Results of the multicenter pELVIS Registry for isolated common iliac aneurysms treated by the iliac branch device

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Multicenter Experience from the pELVIS Registry Shows That Hypogastric Aneurysms Worsen the Outcomes of Endovascular Treatment by the Iliac Branch Devices

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Two Sentence Summary for Table of Contents In the first concise sentence please state the study design and the most important finding of this manuscript. In the second sentence state the most important conclusion. If accepted for publication, this summary will appear on the table of contents under the title of your article. **Example 1:** Intercostal artery reimplantation did not significantly decrease spinal cord injury in this retrospective study of 805 patients with open repair of TAAs and TAAAs. The authors suggest physiologic interventions to reduce the rate of spinal cord ischemia.	The present multicentric and retrospective analysis of 804 patients showed worse outcomes of Iliac and Aortoiliac aneurysms treated by the Iliac Branch Devices in coexistence with hypogastric aneurysms. The authors suggest lengthening the distal sealing zone into the normal hypogastric artery or one of its main branches to improve the outcomes.

Example 2: This retrospective multicenter study analyzed presentation, etiology, management and outcome of 32 patients with post-EVAR aorta-enteric fistula (AEF). The study suggests that AEF is more frequent after EVAR performed for pseudoaneurysm or emergency and that treatment is associated with high mortality.	

Coexisting hypogastric aneurysms worsen the outcomes of endovascular treatment by the iliac branch devices within the pELVIS Registry

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Keywords: Hypogastric aneurysms, internal iliac artery, iliac branch device, bridging stent-graft, endovascular aneurysm repair

Abstract:

OBJECTIVE: Hypogastric aneurysms (HAs) frequently coexist with aorto-iliac aneurysms (AIAs). However, the presence of a HA is a contraindication for endovascular aneurysm treatment by iliac branch devices (IBDs) due to the risk of distal sealing-related endoleaks. However, no robust evidence exists in the published literature and therefore, we sought to evaluate the performance of the IBDs in the presence of HAs within a multicenter registry of 9 vascular centers.

METHODS: Clinical and radiographic information on 804 patients with AIAs treated by IBDs was retrospectively reviewed and analyzed using prearranged, defined and documented protocols. The treatment period was between January 2005 and April 2017.

RESULTS: HA was present in 315 (32.6%) of the overall 910 deployed IBDs. Mean radiological follow-up was 32 months. The incidence of incomplete aneurysm exclusion and type I endoleak was 3% in the HA group vs. 0.7% in the non-HA group (p=.019). The 5-year freedom from IBD-related type I endoleak was 93% vs. 98% in the HA group vs. the non-HA group, respectively (p=.006). Subgroup analysis of the HA group revealed that use of a single distal bridging stent-graft vs multiple bridging devices led to higher rate of type I endoleak (9.6% vs. 2.8%, p=0.031), branch occlusions (8.3% vs. 0.9%, p=.009) and buttock claudication (7.6% vs. 1.9%, p=.038).

CONCLUSIONS: The present series of AIAs with HAs is the largest reported. It shows that HAs coexisting with AIAs, when treated with IBDs, have significantly worse outcomes. Lengthening the distal landing zone with more than one bridging stent-graft into the distal healthy hypogastric artery or one of its main branches improves outcomes.

Introduction

Use of iliac branch devices (IBDs) for the treatment of aneurysms involving the iliac bifurcation (AIAs) has widely increased in the past years. Several studies reported favorable outcomes[1-8] and comparable to the open repair results.[9,10] The main benefit remains the exclusion of the aneurysms maintaining simultaneously the perfusion of the hypogastric artery. However, up to 29% of the AIAs present with a coexistent hypogastric aneurysm (HA).[10] According to the instructions for use, HA represents a contraindication and off-label condition in case of endovascular repair by IBDs, due to the risk of distal sealing-related endoleaks.[11] Consequently, the published evidence about the performance of IBDs in coexistence of a HA is scarce, including treatment of less than 20 patients.[12,13]

The aim of the present study was to analyze the data of a multicenter registry including more than 800 treated patients focusing on the performance of IBDs in the presence of HAs.

Methods

Study Design

Data collection and inclusion criteria have been previously described.[1] The study complied with the principles of the Declaration of Helsinki. Data collection was approved by the local ethics committee. Patient demographics, risk factors, and outcomes were collected according to the reporting standards of the Society for Vascular Surgery.[14] All patients provided informed consent for treatment by IBD.

Participating centers (Appendix) were required to have performed at least 30 IBD implantations. Data on clinical status, duplex ultrasound imaging, and computed tomography angiography (CTA) and/or magnetic resonance angiography (MRA) were predefined between the different centers and collected for each included patient.[15] Follow-up data referred for events during the in-hospital stay and the postoperative last available radiological imaging. The clinical and radiological data were analyzed as to comorbidities, aneurysm morphology, intraoperative variables. The primary endpoints were patency of the bridging devices, presence of endoleaks and secondary endpoints were procedure-related reinterventions, migrations and pelvic ischemia.

Sample

All included patients were candidates deemed to be at high risk for open surgical repair. Use of an IBD was the preferable, first-line endovascular treatment for a >24-mm-diameter aneurysm involving the iliac bifurcation as suggested by Verzini et al.[4] All commercially available IBDs were included.

Follow-up Imaging

Radiological imaging during follow-up included CTA postoperatively, at 12 months, and then annually. Duplex ultrasound examination was performed 6 months postoperatively or in case of renal insufficiency and contraindication to MRA. All included patients had at least one CTA or MRA postoperatively.

Definitions

Surgical high-risk patient was defined as >3 serious cardiovascular comorbidities, such as chronic obstructive pulmonary disease, congestive heart failure, coronary artery occlusive disease, American Society of Anesthesiologists score ≥3, previous myocardial infarction, coronary artery stent or bypass, and redo cases (previous abdominal aortic repair). Details about outcomes stemming from other concurrent strategies at each individual center were not evaluated.

A hypogastric artery with diameter greater than 12mm was defined as HA and in that case implantation of an IBD was considered “off-label” condition.

Pelvic ischemia was determined by the presence of buttock claudication, colon ischemia or erectile dysfunction notified during the follow-up period.

Patency of the common, internal and external iliac arteries was described as the absence of thrombosis assessed using either CT or duplex imaging. A high-grade stenosis was defined by a duplex-derived >2.5 peak systolic velocity ratio or >50% (>70%) luminal narrowing on CT.

IBD-related secondary procedures referred to reintervention caused by high-grade (>70%) stenosis or occlusion of the bridging device, type I/III endoleak, migration or rupture based on CT scan and confirmed by angiography.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics (version 24.0; IBM Corporation, Somers, NY, USA). Continuous data are presented as means ± standard

deviation. Anatomical data due to normal distribution compared using the paired T-students test. Categorical data are given as the counts (percentage and n) and between or in-subgroup analysis was based in Pearson's Chi-square test. Statistical significance was set at level <.05. Kaplan-Meier analysis was used to estimate primary IBDs patency, freedom from IBD-related type I endoleak and secondary interventions.

Results

Retrospective evaluation of prospectively collected records from 804 high-risk patients (mean age 72.1 ± 8.6 years; 768 men) with AIAs, who were treated with placement of 910 IBDs between January 2005 and April 2017 was performed. In 96 patients, a placement of IBD was implanted bilaterally as one-stage procedure and in 10 cases the contralateral IBD was implanted at a later time. HA was present in 264 patients who underwent overall placement of 315 IBDs, representing the 34.6% of the overall used endografts. Table I presents the baseline patient characteristics and aneurysm details. Mean radiological follow-up was 32.6±9.9 months by computed tomography angiography (CTA) or magnetic tomography angiography (MRA).

Early results (<30-day)

Mean hospital stay was 8.1 ± 6.7 days. The 30-day mortality and morbidity were 0.5% (n=4) and 8.8% (n=71), respectively. The reasons for 30-day complications was peripheral embolization (DE, 1.8% - n=15), infectious pneumonia (IP, 1.7% - n=14) and myocardial infarction (MI, 1.2% - n=10). Moreover, MI (n:2) and IP (n:2) were the etiological factors for the early mortality.

Midterm results

The overall IBD-related mortality was 1.2% (9 patients) while the total mortality during the follow-up period was 13.7% (110 patients). Table II presents an overview of the etiology of all recorded deaths and the mid-term results of the entire study cohort. Persistent IBD-related type I endoleak was observed in 2.1% (n=17) of the cases. The rate of IBD-related migration was 0.7% (n=6). Overall, IBD-related reinterventions were performed in 13.7% (n=110) of the cases, while 9 patients (1.1%) required an open surgery conversion to restore vessels patency. The mean aneurysmal sac and treated vessels diameters were significantly decreased during the follow-up period (p<.001,

Table III).

Treatment of aneurysmatic hypogastric arteries (Table IV) revealed to have significantly greater prevalence of pelvic ischemia, especially in terms of buttock claudication. In detail, the incidence of buttock claudication in the HA group was 5.3% (n=14) vs 2.2% (n=12) in the non-HA group (p=.019), respectively. Additionally, survival free from IBD-related mortality and absence of evidence of pelvic ischemia was significantly lower in the HA subgroup (93.2% vs. 98.0%, p=.027). IBD-related migrations rate was 1.9% (n=5) versus 0.2% (n=1) between HA-group and the non-HA subgroup (p<.001), respectively. The incidence of insufficient aneurysm exclusion due to type Ib endoleak from the ipsilateral hypogastric artery was 3% (n=8) in the HA group vs. 0.7% (n=4) in the non-HA group (p=.019). Table IV shows the used bridging devices combination for the pELVIS Registry cohort of patients. More than one balloon expandable covered stent was used in 49%(154 IBDs) of the cases, combination of balloon expandable with self-expanding in 22%(69 IBDs) and use of only self expanding stents in 29.2% (92 IBDs).

The estimated 5-year primary patency was not different between subgroups (94.0% for both cohorts, p=.405, Figure 1). The cumulative 5-year freedom from IBD-related type I endoleak was significantly lower in the HA subgroup compared with the non HA group (93% vs. 98% respectively, p=.006, Figure 2). The estimated 5-year freedom from IBD-related reinteventions was 72% vs 81% in the HA subgroup and non HA group, resepctively (p=.088, Figure 3).

HA Subgroup analysis

Mean follow-up of HA subgroup was of 27.8 ± 25.8 months. The 30-day morbidity and mortality rates were 11.3% (n=30 patients) and 0.4% (n=1 patient), respectively. Similarly, with the entire cohort of the IBD series, main causes for early complications were the PE (3.0%, n=8), IP (2.3%, n=6) and MI (1.9%, n=5).

The total mortality was 9.8% (n=26) during the follow-up period while the total IBD-related mortality in the HA subgroup was 0.8% (n=2). Analysis of evolution of aneurysmal sac and of treated vessels diameters showed significant decrease during the follow-up period (p = .055 and p<.001, table III).

Table V summarizes the mid-term results of the 315 placements of IBDs in the Has group. A single bridging stent-graft for the hypogastric artery was used in 177 (56.2%) HAs and multiple stent-grafts in 138 (43.8%) cases. A higher rate of buttock

claudication was observed in the single vs the multiple stent-graft group (6.8% vs. 1.5%, p=.038), respectively. Additionally, the occlusion or high-grade stenosis in the first group was higher (7.3% vs. 0.7%, p=.009). Survival analysis (figure 4) confirmed that the cumulative 5-year freedom from IBD-related type I endoleak rate was higher in the multiple bridging stent group (100.0% vs. 88.0%, p=.012), while in primary patency the estimated difference, also in favor of the multiple stents, was not significant (99.0% vs 90.0%, p =.036)

The mean total length of used stent-grafts to restore successfully the patency was 77.0 ± 34.3 mm (range 22 – 177mm). We observed more occlusions (6.9% vs 1.4%, p=.028) and IBD-related endoleak (5.7% vs 0.0%, p=.002) in lengths less than 77mm. Figure 5 shows the estimated 5-year freedom from type I endoleak for single vs multiple bridging stent-grafts (100.0% vs 88.0%, p=.007).

Discussion

The present article enclosing 12-year experience with IBDs of 9 European vascular centers represent the largest reported series in the literature. The high effectiveness, low mortality and complication rates reported in this study confirm the safety and feasibility of IBDs. Our mid-term radiological follow-up denoted a low evidence of persistent type I endoleaks and device migration, reflecting also reproducible midterm results.[1-8] The prevalence of HA was noted in more than one third part of the IBD-treated patients and revealed significantly higher rate of buttock claudication, type I endoleak and stenosis/thrombosis of the branch when using a single covered stent compared to multiple covered stents deployment in the aneurysmatic artery. Also, it seems that covering less than 77mm of IIA in the presence of HA showed worse outcomes in terms of patency and IBD-related endoleaks.

Consequently, there is a need to create sufficient landing zone in the distal normal IIA or one of its branches in order to optimize the results of IBDs in presence of HAs. In that sense, the employed bridging devices and technique are paramount to warrant sufficient and durable sealing in the IIA.

To our knowledge, there are only two published studies of less than 20 patients each, describing the use of IBD in HAs. Due to the limited number of included patients (n:15 and n:16)[11,16] vs the 264 patients of our Registry, no report evaluating profoundly on the impact of HA in the IBD outcomes existed up to now in the literature. The

Münster group described a technique for a sufficient peripheral sealing zone in coexisting HAs.[12] The use of a proximal balloon expandable covered stent (BECS) was preferred to stabilize the bridging device in the internal branch of the IBD. Additionally, a self-expanding covered stent (SECS) was deployed distally in the posterior trunk of the IIA to improve the transition in mainly kinked hypogastric arteries, creating a landing zone of at least 2cm in a healthy segment. Finally, a bare metal self-expanding stent was used to reline the transition between the bridging devices. This technique seemed to be successful for this small sample size providing good mid-term patency.[16] Later, Noel-Lamy et al. reported also their outcomes in 15 patients treated with IBDs and coexisting HAs[11]. The Canadian group used only SECS component as bridging device and extended into the superior gluteal artery without relining the stents. The preliminary results were encouraging.

The used techniques in the pELVIS Registry varied among the centers. We observed mainly 3 options; the two of them were similar to the Münster and the Canadian group, but there was also a third option of deploying 2 or more BECS in the hypogastric artery. This last one was the preferable technique in the majority of reported IBDs in our cohort. Due to the heterogeneity, we did not perform a multivariate analysis to evaluate the impact of each technique on the outcomes. However, we noted a trend to more complications and events in the combination of BECS vs the other two therapeutic options. One possible explanation for that remains the fact that the used BECS are rigid and inappropriate to adapt and conform in angulated hypogastric arteries. There is a risk of device separation and a possible consequent rupture of the aneurysm. Contrariwise, the combined placement of balloon expandable and self-expanding covered stents enables stability and flexibility.

Limitations

The study has a retrospective design and the analysis was based on self-reported data with absence of Core Lab evaluation. Despite the mid-term radiological evidence of the findings in more than 800 patients, there was heterogeneity in the sequence of radiological follow-up protocols in the centers.

Conclusion

The present series of AIAs with HAs is the largest reported. It shows worse results of IBDs when IAAs coexist with HAs, especially in case of using a single bridging

device. Creating a sufficient distal sealing zone using more than one bridging stent-graft into the distal normal hypogastric artery or one of its main branches seems to be a paramount condition to optimize the results.

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Figure 1A. On vs off- label. Patency

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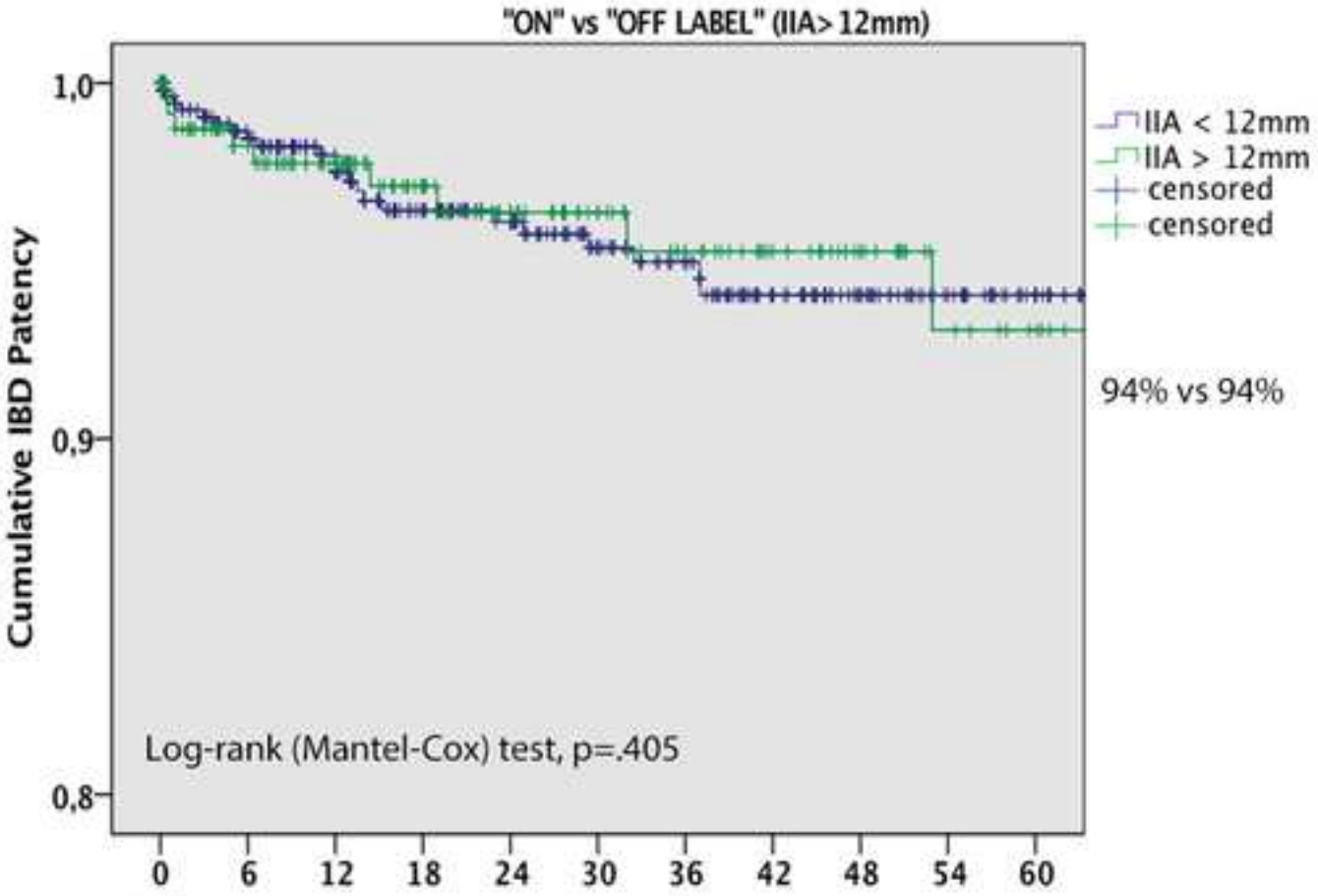
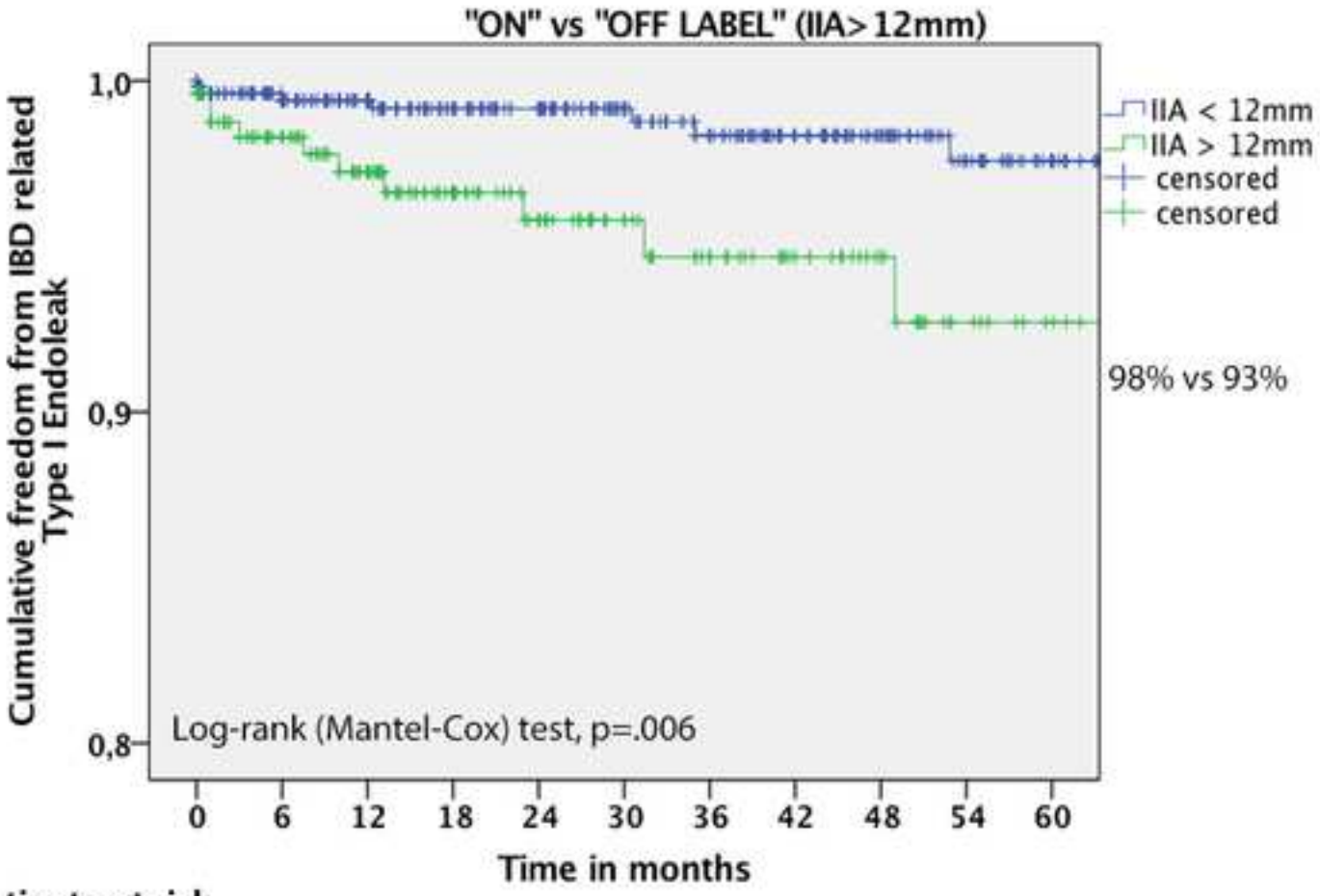


Patients at risk						
IIA<12mm:	540	401	297	217	143	97
Std error:	.01	.01	.01	.01	.01	.01
IIA>12mm:	264	178	119	81	55	37
Std error:	.01	.01	.01	.02	.03	.03
IBDs at risk						
IIA<12mm:	595	420	310	219	145	99
Std error:	.01	.01	.01	.01	.01	.01
IIA>12mm:	315	206	136	94	64	43
Std error:	.01	.01	.01	.02	.02	.02

Figure 1B. On vs off-label. IBD-related endoleaks

Click here to download Figure Figure 1B. On vs off-label. IBD-related endoleaks



Patients at risk

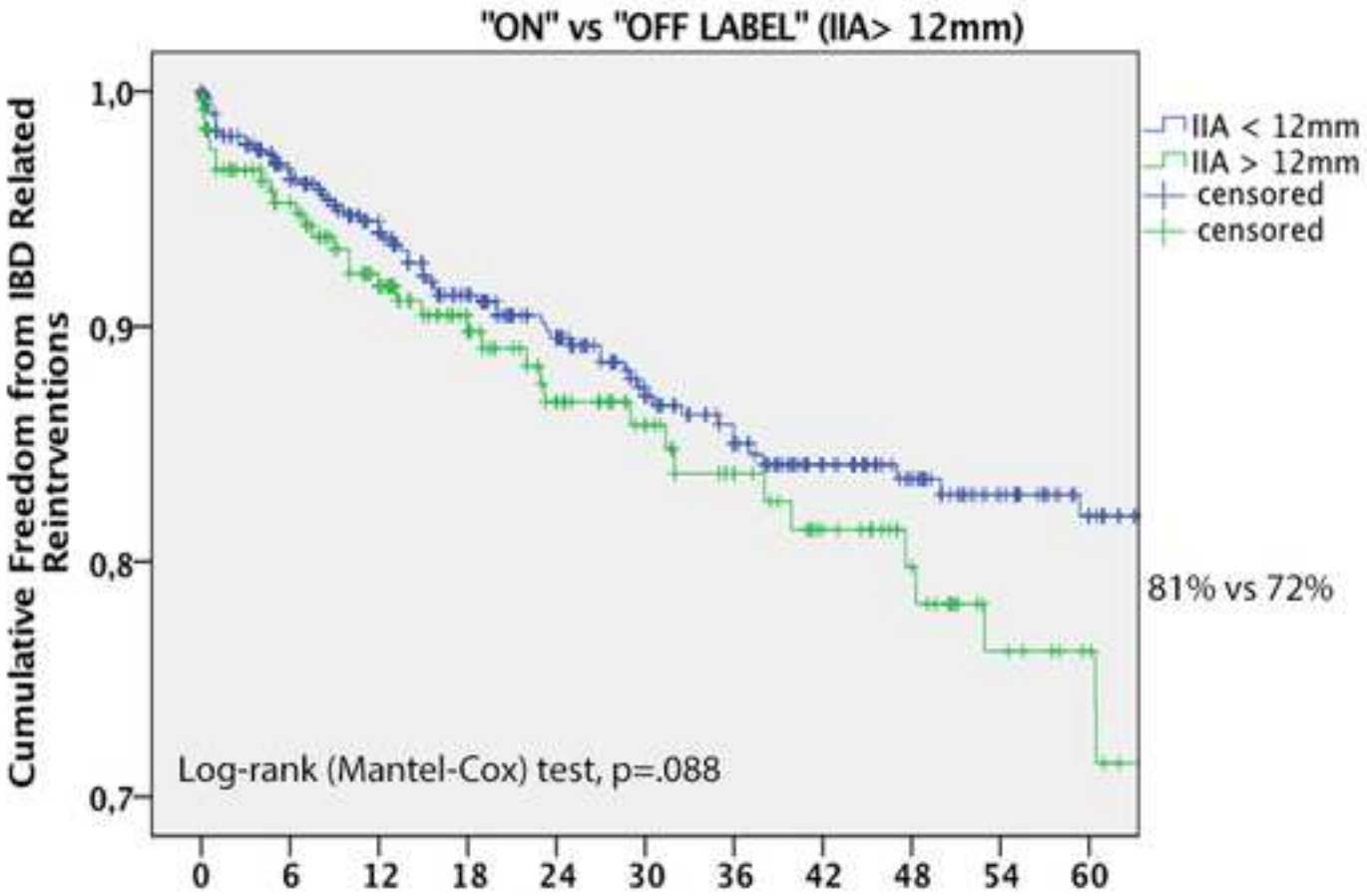
IIA<12mm:	540	405	311	230	156	102
Std error:	.00	.00	.01	.01	.01	.01
IIA>12mm:	264	174	113	77	51	31
Std error:	.01	.01	.01	.02	.03	.03

IBDs at risk

IIA<12mm:	595	429	329	237	159	105
Std error:	.00	.00	.01	.01	.01	.01
IIA>12mm:	315	203	131	92	62	38
Std error:	.01	.01	.01	.02	.02	.02

Figure 1C. On vs off-label. Reinterventions

Click here to download Figure Figure 1C. On vs off-label. Reinterventions

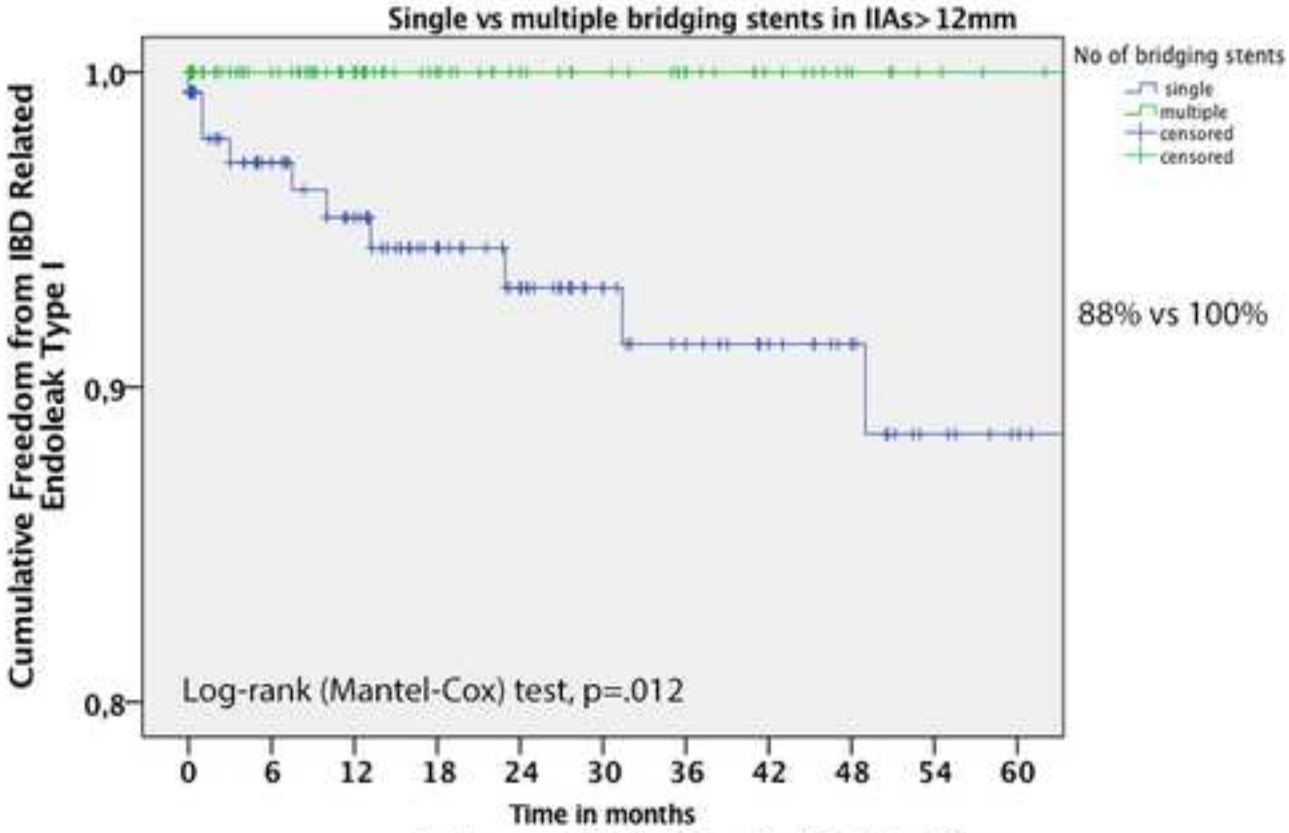


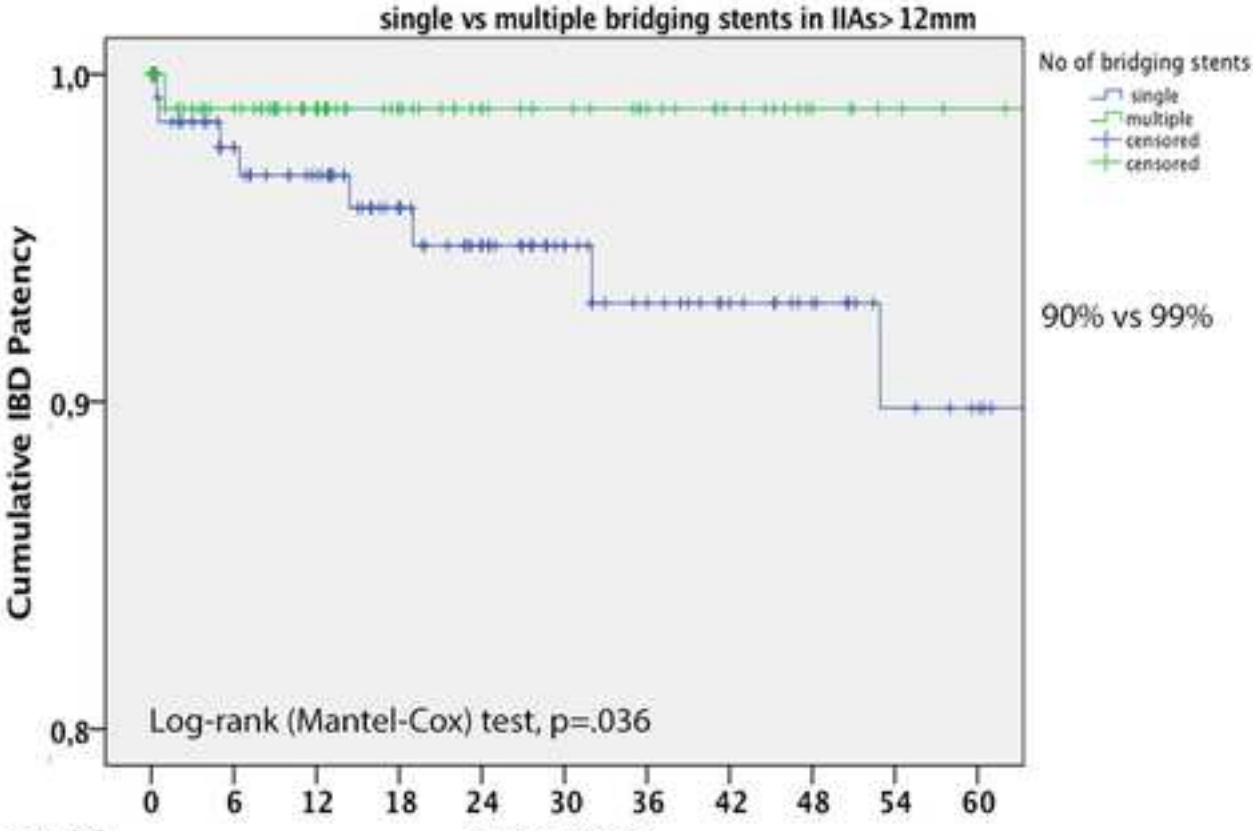
Patients at risk						
IIA<12mm:	540	392	284	206	134	90
Std error:	.01	.01	.02	.02	.02	.02
IIA>12mm:	265	172	112	75	51	33
Std error:	.01	.02	.03	.03	.04	.05
IBDs at risk						
IIA<12mm:	595	417	303	213	137	92
Std error:	.01	.01	.02	.02	.02	.02
IIA>12mm:	315	199	128	87	60	39
Std error:	.01	.01	.02	.03	.04	.05

Figure 1. Analysis of “on- vs off-label” Kaplan-Meier curves of (A) Cumulative IBD-Patency, (B) Cumulative freedom from IBD-related type I endoleak and (C) Cumulative freedom from IBD-related reinterventions.

Figure 2. Single vs. multiple bridging device

Click here to download Figure Figure 2. Single vs. multiple bridging device



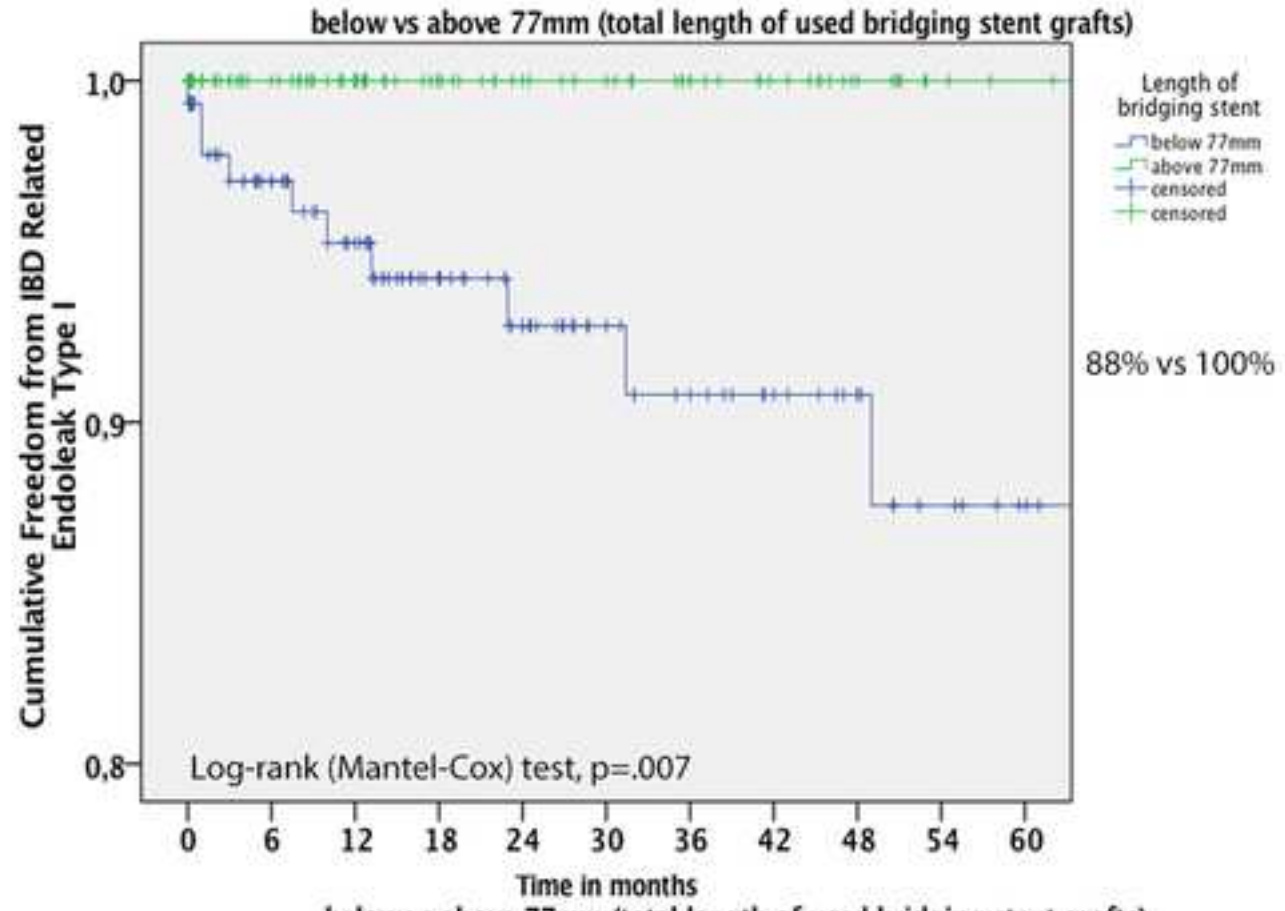


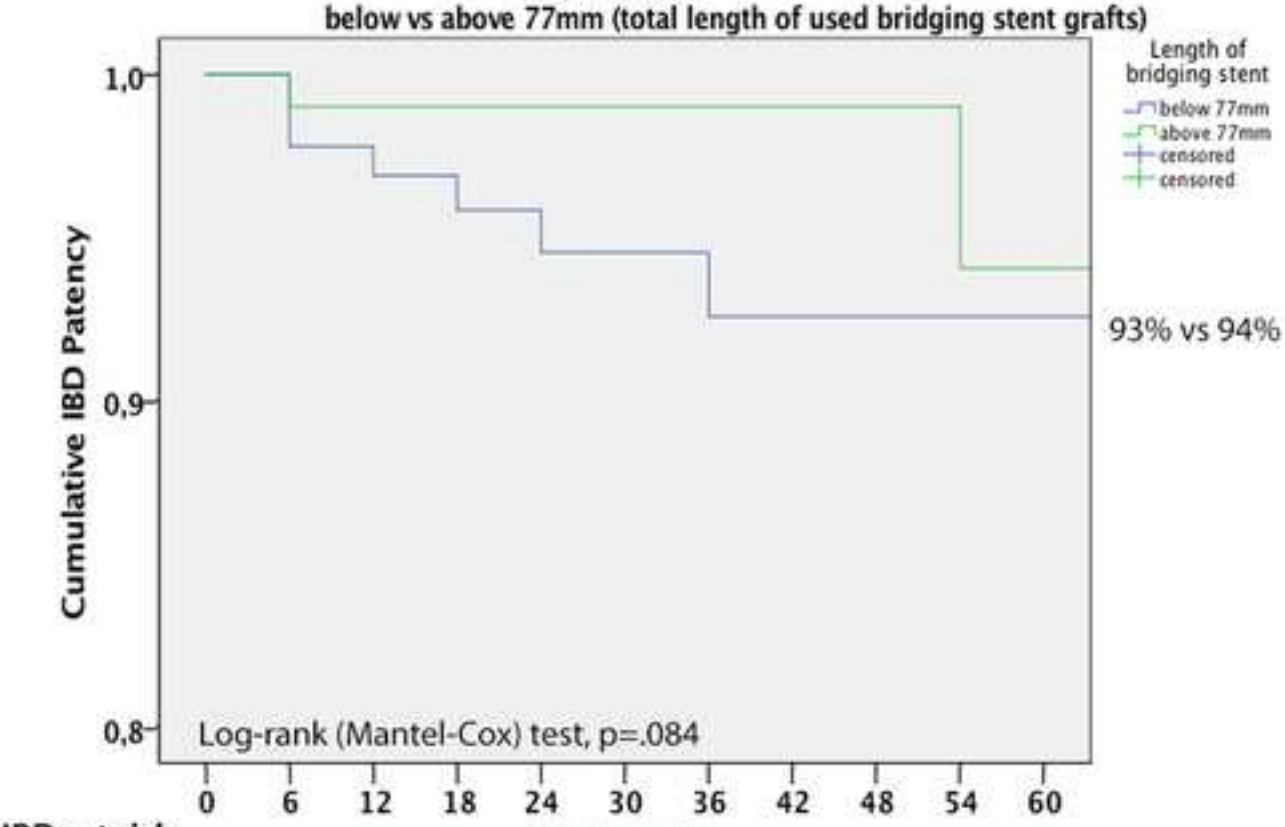
IBDs at risk						
single:	177	118	77	51	38	23
Std error:	.01	.02	.02	.03	.04	.04
multiple:	138	81	50	37	20	13
Std error:	.01	.01	.01	.01	.01	.01

Figure 2. Analysis of single vs. multiple bridging stents Kaplan-Meier curves of cumulative freedom from IBD-related type I endoleak and cumulative IBD patency.

Figure 3. 77mm mean covered length

Click here to download Figure Figure 3. 77mm mean covered length





IBDs at risk

Time in months	0	6	12	18	24	30	36	42	48	54	60
below:	174		114		72		48		35		23
Std error:	.01		.02		.02		.03		.04		.04
above:	141		85		55		40		23		13
Std error:	.01		.01		.01		.01		.01		.01

Figure 3. Analysis according to mean stent length Kaplan-Meier curves of cumulative freedom from IBD-related type I endoleak and cumulative IBD patency.

Table I. Baseline patient and aneurysm characteristics.

Demographics		
Age (years, mean±sd & range)	72.1 ± 8.6	41 – 94
Male / female (n/n % %/%)	768/36	95.5/4.5%
Risk - factors	n	%
Hypertension	684	84.0%
Diabetes mellitus	128	15.7%
Adipositas per magna	219	26.9%
Dyslipidemia	463	56.9%
COPD	250	30.7%
Smoking (current or past)	464	57.0%
Coronary disease or aortocoronary bypass	350	43.0%
Myocardial Infarction (at < 6 months)	10	1.2%
Creatinine (mg/dl, mean ± sd & range)	1.1 ± 0.4	0.6 – 5.0
Dialysis	4	0.5%
PAD	103	12.7%
Previous EVAR	100	12.3%
Previous Laparotomy	105	12.9%
Type of disease		
Aortobiiliac	361	44.9
Aortoiliac right	148	18.4
Aortoiliac left	95	11.8
Isolated iliac	194	24.1
Aneurysm in all vessels	6	0.7
Total patients	804	100
Internal involvement	292	35.9
Internal >12mm (out of IFU)	265	32.6
IBD site right	411	50.5
IBD site left	307	37.7
IBD site bilateral	96	11.8

Abbreviations: COPD, chronic obstructive pulmonary disease; PAD peripheral artery disease, EVAR, endovascular aneurysm repair.

Table II. Overview of etiology of early and mid-term mortality and results of the total series* (n=804 patients/ 814 primary operations/ 910 IBDs).

Early mortality (n=4)	n	%
Infectious Pneumonia	2	0.25
Acute Myocardial Infarction	2	0.25
Mid-term mortality (n=106)		
Unknown/ not well defined	25	3.11
Cardiac	24	2.99
Neoplasmatic	22	2.74
Respiratory	6	0.75
Stroke or other central nervous disease	6	0.75
Sepsis	6	0.75
Proximal or distal arterial disease	5	0.62
Miscellaneous	5	0.62
Renal	2	0.25
Procedure- related (Primary or Secondary)	5	0.62
Total mortality	110	13.68
Other complications		
Persistent endoleaks[#] (all types)	136	16.91
All persistent type I Endoleaks	39	4.85
Persistent IBD- related type I Endoleaks	17	2.11
Total migrations	8	1.00
IBD- related migrations	6	0.75
Claudication (all types)	62	7.71
Pelvic Ischemia (including buttock claudication)	32	3.98
Occlusion or high-grade stenosis of IBD	37	4.60
Common Iliac	17	2.11
External iliac	17	2.11
Total internal iliac	19	2.36
Entire internal iliac	7	0.87
Bridging stent only	12	1.49
Compromised primary patency Non-IBD related	18	2.23
Total reinterventions	147	18.28

IBD- related reinterventions	110	13.68
Non-IBD related reinterventions	37	4.60
Open conversion reinterventions	9	1.12

* Percentage rate per patients. Totally, 9 (1.2%) deaths were considered IBD procedure related. Mid-term procedure related included 2 post-reintervention myocardial infarctions, 2 aneurysm ruptures and 1 death related to colonic ischemia. # Endoleaks detectable beyond the 1st month.

Table III. Evolution of aneurysm and treated vessels diameters in the total series and in the "off-the-label" subgroup.

Vessel Diameter (mm)	Preoperative mean ± sd	Preoperative range	Follow-up mean ± sd	Follow-up range	p*
Total series (n=804 patients/910 IBDs)					
Aortic	45.2 ± 15.3	12.0 – 100.0	41.6 ± 15.1	17.0 – 100.0	<.001
Right common iliac	33.1 ± 11.7	12.0 – 85.0	29.3 ± 10.4	12.0 – 74.0	<.001
Right internal iliac	13.8 ± 9.4	3.0 – 70.0	12.9 ± 7.8	1.0 – 70.0	<.001
Left common iliac	30.4 ± 11.7	10.0 – 74.1	27.6 ± 10.7	9.0 – 85.0	<.001
Left internal iliac	14.6 ± 10.5	4.0 – 90.0	13.9 ± 9.9	4.0 – 80.0	<.001
"Off the label" subgroup (n=264 patients/315 IBDs)					
Aortic	43.3 ± 16.0	17.0 – 92.0	42.1 ± 16.1	17.0 – 100.0	.055
Right common iliac	33.3 ± 12.7	13.0 – 76.1	30.6 ± 11.2	12.0 – 74.0	<.001
Right internal iliac	20.3 ± 10.6	8.0 – 67.4	18.0 ± 9.5	4.0 – 70.0	<.001
Left common iliac	32.1 ± 12.2	12.0 – 74.1	29.1 ± 10.8	9.0 – 85.0	<.001
Left internal iliac	22.9 ± 13.3	4.0 – 90.0	20.5 ± 11.3	4.0 – 80.0	<.001

* Paired samples T-student test. Statistical significant changes at >.05 level appear bold typed.

Table IV. "On- vs off-the-label" use of IBDs, comparison of the mid-term results in total of 804 patients.

Outcome	"On-the-label" (n= 540) n	%	"Off-the-label" (n=264) n	%	p*
IBD's primary patency	517	95.74	250	94.69	.483
IBD- related migration	1	0.18	5	1.89	<.001
Pelvic ischemia	15	2.78	17	6.44	.011
Buttock claudication	12	2.22	14	5.30	.019
Total type I Endoleak	21	3.88	18	6.82	.063
Total IBD- related type I Endoleak	7	1.30	10	3.79	.019
Endoleak Ib ipsilateral HA	4	0.74	8	3.03	.019
Rupture & pelvic ischemia free survival	529	97.96	246	93.18	.027
Total reinterventions	100	18.52	47	17.80	.868
IBD- related reinterventions	72	13.33	38	14.39	.632
Non-IBD related reinterventions	28	5.18	9	3.41	.274
Conversion reintervention	6	1.11	3	1.14	.960

* Pearson Chi square test. Statistical significant difference at >.05 level appear bold typed.

Table V. Mid-term results, in-subgroup analysis of 315 “off the label” IBDs.

Outcome	Stent-graft Single (n= 177) n	%	Stent-graft Multiple (n=138) n	%	p*
IBD occlusion or severe stenosis	13	7.34	1	0.72	.009
IBD- related migration	3	1.69	2	1.45	.863
Pelvic ischemia	12	6.78	5	3.62	.325
Buttock claudication	12	6.78	2	1.45	.038
Total IBD- related type I Endoleak	10	5.64	0	0.0	.003
Endoleak Ib ipsilateral HA	8	4.51	0	0.0	.008
IBD- related reinterventions	24	13.56	14	10.14	.596
	Length < 77mm (n=174) n	%	Length >77mm (n=141) n	%	
IBD occlusion or severe stenosis	12	6.89	2	1.42	.028
IBD- related migration	3	1.72	2	1.42	.829
Pelvic ischemia	10	5.74	7	4.96	.900
Buttock claudication	10	5.74	4	2.83	.274
Total IBD- related type I Endoleak	10	5.74	0	0.0	.002
Endoleak Ib ipsilateral HA	8	4.59	0	0.0	.005
IBD- related reinterventions	24	13.79	14	9.93	.435

* Pearson Chi square test. Statistical significant difference at >.05 level appear bold typed.

Appendix

Additional pELVIS Registry collaborators: Muenster, Germany: Martin Austermann, Mirjam Inchingolo, Theodosios Bisdas; Tor Vergata, Rome, Italy: Giovanni Pratesi, Matteo Barbante; San Camillo Forlanini, Rome, Italy: Piergiorgio Cao, Ciro Ferrer; Perugia, Italy: Fabio Verzini, Gianbatista Parlani, Gioele Simonte; Florence, Italy: Carlo Pratesi, Aaron Fargion and Fabrizio Masciello; Hamburg, Germany: Tilo Kölbel, Nikolaos Tsilimparis; Lille Chru, France: Stephan Haulon; Leipzig, Germany: Daniela Branzan, Andrej Schmidt, Dirk Scheinert.

Centers participating in the PELVIS registry (number of patients enrolled): St. Franziskus Hospital Muenster and University of Muenster, Germany (287); San Camillo Forlanini, Rome, Italy (53); University of Perugia, Italy (130); University of Rome Tor Vergata, Rome, Italy (31); University of Florence, Italy (95); Hamburg, Germany (32), Lille Chru, France (51), Leipzig, Germany (135).