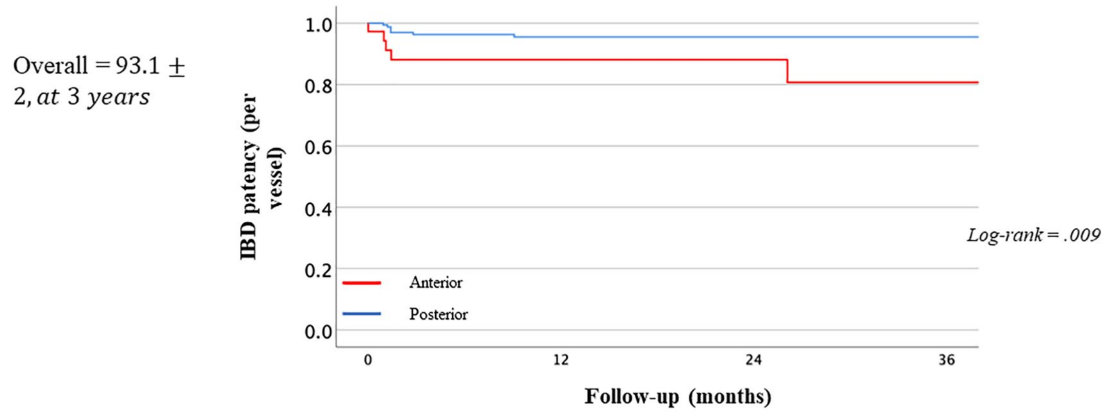
Figure 2. Kaplan-Meier estimates of freedom from branch instability (analysis per vessel).

No significant differences could be found in the 3-year rates of freedom from IBD-related reinterventions (anterior division: 96% vs posterior division: 91%, log-rank test = .287, Figure 5). Seventeen reinterventions were registered, of which only 4 occurred after the first year of follow-up, and all were managed by endovascular means (Supplementary Table II). Also, the 3-year estimates of freedom from IBD-related type I/III endoleak were not significantly different between study groups (anterior division: 100% vs posterior division: 98%, log-rank test = .415, Figure 6).

Sac Changes, Sexual Dysfunction, and Buttock Claudication

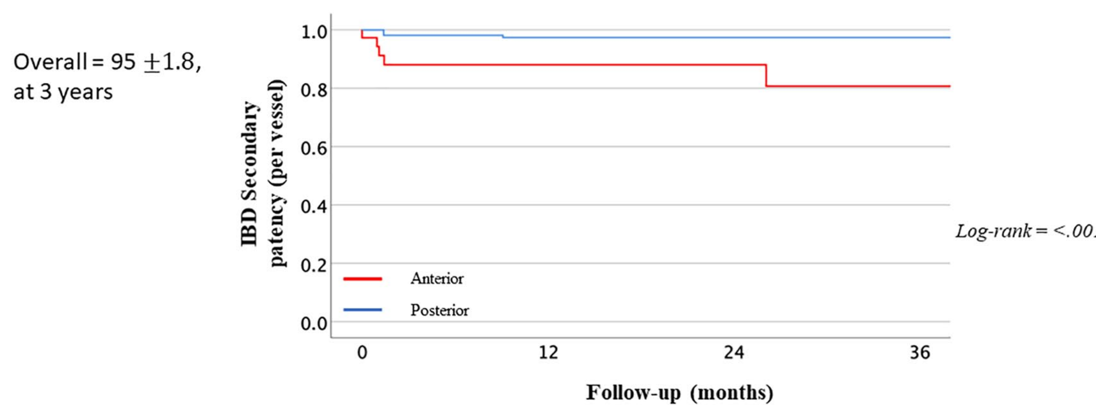
At 3 years, the freedom from iliac sac diameter increase >5 mm was very high in both study groups and did not show significant differences (anterior division: 100% vs posterior division: 99%, P = .642, Supplementary Figure 2).

The 3-year estimates of freedom from sexual dysfunction in male patients were significantly lower in subjects receiving distal landing in the anterior division than in



Anterior (red)	Number at risk	36	20	12	8
	Kaplan – Meir estimate survival rates	1	.881	.881	.807
	Standard error	0	.056	.056	.086
Posterior (blue)	Number at risk	177	107	78	60
	Kaplan – Meir estimate survival rates	1	.955	.955	.955
	Standard error	0	.017	.017	.017

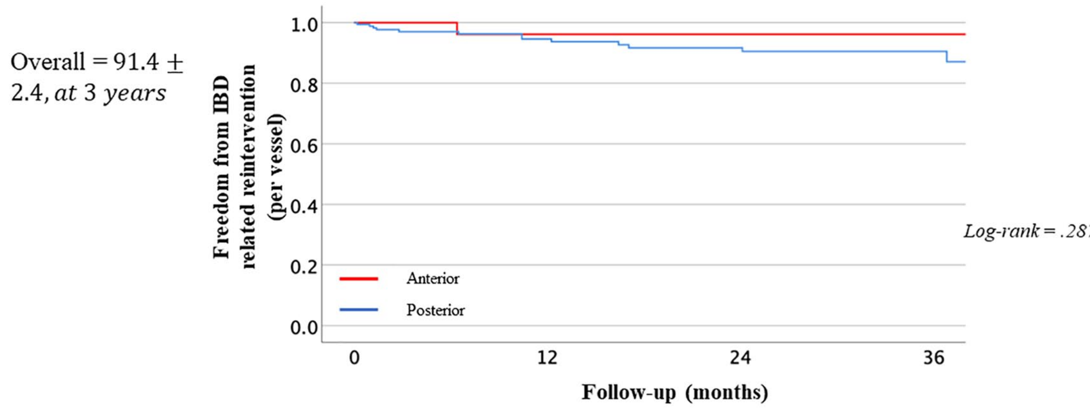
Figure 3. Kaplan-Meier estimates of IBD primary patency (analysis per vessel). IBD, iliac branch device.



Anterior (red)	Number at risk	36	20	12	8
	Kaplan – Meir estimate survival rates	1	.881	.881	.807
	Standard error	0	.056	.056	.087
Posterior (blue)	Number at risk	177	108	78	60
	Kaplan – Meir estimate survival rates	1	.974	.974	.974
	Standard error	0	.013	.013	.013

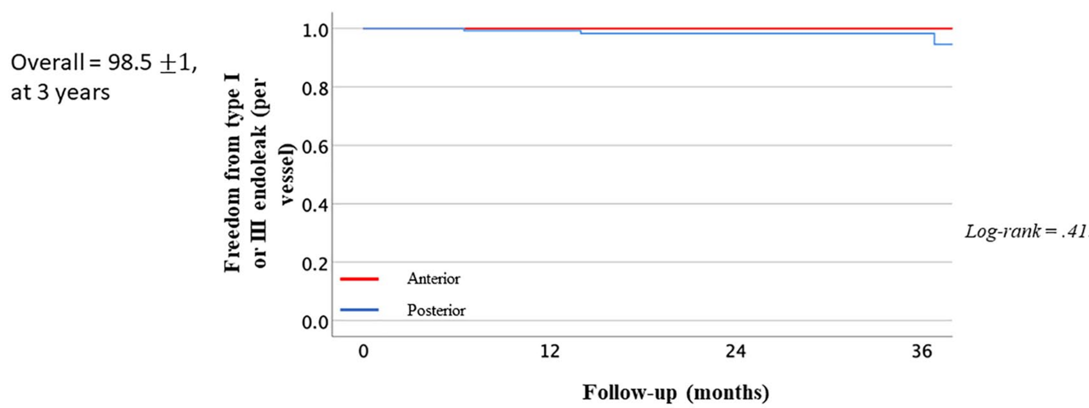
Figure 4. Kaplan-Meier estimates of IBD secondary patency (analysis per vessel). IBD, iliac branch device.

subjects receiving distal landing in the posterior division (89% vs 99%, log-rank test = .02, Supplementary Figure 3). Details of patients who developed sexual dysfunction are reported in Supplementary Table IV. The 3-year estimates of freedom from new-onset buttock claudication, however, were not significantly different between study groups (anterior division: 84% vs posterior division: 98%, log-rank test = .113, Supplementary Figure 4). Details of patients who developed new-onset buttock claudication are reported in Supplementary Table V.



		0	12	24	36
Anterior (red)	Number at risk	36	21	14	8
	Kaplan – Meir estimate survival rates	1	.962	.962	.962
	Standard error	0	.038	.038	.038
Posterior (blue)	Number at risk	177	107	79	60
	Kaplan – Meir estimate survival rates	1	.946	.917	.905
	Standard error	0	.019	.025	.027

Figure 5. Kaplan-Meier estimates of freedom from IBD-related reintervention (analysis per vessel). IBD, iliac branch device.



		0	12	24	36
Anterior (red)	Number at risk	36	21	17	8
	Kaplan – Meir estimate survival rates	1	1	1	1
	Standard error	0	0	0	0
Posterior (blue)	Number at risk	177	107	79	60
	Kaplan – Meir estimate survival rates	1	.992	.983	.983
	Standard error	0	.008	.012	.012

Figure 6. Kaplan-Meier estimates of freedom from IBD-related type I/III endoleak (analysis per vessel). IBD, iliac branch device.

Discussion

The absence of an adequate sealing zone within the CIA is a common limitation to standard EVAR in approximately one-third of the patients.[14] In these cases, the use of an IBD offers preservation of the IIA to avoid complications of pelvic ischemia, buttock claudication, or sexual dysfunction. Iliac branch devices are designed for the purpose of preserving IIA flow and are associated with excellent safety profiles and satisfactory mid-term durability. Current clinical practice guidelines recommend their use for preservation of at least one hypogastric artery.[15]

In fact, IBDs have shown significant benefits as compared to both open surgery[16] or flared iliac limbs[17] (i.e. bell-bottom technique). Nevertheless, involvement of the IIA by aneurysmal disease has limited the use of IBDs. One technique to overcome this challenge is to extend the bridging stent-graft beyond the IIA bifurcation, and within one of the distal branches of the IIA.[18] In the PELVIS registry, the concomitant presence of IIA aneurysms portended worse outcomes following IBD usage.[8] This study has shown that extension of IIA bridging stents into the anterior or posterior divisional branches is safe, feasible, and associated with satisfactory stent-graft-related outcomes.

Further studies that report on landing within divisional branches of the IIA include the one by Simonte et al[19] who reported 9 cases of IBD landing zone in the posterior division in a consecutive series of 157 patients treated with IBD. More recently, Jerkku and colleagues reported 19 patients with landing zone in the posterior division in a series of 46 patients (31.3%),[11] D'Oria and others reported 25 procedures in a total of 85 operations (29.4%),[10] and finally Dueppers and coworkers reported the results of 18 IIA aneurysms treated with IBD whose distal landing zone was in divisional branches in 14 patients.[12]All the above-mentioned studies have confirmed similar profiles of safety, feasibility, and efficacy when divisional branches were used to achieved distal landing zone during IBD procedures. Based on these reports, the unavailability of a suitable distal landing zone within the main hypogastric trunk should not exclude patients from IBD repair.

However, current literature so far has not addressed outcomes of different IIA divisional branches as distal landing zone for bridging covered stents in IBD interventions. Therefore, the focus of this study, was the comparison of clinical and technical outcomes of IBD that were implanted with distal landing in the anterior versus the posterior divisional branches of the IIA. In the current series, the posterior divisional branch was the more frequent artery chosen as distal landing zone in cases requiring extension of repair beyond the hypogastric bifurcation, but technical success remained satisfactorily high in the entire study cohort. Although the freedom from the composite endpoint of branch instability was not significantly different between study groups, patency rates (both primary and secondary) showed a trend that seemed to favor the posterior divisional branch of the IIA. Notably, most IBDs that lost their patency did so within the first year of follow-up, which confirms the established notion that, provided proper placement and good run-off, durability of these devices can be expected even when placed within complex anatomies.[20]

While no strong inferences can be made regarding the reasons that led the physicians to choose preferentially the posterior divisional branch, some assumption can still be reasonably made. In that regard, Jerkku and colleagues explained their preference for the posterior divisional branch as landing zone because the anterior division of the IIA seems to be collateralized better than iliolumbar and lateral sacral divisions.[11]A possible explanation might also be to avoid the most frequent complication after IIA occlusion, which is buttock claudication. Indeed, our results in terms of buttock claudication and sexual dysfunction correlate with the choice of the target vessel: buttock claudication was less frequent when landing posterior divisional branch (2% vs 16%), and sexual dysfunction was also less frequent when landing in posterior divisional branches (1% vs 11%). Although the differences in the rates of such adverse events were not statistically significant (likely owing to the small number of events), they may warrant further prospective studies.

In this study, the amount of iodinated contrast medium that was used (165 ml vs 109 ml) and the mean fluoroscopy time of the procedures (64 min vs 45 min) were significantly higher for patients receiving IBD implantation in the posterior divisional branch, as compared to subjects who received IBD implantation in the anterior divisional branch. Although caution should be exercised before drawing conclusions, these data could reflect an increased technical complexity of the procedure when the operators selected the superior gluteal artery as distal landing zone. Indeed, the need for additional embolization of collateral vessels was higher in the posterior division group (55% vs 13%), and this technical detail may explain the differences in the above-mentioned technical parameters. Indeed, patent side branches may contribute to type 2 EL and aneurysmal sac increase during follow-up.[21] Therefore, it is common practice to embolize these branches at time of index operation, when this adjunctive maneuver is relatively straightforward rather than at later times when it would prove extremely challenging if not unfeasible (Supplementary Figures 5 and 6).

The choice of bridging covered stent is evolving including self-expanding (SECS), balloon-expandable (BECS), or a combination thereof. Although in the univariate analysis branch instability was more frequent when BECS were used (OR 2.88, P = 005), this association disappeared in the multivariate analysis. Recently, Wanhainen et al[22] analyzed the outcomes of different kind of bridging stent-graft(s) in 747 IBD implanted in the PELVIS registry and did not find any significant differences at a mean follow-up of 5 years in the rates of primary patency (99% SESG vs 91% BESG at 62 months) nor freedom from reinterventions (83% SESG vs 80% BESG). Further research will be needed to elucidate how different stents may behave in these anatomical scenarios, and understand whether certain morphologic conditions should indicate preference toward a particular device. As also shown from the present data set, IBD can be used in combination with fenestrated-branched EVAR,[23] in stand-alone configuration,[24,25] after prior EVAR (using either an upper arm access, the up-and-over technique, or with the help of a steerable sheath),[26–28] and also bilaterally in selected patients.[29–32]Therefore, extension of the distal landing zone beyond the hypogastric bifurcation should be seen as a feasible option whenever placement of IBD is indicated, and can contribute to a significant broadening in the indications for repair using these devices.

Study Limitations

The findings from this study must be interpreted within the context of its limitations. First, this was a retrospective study, thereby intrinsically prone to bias, and core lab imaging assessment was not performed. For instance, no details could be ascertained as to why the anterior or posterior branch was selected as distal landing zone. Although the sample size was relatively large and extracted from a contemporary multicentric data set, coupled with a relatively long follow-up duration, it is possible that absence of statistically significant differences in some of the outcomes reported could reflect a type II error. Also, sexual dysfunction and buttock claudication, although assessed in the present study, are difficult to extrapolate without a prospective study design. Since all participating investigators were highly experienced in complex endovascular aortic procedures, the results from this study might not be automatically extrapolated to other centers. Although we tried to account for known confounders using robust multivariate analyses, it is still possible that some unmeasured confounders have remained. Finally, whether these more complex procedures would require different drug regimens (e.g. dual antiplatelet therapy) or stricter follow-up protocols still remain unanswered questions that will need further research.

Conclusions

The use of the anterior or posterior divisional branches of the IIA as distal landing zone for IBD implantation shows comparable profiles in terms of immediate technical success, perioperative safety, and side-branch instability up to 3 years. However, IBD patency at 3 years was higher when the distal landing zone was achieved within the posterior divisional branch of the IIA. Future studies are warranted to highlight whether specific anatomical features may favor the anterior over the posterior branch for distal landing beyond the main hypogastric trunk.

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.

ORCID iDs

Mario D’Oria https://orcid.org/0000-0002-7156-7827
Nuno Dias https://orcid.org/0000-0002-6907-6148
Tilo Kolbel https://orcid.org/0000-0002-9962-0204
Emanuel R Tenorio https://orcid.org/0000-0002-9128-6256

Supplemental Material

Supplemental material for this article is available online.

References

1. Chaikof E, Dalman RL, Eskandari M, et al. The society for vascular surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *J Vasc Surg*. 2018;67:2–77.
2. Wanhainen A, Verzini F, Van Herzeele I, et al. European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg*. 2019;57:8–93.
3. D’Oria M, Mastrorilli D, DeMartino R, et al. Current status of endovascular preservation of the internal iliac artery with Iliac Branch Devices (IBD). *Cardiovasc Intervent Radiol*. 2019;42(7):935–948.
4. D’Oria M, Mendes BC, Bews K, et al. Perioperative outcomes after use of iliac branch devices compared with hypogastric occlusion or open surgery for elective treatment of aortoiliac aneurysms in the NSQIP database. *Ann Vasc Surg*. 2020;62:35–44.
5. Giosdekos A, Antonopoulos CN, Sfyroeras GS, et al. The use of iliac branch devices for preservation of flow in internal iliac artery during endovascular aortic repair. *J Vasc Surg*. 2020;71:2133–2144.
6. Karthikesalingam A, Hinchliffe RJ, Malkawi AH, et al. Morphological suitability of patients with aortoiliac aneurysms for endovascular preservation of the internal iliac artery using commercially available iliac branch graft devices. *J Endovasc Ther*. 2010;17(2):163–171.
7. Pearce BJ, Varu VN, Glocker R, et al. Anatomic suitability of aortoiliac aneurysms for next generation branched systems. *Ann Vasc Surg*. 2015;29(1):69–75.
8. Donas KP, Taneva GT, Pitoulias GA, et al. Coexisting hypogastric aneurysms worsen the outcomes of endovascular treatment by the iliac branch devices within the pELVIS registry. *J Vasc Surg*. 2019;69(4):1072–1079.
9. D’Oria M, Tenorio ER, Oderich GS, et al. Outcomes of the gore excluder iliac branch endoprosthesis using division branches of the internal iliac artery as distal landing zone. *J Endovasc Ther*. 2020;27:316–327.
10. Jerkku T, Mohammed WM, Kapetanios D, et al. Extension of iliac branch device repair into the superior gluteal artery is a safe and effective maneuver. *Ann Vasc Surg*. 2020;62:195–205.
11. Dueppers P, Duran M, Floros N, et al. The JOTEC iliac branch device for exclusion of hypogastric artery aneurysms: ABRAHAM study. *J Vasc Surg*. 2019;70(3):748–755.

12. D'Oria M, Pipitone M, Sgorlon G, et al. Endovascular exclusion of hypogastric aneurysms using distal branches of the internal iliac artery as landing zone: a case series. *Ann Vasc Surg*. 2018;46:369.e13–369.e18.
13. Chaikof EL, Blankensteijn JD, Harris PL, et al. Reporting standards for endovascular aortic aneurysm repair. *J Vasc Surg*. 2002;35:1048–1060.
14. Parlani G, Zannetti S, Verzini F, et al. Does the presence of an iliac aneurysm affect outcome of endoluminal AAA repair? An analysis of 336 cases. *Eur J Vasc Endovasc Surg*. 2002;24(2):134–138.
15. Wanhainen A, Verzini F, Van Herzeele I, et al. Editor's choice—European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg*. 2019;57(1):8–93.
16. Mendes BC, Oderich GS, Sandri GA, et al. Comparison of perioperative outcomes of patients with iliac aneurysms treated byb open surgery or endovascular repair with iliac branch endoprosthesis. *Ann Vasc Surg*. 2019;60:76–84.
17. Pini R, Faggioli G, Indelicato G, et al. Early and late outcome of common iliac aneurysms treated by flared limbs or iliac branch devices during endovascular aortic repair. *J Vasc Interventi Radiol*. 2019;30:503–510.
18. Kliewer M, Plimon M, Taher F, et al. Endovascular treatment of hypogastric artery aneurysms. *J Vasc Surg*. 2019;70: 1107–1114.
19. Simonte G, Parlani G, Farchioni L, et al. Lesson learned with the use of iliac branch devices: single centre 10 year experience in 157 consecutive procedures. *Eur J Vasc Endovasc Surg*. 2017;54(1):95–103.
20. Parlani G, Verzini F, De Rango P, et al. Long-term results of iliac aneurysm repair with iliac branched endograft: a 5-year experience on 100 consecutive cases. *Eur J Vasc Endovasc Surg*. 2012;43(3):287–292.
21. D'Oria M, Mastrorilli D, Ziani B. Natural history, diagnosis, and management of type II endoleaks after endovascular aortic repair: review and update. *Ann Vasc Surg*. 2020;62:420–431.
22. Verzini F, Parlani G, Varetto G, et al. Late outcomes of different hypogastric stent grafts in aortoiliac endografting with iliac branch device: results from the pELVIS registry. *J Vasc Surg*. 2020;72(2):549–555.
23. Spanos K, Kolbel T, Scheerbaum M, et al. Iliac branch devices with standard vs fenestrated/branched stent-grafts: does aneurysm complexity produce worse outcomes? Insights from the pELVIS registry. *J Endovasc Ther*. 2020;27(6):910–916.
24. Giaquinta A, Ardita V, Ferrer C, et al. Isolated common iliac artery aneurysms treated solely with iliac branch stent-grafts: midterm results of a multicenter registry. *J Endovasc Ther*. 2018;25(2):169–177.
25. D'Oria M, Tenorio ER, Oderich GS, et al. Outcomes after standalone use of Gore Exclude Iliac Branch Endoprosthesis for endovascular repair of isolated iliac artery aneurysms. *Ann Vasc Surg*. 2020;67:158–170.
26. D'Oria M, Chiarandini S, Pipitone M, et al. Urgent use of Gore Excluder Iliac Branch Endoprosthesis with left transaxillary approach for preservation of the residual hypogastric artery: a case series. *Ann Vasc Surg*. 2018;51:326.e17–326.e21.
27. Tenorio ER, Oderich GS, Sandri GA, et al. Outcomes of an iliac branch endoprosthesis using an "up and over" technique for endovascular repair of failed bifurcated grafts. *J Vasc Surg*. 2019;70(2):497–508.
28. Oberhuber A, Duran M, Ertas N, et al. Implantation of an iliac branch device after EVAR via a femoral app-roach using a steerable sheath. *J Endovasc Ther*. 2015;22:610–612.
29. Marques de Marino P, Botos B, Kouvelos G, et al. Use of bilateral cook Zenith Iliac Branch Devices to preserve internal iliac artery flow during endovascular aneurysm repair. *Eur J Vasc Endovasc Surg*. 2019;57(2):213–219.
30. Maldonado TS, Mosquera NJ, Lin P, et al. Gore Iliac Branch Endoprosthesis for treatment of bilateral common iliac artery aneurysms. *J Vasc Surg*. 2018;68(1):100–108.
31. D'Oria M, Pitoulias GA, Torsello GF, et al. 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 [published online ahead of print May 17, 2021]. *J Endovasc Ther*. doi:10.1177/15266028211016439.
32. D'Oria M, Tenorio ER, Oderich GS, et al. Outcomes of unilateral versus bilateral use of the iliac branch endoprosthesis for elective endovascular treatment of aorto-iliac aneurysms. *Cardiovasc Intervent Radiol*. 2022;45(7): 939–949. doi:10.1007/s00270-022-03166-3.