From the Society for Vascular Surgery

Patients with large neck diameter have a higher risk of type IA endoleaks and aneurysm rupture after standard endovascular aneurysm repair

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ABSTRACT

Objective: Standard endovascular aneurysm repair (EVAR) is the most common treatment of abdominal aortic aneurysms (AAAs). EVAR has been increasingly used in patients with hostile neck features. This study investigated the outcomes of EVAR in patients with neck diameters ≥30 mm in the prospectively maintained Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE).

Methods: This is a retrospective study comparing patients with neck diameters ≥30 mm with patients with neck diameters <30 mm. The primary end point was type IA endoleak (EL1A). Secondary end points included secondary interventions to correct EL1A, aneurysm rupture, and survival.

Results: This study included 1257 patients (mean age, 73.1 years; 89.4% male) observed for a median 4.0 years (interquartile range, 2.7-4.8 years). A total of 97 (7.7%) patients had infrarenal neck diameters ≥30 mm and were compared with the remaining 1160 (92.3%) with neck diameters <30 mm. At baseline, there were no differences between groups regarding demographics and comorbidities other than cardiac disease, which was more frequent in the ≥30-mm neck diameter group ($P = .037$). There were no significant differences between the groups regarding neck length, angulation, thrombus, or calcification. Mean preoperative AAA diameter was 64.6 ± 11.3 mm in the ≥30-mm neck diameter group and 60.0 ± 11.6 mm in the <30-mm neck diameter group ($P < .001$). Stent graft oversizing was significantly less in the ≥30-mm neck diameter group (12.2% ± 8.9% vs 22.1% ± 11.9%; $P <. 001$). Five patients (5.2%) in the ≥30-mm neck diameter group and 30 (2.6%) with neck diameters <30 mm developed EL1A, yielding a 4-year freedom from EL1A of 92.4% vs 96.6%, respectively ($P = .09$). Oversizing was 21.8% ± 13.0% for patients developing EL1A and 21.3% ± 12.4% for the remaining cohort ($P = .99$). In adjusting for neck length, AAA diameter, and device oversizing, patients with neck diameter ≥30 mm were at greater risk for development of EL1A (hazard ratio, 3.0; 95% confidence interval, 1.0-9.3; $P = .05$). Secondary interventions due to EL1A did not differ between groups ($P = .36$). AAA rupture occurred in three patients with neck diameter ≥30 mm (3.1%) and in eight patients with neck diameter <30 mm (0.7%; hazard ratio, 5.1; 95% confidence interval, 1.4-19.2; $P = .016$); two cases were EL1A related in each group. At 4 years, overall survival was 61.6% for the ≥30-mm neck diameter group and 75.2% for the <30-mm neck diameter group ($P = .009$), which remained significant on correcting for sex and AAA diameter ($P = .016$).

Conclusions: In this study, patients with infrarenal neck diameter ≥30 mm had a threefold increased risk of EL1A and fivefold risk of aneurysm rupture after EVAR as well as worse overall survival. This may influence the choice of AAA repair

and underlines the need for regular computed tomography-based imaging surveillance in this subset of patients. Furthermore, these results can serve as standards with which new, possibly improved technology, such as EndoAnchors (Medtronic, Santa Rosa, Calif), can be compared. (J Vasc Surg 2019;69:783-91.)

Endovascular aneurysm repair (EVAR) has become the preferential treatment of abdominal aortic aneurysms (AAAs), leading to an increase in the overall number of electively performed repairs while reducing perioperative morbidity and mortality.[1,2]

Despite that encouraging results have been reported after EVAR in wide infrarenal necks in the short term, contradictory evidence has been published during longer term follow-up.[3-5] In addition, as many series included several devices, the extent to which specific device-related factors may have influenced the reported results is not clear.[6] Consequently, EVAR outcomes with contemporary endografts in wide necks warrant investigation as these may influence the choice of the method of repair as well as postoperative surveillance in contemporary practices.

The Endurant stent graft (Medtronic AVE, Santa Rosa, Calif) is a late-generation endograft that combines high flexibility with enhanced proximal fixation, making it a device with proved performance for AAA patients with hostile neck anatomy up to midterm follow-up.[7,8] Instructions for use (IFU) define the range of eligible neck diameters from 18 to 32 mm.[9] Importantly, this endograft has been engineered to exert similar radial forces on the aorta given the same oversizing irrespective of the implanted endograft's nominal diameter (personal presentation from Research & Development, Medtronic). At the manufacturer's expectation, this feature is believed to minimize the endograft's impact on infrarenal neck anatomy, making it particularly well suited to treat patients with wide neck diameter.

The purpose of this study was to determine the impact of wide infrarenal neck diameter on midterm outcomes after EVAR in the Endurant Stent Graft Natural Selections Global Postmarket Registry (ENGAGE).

METHODS

Study design and population. This is a retrospective study based on the prospectively maintained ENGAGE registry. A study group including patients with a neck diameter ≥30 mm measured just below the lowermost renal artery if neck length was >10 mm or an infrarenal neck diameter ≥30 mm measured just above the beginning of the aneurysm if neck length was ≤10 mm was selected. These patients were compared with the remaining population of the registry with regard to comorbidities and baseline anatomic characteristics. ENGAGE includes only adult patients who consented to collection and analysis of their personal medical data.[10] The 79 participating centers were distributed throughout 30 different countries worldwide. The study was conducted according to the Helsinki Declaration on research ethics and approved by local ethics committees. Only EVAR-suitable patients treated electively for intact AAA with an Endurant stent graft were included. Strict adherence to the device's IFU was not required, particularly in regard to the proximal neck but also for other anatomic characteristics. Concurrent participation in other studies or predictable nonadherence to follow-up was not permitted. Adhering centers were selected on the basis of an annual case volume of at least 20 EVAR cases including at least 3 previously successful Endurant implantations. Inclusion in the registry was based on intention to treat, and the enrollment of a minimum of five patients per center was recommended. Although the number of patients treated with other stent grafts by each center is not able to be determined, all patients included in the registry were enrolled consecutively.

Data collection and postoperative surveillance. Each center submitted prospective patient data electronically. Baseline demographic variables as well as medical comorbidities including smoking habits, hypertension, diabetes, hyperlipidemia, cardiac disease, pulmonary disease, renal insufficiency, and peripheral arterial disease were collected. Entered anatomic features included maximum AAA diameter, proximal neck diameter, neck length, infrarenal neck angulation, and neck involvement by mural thrombus or calcification. Protocol-defined adverse events including aneurysm-related complications and secondary interventions were registered. Aneurysm sac changes were also assessed in postoperative imaging. Planned follow-up was scheduled at 30 days, at 1 year, and annually thereafter with obligatory imaging studies. Computed tomography (CT) was recommended, but duplex ultrasound and magnetic resonance imaging were also accepted imaging modalities. All clinical data entry was monitored by external auditors.

Definitions. Outer-to-outer wall neck diameters were measured immediately below the lowermost renal artery and just cranial to the beginning of the aneurysm on CT imaging. Oversizing was calculated by dividing the difference between the implanted endograft's diameter and the measured neck diameter at the lowermost renal artery level by the neck diameter. Endograft migration was determined as distance changes between the first covered stent and the lowermost renal artery during follow-up relative to 30-day imaging. The patients'

comorbidities and aneurysm-related outcomes are reported according to the Society for Vascular Surgery reporting standards.[11] Accordingly, sac growth was defined as >5-mm-diameter increases after EVAR. Baseline renal insufficiency was directly reported by each site as part of the patient's medical history. Postoperative renal failure was defined per protocol as the need for dialysis or a doubled serum creatinine level relative to baseline values. Major adverse events were defined per protocol as any of the following: all-cause mortality, stroke, myocardial infarction, renal failure, respiratory failure (need for >24 hours of postoperative mechanical ventilation or reintubation for any reason), paraplegia, bowel ischemia, or procedural blood losses >1000 mL. Secondary endovascular interventions performed to correct type IA endoleaks (EL1As) included Palmaz stents, proximal cuff implantation, and other endovascular interventions.

End points. The primary study end point was EL1A, which also included undetermined endoleaks. Secondary interventions performed to correct EL1A, aneurysm sac growth, major adverse events, aneurysm rupture, overall mortality, and aneurysm-related mortality were assessed as secondary end points.

Statistical analysis. Categorical variables are presented as count and percentage and compared using the Pearson χ^2 test. Continuous variables are presented as mean and standard deviation and compared using Student t-tests if normally distributed. If continuous data were skewed, they were presented as median and range and compared using the Mann-Whitney U test for independent samples. Survival curves and estimates obtained by Kaplan-Meier methods and equality were assessed with the Mantel-Cox log-rank test. Multivariable proportional hazards regression was performed including predefined variables for risk assessment of the main outcomes. Confidence intervals (CIs) of 95% are presented, and statistical significance was considered for $\alpha \leq .05$. All statistical analyses were performed using SAS software (SAS Institute, Cary, NC) and Statistical Package for the Social Sciences 21.0 (IBM Corp, Armonk, NY).

RESULTS

The ENGAGE registry enrolled 1263 patients from March 2009 to May 2011. Among these, there were six patients in whom the primary implantation of the Endurant stent graft was not completed (as reported elsewhere) who were excluded from this analysis.[12] Among the remaining 1257 patients with a median follow-up of 4.04 years (interquartile range, 2.73-4.69 years), 97 (7.7%) had a baseline infrarenal neck diameter ≥30 mm and formed the study group. These were compared with the remaining 1160 (92.3%) patients. At the time of this study, 46 patients (47.4%) with a ≥30-mm neck diameter and 608 (52.4%) among the control group had reached 4-year follow-up ($P = .26$). Baseline demographics and

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective study of prospectively collected data of the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE)
- **Key Findings:** Of 1257 patients who underwent endovascular aneurysm repair using the Endurant device, 97 patients (7.7%) had an infrarenal neck diameter ≥30 mm and had significantly greater risk of type IA endoleaks, higher risk for aneurysm rupture, and worse overall survival during a median of 4 years than those with a smaller aneurysm neck.
- **Take Home Message:** Abdominal aortic aneurysms with an infrarenal neck diameter ≥30 mm have more type I endoleaks, higher mortality, and more ruptures than aneurysms with a smaller neck. They should be observed closely with computed tomography scans and should be considered for EndoAnchors or fenestrated stent grafts.

anatomic characteristics are presented in Table I. There were no differences between groups regarding demographics and comorbidities other than cardiac disease, which was more frequent in the ≥30-mm neck diameter group (63.9% vs 52.9%; $P = .037$). Patients with a neck diameter ≥30 mm had larger AAAs (mean diameter, 64.6 ± 11.3 mm) than the <30-mm neck diameter patients (mean, 60.0 ±11.6 mm; $P < .001$). Among the ≥30-mm neck diameter group, 18 patients (18.6%) had an infrarenal neck diameter >32 mm. Mean endograft oversizing was 12.2% (±8.9%) and 22.1% (±11.9%) in the ≥30-mm and <30-mm neck diameter groups, respectively ($P < .001$).

Type IA endoleaks and associated secondary interventions. EL1A occurred in 35 patients (2.8%): 5 patients (5.2%) in the ≥30-mm neck diameter group (3 of whom with baseline neck diameters >32 mm) and 30 patients (2.6%) in the <30-mm neck diameter group ($P = .12$). At 4-year follow-up, freedom from EL1A was 92.4% (n = 56; standard error [SE], 0.035) in the ≥30-mm neck diameter group and 96.6% (n = 781; SE, 0.007) in the <30-mm neck diameter group ($P = .09$; Fig 1). Stent graft oversizing was 21.8% ± 13.0% for patients who developed EL1A and 21.3% ± 12.4% for the remaining cohort ($P = .99$). On correcting for infrarenal neck length, AAA diameter, and endograft oversizing, an infrarenal neck diameter ≥30 mm was associated with a greater chance for development of EL1A over time (hazard ratio [HR], 3.0; 95% CI, 1.00-9.25; $P = .049$).

Secondary interventions were performed to correct EL1A in 3 patients (3.1%) in the ≥30-mm neck diameter group (2 with reference neck diameters >32 mm) and in 21 patients (1.6%) in the <30-mm neck diameter group ($P = .36$; Table II). Eleven patients with EL1A were not

Table I. Baseline demographic and anatomic characteristics

Variables	Proximal neck diameter ≥30 mm (n = 97)	Proximal neck diameter <30 mm (n = 1160)	*P* value
Age, years	73.3 (±7.7)	73.1 (±8.1)	.785
Male sex	92 (94.8)	1032 (89.0)	.071
Hypertension	80 (83.3)	856 (74.8)	.061
Diabetes mellitus	17 (18.5)	219 (19.1)	.888
Hyperlipidemia	59 (64.1)	661 (60.5)	.491
Renal insufficiency	18 (18.9)	175 (15.2)	.331
Tobacco use	43 (44.8)	562 (49.6)	.361
ASA class 3/4	55 (56.7)	600 (51.7)	.724
Neurologic disease	13 (13.4)	148 (12.8)	.856
Cardiac disease	62 (63.9)	614 (52.9)	.037
Pulmonary disease	29 (30.9)	286 (25.0)	.213
AAA diameter, mm	64.6 (±11.3)	60.0 (±1.6)	<.001
Proximal neck diameter, mm	31.1 (±2.1)	23.1 (±2.8)	<.001
Proximal neck length, mm	24.8 (±12.5)	27.2 (±2.4)	.065
Neck thrombus or calcification >25%	12 (12.4)	157 (13.5)	.674
Infrarenal angle, degrees	28.9 (±21.6)	30.5 (±23.9)	.526
Endograft diameter, mm	34.8 (±2.3)	28.1 (±3.5)	<.001
Oversizing, %	12.2 (±8.9)	22.1 (±11.9)	<.001

AAA, Abdominal aortic aneurysm; *ASA,* American Society of Anesthesiologists.
Continuous data are presented as mean (±standard deviation) and categorical data as count (%).

intervened on. Four patients died of unrelated causes before undergoing any intervention (cardiac failure, two patients; cancer-related causes, two patients). Four patients were considered unfit or unsuitable for any intervention. Two patients had transient EL1A (one patient in each of the groups, both confirmed on CT angiography). These patients were managed conservatively, and the EL1A was not observed on subsequent CT imaging. Although short proximal seal was noted in both, no subsequent intervention had been planned by the treating physician at the time of this report. Finally, one patient was offered a secondary endovascular intervention but refused any additional repair.

Aneurysm sac enlargement, major adverse events, and aneurysm rupture. Imaging was performed at 4-year follow-up for 36 patients (37.1%) in the ≥30-mm neck diameter group and for 544 patients (46.9%) in the <30-mm neck diameter group. At 4-year imaging, aneurysm sac growth was found in 3 patients (8.3%) in the ≥30-mm neck diameter group and in 60 patients (11.0%) in the <30-mm neck diameter group (*P* = .62). After adjusting for sex and aneurysm diameter, infrarenal neck diameter ≥30 mm was not associated with aneurysm sac growth at 4-year imaging (*P* = .62).

Major adverse events occurred in 35 (36.1%) patients in the ≥30-mm neck diameter group and in 314 (27.1%) in the <30-mm neck diameter group (*P* = .049; Table II). On correcting for sex and preoperative aneurysm

diameter, this difference lost statistical significance (*P* = .08). Aneurysm rupture occurred in three patients (3.1%) with infrarenal neck diameters ≥30 mm (two with neck diameter >32 mm) and eight (0.7%) patients with neck diameter <30 mm (HR, 5.1; 95% CI, 1.4-19.2; *P* = .016). Mean stent graft oversizing was 21.6% (±9.8%) for patients with aneurysm rupture and 21.3% (±12.5%) for the remaining cohort (*P* = .61). All three ruptures in the ≥30-mm neck diameter group and three of the ruptures in the <30-mm neck diameter group occurred before the third postoperative year, whereas there were an additional five patients in the <30-mm neck diameter group who ruptured later on. Aneurysm rupture was due to EL1A in two cases in the ≥30-mm neck diameter group and two cases in the <30-mm neck diameter group.

All-cause mortality and aneurysm-related mortality. During the study period, 33 patients (34.0%) died in the ≥30-mm neck diameter group and 261 patients (22.5%) in the <30-mm neck diameter group. At 4 years, overall survival was 61.6% among patients with neck diameters ≥30 mm (n = 58; SE, 0.055) and 75.2% among patients with neck diameters <30 mm (n = 795; SE, 0.015; HR, 1.59; 95% CI, 1.12-2.25; *P* = .009; Fig 2). This difference remained significant on correcting for sex and AAA diameter (*P* = .016).

The cause of death was aneurysm related in one patient (1%) in the ≥30-mm neck diameter group and 19 (1.6%) in the <30-mm neck diameter group (*P* = .49).
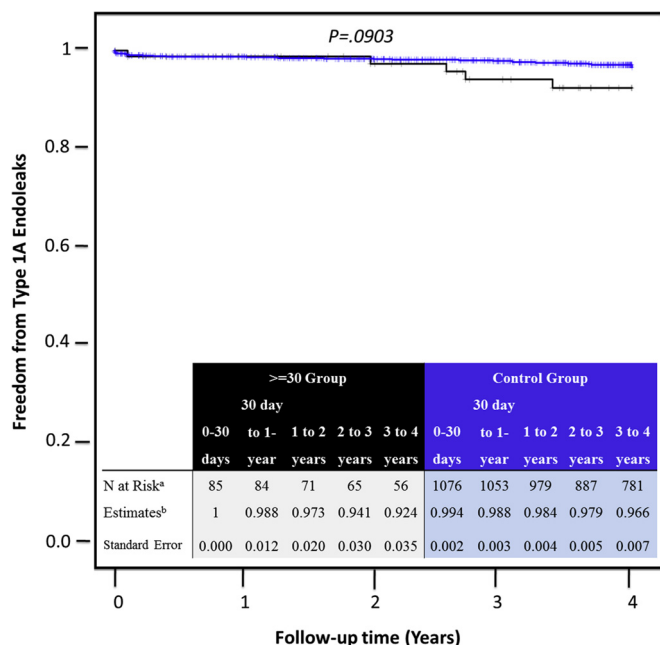
Fig 1. Freedom from type IA endoleaks (EL1As). Although the survival curves representing the patients with ≥30-mm neck diameter (*black line*) and the control group (*blue line*) diverged after 2 years of follow-up, this was not statistically significant in univariable analysis (*P* = .0903). [a]Number of patients at risk at the beginning of interval. [b]Estimate made at end of time interval.

At 4 years, freedom from aneurysm-related mortality was 99.0% (n = 58; SE, 0.01) in the ≥30-mm neck diameter group and 98.3% (n = 795; SE, 0.005) in the <30-mm neck diameter group (*P* = .64; Fig 3). On adjusting for sex and aneurysm diameter, these differences remained nonsignificant (*P* = .49).

DISCUSSION

The results from the ENGAGE registry show that patients with neck diameters ≥30 mm have a threefold greater risk for development of EL1A and a fivefold risk of aneurysm rupture after standard EVAR. In addition, overall survival was worse for patients with infrarenal neck diameters ≥30 mm, although aneurysm-related mortality did not differ between groups.

Histologic studies have found the infrarenal neck to be affected well before the development of dilation.[13] In addition, wider necks have been suggested to dilate more after standard infrarenal EVAR.[14] However, when the clinical impact of baseline neck diameter on EVAR outcomes was analyzed, the results have been conflicting, such as in the report from Aburahma et al,[15] who did not find an increased risk of EL1A (odds ratio, 0.6; 95% CI, 0.1-2.4) among a group of 258 patients. Importantly, mean follow-up was only 22 months. Similarly, in a previous ENGAGE-based study, Bastos Gonçalves et al[4] also could not find an increased risk of neck-related adverse events (defined as a composite of postoperative EL1A or undetermined endoleak, device migration, need for proximal neck secondary intervention, or postimplantation rupture) in those 398 patients treated with a 32- or 36-mm-diameter endograft (*P* = .40). However, only 38% of the cohort had reached the 2-year follow-up. This may explain the conflicting results between that report and the results herein presented. Moreover, other methodologic differences, such as a stricter study group selection in this study, may have exposed more subtle differences, unveiling an increased risk of EL1A and aneurysm rupture in patients with neck diameters ≥30 mm.

The results presented in this study are in line with other larger studies that find an association between baseline neck diameter and complications after EVAR. In the report from Schanzer et al[5] (N = 10,228; mean follow-up, 31 months), patients with neck diameters >32 mm had a twofold increased risk of sac growth (95% CI, 1.5-2.9). Nevertheless, neck-related complications such as EL1A were not disclosed. Stather et al[6] also investigated the implications of several hostile neck features on the outcomes after standard EVAR in a population of 552 (mean follow-up, 4.1 years). Accordingly, patients with neck diameters >28 mm were also at greater risk of late EL1A (*P* = .008). Noteworthy in both of these studies, several endograft models were used, some even withdrawn from the market many years ago. Consequently, as device stratification was not provided, the applicability of their results may be limited. The importance of endograft-related features in EVAR outcomes is particularly reflected in the European Collaborators on Stentgraft Techniques for Aortic Aneurysm Repair (EUROSTAR)-based study from Waasdorp et al[16] (N = 1317; median follow-up, 17 months), who reported an 8.7% rate of EL1A and a 5.3% rate of device migration in the group of patients with neck diameter >26 mm (both *P* < .05), which is higher than the 4-year rates of EL1A we herein present. Importantly, that study included only patients treated with the Talent stent graft (Medtronic), a second-generation device that lacks fixating barbs, which makes it less resistant to distal displacement compared with other contemporary devices.[17] More recently, this has been highlighted in a head-to-head comparison between the Talent and the Endurant endografts by 't Mannetje et al,[18] who reported an 18.2% rate of neck-related interventions among Talent-implanted patients (n = 90), which was significantly higher than the 4.8% rate among Endurant implants (n = 131; *P* = .001). Furthermore, our study suggests that the mechanism of proximal seal loss in an Endurant-implanted patient is not preceded by significant device migration but rather is due to progressive dilation of the infrarenal neck, which differs from other devices as well. In a multicenter report from our group on a different cohort of patients treated solely with Endurant stent grafts, no differences were found among

Table II. Clinical and device-related outcomes after endovascular aneurysm repair (EVAR)

	Neck diameter ≥30 mm (n = 97)	Neck diameter <30 mm (n = 1160)	Univariable P value
Follow-up, years	3.9 (2.0-4.5)	4.1 (2.8-4.7)	.07
Major adverse event (at least one)	35 (36.1)	314 (27.1)	.049
All-cause mortality	33 (34.0)	261 (22.5)	.008
Aneurysm-related mortality	1 (1.0)	19 (1.6)	.642
Stroke	1 (1.0)	25 (2.2)	—
Myocardial infarction	3 (3.1)	44 (3.8)	—
Renal failure	1 (1.0)	25 (2.2)	—
Respiratory failure	0 (0.0)	5 (0.4)	.514
Bowel ischemia	0 (0.0)	5 (0.4)	.514
EL1A (and undetermined endoleaks)	5 (5.2)	30 (2.6)	.117
Type IB endoleak	2 (2.1)	25 (2.2)	.986
Aneurysm diameter increase[a]	3 (8.3)[a]	60 (11.0)[a]	.615
Aneurysm rupture	3 (3.1)	8 (0.7)	.017
Open conversion	1 (1.0)	12 (1.1)	.976
Due to EL1A	1 (1.0)	3 (0.3)	.205
Secondary endovascular procedure	11 (11.3)	123 (10.9)	.895
To correct EL1A	2 (2.1)	17 (1.5)	.670
To correct type I or type III endoleak	3 (3.1)	42 (3.7)	.751
Migration >10 mm	0 (0.0)	1 (0.1)	—
Suprarenal bare stent fracture	0 (0.0)	1 (0.1)	—
Suprarenal bare stent detachment from fabric	0 (0.0)	0 (0.0)	—
Extrusion or erosion of stent graft metal frame	0 (0.0)	0 (0.0)	—

EL1A, Type IA endoleak.
Data are presented as count (percentage) or median (interquartile range).
[a]Aneurysm diameter measurements at both 1 month and 48 months were available for 36 patients (37.1%) in the ≥30-mm neck diameter group and for 544 patients (46.9%) in the <30-mm neck diameter group.

patients with neck diameters ≥30 mm and neck diameters <30 mm in respect to endograft migration, despite an increased rate of EL1A among the wider neck cohort of patients (9.5% vs 3.7%; P = .005).[19] Importantly, although neck dilation did not differ significantly between groups (16% vs 13%, respectively; P = .45), median follow-up was shorter (3.1 vs 4.1 years; P < .001), and endograft oversizing (12.5% vs 16.6%) was significantly less in the ≥30-mm neck diameter group. This suggests that patients with neck diameters ≥30 mm may experience increased dilation rates. Consequently, it may be considered that serial radiography and duplex ultrasound may have a limited role in the postoperative surveillance of patients treated with Endurant stent grafts as subtle changes in the proximal seal zone are undetectable by these imaging modalities and significant device migration is unlikely to occur. Thus, we emphasize the need for regular CT-based imaging in these patients for timely detection of any progressive loss of proximal seal to elicit pre-emptive treatment. In addition, three of the five EL1As reported among wide-neck patients occurred in patients with neck diameters >32 mm, which emphasizes the importance of IFU

compliance in regard to neck diameter. Currently available accessory technology, such as EndoAnchors (Medtronic), may play a role in reducing neck dilation and may be well suited for this subgroup of patients.[20] However, whereas longer term results are lacking, baseline neck diameter was found to be associated with neck dilation at 1-year follow-up despite the use of EndoAnchors.[20]

In this report, stent graft oversizing was significantly less in the ≥30-mm neck diameter group, which may have also contributed to the reported higher risks of EL1A and aneurysm rupture. It could be argued that if increased stent graft oversizing had been provided or feasible, this risk could be reduced. Nevertheless, analyses correcting for the differences among groups in device oversizing show that the risk persists. In our opinion, increased device oversizing might postpone loss of proximal seal but would not entirely eliminate the risk. Alternative endovascular methods targeting a more durable sealing zone in the suprarenal aorta in anatomically suitable patients (fenestrated EVAR [F-EVAR] or chimney/snorkel EVAR [Ch/Sn-EVAR]) may be considered. In a systematic review from Li et al,[21]
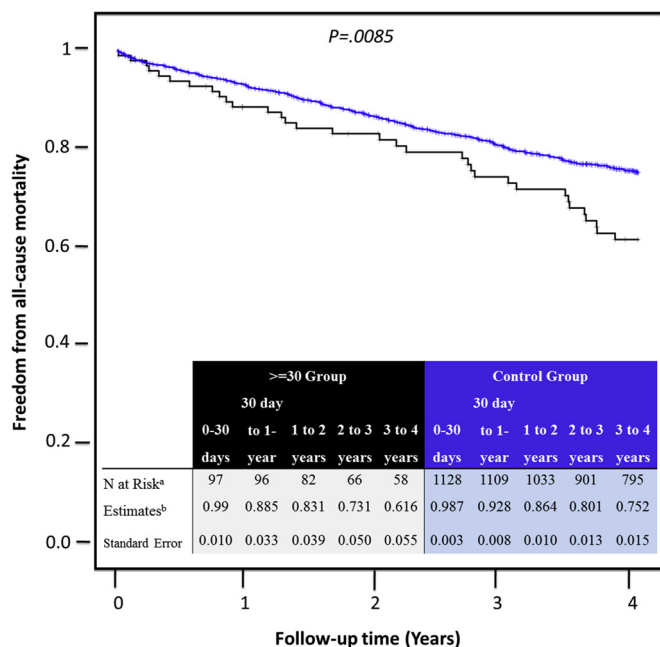
Fig 2. Freedom from all-cause mortality. A statistically significant divergence is observed between the curves representing the ≥30-mm neck diameter group (*black line*) and the control group (*blue line*; P = .0085). [a]Number of patients at risk at the beginning of interval. [b]Estimate made at end of time interval.
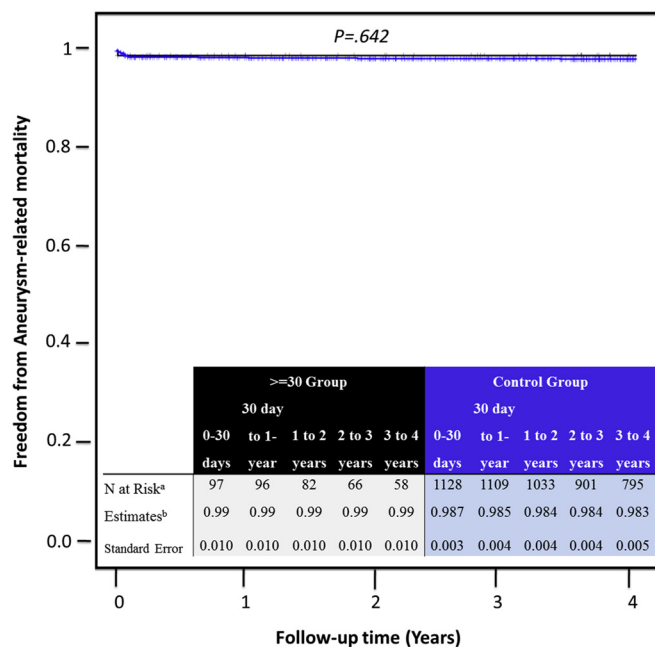

Fig 3. Freedom from aneurysm-related mortality No differences were observed between the ≥30-mm neck diameter group (*black line*) and the control group (*blue line*; P = .642). [a]Number of patients at risk at the beginning of interval. [b]Estimate made at end of time interval.

perioperative mortality rates were 1.1% for F-EVAR and 3.8% for Ch/Sn-EVAR. Type I endoleaks occurred in 5.4% of the F-EVAR group (29/542; mean follow-up, 13 months) and in 7.6% of the Ch/Sn-EVAR group (12/158; mean follow-up, 14.7 months). Verhoeven et al[22] also presented a low perioperative mortality (0.7%) among a group of 281 F-EVAR patients. In this study, during a mean follow-up of 21 ± 16 months, only four patients (1.4%) developed type IB endoleaks and two patients (0.7%) had a type III endoleak. In a report from Roy et al[23] including 173 patients (median follow-up, 34 months), freedom from secondary interventions was 62.8% at 5 years, whereas graft-related endoleaks occurred in 10.4% of the cases (18/173). Compared with these series, standard infrarenal EVAR in patients with wide aneurysm necks yields similar results but with significantly less procedural costs and complexity. In a longer term outcome assessment including 54 patients who underwent F-EVAR from Kristmundsson et al,[24] the 5-year freedom from secondary interventions was 56% ± 5%. Despite having observed their patients for a median 67 months, this study had a relatively small population (N = 54). Consequently, whether sealing in the suprarenal aorta provides a more durable repair than standard infrarenal EVAR in wide infrarenal necks after long-term follow-up remains to be determined. In regard to open repair of juxtarenal AAAs, perioperative mortality rate was 2.9% in a systematic review from Jongkind et al.[25] In

another study focusing on the morphologic outcomes after open repair of juxtarenal aneurysms from Baker et al,[26] only one patient (N = 161) developed an aorta-related complication, yielding a 5-year freedom from reinterventions survival of 92%. Interestingly, the aortic diameter increased a mean 0.6 ± 1.6 mm at the renal level and 1.3 ± 2.1 mm at the suprarenal level, regardless of whether the anastomosed aorta was ectatic or not. Consequently, if the patient is surgically fit, open repair may be a preferable option in patients with wide infrarenal necks.

Despite many advances in the medical management of patients' comorbidities and risk factors, survival after intact AAA repair remains shorter compared with age- and sex-matched controls.[27] Mortality rates reach 31% at 5 years and are mostly due to cardiovascular diseases and cancer.[28] An interesting finding in this study is that patients with ≥30-mm neck diameters have a significantly decreased survival compared with the remaining EVAR cohort, although mean age did not differ among groups. In the general population, anatomic features such as aortic calcification have been associated with a greater risk of cardiovascular disease-related death.[29] Among EVAR patients, advanced age and large AAA diameter have also been reportedly linked to shorter survival rates.[30] In a EUROSTAR-based report, Waasdorp et al[16] reported significantly worse survival for those patients with AAA diameters >60 mm but also neck diameters >26 mm.

Importantly, in our study, the reported relative excess of mortality was not at the expense of aneurysm-related causes, but it may have been related to the relative excess of cardiac disease among the ≥30-mm neck diameter group. As causes of death were not obtainable, we speculate that a wide neck diameter may be a sign of a more unfavorable general health state. Future reports should be performed to further investigate this hypothesis. Meanwhile, these results suggest that patients with wide infrarenal neck diameters might benefit from a more aggressive control of their comorbidities after standard EVAR.

There are some limitations to this study that warrant clarification. The ENGAGE is a large prospective registry that aims to capture EVAR outcomes in a "real-world" environment. Only centers with an annual case volume of >20 EVAR cases were eligible to participate in this registry. Patient enrollment was voluntary by the participating centers, and no information was available on the number of patients offered EVAR with other devices, open repair, or no treatment for each participating center. Consequently, the extent of the selection bias is impossible to determine. However, the prospective nature of this registry, including consecutively all successful Endurant implants from 79 centers worldwide, reduces the risk of selection bias as well as the possibility of type II error. As this report is based on a single-device registry, application of the currently reported findings to other devices is limited. Also, the low number of events regarding primary outcomes limited the performed analyses, but adjustment for the most significant and clinically relevant variables was performed when possible. Reporting in the ENGAGE registry was performed according to the Society for Vascular Surgery reporting standards, which recommend the threshold of 10 mm as device migration standard. Considering the features of the Endurant stent graft and the frequently treated complex anatomy, this length may be excessive for EVAR-related outcomes. In addition, the ENGAGE registry was not specifically designed to capture baseline morphologic data thoroughly. CT-based follow-up was not mandatory in this registry, and an undetermined proportion of AAA diameters were obtained from other imaging modalities, such as duplex ultrasound, and used for aneurysm sac dynamics assessment, which limits these results. Last, although a survival disadvantage was found among patients with neck diameters ≥30 mm, the exact causes of death in this population were not retrievable. Consequently, these data should be interpreted with caution.

CONCLUSIONS

This study suggests that patients with infrarenal neck diameters ≥30 mm have a higher risk for development of EL1A and aneurysm rupture after standard infrarenal EVAR. Consequently, as these seem not to be preceded by significant endograft migration, CT-based imaging should not be entirely waived from surveillance protocols in this group of patients for timely detection of loss of proximal seal. In patients with infrarenal neck diameters ≥30 mm, particularly outside device IFU, endovascular repair providing suprarenal seal in anatomically suitable high-risk patients or open aortic repair in low-risk patients may be considered, but their increased costs and expected outcomes should be balanced against the risks of proximal seal-related complications after standard EVAR. Finally, an increased focus on the management of these patients' medical comorbidities may increase survival in this particular group of patients.

AUTHOR CONTRIBUTIONS

Conception and design: NO, HV
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