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# Incidence and Treatment of Limb Occlusion of the Anaconda Endograft After Endovascular Aneurysm Repair

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## Abstract

**Purpose:** To evaluate the incidence and treatment of limb occlusions of the second- and third-generation Anaconda endografts. **Methods:** A single-center retrospective study was conducted involving 317 consecutive patients (mean age 76 years; 289 men) who underwent endovascular aneurysm repair for elective asymptomatic, symptomatic intact, and ruptured infrarenal abdominal aortic aneurysm with 2 versions of the Anaconda device. From September 2003 to July 2011, the second-generation device was used in 189 patients (mean age 77 years; 169 men) and from July 2011 to September 2015, the third-generation device was implanted in 128 patients (mean age 75 years; 120 men). The rates of limb occlusion were compared between groups and according to compliance with the instructions for use (IFU); predictors were sought in multivariate analysis. The results of the latter are given as the hazard ratio (HR) and 95% confidence interval (CI). **Results:** Kaplan-Meier freedom of occlusion estimates for second- and third-generation devices, respectively, was 96.6% and 95.0% at 1 year, 89.9% and 95.0% at 2 years, and 86.5% and 88.6% at 5 years. There was no significant difference in overall occlusion rate between the second-generation devices ( $p=0.332$ ) or with regard to use within the IFU ( $p=0.827$ ); however, there was a clinically relevant decrease in the occlusion rate for elective patients treated with the third-generation device (6.4% vs 13.1%,  $p=0.077$ ). There was an increase in the occlusion rate when the iliac limb diameter was  $\leq 13$  mm. In multivariate analysis, the only independent predictor of limb occlusion was a small distal prosthesis diameter (HR 0.732, 95% CI 0.63 to 0.86,  $p<0.001$ ). Symptomatic nonruptured and ruptured abdominal aortic aneurysm (AAA) interventions had an almost 2-fold increased risk of occlusion (HR 1.95, 95% CI 0.93 to 4.11,  $p=0.078$ ), though this did not reach statistical significance. **Conclusion:** The Anaconda design has proven effectiveness in AAA exclusion in daily practice inside the IFU. However, efforts could be made to further reduce the limb occlusion rate.

## Keywords

abdominal aortic aneurysm, endograft, iliac artery, instructions for use, limb occlusion, stent-graft

## Introduction

From the first introduction of the Anaconda endograft (Vascutek/Terumo, Inchinnan, Scotland) in 1998, special attention was paid to the configuration of both body and limbs to achieve durable endovascular repair of challenging infrarenal abdominal aortic aneurysm (AAA) anatomy and to address some of the failures observed with other aortic stent-grafts in the 1990s, among them endograft limb occlusion.<sup>1–5</sup> In the second-generation Anaconda device with independent nitinol rings and zero columnar support, the infrarenal and iliac fixation and sealing was durable, but the observed number of limb occlusions was somewhat higher than expected. The ANA-004 study<sup>6</sup> and product registries suggested that limb occlusions were mainly observed with the combination

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of small body diameters and relatively large diameter limbs. As a consequence, the third-generation Anaconda device, the One-lok, was launched in 2011. In this third iteration, the docking zone limb diameter was standardized to optimize the body-limb combinations and ease the size selection. Two additional nitinol rings supporting the body were added to maximize lumen diameter and prevent possible kinking in angulated AAA neck anatomy. Device planning and selection were done using the instructions for use (IFU) and the product ordering information sheet.

In the second-generation device the limb design was straight; the third generation was designed such that the proximal part of the iliac limb attached to the body had a diameter of 12 mm. Three types of distal outflow configurations of the graft were designed in the third-generation endograft: a tapered limb if the iliac artery diameter was between 8.5 and 9.5 mm, a straight limb if between 10.0 and 11.5 mm, and a flared distal limb if between 11.0 and 23.0 mm. Using the recommended product ordering information, the maximum oversizing should vary between 18% and 25%. The present study focuses on the incidence and treatment of limb occlusions of both second- and third-generation Anaconda devices.

## Materials and Methods

### Study Design

A single-center retrospective study was conducted using prospectively recorded data from all consecutive AAA patients treated with the Anaconda device between September 2003 and September 2015. The second-generation device was used until July 2011, when the third-generation device became available. The primary outcome measure was limb occlusion, including symptomatic and asymptomatic. Only the first occlusion of an individual patient was used in the statistical analysis. Body occlusions were counted as one occlusion. The Ethics Committee of the University Medical Center Groningen waived the need for ethics approval or informed consent for the use of anonymized and retrospectively analyzed data.

Demographics and general health status, including the Society of Vascular Surgery/International Society of Cardiovascular Surgery risk scores,<sup>7</sup> the American Society of Anesthesiologist (ASA) classification,<sup>8</sup> as well as AAA anatomical characteristics, were collected. Patients were categorized as asymptomatic, symptomatic nonruptured, and ruptured AAA. The preoperative work-up was outlined in detail earlier.<sup>6</sup> Definitions according to Chaikof et al<sup>9</sup> were used.

### Patient Population

A total of 317 patients (mean age 76 years; 289 men) were treated for infrarenal AAA with the Anaconda endograft during the observation period: 189 patients (mean age 77

years; 169 men) received a second-generation device and 128 patients (mean age 75 years; 120 men) received a third-generation device. Patient characteristics, anatomical characteristics, and characteristics of the endovascular aneurysm repair (EVAR) procedure are summarized in Tables 1 to 3, respectively. In 225 (71%) patients the EVAR procedures were performed electively (Table 4). Thirty-eight (12%) patients had a symptomatic nonruptured AAA and were treated within 24 hours. Fifty-four (17%) patients had a ruptured AAA and were treated in the acute setting. A total of 184 patients were treated within the IFU for Anaconda (Table 5).

### Follow-up Protocol

Patients were seen in follow-up at 3, 6, 12, 18, and 24 months and yearly thereafter. The evaluations included duplex ultrasound and biplanar abdominal radiography or contrast-enhanced computed tomography angiography (CTA). Limb occlusion was detected using duplex ultrasound or CTA.

### Statistical Analysis

Categorical variables are reported as numbers with percentages. The distribution of continuous variables were summarized as means or medians (with interquartile range), as appropriate. The relationships between type of Anaconda device and categorical data were analyzed using the chi-square test, while differences in continuous variables between the 2 types of devices were analyzed using a *t* test (normal distribution) or Mann-Whitney *U* test (skewed distribution), as appropriate. Normal distribution was tested using the Kolmogorov-Smirnov nonparametric test.

To compare the occlusion rate to data in the literature, a subanalysis was performed for second- and third-generation devices that were implanted following the criteria in the IFU. Time-to-event data were analyzed using the Kaplan-Meier method with log rank test or univariate Cox regression. Variables that were associated both with time-to-event and type of Anaconda (at  $p < 0.10$ ) were entered into a multivariate Cox regression model (stepwise, forward) to obtain a model identifying independent predictors of the time to occlusion. The generation of Anaconda device was forced into the model. The results are presented as the hazard ratio (HR) and 95% confidence intervals (95% CI). Significance was set at  $p < 0.05$ . Analyses were performed using IBM SPSS Statistics for Windows (version 22.0; IBM Corporation, Armonk, NY, USA).

## Results

Over a mean follow-up of 47 months (range 0–134), 31 (9.8%) index occlusions were diagnosed (4 body and 27

**Table 1.** Patient Characteristics.<sup>a</sup>

Variable	Second-Generation Device (n=189)	Third-Generation Device (n=128)	Total (n=317)
Age, y	77 (58–95)	75 (42–90)	76 (42–95)
Men	169	120	289 (91.2)
ASA grade			
I	1	4	5 (1.6)
II	130	83	213 (68.3)
III	18	20	38 (12.2)
IV	4	4	8 (2.6)
V	33	15	48 (15.4)
Diabetes			
Diet-controlled	22	11	33 (10.4)
Diet and drug	6	5	11 (3.5)
Smoking	55	35	98 (28.8)
Hypertension			
1 or 2 drugs	88	73	161 (50.8)
3+ drugs or uncontrolled	36	19	55 (17.4)
Hyperlipidemia <sup>b</sup>	88	90	178 (56.7)
Cardiac disease			
Asymptomatic, MI	80	58	138 (43.7)
Unstable angina, etc	2	6	8 (2.5)
Carotid disease <sup>c</sup>	22	27	53 (15.5)
Renal disease	13	12	25 (7.9)
Pulmonary disease			
Mild	37	20	28 (18.0)
Severe	1	0	1 (0.3)

Abbreviations: ASA, American Society of Anesthesiologists; MI, myocardial infarction.

<sup>a</sup>Continuous data are presented as the mean (range); categorical data are given as the number (percentage).

<sup>b</sup> $p < 0.001$ .

<sup>c</sup> $p < 0.024$ .

limb). The mean follow-up was 57 months (range 0–134) and 33 months (range 0–66) for second- and third-generation device cohorts. Freedom from occlusion estimates were 96.6% (95% CI 93.9% to 99.3%) and 95.0% (95% CI 91.1% to 98.9%) at 1 year, 89.9% (95% CI 85.2% to 94.6%) and 95.0% (95% CI 91.1% to 98.9%) at 2 years, and 86.5% (95% CI 80.8% to 92.2%) and 88.6% (95% CI 81.6% to 95.6) at 5 years, respectively (Figure 1A). There was no statistically significant difference in occlusion between the 2 generations of the devices ( $p=0.591$ ). In the second-generation group there was a significant difference in the occlusion rate related to the timing of surgery, predominately because of the much higher occlusion rate in symptomatic patients compared with elective patients ( $p=0.001$ ).

The cumulative number of occlusions during follow-up of the total cohort and the subcohorts with criteria inside the IFU is presented in Table 6. At 5-year follow-up the cumulative occlusion rate inside the IFU was 9.8% (18/184). The Kaplan-Meier freedom from occlusion inside the IFU for both types of devices is reported in Figure 1B. There was no significant difference in occlusion estimates between the second-generation devices ( $p=0.827$ ). Freedom from

occlusion estimates for second- and third-generation devices were 98.1% (95% CI 89% to 100%) and 95.9% (95% CI 91.4% to 100%) at 1 year and 94.8% (95% CI 90.3% to 99.3%) and 95.9% at 2 years, respectively. For the second-generation device the 5-year freedom from occlusion was 87.1% (95% CI 79.8% to 94.4%).

### Treatment of Limb Occlusions

In 31 patients experiencing one or more occlusions, one occlusion occurred in 15 patients treated with second-generation vs 9 patients with third-generation endografts. Two occlusion events occurred in 6 patients, all with second-generation devices. One patient with a third-generation device experienced 3 limb occlusions: one event in 1 limb and 2 events in the other limb. Limb occlusions did not result in any minor or major amputations.

In total, 5 (1.6%) conversions to open repair were performed for body occlusions in 4 cases and a contained rupture after initial successful thrombectomy of the body occlusion in the other. Further details of treatment are described in Table 7.

**Table 2.** Anatomical Characteristics.<sup>a</sup>

Characteristics	Second-Generation Device (n=189)	Third-Generation Device (n=128)	Total (n=317)
<b>Infrarenal aortic neck</b>			
Diameters, mm			
Proximal	22.6	23.1	22.8 (10–34 <sup>b</sup> )
Mid	23.0	23.3	23.1 (14–32)
Distal	23.5	24.1	23.7 (14–33)
Length, mm	28.4	31.6	29.7 (10–146 <sup>c</sup> )
Circumferential thrombus, %	8	8	8 (0–100)
Circumferential calcification, %	9	7	7.9 (0–100)
Angulation, deg [median]	37 (0–133) [30]	36 (0–100) [35]	36.4 (0–133) [30]
Maximum AAA diameter, mm	64 (18–125)	65 (25–130)	64.2 (18 <sup>c</sup> –130)
<b>Iliac arteries</b>			
Diameter, mm			
RCIA	15.7	17.2	16.3 (7–100)
LCIA	14.3	15.2	14.7 (7–63)
Angulation, deg			
RCIA <sup>d</sup>	61 (0–180)	51 (0–180)	57 (0–180)
LCIA	66 (0–320)	56 (0–180)	63 (0–320)
REIA	63 (0–180)	67 (0–180)	64 (0–180)
LEIA	58 (0–180)	57 (0–150)	57 (0–180)
Circumferential thrombus, %			
RCIA	10	11	10 (0–100)
LCIA	9	8	8 (0–100)
Circumferential calcification, %			
RCIA	25	27	26 (0–100)
LCIA	26	26	26 (0–100)

Abbreviations: AAA, abdominal aortic aneurysm; LCIA, left common iliac artery; LEIA, left external iliac artery; RCIA, right common iliac artery; REIA, right external iliac artery.

<sup>a</sup>Data are presented as the mean (range).

<sup>b</sup>Tapered neck.

<sup>c</sup>Iliac aneurysm.

<sup>d</sup>p=0.018.

### Uni- and Multivariate Analyses

The following variables were related to time to limb occlusion at univariate analysis: timing of surgery, neck calcification, left external iliac artery diameter, right iliac artery angulation, proximal prosthesis diameter, distal prosthesis diameter (left and right), device length, additional procedures, direct postoperative endoleak, procedure time, and blood loss (all at  $p < 0.10$ ). Embolization of the internal iliac artery was not a significant factor for limb occlusion, although occlusion did occur in 2 patients with prior embolization of the internal iliac artery. Iliac diameter was also small in these 2 patients, that is, 10 and 11 mm on both limb sides.

In a forward, stepwise multivariate Cox regression analysis only the distal right prosthesis diameter (HR 0.732, 95% CI 0.63 to 0.86,  $p < 0.001$ ) was an independent predictor of time to occlusion; Anaconda generation (HR 0.996,

95% CI 0.41 to 2.44,  $p = 0.991$ ) and timing of surgery (HR 1.95, 95% CI 0.93 to 4.11,  $p = 0.078$ ) were not. When the generation of the Anaconda device was removed from the model, the outcomes for the remaining variables remained largely unchanged.

In the limb occlusion group, 19 (61%) of 31 patients had 1 or more iliac extensions compared with 98 (34%) of 286 patients without limb occlusion ( $p = 0.01$ ). In 54 (29%) of 189 patients with a second-generation device, the right iliac diameter was  $\leq 13$  mm; 11 of 21 occlusions occurred in this group. In 69 (54%) of 128 patients with a third-generation device, the right iliac diameter was  $\leq 13$  mm; 9 of 10 occlusions occurred in this group. This increase in the occlusion rate when the iliac limb diameter is  $\leq 13$  mm, which was confirmed in the multivariate analysis, suggests that a larger distal prosthesis diameter leads to fewer occlusions.

**Table 3.** Procedure Characteristics.

Parameters	Second-Generation Device (n=189)	Third-Generation Device (n=128)	Total (n=317) <sup>a</sup>
Type of anesthesia			
General	22	22	44 (14)
Regional	150	98	248 (78)
Local	17	8	25 (8)
Additional dilation	15	11	26 (8)
Additional distal extensions			
Right			
1	64	43	107 (34)
2	8	2	10 (3)
Left			
1	22	3	25 (8)
≥2	1	1	2 (1)
Intraoperative endoleak			
Type I	8	3	11 (4)
Type II	43	60	103 (32)
Fluoroscopy time, min			
≤30	182	127	309 (97)
31–60	5	1	6 (2)
>60–177 (max)	2	0	2 (1)
Contrast, mL			
≤100	89	76	165 (52)
101–200	83	46	129 (41)
>200–360 (max)	17	6	23 (7)
Blood loss, mL			
≤200	133	88	221 (70)
201–500	41	29	70 (22)
501–1000	10	7	17 (5)
>1000–5000 (max)	5	4	9 (3)

<sup>a</sup>Data are given with the percentage in parentheses.

**Table 4.** Timing of Surgery and Occlusions.<sup>a</sup>

Timing of Surgery and Occlusion	Second-Generation Device	Third-Generation Device	Total Cohort (n=317)
Elective	20/153 (13.1)	7/110 (6.4)	27/263 (10.2)
Asymptomatic AAA	11/125 (8.8)	7/100 (7.0)	18/225 (8.0)
Symptomatic AAA	9/28 (32.0) <sup>b</sup>	0/10 (0)	9/38 (23.7)
Emergency (ruptured AAA)	1/36 (2.8)	3/18 (16.7)	4/54 (7.4)
Total occlusions	21/189 (11.1)	10/128 (7.8)	31/317 (9.8)

Abbreviation: AAA, abdominal aortic aneurysm.

<sup>a</sup>Data are presented as the number of occlusions per patient sample (percentage).

<sup>b</sup>p=0.001.

## Discussion

The most striking findings in this study were the relationship of limb occlusion to the timing of surgery in the second-generation group and to small distal prosthesis diameter, not to the generation of the Anaconda. In patients who underwent elective surgery there was a clinically significant

decrease in the proportion of patients who developed a limb occlusion in the third-generation Anaconda; however, this did not reach statistical significance.

Comparing EVAR studies and especially limb occlusion rates in the literature is not straightforward. Variations in type of endograft device, selection criteria, treatment within or outside the IFU, follow-up protocol, multi- or monocentric

**Table 5.** Instructions for Use for the Second- and Third-Generation Anaconda Stent-Graft (Elective Surgery).

Infrarenal aortic neck	
Length (H1), mm	>15
Thrombus, %	<50
Calcification, %	<50
Diameter (D2), mm	>16 to <31 second generation; >17.5 to <31 third generation
Neck shape	Parallel or conical
Infrarenal angulation, deg <sup>a</sup>	<90
CIA diameter, mm	>8.5 to <21
Distal fixation length, mm	>20

Abbreviation: CIA, common iliac artery.

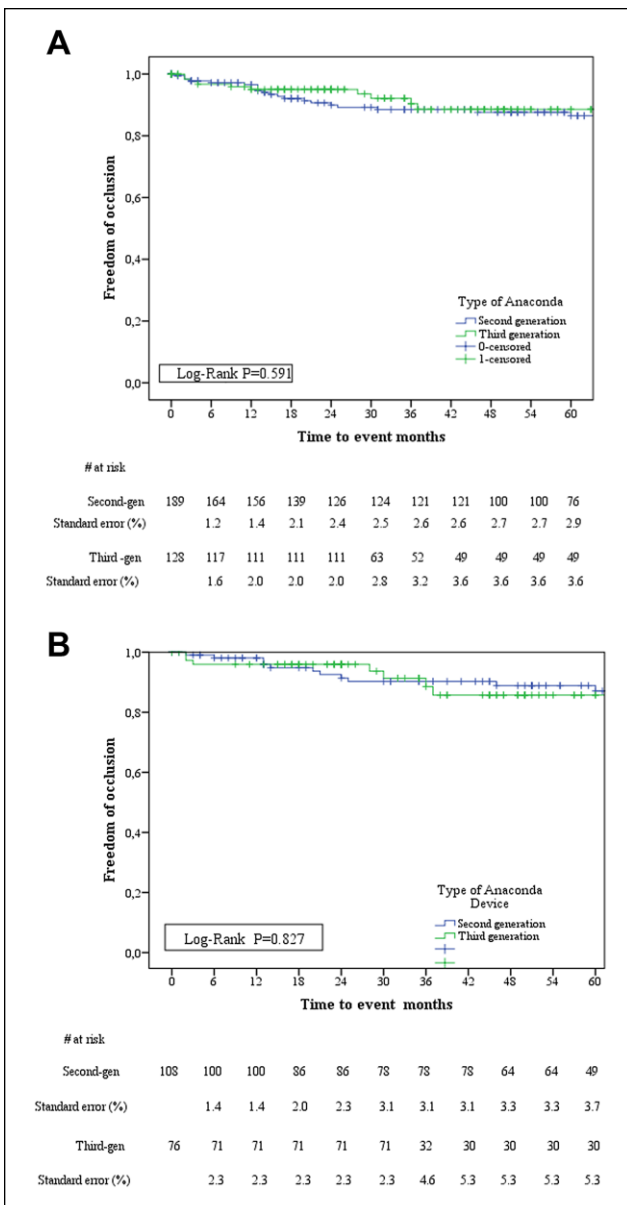
<sup>a</sup>In the ANA 004-study,<sup>6</sup> the instructions for use (IFU) infrarenal angulation was <45°; for this analysis the present maximum infrarenal angulation within the IFU (≤90°) was accepted for both cohorts.

study, and patient and anatomical characteristics make a balanced comparison between studies challenging.

Faure et al<sup>2</sup> published a literature overview on predictive factors for limb occlusion in various types of endografts. Mean follow-up varied between 1 and 77 months with limb occlusion rates between 0% and 7.2%. The limb occlusion rate of the present study after a mean follow-up of 47 months was 9.8% overall, but the rate was 6.4% for the third-generation device used in elective cases, which seems at the upper end of the acceptable range for limb occlusion.

Our reported rate of limb occlusion is higher than others have reported for the Anaconda device, but this may reflect the complexity of some of our cases outside the IFU and the inclusion of a substantial proportion of emergency cases. In their single-center study using the Anaconda, Freyrie et al<sup>10</sup> reported their results of 177 electively treated AAA patients with anatomical criteria inside the IFU. Mean follow-up was 33 months (range 1–77). The overall rate of iliac limb occlusion was 4.5% (8/177). In another single-center study, Karkos et al<sup>11</sup> reported a 4.8% occlusion rate at a mean 29 months. Of the 68 patients included, 5 patients had ruptured AAA. One body occlusion occurred on day 8 postoperatively likely, due to graft twist. One limb graft occlusion occurred after 43 months. An asymptomatic limb occlusion was managed conservatively. No specific causes were specified.

Nano et al<sup>12</sup> reported just 0.8% limb occlusion among 118 patients at a mean of 48 months. One acute thrombotic limb ischemia occurred 15 months after the procedure. In a recently published study,<sup>13</sup> 2 generations of Medtronic endografts were compared in 221 patients (131 Endurant and 90 Talent) with an overall mean follow-up of 61 months. With the new Endurant endograft design, the number of complications at the level of the aortic neck was reduced, but the number of iliac interventions increased. However, an iliac limb occlusion occurred in 5.6% of the Endurant patients compared with 3.4% of the Talent patients, so an updated Endurant design was recently introduced.



**Figure 1.** Kaplan-Meier curves for freedom from occlusion for the (A) total cohort and (B) patients inside the instructions for use.

In our multivariate analyses, distal prosthesis diameter was an independent predictor of time to limb occlusion, which is in line with earlier studies.<sup>1,2,14</sup> Mantas et al<sup>5</sup> could not prove this particular result in their study but suggested that an iliac angle ≥60°, calcification ≥50%, and endograft limb oversizing ≥15% of the common iliac artery diameter may increase the risk of occlusion fivefold. In the study of Faure et al,<sup>2</sup> a prediction model was constructed to divide EVAR patients developing limb occlusions into high- and low-risk groups depending on the anatomical criteria. Intensifying the follow-up schedules and promoting early awareness of possible problems could be a necessary

**Table 6.** Cumulative Number of Occlusions During Follow-up of the Total Cohort and the Subcohorts With Criteria Inside the Instructions for Use (IFU).<sup>a</sup>

Time to Occlusion, mo	Total Cohort (n=317)	Inside IFU (n=184)	Inside IFU Second Generation (n=108)	Inside IFU Third Generation (n=76)
<1	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
<3	5 (1.6)	3 (1.6)	1 (0.9)	2 (2.6)
<12	11 (3.5)	5 (2.7)	2 (1.9)	3 (3.9)
<24	21 (6.6)	9 (4.9)	5 (4.6)	4 (5.3)
<36	26 (8.2)	14 (7.6)	9 (8.3)	5 (6.6)
<48	28 (8.8)	17 (9.2)	10 (9.3)	7 (9.2)
<60	29 (9.1)	18 (9.8)	11 (10.2)	7 (9.2)
Total	31 (9.8)	18 (9.8)	11 (10.2)	7 (9.2)

<sup>a</sup>Data are given as the number (percentage).

**Table 7.** Leg Occlusions and Type of Intervention.

Events	Patients With Second-Generation Device	Patients With Third-Generation Device	Interventions
1	2	1	Thrombectomy
		1	Thrombectomy with patch
	5	4	Recanalization and stenting
	2	2	Conversion to open
	3		Fem-fem crossover
	3	1	Conservative treatment
2	1		(1)Thrombectomy
			(2) Recanalization and stenting
	3		(1) Recanalization and stenting
			(2) Recanalization and stenting
3	1		(1) Stent, thrombectomy (body)
			(2) Conversion (contained rupture)
	1		(1) Thrombectomy
			(2) Thrombectomy with patch
3		1	(1) Recanalization and stenting
			(2) Thrombectomy
			(3) Recanalization and stenting
Total	21	10	

prerogative for the high-risk patient cohort in the first 2 years. Correction of intraoperative factors for limb occlusion, such as stenting of a possible compromised device limb lumen, could reduce the limb occlusion rate.<sup>15</sup>

The strong point of the current study is the long-term follow-up and very low number of cases lost to follow-up. The substantial number of first limb occlusions presenting between 2 and 5 years suggested an ongoing interaction between the anatomical configuration and blood flow. However, this study is potentially biased with regard to the comparisons made between the second- and third-generation devices, as it was not designed as a randomized trial. Heterogeneity of both cohorts could also be a bias because the devices were implanted in 2 different time frames and improvement in experience and imaging quality likely occurred. Furthermore, the increase in the proportion of AAA patients treated today with EVAR (up to 90%) could jeopardize the clinical outcome.

## Conclusion

The Anaconda design has proven durable in AAA exclusion in daily practice both inside the IFU and in challenging AAA anatomy.<sup>16</sup> However, efforts could be made to further reduce the limb occlusion rate.


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