From the Eastern Vascular Society

Comparative study of clinical outcome of endovascular aortic aneurysms repair in large diameter aortic necks (>31 mm) versus smaller necks

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ABSTRACT

Background: This study compares short-term (30 days) and intermediate term (3 years) clinical outcomes in patients with large (≥31 mm) versus small aortic neck diameters (≤28 and ≤31 mm).

Methods: Prospectively collected data from 741 patients who underwent endovascular aortic aneurysm repair were analyzed. Some surgeons have reported the threshold for a large aortic neck for endovascular aortic aneurysm repair to be 28 mm, whereas for others it is 31 mm. Therefore, we classified aortic neck diameter into less than or equal to 28 versus greater than 28 mm; and less than or equal to 31 versus greater than 31 mm. Logistic regression and Kaplan-Meier analyses were used to compare outcomes.

Results: There were 688 patients who had a defined aortic neck diameter: 592 with less than or equal to 28 mm, 96 with greater than 28 mm, 655 with less than or equal to 31 mm, and 33 with greater than 31 mm. The mean follow-up was 25.2 months for less than or equal to 31 mm versus 31.8 months for greater than 31 mm. Clinical characteristics were similar in all groups, except that there were more patients outside the instructions for use in the greater than 31 mm versus less than or equal to 31 mm group (94% vs 44%; $P < .0001$). There was a significant increase in early type I endoleak for patients with an aortic neck diameter of greater than 31 versus less than or equal to 31 mm (9 [27%] vs 74 [11%]; $P = .01$); late type I endoleaks (4 [14%] vs 18 [3%]; $P = .01$); sac expansion (5 [17%] vs 28 [5%]; $P = .01$); late intervention (5 [17%] vs 23 [4%]; $P = .01$); and death (9 [31%] vs 48 [8%]; $P < .0001$). There were no differences in outcomes between the patients with greater than 28 mm aortic neck diameters and the less than or equal to 28 mm diameters. Freedom from late type I endoleak at 1, 2, and 3 years were 96%, 88%, and 88% for patients with a neck diameter of greater than 31 mm versus 97%, 97%, and 97% for a diameter less than or equal to 31 mm ($P = .19$). The rate of freedom from sac expansion for patients with a diameter greater than 31 mm was 88%, 81%, and 81% at 1, 2, and 3 years versus 99%, 97%, and 92% for a diameter less than or equal to 31 mm ($P = .02$). Freedom from late intervention for 1, 2, and 3 years for patients with a diameter greater than 31 mm were 91%, 91%, and 91% versus 99%, 97%, and 96% for those with a diameter less than or equal to 31 mm. Survival rates at 1, 2, and 3 years for a diameter greater than 31 mm were 83%, 74%, and 68% versus 96%, 92%, and 90% for a diameter less than or equal to 31 mm ($P < .001$). Multivariate logistic regression analysis showed that patients with a diameter greater than 31 mm had an odds ratio of 6.1 (95% confidence interval [CI], 2.2-16.8) for mortality, 4.7 (95% CI, 1.4-15.5) for sac expansion, and 4.9 (95% CI, 1.4-17.4) for late type I endoleak.

Conclusions: Patients with large aortic neck diameters (>31 mm) had higher rates of early and late type I endoleak, sac expansion, late intervention, and mortality. (J Vasc Surg 2018;■:1-9.)

Keywords: Endovascular; Abdominal aortic aneurysms; EVAR; Aortic neck size; Endovascular aneurysm repair

Several clinical trials comparing traditional open repair for endovascular aortic aneurysm repair (EVAR) have confirmed the perioperative benefits of an endovascular repair.[1-5] Two randomized trials, EVAR 1 and DREAM (Dutch Randomized Endovascular Aneurysm Management), reported significantly reduced operative time, perioperative mortality, duration of hospital stay, and transfusion requirements.[6,7] Meanwhile, a significant number of patients with an abdominal aortic aneurysm (AAA) patients have undergone EVAR outside the instructions for use (IFU) over the past decade,[8-13] including patients with hostile aortic neck anatomy (specifically short necks [<10 mm], angulated necks [>60°], and an aortic neck diameter of >31 mm).

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Author conflict of interest: none.

Presented at the Thirty-first Annual Meeting of the Eastern Vascular Society, Savannah, Ga, October 5-8, 2017.

Additional material for this article may be found online at www.jvascsurg.org.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2018.02.037

Presently, five devices are commercially available to treat patients with large aortic neck diameters up to 32 mm: Zenith Flex (Cook, Bloomington, Ind), Excluder (W. L. Gore, Flagstaff, Ariz), Powerlink (Endologix, Irvine, Calif), and Endurant II (Medtronic Corp., Santa Rosa, Calif). In addition, the Aorfix (Lombard Medical, Oxford, United Kingdom) stent graft is now available, and can be used to treat AAAs with aortic neck diameters up to 29 mm, Trivascular Ovation (Trivascular, Endologix) can be used for aortic necks up to 30 mm, and the Anaconda (Vascutek, Terumo, Scotland, United Kingdom) for 31 mm. However, long-term clinical outcomes for patients with large aortic diameter necks are lacking.

Our present study analyzes the early and intermediate outcomes for EVAR patients with an aortic neck diameter of greater than 31 mm and compare them with patients with an aortic neck diameter of less than or equal to 31 mm, and also compare less than or equal to 28 mm versus greater than 28 mm neck diameters.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected single-center registry data
- **Take Home Message:** Endovascular aortic aneurysm repair in 33 patients with an aortic neck diameter of greater than 31 mm resulted in an increase in early and late type I endoleak, late sac expansion, late intervention, and death compared with 655 patients with an aortic neck diameter of less than or equal to 31 mm.
- **Recommendation:** This study suggests that standard endovascular aortic aneurysm repair should likely not be performed in patients with an aortic neck diameter of greater than 31 mm.

METHODS

This study is a retrospective analysis of prospectively collected data of 741 patients who underwent EVAR for elective infrarenal AAAs at our medical center over a 13-year period (2003 to December, 2015), using only devices approved by the U.S. Food and Drug Administration. Patients' electronic medical records, including demographic and clinical characteristics, were reviewed retrospectively to supplement prospectively collected data. This study only included patients done by our full-time academic vascular surgeons and excluded those done by other physicians, because we had no control over their follow-up (n = 96).

All procedures were performed under general or epidural anesthesia using modern imaging systems (General Electric Medical, Milwaukee, Wisc, and Siemens, Munich, Germany). Patients were asked to participate in postoperative surveillance protocol, including computed tomography angiography (CTA) and/or color duplex ultrasound examination within 30 days of the procedure, and were followed at 6 months, 12 months, and every 12 months thereafter. However, this protocol was modified in the past few years: if the CTA or color duplex ultrasound examination done within 30 days was normal (no evidence of endoleak or other abnormalities), then a color duplex ultrasound examination was repeated at 6 months, 12 months, and every 12 months thereafter. A CTA was only obtained if there was evidence of endoleak and/or sac enlargement postoperatively. All CTA scans were reviewed by a board-certified vascular surgeon, a vascular interventionalist, or both.

Every effort was made to follow the recommendations of the Ad Hoc Committee of the Stent Standardized Reporting Practice in Vascular Surgery.[14] In summary, the proximal aortic neck diameter was recorded in the minor axis from adventitia to adventitia, just below the lowest renal artery, and 15 mm below the lowest renal artery or at the distal end of the aortic neck in patients with a short neck. Patients were classified according to aortic neck diameters of greater than 31 mm versus less than or equal to 31 mm and, greater than 28 versus less than or equal to 28 mm. These measurements were selected based on prior observation. Other aortic neck measurements were described by us previously.[8] These included aortic neck length, aortic neck angle, aortic neck greater than or equal to 50% of the circumferential thrombus, aortic neck calcification, and reverse taper.

Endoleak was determined using computed tomography (CT) scanning if extravasation of contrast between the prosthesis and the aneurysms wall was noted or by color duplex ultrasound examination, where the flow and spectral signal were outside the prosthesis, or both. If the duplex ultrasound examination and CT results differed, conventional contrast arteriography was done to confirm the endoleak. Significant AAA sac expansion was defined as a 5 mm or greater increase in sac size, compared with the preoperative sac size.

The primary end point included early 30-day perioperative outcomes: rate of early endoleak (specifically proximal type I), and the use of proximal aortic neck cuffs or Palmaz stents to seal proximal aortic endoleaks (early intervention). These early interventions included intraoperative endoleaks, which was noted at completion angiography (most of them) or within 30 days. Endoleak was determined using CT, based on extravasation of contrast between the aneurysm wall and the prosthesis or by color duplex ultrasound imaging, where the flow and spectral signals were outside the prosthesis, or both. If the CT and duplex ultrasound results differed, contrast angiography was done to confirm the endoleak. Late clinical outcomes included late type I endoleaks, aortic sac expansion, late intervention to treat endoleak or other complications, stent migration, conversion to open repair, aneurysm rupture, and late mortality (aneurysm-related deaths). Migration was determined

Table I. Demographic and clinical characteristics

Characteristics	≤28 mm, No. (%)	>28 mm, No. (%)	*P*	≤31 mm, No. (%)	>31 mm, No. (%)	*P*
Mean age, y (range)	72.9 (45-101)	75.5 (55-92)	.01	73.2 (45-101)	74.7 (55-86)	.35
Male gender	472 (80)	79 (82)	.56	521 (80)	30 (91)	.11
Hypertension	493 (83)	85 (89)	.19	548 (84)	30 (91)	.27
Diabetes mellitus	118 (20)	27 (28)	.07	137 (21)	8 (24)	.65
Smoking	372 (63)	60 (63)	.95	408 (62)	24 (73)	.23
Coronary artery disease	336 (57)	57 (59)	.63	374 (57)	19 (58)	.96
Hyperlipidemia	381 (64)	61 (64)	.88	421 (64)	21 (64)	.94
Peripheral artery disease	71 (12)	16 (17)	.20	81 (12)	6 (18)	.29
COPD	209 (35)	36 (38)	.68	232 (35)	13 (39)	.64
Congestive heart failure	68 (11)	18 (19)	.05	79 (12)	7 (21)	.17
Home oxygen	33 (6)	5 (5)	.88	37 (6)	1 (3)	1.00
Chronic renal failure	108 (18)	26 (27)	.04	124 (19)	10 (30)	.11
Outside IFU	239 (41)	76 (79)	<.0001	284 (44)	31 (94)	<.0001

COPD, Chronic obstructive pulmonary disease; *IFU,* instructions for use.

by measuring the distance from the lowest renal artery and the most cephalad portion of the stent graft, as seen on CT images. Significant migration was defined as displacement of 10 mm or more from the predischarge study or any displacements requiring secondary intervention. All deaths were reported by our health system records and verified using the Social Security Death Index. Secondary early end points included other perioperative complications, blood transfusions/blood loss, and contrast volume. The study was approved by the Institutional Review Board of Charleston Area Medical Center/West Virginia University and informed consent was not required.

Statistical methods. The data were analyzed using SAS 9.1 (SAS Institute, Inc, Chicago, Ill). Comparisons between various aortic neck diameter groups (aortic neck of >31 mm vs ≤31 mm and >28 mm versus ≤28 mm) were done using a contingency table analysis with a Fisher's exact test or χ^2 (categorical variables) and *t*-tests. A logistic regression analysis and the Kaplan-Meier method were used to determine late clinical outcomes. The survival distributions were compared based on the log-rank test.

RESULTS

Seven hundred forty-one EVAR patients were reviewed; however, 53 patients were excluded from analysis because their aortic neck diameter measurements were not available. Five hundred ninety-two patients had an aortic neck diameter of less than or equal to 28 mm, 96 with a diameter of greater than 28 mm, 655 with a diameter of less than or equal to 31 mm, and 33 with a diameter of greater than 31 mm. A total of 20 of these necks with a diameter of greater than 31 mm had an aortic neck of 32 mm, that is, within the IFU device (these included nine Gore Excluder, six Cook Zenith, one AneuRx, and four other devices). Five had a 33-mm neck diameter (one Gore Excluder, two Cook Zenith, and two others). The remaining eight patients included four with an aortic neck diameter of 34 mm (two Gore Excluder and two Cook Zenith). Three patients had a 35-mm neck diameter (two Gore Excluder and one Cook Zenith) and one patient had a 36-mm diameter (Gore Excluder). It should be noted that five of these patients outside of the IFU required early intervention, which was either a large Palmaz stent or an aortic cuff extension to treat immediate early type I endoleaks after completion of the procedure. Overall, this series included 416 Gore Excluder (W. L. Gore), 115 Cook Zenith (Cook), 74 AneuRx (Medtronic Corp.), 33 Talent (Medtronic Corp.), 28 Powerlink (Endologix), 14 Endurant (Medtronic Corp.), 4 Trimodular (INCRAFT, Cordis Corp., Johnson & Johnson, Fremont, Calif), and 4 Aorfix (Lombard Medical, Irvine, Calif). Six hundred thirty-six patients had late follow-up beyond 30 days postoperatively. The technical success rate was 99.5%, where all devices were successfully deployed, except for two patients with the Zenith graft that failed to be deployed in the early stage of our experience. The mean follow-up was 25.2 months for aortic necks of less than or equal to 31 mm (range, 1-140 months) and 31.8 months (range, 3.1-93.0 months) for aortic necks greater than 31 mm in diameter. Fifty-three patients had no follow-up or surveillance studies.

Table I summarizes the demographic and clinical characteristics according to aortic neck diameter. The clinical characteristics were similar in all groups, except for age, where patients with a neck diameter of greater than 28 mm had a mean age of 75.5 years versus 72.9 years for patients with a neck diameter of less than or equal to 28 mm ($P = .01$). There were also more patients outside the IFU in the greater than 28-mm

Table II. Comparison of aortic neck diameter (less than or equal to 31 mm vs >31 mm)

	≤31 mm, No. (%)	>31 mm, No. (%)	Total	*P*
Early type I endoleak	74 (11.3)	9 (27.3)	605	.01
Early intervention	59 (9)	5 (15.2)	64	.22
Late type I endoleak	18 (3)	4 (13.8)	22	.01
Sac expansion	28 (4.6)	5 (17.2)	33	.01
Late intervention	23 (3.8)	5 (17.2)	28	.01
Death	48 (7.9)	9 (31)	57	<.0001

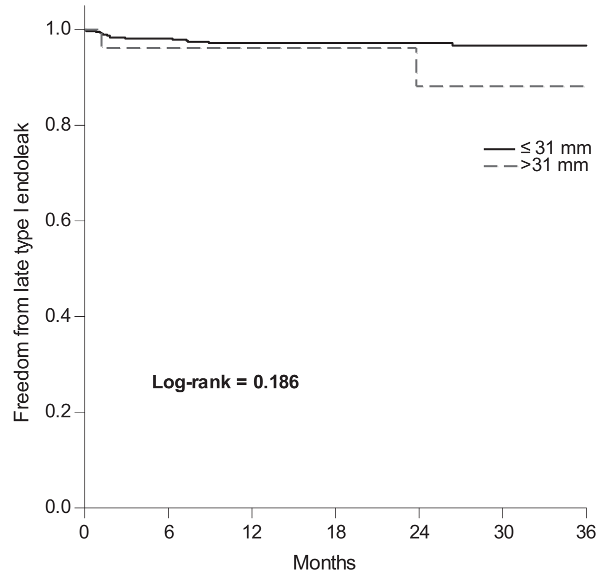
diameter group (79% vs 41%; $P < .0001$). Similarly, there were more patients outside the IFU for patients with a diameter of greater than 31 mm versus those with a diameter of less than or equal to 31 mm (94% vs 44%; $P < .0001$).

Supplementary Table I (online only) summarizes the intraoperative and hospital variables according to aortic neck diameter and, as noted, there were no differences between the groups regarding fluoroscopy time, estimated blood loss/blood transfusion, the amount of contrast used, and duration of stay. Similarly, there were no differences between various 30-day perioperative complications between the groups (Supplementary Table II, online only).

When patients with a neck diameter of greater than 31 mm were compared with those with a neck diameter of less than or equal to 31 mm, there were significant differences in early type I endoleak (27.3% vs 11.3%; $P = .01$). The rate of late type I endoleaks was also significantly higher for patients with necks greater than 31 mm in diameter (13.8% vs 3%; $P = .01$); and the rate of sac expansion was significantly higher for greater than 31 mm necks (17.2% vs 4.6%; $P = .01$). Similarly, the rate of late intervention was significantly higher in necks greater than 31 mm (17.2% vs 3.8%; $P = .01$). The overall death rate was higher in greater than 31 mm necks in diameter (31% vs 7.9%; $P < .0001$; Table II). It should be noted that there was no threshold effect when comparing necks greater than 28 mm with those less than or equal to 28 mm in diameter.

The Gore Excluder device (n = 401) was used more often than the other devices (n = 104 Cook Zenith, n = 73 AneuRx, and n = 76 others). However, there were no differences between various devices in rates of late endoleak ($P = .42$) and sac expansion ($P = .05$); however, there was more late intervention for the AneuRx ($P = .05$), but this device is not used anymore.

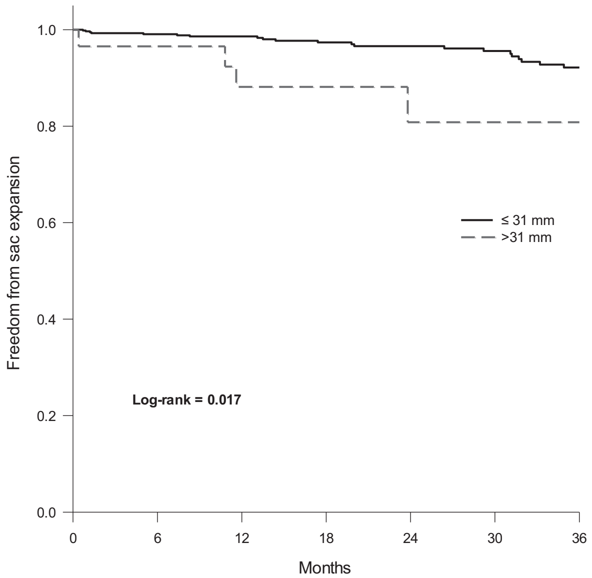
Overall, there were 28 patients who had late intervention (12 for late endoleak with sac expansion, 6 for late endoleak, and 10 for sac expansion), which included proximal aortic cuffs, Palmaz stents, fenestrated grafts, open conversion, aortounilateral device with femorofemoral bypass, or coil embolization. The remaining patients with late endoleak (n = 4) or sac expansion (n = 11) underwent no intervention owing to death or because they refused. To be noted, the average open repair for AAA in our center was 15 to 20 cases annually during this study period. It should be noted that over the past few years, a few of our surgeons opted for an open repair on patients with larger aortic necks (>31 mm) who were good surgical risks and reserved EVAR for patients who were high risk for open surgery.



	≤31 mm*		>31 mm*	
	At risk	%	At risk	%
6 mo	444	98.1	23	96.2
12 mo	350	97.2	20	96.2
18 mo	264	97.2	17	96.2
24 mo	211	97.2	11	88.1
36 mo	138	96.7	8	88.1

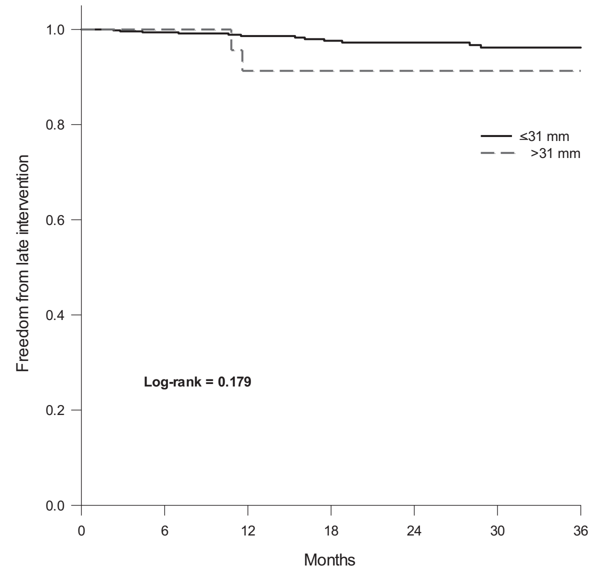
Fig 1. Freedom from late type I endoleak comparing less than or equal to 31 mm with greater than 31 mm aortic neck diameters. Log rank = 0.19. *The standard error never exceeded 10%.

Comparison of neck diameters greater than 31 mm versus less than or equal to 31 mm. Rates of freedom from late type I endoleak at 1, 2, and 3 years were 96%, 88%, and 88% for neck diameters greater than 31 mm versus 97%, 97%, and 97% for those less than or equal to 31 mm ($P = .19$; Fig 1). The rates of freedom from sac expansion at 1, 2, and 3 years were 88%, 81%, and 81% for neck diameters greater than 31 mm and 99%, 97%, and 92% for those less than or equal to 31 mm ($P = .02$; Fig 2). The rates of freedom from late intervention were 91%, 91%, and 91% for neck diameters greater than 31 mm and 99%, 97%, and 96% for those less than or equal to 31 mm ($P = .18$; Fig 3). The survival rates at 1, 2, and 3 years were 83%, 74%, and 68 for neck diameters greater than



	≤ 31 mm *		>31 mm*	
	At risk	%	At risk	%
6 mo	455	99.1	25	96.6
12 mo	362	98.6	21	88.2
18 mo	274	97.4	18	88.2
24 mo	217	96.6	11	80.8
36 mo	143	92.1	8	80.8

Fig 2. Freedom from sac expansion comparing less than or equal to 31 mm with greater than 31 mm aortic neck diameter. *The standard error never exceeded 10%.



	≤31 mm*		>31 mm*	
	At risk	%	At risk	%
6 mo	455	99.4	26	100
12 mo	360	98.6	21	91.3
18 mo	274	97.6	18	91.3
24 mo	216	97.2	14	91.3
36 mo	144	96.2	10	91.3

Fig 3. Freedom from late intervention comparing less than or equal to 31 mm with greater than 31 mm aortic neck diameter. Log rank = 0.18. *The standard error never exceeded 10%.

31 mm and 96%, 92%, and 90% for those less than or equal to 31 mm ($P < .001$; Fig 4).

To be noted, none of the late deaths in these groups were related to an aortic aneurysm rupture.

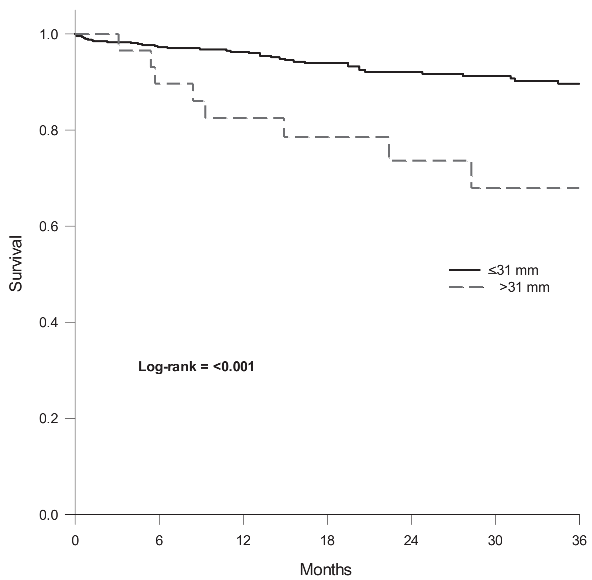
Regression analysis. Table III summarizes the univariate analysis comparing neck diameters greater than 28 mm versus those less than or equal to 28 mm and those greater than 31 mm versus those less than or equal to 31 mm. When comparing those greater than 31 mm versus those less than or equal to 31 mm, the odds ratio for mortality was 5.2 (95% confidence interval [CI], 2.26-12.14), 4.3 (95% CI, 1.53-12.13) for sac expansion, 5.3 (95% CI, 1.85-15.11) for late intervention, and 5.2 (95% CI, 1.65-16.62) for late type I endoleak.

In the multivariate analysis, patients with an aortic neck diameter greater than 31 mm had an odds ratio for mortality of 6.1 (95% CI, 2.21-16.82), 4.7 (95% CI, 1.42-15.52) for sac expansion, and 4.9 (95% CI, 1.39-17.44) for late type I endoleak.

DISCUSSION

In the modern era of infrarenal AAA management, EVAR has become the preferred method of treatment assuming that the anatomic characteristics are favorable for endovascular repair. Improvements in endograft design have resulted in improved outcomes,[15] with various randomized trials demonstrating that EVAR is associated with less perioperative morbidity and mortality than open repair.[6,16] EVAR now provides significantly reduced operative time, transfusion requirements, and duration of hospital stay.[4] Key anatomic considerations contributing to favorable aneurysm configurations include an adequate aortic neck length, minimal tortuosity, and a nominal neck diameter to allow adequate sealing between the aortic wall and the endograft.[17] However, as technology has expanded and improved the design of endografts available for use in the market today, physicians now use devices outside the IFU to treat more challenging anatomic variations. Treatment is now offered to those with aortic neck lengths of greater than 15 mm, severe aortic angulation (>60°), and larger proximal aortic neck diameters. Neck diameters ranging from 24 to 34 mm are considered large. Larger necks are considered outside the IFU. The largest devices available have maximum diameters of 36 mm designed to treat aortic necks only up to 32 mm.[18]

It is our contention with this study that the treatment of large proximal aortic neck diameters (>31 mm) can have



	≤31 mm*		>31 mm*	
	At risk	%	At risk	%
6 mo	459	97.2	26	89.7
12 mo	367	96.2	23	82.5
18 mo	281	93.9	20	78.6
24 mo	223	92.1	14	73.6
36 mo	151	89.6	10	68

Fig 4. Survival analysis comparing less than or equal to 31 mm with greater than 31 mm aortic neck diameter. Log rank <0.001. *The standard error never exceeded 10%.

unfavorable results with conventional EVAR and that caution and close postendograft placement surveillance are paramount for these subgroup of patients. Although some earlier studies did not show any significant correlation with adverse outcomes with treatment of large diameter proximal aortic necks, the findings of many current studies parallel our results.

In 2002, Ingle et al[19] found that 14 patients with aortic neck diameters of 28 mm or greater had no increase in size of the aortic neck, nor was there any increase in the incidence of proximal endoleak. However, they used only the Talent endograft, and the average follow-up was only 12 months. In 2007, Goodman et al[20] used the Cook 36-mm Zenith endograft to treat 67 patients with neck diameters ranging from 28 to 34 mm. Aneurysm-related mortality was 4.5% within a mean follow-up of 27 months; however, the minimum length of the necks was 20 mm. Two other studies, one by Zayed et al[21] using large Zenith endografts and another by Jordan et al[22] using the Endologix Powerlink XL, demonstrated good results with wide aortic necks, but only 6 of 25 patients in the Zenith study had necks shorter than 15 mm, and the Powerlink XL study excluded neck lengths of that size. Additionally, the follow-up ranged from 6 months in the study by Zayed et al to 1 year in the study by Jordan et al. Bastos Goncalves et al,[23] reporting from the Endurant Stent Graft Natural Selection Global Post-market Registry (ENGAGE), found that 398 patients treated with 32- or 36-mm diameter stent grafts did not have any increased risk of neck-related adverse events. However, the study did not delineate the specific aortic neck diameters for those patients treated with these large diameter stent grafts,[23] so it is uncertain how many of these 398 patients truly had wide aortic necks, namely, those with diameters greater than 28 mm, and in particular those with diameters greater than 31 mm. Jim et al[17] looked at the effectiveness of the Talent stent graft on 156 patients, with a subgroup analysis evaluating 53 of those patients with a large aortic neck diameter defined as 28 mm or greater. Although this subgroup of patients had higher rates of major adverse events within the first year and lower freedom from all-cause mortality at 30 days and aneurysm-related death at 1 year, at 5 years there were no differences in rates of endoleaks or aneurysm changes, and the freedom from aneurysm-related mortality at 5 years was not significant. Indeed, even in our own previous study assessing clinical outcomes of hostile versus favorable neck anatomy,[8] we found no relation between neck diameter and type IA endoleaks, but in our study the mean neck diameter was only 25 mm and only a relatively few patients had a neck diameter of greater than 28 mm.

Other studies have found unfavorable results with treatment of large infrarenal aortic neck diameters with endovascular devices.[24] Oliveria et al[24] found an increased risk of type IA and III endoleaks, neck-related secondary interventions, and proximal neck-related adverse events in 74 patients with a neck diameter 30 mm or greater. In 2011, Schanzer et al[25] analyzed 10,228 patients undergoing EVAR between 1999 and 2008 and found that patients with large neck diameters (≥28 mm) had an increased risk of secondary sac enlargement. Jim et al[17] found that patients with neck diameters of 28 mm or greater had higher rates of major adverse events within the first year, as well as lower freedom from all-cause mortality at 30 days and aneurysm-related death at 1 year. Stather et al[11] reviewed 552 patients who underwent EVAR and found increased risks of late type IA endoleaks and secondary interventions for patients with an aneurysm diameter of greater than 28 mm. Gargiulo et al[26] reported their experience with 118 patients undergoing EVAR with aortic necks 28 mm or greater in diameter with a midterm follow-up period of approximately 38 months. They found a large aortic neck to be associated with significant aortic neck enlargement at 24 months as well as a high risk of type IA endoleaks and proximal neck-related interventions.

In the current study, comparing the groups individually, rates of early type I endoleaks and early interventions were more prevalent in patients with a neck diameter

Table III. Logistic regression analysis

Neck diameter features	Mortality, OR (95% CI)	Sac expansion, OR (95% CI)	Early intervention, OR (95% CI)	Late reintervention, OR (95% CI)	Late type I endoleak, OR (95% CI)
Univariate					
>28 mm vs ≤28 mm	1.99 (1.02-3.86)	2.09 (0.91-4.80)	1.32 (0.66-2.62)	2.17 (0.89-5.27)	2.43 (0.93-6.40)
>31 mm vs ≤31 mm	5.24 (2.26-12.14)	4.31 (1.53-12.13)	1.80 (0.67-4.85)	5.29 (1.85-15.11)	5.24 (1.65-16.62)
Multivariate (includes diameter >31 mm)					
Neck angle >60°	5.70 (2.69-12.09)	—	3.72 (1.77-7.83)	—	—
Neck length <10 mm	—	—	4.82 (2.11-10.99)	4.80 (1.79-12.92)	4.25 (1.36-13.31)
Diameter >31 mm	6.10 (2.21-16.82)	4.69 (1.42-15.52)	—	—	4.92 (1.39-17.44)
Neck thrombus ≥50%	2.29 (1.22-4.29)	0.25 (0.07-8.34)	—	—	—
Male gender	—	—	0.46 (0.23-0.89)	—	—
COPD	2.74 (1.47-5.10)	—	—	—	—
Reverse taper	—	—	2.21 (1.19-4.11)	—	—
Multivariate (includes diameter >28 mm)					
Neck angle >60°	6.04 (2.88-12.63)	2.84 (1.08-7.52)	3.72 (1.77-7.83)	—	—
Neck length <10 mm	—	—	4.82 (2.11-10.99)	4.80 (1.79-12.92)	5.47 (1.85-16.17)
Diameter >28 mm	2.20 (1.03-4.67)	2.67 (1.06-6.70)	—	—	—
Neck thrombus ≥50%	2.15 (1.15-4.04)	0.22 (0.06-0.74)	—	—	—

CI, Confidence interval; *COPD,* chronic obstructive pulmonary disease; *OR,* odds ratio; *IFU,* instructions for use.

greater than 31 mm at 27% and 15%. When comparing the less than or equal to 31 mm group versus the greater than 31 mm group, the results demonstrate unfavorable results as the diameter of the aortic neck increases. This comparison is important, because it focuses on determining whether patients with aortic necks measuring above the upper limit of device-approved diameters, that is, 31 mm, are the majority of patients in our analysis who experienced adverse results with EVAR. Based on our results, it seems that this may indeed be the case. This group had an early type I endoleak rate of 27.3% versus 11.3% for the less than or equal to 31 mm neck group; and late type I endoleak, sac expansion, and late intervention rates of 13.8%, 17.2%, and 17.2% versus 3%, 4.6%, and 3.8%, respectively. Furthermore, the survival rates at 3 years were 68% for the greater than 31 mm group versus 90% for the less than or equal to 31 mm group.

These results could be explained by the intuitive conclusion that modern devices simply are not large enough to achieve a proper seal in these large aortic neck diameters. Usually, neck dilation after EVAR is a well-documented phenomenon, especially when one uses oversized self-expanding endografts.[24] Cao et al[27] found significant proximal aortic neck dilation in 30% of patients, whereas Gargiulo et al[26] found significant enlargement of the infrarenal neck in 41% of patients. Dilation can occur owing to the chronic outward radial force of the endograft on the infrarenal neck.[28] A 30% oversizing has been found to increase the chance of device migration[29] and that a 20% oversizing increased the risk of proximal neck dilation.[30] Thus, an oversizing of approximately 15% to 20% seems to be reasonable to achieve adequate seal without necessarily provoking these untoward results.[26,31]

A second explanation of aortic neck dilation involves the pathophysiology of the aortic neck wall itself. The infrarenal neck has been shown to be histologically diseased, which may lead to progressive dilation.[24] Immune pathways are upregulated within the nondilated aorta proximal to the aneurysmal segment, and these areas have demonstrated histologic signs of destruction.[32] An increased aneurysmal burden demonstrated by the presence of larger aortic neck diameters and AAA size has been shown to be an independent risk factor for continuing aortic neck dilation.[32,33] Thus, large aortic neck diameters may already be damaged and weakened so that endovascular devices that could initially achieve a sufficient seal will ultimately develop endoleaks over time.

Our study has some limitations, including being retrospective; therefore, these results should be examined with caution. The Gore Excluder device was used more often than the other devices, and this factor could have a profound effect on determining outcome differences between the device groups. However, there were no differences between various devices in rates of late endoleak and sac expansion, although there was more late intervention for AneuRx5, but this device is not used anymore. Device selection was based on physician preference, and this heterogeneous selection may carry a selection bias.

CONCLUSIONS

Our data demonstrate that, as the aortic diameter widens, the treating physician should proceed with extreme caution and explore all treatment options before proceeding with standard EVAR procedures with currently available devices. Follow-up CTA/duplex ultrasound examination should be mandatory for a long period of time. Although there may be some risk inherent in treating patients with aortic necks between 28 and 31 mm, these seem to be reasonably calculated risks supported, not only by our current findings, but from other recent studies as well. However, once the aortic diameter exceeds 31 mm, and effectively beyond the maximum allowable diameter by current device standards, it is imperative that patients understand the potential risks involved and consider any other options, because EVAR in this situation requires intense surveillance and may require additional interventions.

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

AUTHOR CONTRIBUTIONS

Conception and design: AA, TD, ZA, SH, MY, LD, SA, AM
Analysis and interpretation: AA, ZA, SH, MY, LD, SA, AM
Data collection: AA, TD, ZA, SA, AM
Writing the article: AA, SH
Critical revision of the article: AA, TD, ZA, SH, MY, LD, SA, AM
Final approval of the article: AA, TD, ZA, SH, MY, LD, SA, AM
Statistical analysis: AA, LD
Obtained funding: Not applicable
Overall responsibility: AA

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Submitted Aug 23, 2017; accepted Feb 20, 2018.

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Supplementary Table I (online only). Intraoperative and Hospital Variables According to Aortic Neck Diameter

Variable	≤28 mm, mean (range)	>28 mm, mean (range)	*P*	≤31 mm, mean (range)	>31 mm, mean (range)	*P*
Fluoroscopy time, min	23.5 (5.8-102.0)	25.3 (8.0-150.0)	.56	26.6 (5.8-150.0)	26.2 (12.0-78.0)	.29
Blood loss, mL	206.6 (0.0-2,100.0)	280.8 (0.0-2,500.0)	.63	213.9 (0.0-2,500.0)	268.6 (0.0-1,700.0)	.68
Blood transfusion, U	0.29 (0.00-8.00)	0.60 (0.00-11.00)	.09	0.30 (0.00-8.00)	0.80 (0.00-11.00)	.07
Contrast amount, mL	112.1 (15.0-355.0)	101.2 (20.0-280.0)	.20	110.8 (15.0-355.0)	104.1 (35.0-215.0)	.82
Duration of stay, d	3.5 (1.0-43.0)	4.3 (1.0-45.0)	.76	3.5 (1.0-43.0)	5.5 (1.0-45.0)	.08

Supplementary Table II (online only). Perioperative complications

Complication	≤28 mm, No. (%)	>28 mm, No. (%)	*P*	≤31 mm, No. (%)	>31 mm, No. (%)	*P*
Graft limb thrombosis	13 (2.2)	3 (3.1)	.48	15 (2.3)	1 (3)	.55
Iliac rupture	1 (0.2)	0 (0)	1	1 (0.2)	0 (0)	1
Deep vein thrombosis	3 (0.5)	0 (0)	1	3 (0.5)	0 (0)	1
Myocardial infarction	8 (1.4)	1 (1)	1	8 (1.2)	1 (3)	.36
Wound infection	7 (1.2)	1 (1)	1	8 (1.2)	0 (0)	1
Wound hematoma	4 (0.7)	1 (1)	.53	5 (0.8)	0 (0)	1
Acute renal failure	14 (2.4)	5 (5.2)	.17	18 (2.8)	1 (3)	.6
Colon ischemia	6 (1)	1 (1)	1	6 (0.9)	1 (3)	.29
Sepsis	4 (0.7)	1 (1)	.53	4 (0.6)	1 (3)	.22
All perioperative complications	49 (8.3)	11 (11.5)	.31	56 (8.6)	4 (12.1)	.52