Published in final edited form as:

J Am Coll Surg. 2016 April ; 222(4): 579–589. doi:10.1016/j.jamcollsurg.2015.12.037.

Aortic Neck Anatomic Features and Predictors of Outcomes in Endovascular Repair of Abdominal Aortic Aneurysms Following vs Not Following Instructions for Use

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Abstract

BACKGROUND—A significant number of patients undergo endovascular repair of abdominal aortic aneurysms (EVAR) outside the instructions for use (IFU). This study will examine various aortic neck features and their predictors of clinical outcomes.

STUDY DESIGN—We performed a retrospective analysis of prospectively collected data on EVAR patients. Neck features outside IFU were analyzed. Kaplan-Meier and multivariate analyses were used to predict their effect as single features, or in combination, on outcomes.

RESULTS—Fifty-two percent of 526 patients had 1 or more features outside the IFU. The overall technical success rate was 99%, and perioperative complication rates were 7% and 12% for IFU vs outside IFU use, respectively ($p = 0.04$). Type I early endoleak and early intervention rates were 7% and 10% for IFU vs 18% and 24% for outside IFU ($p = 0.0002$ and $p < 0.0001$). At a mean follow-up of 30 months, freedom from late type I endoleak and late reintervention at 1, 2, and 3 years for IFU were 99.5%, 99.5%, and 98.4%, and 99.4%, 98%, and 96.8%; vs 98.9%, 98.1%, and 98.1%, and 97.5%, 96.2%, and 95.2% for outside IFU ($p = 0.049$ and 0.799), respectively. Survival rates at 1, 2, and 3 years for IFU were 97%, 93.5%, and 89.8%; vs 93.7%, 88.8%, and 86.3% for outside IFU ($p = 0.035$). Multivariate analysis showed that a neck angle > 60 degrees had odds ratios for death, sac expansion, and early intervention of 6, 2.6, and 3.3, respectively; neck length < 10 mm had odds ratios of 2.8 for deaths, 3.4 for early intervention, 4.6 for late reintervention, and 4.3 for late type I endoleak.

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Disclosure Information: Nothing to disclose.

Presented at the Southern Surgical Association 127th Annual Meeting, Hot Springs, VA, December 2015.

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CONCLUSIONS—Patients with neck features outside IFU can be treated with EVAR; however, they have higher rates of early and late type I endoleak, early intervention, and late death.

Endovascular repair of abdominal aortic aneurysms (EVAR) has been advocated as the treatment of choice for many patients with infrarenal abdominal aortic aneurysms over the past 2 decades. When used within the instructions for use (IFU), EVAR has proven to be effective in preventing aneurysm-related death secondary to rupture and abdominal aortic aneurysm (AAA) sac expansion in the long-term. However, a significant number of patients over the past decade have been undergoing EVAR outside the IFU,^{1–6} including patients with various hostile neck anatomic features such as neck length less than 10 mm, neck angle > 60 degrees, 50% circumferential proximal neck thrombus (≥ 2 mm thick), 50% calcified proximal neck, reverse taper, and a diameter > 31 mm.¹ Early and late outcomes of EVAR when it is used in patients outside the IFU have been controversial.^{1,5,7} This study will examine the effects of various aortic neck features in EVAR patients according to IFU vs outside the IFU and analyze their predictors for endoleak, re-intervention, sac expansion, and survival.

METHODS

This is a retrospective analysis of prospectively collected data from 525 patients who underwent endovascular aortic aneurysm repair (EVAR) for nonruptured infrarenal abdominal aortic aneurysms (AAA) at our medical center during a 10-year period (2003 to 2013), using only Food and Drug Administration-approved devices (Excluder, WL Gore and Associates; AneuRx, Talent, and Endurant, Medtronic Corporation; Zenith, Cook Corporation, Indianapolis, IN; Powerlink, Endologix). This study included only patients operated on by our 6 full-time academic vascular surgeons at the Vascular Center of Excellence at Charleston Area Medical Center/West Virginia University, Charleston, WV. The study excluded patients who were operated on by other physicians because we had no control over their follow-up. It also excluded patients who lacked preoperative infrarenal aortic neck measurements due to lack of good quality CT scanning. This study was approved by the Institutional Review Board of Charleston Area Medical Center/West Virginia University and informed consent was not required.

All procedures were performed in an independent circulatory dynamics laboratory under general or epidural anesthesia using a modern imaging system (General Electric Medical and Siemens). Device selection was based on physician preference. All devices were deployed flush with the level of the lowest renal artery. Patients were advised to participate in our postoperative surveillance protocol, which included color duplex ultrasound and/or CT angiography (CTA) with plain abdominal radiography within 30 days of the procedure, followed at 6 months, 12 months, and then every 12 months thereafter. It should be noted that our protocol of post-EVAR surveillance was modified over the past 5 years. A CT angiograph or color duplex ultrasound was done within 30 days of the procedure, and if normal (no evidence of endoleak or other abnormalities), a color duplex ultrasound was repeated at 6 months, 12 months, and every 12 months thereafter; and CT was obtained only if there was evidence of endoleak and/or sac enlargement postoperatively.

All patients' electronic medical records were retrospectively reviewed to supplement prospectively collected data. The demographic and clinical characteristics of these patients were analyzed, including 6 aortic neck anatomic features: neck angle, neck length, neck diameter, neck calcification, neck thrombus, and reverse taper. All intra-operative data, 30-day postoperative adverse events, and late events were analyzed.

Definitions

Patients were classified according to their neck features into 2 groups: those who followed the instructions for use (IFU) in regard to neck features vs those who were outside the IFU. The term "outside the IFU" was used if 1 or more of the following 6 neck features were present: neck length < 10 mm, neck angle > 60 degrees, 50% circumferential proximal neck thrombus (≥ 2 mm thick), 50% calcified proximal neck, reverse taper, and a diameter > 31 mm. All CT scans were reviewed by board-certified vascular surgeons or a vascular interventionalist, or both. Every effort was also made to follow the recommendations of the Ad Hoc Committee of the Stent Standardized Reporting Practice in Vascular Surgery.⁸

The proximal aortic neck diameter was recorded in the minor axis from adventitia to adventitia, just below the lowest renal artery with another measurement made at 15 mm below the lowest renal artery or at the distal end of the aortic neck in patients with a short neck. The infrarenal aortic neck length was measured on CT angiography as the distance between the lowest renal artery and the point of aneurysmal dilatation. The aortic angle was measured between the aortic neck and the longitudinal axis of the aneurysm, as seen on angiography.

The term reverse taper was used if gradual neck dilatation ≥ 2 mm within the first 10 mm after the most caudal renal artery was present. It should be noted that for patients with an aortic diameter > 31 mm, in devices in which this neck feature was within the IFU, another additional hostile neck feature should be present to be considered outside the IFU. Endoleak was determined using CT scanning if extravasation of contrast between the prosthesis and the aneurysm wall was noted or by color duplex ultrasound where the flow and spectral signal were outside the prosthesis, or both. If the duplex ultrasound and CT results differed, conventional contrast arteriography was done to confirm the endoleak. The term early endoleak was used for a leak detected intraoperatively or less than 30 days postoperatively, and a late endoleak was defined as a leak discovered 30 days or more postoperatively. The term migration was determined by measuring the distance from the lowest renal artery and the most cephalad part of the stent graft as seen on CT images. Significant migration was referred to as displacement of ≥ 10 mm from the previous study or displacement requiring secondary intervention. Accordingly, significant AAA sac expansion was defined as ≥ 5 mm increase in sac size (compared with preoperative sac size), and significant shrinkage was defined as a decrease of ≥ 5 mm from the preoperative size.

The primary endpoint included early 30-day perioperative outcomes: the rate of early endoleak (specifically, proximal type I) and the use of proximal aortic neck cuffs or proximal aortic stents to seal proximal aortic endoleak. Secondary early endpoints included other perioperative complications, blood transfusions/blood loss, contrast volume, other endoleaks (eg, type II, type III, and type IV), and mortality. Late clinical outcomes included

late type I and type II endoleaks, aortic sac expansion, late reintervention to treat endoleak or other complications, stent migration, conversion to open repair, aneurysm rupture, and late mortality (aneurysm-related deaths). All deaths were verified using the Social Security Death Index.

Statistical methods

Data were analyzed using SAS 9.1. Comparisons between the IFU group and outside the IFU group were performed using contingency table analysis, with chi-square or Fisher's exact test (categorical variables) and t-tests (continuous variables) to determine statistically significant differences. Univariate and multivariate logistic regression analyses were used to predict which neck features outside the IFU were associated with mortality, sac expansion, late endoleak, and early/late intervention. The Kaplan-Meier method was used to estimate survival distributions: survival, freedom from late type I endoleak, freedom from late intervention, and sac expansion for both groups. Comparison between these 2 survival distributions was based on the log-rank test.

RESULTS

Overall, 526 patients were included in this analysis: 289 Gore Excluder (WL Gore); 74 AneuRx, 33 Talent, and 8 Endurant (Medtronic Corporation); 96 Cook Zenith and 25 Powerlink (Endologix); and 1 Trimodular (INCRAFT, Cordis Corporation, Johnson & Johnson). The overall technical success rate was 99.5%, where all devices were successfully deployed, except for 2 patients with the Zenith graft that failed to be deployed through the iliac arteries in the early stage. One refused further treatment and the other patient underwent an open repair. Table 1 summarizes the demographics and clinical characteristics according to the IFU use vs outside the IFU. Tables 2 and 3 summarize the number of patients with each neck feature outside the IFU. Table 4 summarizes intraoperative and hospital variables between IFU patients vs patients outside the IFU. As noted, patients outside the IFU had a significantly longer fluoroscopic time and hospital stay, experienced more blood loss, had more blood transfusions, and more contrast was used.

The early (30-day) perioperative complications according to IFU use are summarized in Table 5. Patients outside the IFU had a significantly higher overall complication rate (12% vs 7%, $p = 0.0463$). Table 6 summarizes all perioperative complications and type of grafts. As noted, there were no significant differences between various grafts used and all perioperative complications ($p = 0.2294$) for the whole series and in patients outside the IFU ($p = 0.4101$). However, there were significant differences in perioperative complications between various grafts in IFU patients ($p = 0.0258$).

Table 7 summarizes the rates of early and late endoleak and early and late intervention according to IFU use vs outside IFU. As noted, early type I proximal endoleak and early intervention were significantly higher in patients outside the IFU, particularly the use of proximal aortic cuffs to seal early endoleak. Late type I endoleak was also significantly higher in patients outside the IFU.

There were no significant differences between the type of device, the rates of early or late type I endoleak, early or late intervention, and sac expansion in IFU patients. However, there was a significant difference in patients outside IFU for early type I endoleak (7.4% for Cook, 17% for AneuRx, 23% for Excluder, and 24% for Talent [$p = 0.048$]); but there were no significant differences in early intervention, late type I endoleak, late intervention, or sac expansion.

Overall, 31 patients had sac expansion (6.6%), 173 (37%) had sac contraction, and 264 (56.4%) were stable. The mean time to sac expansion was 24.5 months (range 1 to 91 months).

Kaplan-Meier analysis of late outcomes and use of instructions for use

At a mean follow-up of 30 months (range 1 to 140 months), the sac expansion rates at 1, 2, and 3 years were similar ($p = 0.288$, Fig. 1). The sac expansion rates at 1, 2, and 3 years for IFU patients were 98.6%, 95.8%, and 90.9%, respectively; and for patients with 1 or more hostile neck features (outside IFU) were 97.1%, 95%, and 91.1%, respectively. The sac expansion rates for patients with 2 or more hostile neck features were: 96.2%, 94.1%, and 86%, at 1, 2, and 3 years, respectively.

Freedom from late type I endoleak and freedom from late reintervention at 1, 2, and 3 years for IFU patients were 99.5%, 99.5%, and 98.4%, and 99.4%, 98%, and 96.8%; vs 98.9%, 98.1%, and 98.1%, and 97.5%, 96.2%, and 95.2% for outside IFU, respectively ($p = 0.049$ and 0.799, Figs. 2 and 3). The survival rates at 1, 2, and 3 years for IFU were 97%, 93.5%, and 89.8%; vs 93.7%, 88.8%, and 86.3% for outside IFU, respectively ($p = 0.035$, Fig. 4).

Overall, there were 49 late deaths: 34 (13.4%) in patients outside the IFU vs 15 (6.3%) for IFU patients ($p = 0.008$). Only 1 patient died secondary to a ruptured AAA. Late interventions included coil embolization, proximal aortic cuffs, fenestrated grafts, distal extension, or an aorta unilateral device with a femorofemoral bypass. These were done to treat persistent late type I or type II endoleaks, migration (2 patients), infected grafts, and/or sac expansion.

Univariate and multivariate logistic regression analysis

Table 8 summarizes predictors of aortic neck features on early and late intervention, late endoleak, sac expansion, and mortality. Logistic regression showed that having 1 or more hostile neck features outside IFU has odds ratios for death, early and late intervention, and late type I endoleak of 2.3, 2.9, 1.5, and 2.7; and for 2 or more hostile neck features 2.9, 4, 1.2, and 2.1, respectively. Multivariate analysis showed that angles > 60 degrees had an odds ratio for death, sac expansion, and early intervention of 6, 2.6, 3.3, respectively; while length < 10 mm had odds ratios of 2.8 for deaths, 3.4 for early intervention, 4.6 for late reintervention, and 4.3 for late type I endoleak.

DISCUSSION

The results of our study indicated that extending use of commercially available endovascular devices outside of the accepted standards for IFU was associated with higher rates of early and late type I endoleak, early intervention, and late death.

With EVAR entering the third decade since its inception, resulting in more physician experience in treating patients with high risk anatomy, its usage has increased and pushed the envelope even further for more challenging cases that fall outside the current IFU standards. We previously reported¹ that the use of EVAR has increased by up to 63% in patients with hostile neck anatomy, and this is comparable to this study, in which EVAR was used outside the IFU in 52% of patients. However, there is ongoing uncertainty regarding the outcomes of this practice.

Interestingly, our initial technical success rate, as well as that of others, has been reported to be up to 99%.^{1,4,9} Proponents of EVAR usage outside the IFU have reported midterm outcomes comparable to those within the IFU, with preferential use of active suprarenal fixation and aggressive use of proximal cuffs.¹⁰ Some have advocated the use of unsupported endografts with active fixation while treating medically compromised patients with hostile neck anatomy.¹¹ Choke and colleagues¹² reported similar results, but they suggested that severely angulated necks may require additional intraoperative procedures. Likewise, some researchers have advocated the use of prophylactic balloon-expandable stents to achieve proximal sealing in such hostile anatomy.⁹ Farley and associates¹³ reported that the Palmaz stents (Cordis) can effectively treat proximal type 1 endoleak and effectively minimize all related adjunctive maneuvers.

Furthermore, Lee and coworkers,¹⁰ in his retrospective review of 218 patients, reported no early or late surgical conversions. In addition, the rates of migration, endoleak, need for reintervention, sac regression, and freedom from aneurysm-related death were all similar between the 2 groups ($p > 0.05$).

On the other hand, some researchers take more of a wait and see approach. Antoniou and associates,² in their meta-analysis, reported on 7 observational studies with 714 hostile neck patients. These patients were 3 times more likely to undergo adjunctive procedures to achieve proximal sealing; therefore, the authors concluded that there is still insufficient evidence to argue for or against using EVAR in hostile neck patients.

Others have suggested that extending the usage of EVAR outside of the IFU recommendations may result in poor outcomes. A meta-analysis³ of 3,039 patients with hostile neck anatomy, with a follow-up range of 9 to 49 months, reported that the 30-day mortality and migration rates in the hostile neck anatomy group were 1.6 and 2 times higher, respectively. In addition, the 30-day type I endoleak rate was 3 times higher in the hostile neck anatomy group, while late type I endoleak was 1.7 times higher. The authors of this extensive review concluded that use of EVAR in patients with a more challenging anatomy resulted in poor outcomes. Likewise, other researchers found a significantly increased risk of short- and mid-term proximal endoleaks after EVAR⁶ when the neck length was < 15 mm.

More devastating outcomes, such as early and delayed aneurysmal rupture, were reported in a review of a 10-year multicenter patient registry.¹⁴

Our study highlighted a very important fact: a high overall technical success rate (99%) was not necessarily protective against perioperative complications in cases performed outside the IFU. We found significantly more perioperative complications in cases performed outside the IFU (12% vs 7%, $p = 0.04$).

Although all types of endoleak should be addressed at the time of intervention, a type I endoleak, in particular, is of special concern because it is directly related to sac expansion and device migration. This study showed the risk of early type I endoleak to be more than double in cases performed outside IFU (18% vs 7% for IFU cases, $p < 0.0001$). It's likely that the higher risk of type I endoleak contributed to the increased chance of early intervention for those outside the IFU (24% vs 10%) and the use of aortic proximal cuffs (16% vs 5%). Other researchers have reported an increased rate of intraoperative adjunctive procedures for cases performed outside the IFU.^{1,6,15} Our results are somewhat similar to those in another meta-analysis that reported a 4-fold increase in the risk of developing a type I endoleak in patients with hostile neck anatomy.²

Subsequently, those cases performed outside the IFU required an increased number of adjunctive procedures to achieve proximal seal, compared with those performed within the IFU standards (odds ratio [OR] 3.050; 95% CI 1.884 to 4.938).² In a meta-analysis, Stather and associates³ reported a similar finding of increased secondary interventions for cases performed outside the IFU standards (OR 1.29, 95% CI 1.00 to 1.66; $p = 0.05$). Another retrospective review⁴ of 552 patients found the type 1 endoleak rate to be significant when the device was used outside the standards for IFU ($p = 0.002$).

Our study also showed that freedom from late type I endoleak and freedom from late reintervention at 1, 2, and 3 years for IFU patients were 99.5%, 99.5%, and 98.4%, and 99.4%, 98%, and 96.8%; vs 98.9%, 98.1%, and 98.1%, and 97.5%, 96.2%, and 95.2%, respectively, for patients outside the IFU ($p = 0.049$ and 0.799). An investigator of the EUROSTAR registry¹⁶ reported that neck angulation was associated with proximal type I endoleak, while the relationship with stent-graft migration was not clear.

The sac expansion rate at a mean follow-up of 30 months in our study was similar between the 2 groups. However, Schanzer and colleagues¹⁷ indicated that 41% of cases performed outside the IFU were associated with sac expansion at 5 years. The similar sac expansion in our series between IFU patients and patients outside the IFU can be secondary to a shorter mean follow-up. Schanzer and coauthors¹⁷ also concluded that independent predictors of AAA sac enlargement after EVAR included age greater than 80 years, endoleak, aortic neck angle > 60 degrees, aortic neck diameter ≥ 28 mm, and common iliac artery diameter > 20 mm. We could not identify these predictors in our study, but the sample size was smaller than in their study, which analyzed 10,228 patients. Candell and associates,¹⁴ in a study of early and late rupture after EVAR in a 10-year multicenter registry, identified 20 patients with rupture in 1,756 EVAR patients. In 15 of these patients, the median time from initial EVAR to rupture was 31.1 months (range 14 to 57 months). Ten of 15 of these delayed

ruptures were preceded by an increase in AAA sac size, which included 3 patients with known endoleaks who underwent reintervention. Nine of these 15 patients also had a new endoleak at the time of delayed rupture. Although the number of ruptures in this study population was extremely small, a word of caution must be added regarding these patients with continued endoleak after EVAR.¹⁴ Likewise, other researchers have suggested a direct relationship between poor outcomes and mortality.² Survival rates at 1, 2, and 3 years for IFU patients in our series were 97%, 93.5%, and 89.8%; vs 93.7%, 88.8%, and 86.3%, respectively, for patients operated on outside the IFU ($p = 0.035$).

A multivariate analysis of this study also showed that an angle > 60 degrees had an odds ratio for death, sac expansion, early intervention of 6, 2.6, 3.3, respectively; a length < 10 mm had an odds ratio of 2.8 for deaths, 3.4 for early intervention, 4.6 for late reintervention, and 4.3 for late type I endoleak.

There is no question that constraining indications to those cases that fall within IFU standards will guard against device-related failure in treating complex anatomy. Still, we believe that technologic advances of new devices may provide a better approach for complex anatomies with fewer device failures.

Although many patients with hostile neck features (outside the IFU) can be treated with other new technology, such as fenestrated/branched stent grafts or chimney grafts, recent reports suggest that fenestrated FEVAR, with the systems that are currently available, have significantly higher risks than standard EVAR.¹⁸ Fenestrated EVAR can also be technically demanding and usually incurs significant cost and delay in treatment, compared with standard devices. Their use is somewhat limited to some centers of expertise, which may not be accessible in many centers treating patients with AAA. Some other technology, including the Aptus system (Aptus Endosystems) to endostable the device proximally can also be used in patients with hostile neck anatomy.¹⁹

There are some limitations to this study. First and foremost, the retrospective design, as often is the case, carries all of the inherent bias associated with patient selection, as well as device choice, which is directly related to physician discretion. In addition, we were limited to data that were routinely collected and stored in electronic medical records. Finally, there was no uniformity in the chosen surveillance method after EVAR, which can be related to affordability, patient demographics, and/or insurance restrictions.

CONCLUSIONS

In conclusion, current standards of IFU should be addressed in relation to anticipated outcomes. Our study results highlighted the fact that higher rates of early and late type I endoleak, early intervention, and late death resulted when recommendations were not followed. Patient selection, interventionist experience, and refining renovations of the new devices will revolutionize the applicability and outcomes of patients with challenging anatomy in the near future.

Off-label use of EVAR devices may fill the void in patients outside the IFU until new stent grafts can be introduced to the market, and physicians should be cautious in obtaining proper informed consent from these patients.

Acknowledgments

The authors gratefully acknowledge Mary Emmett, PhD for her assistance and Mona Lett for her editorial assistance in the preparation of this manuscript.

Abbreviations and Acronyms

AAA	abdominal aortic aneurysm
EVAR	endovascular repair of abdominal aortic aneurysms
IFU	instructions for use

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	IFU			1+ HNF			2+ HNF			3+ HNF		
	N	%	SE	N	%	SE	N	%	SE	N	%	SE
1yr	173	98.6	0.79	167	97.1	1.17	64	96.2	2.17	17	86.9	7.14
2yr	102	95.8	1.59	114	95	1.69	44	94.1	3	12	80.2	9.2
3yr	60	90.9	2.84	85	91.1	2.5	29	86	5.25	7	80.2	9.2

Figure 1.
Freedom from sac expansion. HNF, hostile neck features; IFU, instructions for use.

	IFU			1+HNF			2+HNF			3+HNF		
	N	%	SE	N	%	SE	N	%	SE	N	%	SE
1yr	172	99.5	0.46	155	93.9	1.64	59	93.2	2.94	17	100	
2yr	108	99.5	0.46	107	93.1	1.84	42	91.1	3.58	13	92.9	6.88
3yr	60	98.4	1.19	80	93.1	1.84	28	91.1	3.58	7	92.9	6.88

Figure 2.
Late type I endoleaks. HNF, hostile neck features; IFU, instructions for use.

	IFU			1+ HNF			2+ HNF			3+ HNF		
	N	%	SE	N	%	SE	N	%	SE	N	%	SE
1yr	173	99.4	0.57	165	97.5	1.09	63	97.3	1.86	17	95.2	4.65
2yr	102	98	1.17	113	96.2	1.44	43	95.6	2.53	13	95.2	4.65
3yr	60	96.8	1.65	86	95.2	1.71	30	93	3.5	7	86.6	9.27

Figure 3.
Late intervention. HNF, hostile neck features; IFU, instructions for use.

IFU			1+ HNF			2+ HNF			3+ HNF		
N	%	SE	N	%	SE	N	%	SE	N	%	SE
174	97	1.2	171	93.7	1.63	65	90	3.37	18	84	7.4
104	93.5	1.93	118	88.8	2.3	45	83.8	4.33	13	79.3	8.33
62	89.8	2.86	91	86.3	2.65	32	81.7	4.72	7	72.1	10.2

Figure 4. Survival. HNF, hostile neck features; IFU, instructions for use.

Table 1

Demographic and Clinical Characteristics

Demographic	IFU (n = 251)	Outside IFU (n = 275)	Total (n = 526)	p Value
Age, y, mean	72.6	73.5		0.2564
Sex, n (%)				
Male	213 (85)	220 (80)	433	0.1444
Female	38 (15)	55 (20)	93	
Race, n (%)				
White	246 (98)	270 (98)	516	1
Other	5 (2)	5 (2)	10	
Hypertension, n (%)	213 (85)	237 (86)	450	0.6668
Coronary artery disease, n (%)	155 (62)	160 (58)	315	0.4039
COPD, n (%)	73 (29)	96 (35)	169	0.153
Peripheral arterial disease, n (%)	24 (10)	36 (13)	60	0.2035
Current tobacco use, n (%)	70 (28)	72 (26)	142	0.6597
Previous tobacco use, n (%)	98 (39)	132 (48)	230	0.0386
Congestive heart failure, n (%)	22 (9)	46 (17)	68	0.0066
Atrial fibrillation, n (%)	28 (11)	39 (14)	67	0.2984
Stroke/transient ischemic attack, n (%)	16 (6)	34 (12)	50	0.0193
Type of graft, n (%)				
Gore Excluder	139 (55)	150 (55)	289	0.731
Cook Zenith	42 (17)	54 (20)	96	
AneuRx	39 (16)	35 (13)	74	
Endologix	11 (4)	14 (5)	25	
Endurant	4 (2)	4 (1)	8	
Talent	16 (6)	17 (6)	33	

IFU, instructions for use.

Table 2

Number of Patients with Each Neck Feature Outside the Instructions for Use (n = 275)

Outcomes predictor	Outside IFU (n = 275/526)	
	n	%
Neck angle > 60 degrees	49	18
Neck length < 10 mm	35	13
Neck diameter > 31 mm	16	6
Neck calcium 50%	51	19
Neck thrombus 50%	135	49
Reverse taper	133	48

IFU, instructions for use.

Table 3

Hostile Neck Features Outside Instructions for Use

Number of hostile neck features outside IFU	Frequency	Percentage
0	251	48
1	174	33
2	69	13
3	23	4
4	7	1
5	2	0.4

IFU, instructions for use.

Table 4
Intraoperative and Hospital Variables According to Instructions for Use vs Outside Instructions for Use

Variable	Mean	SD	Minimum	Maximum	p Value
Fluoroscopic time, min					
IFU	22	11.7	7	70	< 0.0001
Outside IFU	27	15.0	7	102	
Estimated blood loss, mL					
IFU	203	200	0	1,200	0.0247
Outside IFU	261	314	0	2,500	
Amount of contrast, mL					
IFU	110.0	52	18	260	0.0011
Outside IFU	130.0	61	15	355	
Blood transfusion, U					
IFU	0.2	0.8	0	6	0.0012
Outside IFU	0.6	1.5	0	11	
Length of hospital stay, d					
IFU	3.3	4.2	1	34	0.0194
Outside IFU	4.3	5.4	1	45	

IFU, instructions for use.

Table 5

Perioperative Complications According to Instructions for Use

Perioperative complication	IFU (n = 251)		Outside IFU (n = 275)		p Value
	n	%	n	%	
Myocardial infarction	6	2.4	2	0.7	0.1599
Graft thrombosis	4	1.6	12	4.4	0.0646
Acute renal failure	6	2.4	10	3.6	0.4059
Hematoma/bleeding	1	0.4	3	1.1	0.6251
Deep vein thrombosis	1	0.4	2	0.7	1
Colon ischemia	3	1.2	1	0.4	0.3522
Wound infection	2	0.8	6	2.2	0.2894
Paralysis	0	–	2	0.7	0.5001
Death	1	0.4	4	1.5	0.3752
All perioperative complications	18	7.0	34	12.0	0.0463

IFU, instructions for use.

Table 6

Type of Grafts and Perioperative Complications

Type of graft	All complications	Patients with 1+ neck features outside IFU	Patients with IFU
Gore Excluder, n (%)	22/289 (7.6)	17/150 (11.3)	5/139 (3.6)
Cook Zenith, n (%)	11/96 (11.5)	8/54 (14.8)	3/42 (7.1)
AneuRx, n (%)	8/74 (10.8)	2/35 (5.7)	6/39 (15.4)
Endologix, n (%)	4/25 (16)	2/14 (14.3)	2/11 (18.2)
Endurant, n (%)	2/8 (25)	1/4 (25)	1/4 (25)
Talent, n (%)	5/33 (15.2)	4/17 (23.5)	1/16 (6.3)
Trimodular, n (%)	0/1	0/1	—
p Value	0.2294	0.4101	0.0258

IFU, instructions for use.

Table 7

Early and Late Endoleak and Intervention

Endoleak/intervention	IFU (n = 251)		Outside IFU (n = 275)		p Value
	n	%	n	%	
Early type I	18	7	50	18	0.0002
All early endoleak and type					
0	177	71	176	64	
1	18	7	50	18	
2	52	21	47	17	
4	4	2	2	0.7	
Aortic proximal cuff	13	5	43	16	0.0001
Proximal aortic stent	12	5	20	7	0.2324
All early intervention	25	10	66	24	< 0.0001
Late type I endoleak	5	2	14	6	0.0477
All late endoleak and type					
0	191	80	212	83	
1	5	2	14	6	
2	44	18	27	11	
3	0	–	1	0.4	
Late intervention	9	4	14	6	0.3529
Sac expansion	17	7	14	6	0.4716

IFU, instructions for use.

Table 8
Univariate and Multivariate Logistic Regression Analysis According to Outside Instructions for Use

	Mortality	Sac expansion	Early intervention	Late re-intervention	Late type 1 endoleak
Univariate					
Features outside the IFU					
1+	2.32 (1.23–4.38)	0.76 (0.37–1.59)	2.86 (1.74–4.69)	1.5 (0.64–3.53)	2.74 (0.97–3.63)
2+	2.91 (1.55–5.48)	1.57 (0.68–3.63)	3.97 (2.42–6.52)	1.23 (0.44–3.39)	2.09 (0.77–5.65)
3+	2.68 (1.03–6.98)	3.68 (1.29–10.46)	2.71 (1.26–5.84)	1.63 (0.36–7.33)	0.92 (0.12–7.17)
Neck features outside the IFU					
Neck angle > 60 degrees	6.10 (3.00–12.43)	2.61 (1.01–6.74)	3.56 (1.90–6.67)	1.53 (0.44–5.37)	1.93 (0.54–6.91)
Neck length < 10 mm	2.80 (1.14–6.86)	1.60 (0.46–5.89)	4.10 (2.01–8.35)	4.57 (1.58–13.24)	4.26 (1.33–13.68)
Diameter > 31 mm	2.57 (0.69–9.56)	2.59 (0.55–12.13)	0.68 (0.15–3.03)		
50% calcification	1.06 (0.40–2.82)	2.41 (0.94–6.20)	2.44 (1.29–4.63)	1.42 (0.41–4.97)	2.61 (0.83–8.21)
50% circumferential thrombus	2.64 (1.44–4.83)	0.29 (0.09–0.98)	1.20 (0.72–1.98)	0.80 (0.29–2.19)	1.03 (0.37–2.93)
Reverse taper	0.81 (0.39–1.68)	1.58 (0.72–3.47)	2.57 (1.60–4.13)	1.15 (0.44–2.97)	1.16 (0.41–3.28)
Multivariate (includes all 6 neck features in the model)					
Neck features outside the IFU					
Neck angle > 60 degrees	5.95 (2.87–12.37)	2.81 (1.06–7.47)	3.28 (1.71–6.29)		
Neck length < 10 mm	2.76 (1.07–7.10)		3.42 (1.62–7.24)	4.57 (1.58–13.24)	4.26 (1.33–13.68)
Diameter > 31 mm					
50% Calcification		2.72 (1.02–7.23)			
50% Circumferential thrombus	2.38 (1.27–4.48)	0.25 (0.07–0.84)			
Reverse taper			2.07 (1.25–3.40)		

All data are presented as odds ratios (95% CI). IFU, instructions for use.