Possible implications of device-specific variability in post-endovascular aneurysm repair sac regression and endoleaks for surveillance categorization

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ABSTRACT

Objective: Significant sac regression during early surveillance has been shown to best predict reintervention-free long-term surveillance after endovascular aneurysm repair (EVAR). Furthermore, a persistent endoleak has been related to a worse outcome. Individualized surveillance algorithms based on these findings have been suggested. There are no studies comparing the performance of different stent grafts regarding sac regression, the presence of type II endoleaks, and their possible implications for individualized surveillance. The objective of this study was to evaluate device-specific differences and how these may affect patient categorization for surveillance.

Methods: Patients were treated electively with standard EVAR between 2005 and 2015 using three different devices (Zenith by Cook, Excluder by Gore, and Endurant by Medtronic). The data were reviewed retrospectively until 2020. Patients' computed tomography angiographies (CTAs) at 30 days and at 2 years were analyzed for freedom from endoleaks and for sac regression of ≥5 mm. Reinterventions during long-term surveillance were counted. Patients were categorized according to the presence of any endoleak and sac regression at 30 days and 2 years, and the probability of reintervention-free long-term surveillance was evaluated based on these findings.

Results: A total of 435 patients were treated for an abdominal aortic aneurysm with EVAR during the study period. At 30 days, 80.0% (n = 339) of the patients were free from endoleaks, and at 2 years, 78.9% (n = 273) were free from endoleaks. There was a significant difference in endoleak rate at 30 days and 2 years between the devices ($P < .001$ and $P = .001$). There was no significant difference in sac regression between the devices at 2 years ($P = .096$). The categorization at 30 days based on endoleak status had a sensitivity of 44.9%, specificity of 87.4%, and negative predictive value of 84.1% for finding a reintervention-requiring complication during long-term follow-up. The corresponding figures at 2 years were 63.3%, 91.4%, and 89.4%, respectively. The combination of freedom from endoleaks and sac regression of ≥5 mm in the 2-year CTA best predicted an uneventful long-term surveillance. Patients who met this criterion had a 95.6% probability (negative predictive value) of having a reintervention-free long-term surveillance.

Conclusions: There are significant differences in the prevalence of endoleaks between devices at 30 days and 2 years, but there is no difference in sac regression. Patients with sac regression of ≥5 mm and no endoleaks in the 2-year CTA can be safely categorized for infrequent surveillance regardless of the stent graft model that has initially been used. (J Vasc Surg 2023;78:1204-11.)

keywords: Abdominal aortic aneurysm; Device-specific; Endoleak; Endovascular aneurysm repair; Endurant; Excluder; Follow-up; Sac regression; Surveillance; Zenith

The long-term efficacy of endovascular aneurysm repair (EVAR) remains a concern despite favorable early outcomes, and surveillance imaging is therefore considered mandatory after EVAR.[1-3] Many patients are lost to follow-up, and existing surveillance protocols have a wide heterogeneity.[4,5] Lifelong annual imaging surveillance also places a burden on health care resources, as approximately 77% of elective patients with an abdominal aortic aneurysm (AAA) undergo EVAR.[6-8]

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Funding: This study was financially supported by the Competitive State Research Financing of the Expert Responsibility area of Tampere University Hospital.

Author conflict of interest: none.

Presented at the Thirdy-sixth Annual Meeting of the European Society for Vascular Surgery, Rome, Italy, September 20-23, 2022.

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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.2023.07.001

Surveillance imaging after EVAR is performed to identify patients with possible complications in general, and specifically those who would benefit from a reintervention to prevent rupture.[9,10] Multiple factors have been identified to predict the late failure of EVAR, such as large preoperative AAA size, poor sealing, persistent type II endoleak, and instructions for use (IFU) adherence.[11-13] At the same time, several studies have shown that patients with significant sac regression in the early postoperative phase will experience fewer complications.[14-18] However, participation in post-EVAR surveillance to find late complications is currently considered equally important regardless of pre- and postoperative findings, although controversy also exists.[6,19]

There are studies assessing the risk factors for reinterventions based on preoperative findings as well as imaging findings in later surveillance.[15,16,20] Some studies suggest that categorization for individualized surveillance could be based on the first computed tomography angiography (CTA) after EVAR, whereas other authors recommend relying on later categorization.[15,16] There are also discrepancies in the current guidelines for post-EVAR surveillance.[21-23] No studies have been published comparing the performance of different stent grafts regarding sac regression and the presence of type II endoleaks as well as their possible implications for individualized surveillance.

The objective of this study was to evaluate device-specific differences in sac regression and endoleaks during post-EVAR surveillance and to determine how these may affect the patients' categorization for individualized surveillance.

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center retrospective study
- **Key Findings:** Study of 435 patients with abdominal aortic aneurysms treated with standard endovascular aneurysm repair shows that there are significant differences in the prevalence of endoleaks between devices at 30 days and 2 years, but no difference in sac regression. Patients without a detectable endoleak and sac regression of ≥ 5 mm in 2-year computed tomography angiography best predicted an uneventful long-term surveillance, with a probability of 95.6% having a reintervention-free long-term surveillance. Patients can be safely categorized for infrequent surveillance based on these criteria regardless of the stent graft model that has initially been used.
- **Take Home Message:** There are significant differences in the prevalence of endoleaks between devices, but no difference in sac regression. Patients without an endoleak and sac regression of ≥5 mm in 2-year computed tomography angiography have a very high probability of having a reintervention-free long-term surveillance regardless of the stent graft model that has initially been used.

PATIENTS AND METHODS

This retrospective study included all patients assigned to elective treatment of an AAA using standard EVAR in one academic institution between 2005 and 2015, comprising a total of 435 patients. The initial indication for treatment was an aneurysm with a diameter of 55 mm or greater in men and 50 mm or greater in women, or an increase of 5 mm in diameter over a period of 6 months. Patients were treated with three different stent grafts: Endurant (Medtronic), Excluder (W.L. Gore & Associates), and Zenith (Cook Inc). After institutional approval of the study, data were collected retrospectively through a review of electronic medical records. All CTAs were reanalyzed for the study.

All procedures were performed by a vascular surgeon together with an interventional radiologist in a hybrid suite. The number of treating specialists was limited to a few vascular surgeons and interventional radiologists. Patients were followed continuously until the end of 2020 according to a prearranged program, including CTA at 1 and 24 months and color Doppler ultrasonography annually. In the case of sac enlargement, an additional CTA was scheduled to detect a possible endoleak. Indications for a reintervention included a type I, III, and IV endoleak, migration, thrombosis, endotension, and AAA rupture. The indication for treating a type II endoleak at the time of the study was a 5-mm increase in AAA sac size. Deaths were ascertained by record linkage between the study population and the National Causes of Death Register on the basis of the personal identification code unique to every resident.

The primary endpoints were device-specific differences in sac regression and endoleaks at 30 days and 2 years. We determined the safety of early (30 days) and late (2 years) categorization for individualized surveillance by calculating the specificity and sensitivity, as well as the negative predictive value (NPV) for each device to predict reintervention-free surveillance.

Patients' outcomes were analyzed using the Pearson χ^2 test or the Fisher exact test and the Kruskal-Wallis test, where appropriate (SPSS 26.0 for Windows). A P value of $< .05$ was considered statistically significant. Confidence intervals for sensitivity and specificity, as well as NPV, were calculated by means of the Clopper-Pearson method using the MED-CALC statistical software (Medcalc Software Ltd).

RESULTS

The implanted grafts included the Cook Zenith (48.3%; n = 210), Gore Excluder (34.5%; n = 150), and Medtronic Endurant (17.2%; n = 75). Routine embolization of patent inferior mesenteric artery (IMA) was done during the

Journal of Vascular Surgery
November 2023

Table I. Baseline patients' and abdominal aortic aneurysm (AAA)-related characteristics of the study population stratified by stent grafts

	Zenith	Excluder	Endurant
No. patients, n (%)	210 (48.3)	150 (34.5)	75 (17.2)
Age, years	76.3	76.1	75.8
Gender, male	185 (88.1)	132 (88.0)	65 (86.7)
Race, white	210 (100)	150 (100)	75 (100)
Aneurysm diameter, mm	62.9	61.2	63.6
IFU adherence[a]	85.0	94.7	92.2
IMA open, not embolized	35 (16.7)	53 (35.3)	31 (41.3)
IMA open, embolized	101 (48.1)	56 (37.3)	22 (29.3)
IMA occluded	74 (35.2)	41 (27.3)	22 (29.3)
Mean IMA diameter, mm	3.3	3.1	2.9
Diameter ≥ 4 mm	22 (16.1)	18 (16.5)	7 (13.2)

IFU, instructions for use; *IMA*, inferior mesenteric artery.
Data are presented as mean, percentage, or number (%).
[a]IFU adherence was defined based on criterion of the device-specific IFU including aneurysm neck diameter, length and angulation, iliac fixation length and size.

EVAR procedure. The IMA was patent in 298 patients (68.5%), and embolization was performed in 179 cases (59.3%). Embolization of the IMA was attempted in an additional 45 cases. The main reason for abstaining from the embolization was a significant ostium stenosis or a lack of visualization in angiogram. Baseline patient and AAA-related characteristics are presented in Table I. The mean follow-up time was 70.0 months (standard deviation, 32 months).

Thirty-day findings. Thirty-day mortality was 1.5% (n = 5), with no significant differences between the devices (P = .397). Imaging data for those surviving the first 30 days were available in 98.4% of the cases (n = 424). In 80.0% of the cases (n = 339), no endoleak was detected in the 30-day CTA, and none of the patients had significant sac shrinkage (≥5 mm). The detected endoleak included type I (n = 9) and II (n = 67). An endoleak was found most often with the Excluder stent graft (33.6%) and most infrequently with Endurant (4.1%), and this finding was statistically significant (P < .001) (Table I). The device-specific endoleak findings were as follows: Excluder: type I, n = 5 and type II, n = 44; Zenith: type I, n = 3 and type II, n = 30; and Endurant: type I, n = 1 and type II, n = 2).

Two-year findings. At 2 years, 86.0% of the patients (n = 374) were alive, and there were no significant differences in mortality rates between the devices (P = .417). Imaging data were available for 92.5% of the patients (n = 346).

Of these patients, 78.9% (n = 273) were free of any endoleaks. The difference between the device in endoleak rates was significant at 2 years (P = .001) (Table I). The endoleaks included type I (2.9%; n = 10) and type II (18.2%; n = 63). Of patients with a type II endoleak, 54.0% (n = 34) had a persistent early endoleak, and 46.0% (n = 29) had developed a new-onset type II endoleak at 2 years. In further surveillance, 10.6% of the endoleak-free patients (n = 29) had a complication requiring a reintervention. Of the early endoleaks, 34.2% (n = 25) had resolved spontaneously by 2 years.

At 2 years, 53.5% of the patients (n = 185) showed an at least 5-mm sac regression when compared with the preoperative CTA. The median shrinkage was 11.0 mm among all EVAR patients who had any sac regression at 2 years. There was no significant difference in sac shrinkage rate between the devices (P = .096), but the median shrinkage (mm) was most pronounced with Excluder and Zenith devices (P = .017) (Table II).

Safety of early (30-day) categorization for individualized surveillance. Of the patients with no endoleak at 30 days, 13.6% (n = 46) developed a complication that required a reintervention during further surveillance.

The sensitivity for reintervention-free long-term surveillance based on a negative 30-day endoleak finding was 44.8%, with specificity of 80.2%. A negative endoleak finding predicted reintervention-free long-term surveillance with a probability (NPV) of 81.1%. There was wide variety in sensitivity, specificity, and NPV between the devices (Table II).

Safety of late (2-year) categorization for individualized surveillance. Of the patients with no endoleak at 2 years, 11.8% (n = 32) developed a complication requiring a reintervention during further surveillance. Categorization based on a negative 2-year endoleak finding had a sensitivity of 63.3%, specificity of 91.4%, and NPV of 89.4% for predicting reintervention-free surveillance. In long-term surveillance, 5.7% of the patients with significant sac regression (≥5 mm) at 2 years had a complication requiring a reintervention. Categorization based on a

Table II. Device-specific findings at 30 days and 2 years after endovascular aneurysm repair (EVAR)

	Zenith (n = 210)	Excluder (n = 150)	Endurant (n = 75)	Total (N = 435)	*P* value
30 Days					
Mortality	2 (1.0)	1 (0.7)	2 (2.7)	5 (1.5)	.397
CTA available	205 (97.6)	146 (97.3)	73 (97.3)	424 (97.5)	
No endoleak[a]	172 (83.9)	97 (66.4)	70 (95.9)	339 (80.0)	<.001
2 Years					
Mortality	34 (16.2)	19 (12.7)	8 (10.7)	61 (14.0)	.417
CTA available	162 (92.0)	125 (94.7)	59 (89.4)	346 (79.5)	
No endoleak[b]	129 (79.6)	88 (70.4)	56 (94.9)	273 (78.9)	.001
Sac shrinkage ≥5 mm[c]	97 (59.9)	58 (47.2)	30 (51.7)	185 (53.9)	.096
Sac shrinkage & no endoleak[d]	97 (59.9)	54 (43.5)	30 (51.7)	181 (52.6)	.023
Median sac shrinkage, mm	12.0	12.5	9.0	11.0	.017
Categorization[a]					
Sensitivity, %	35.29	71.88	20.00	44.90	
Specificity, %	90.26	77.19	100.00	87.42	
NPV, %	80.81	90.72	82.86	84.07	
Categorization[b]					
Sensitivity, %	63.16	82.14	23.08	63.29	
Specificity, %	92.74	85.57	100.00	91.39	
NPV, %	89.15	94.32	82.14	89.38	
Categorization[c]					
Sensitivity, %	92.11	89.29	71.43	87.34	
Specificity, %	75.81	57.89	59.09	66.29	
NPV, %	96.91	94.83	86.67	94.59	
Categorization[d]					
Sensitivity, %	92.11	96.43	69.23	90.00	
Specificity, %	75.81	55.21	57.78	65.53	
NPV, %	96.91	98.15	86.67	95.58	

CTA, Computed tomography angiography; *NPV*, negative predictive value.
The sensitivity, specificity, and NPV for reintervention-free surveillance based on these findings, as well as different categorizations for each device.
[a]Categorization: No endoleak at 30 days.
[b]Categorization: No endoleak at 2 years.
[c]Categorization: Sac shrinkage (≥5 mm) at 2 years.
[d]Categorization: Sac shrinkage (≥5 mm) and no endoleak at 2 years.

positive 2-year sac shrinkage (≥5 mm) result had a sensitivity of 87.3% and specificity of 66.3% for predicting reintervention-free surveillance. A positive sac shrinkage (≥5 mm) result predicted reintervention-free long-term surveillance with 94.6% probability.

The combination of sac regression (≥5 mm) and no endoleak at 2 years yielded a long-term reintervention rate of 3.2% (Fig 1). This categorization was associated with a sensitivity of 90.0%, specificity of 65.53%, and NPV of 95.6% for reintervention-free long-term surveillance. Four patients who were initially treated with an Excluder device had a shrinking aneurysm sac with an endoleak at 2 years. Three of these patients required reinterventions during further surveillance. A positive endoleak finding combined with positive sac regression was not found with any other device model.

The categorization of patients based on endoleak-free status and sac regression (≥5 mm) findings resulted in favorable outcomes regardless of the device that had been used, as the NPV was high with all three devices (Table II). A particularly high NPV was achieved with the Excluder device. No patients with an Excluder device and a shrinking AAA with no endoleak at 2 years underwent reinterventions after that point. One patient with a shrinking AAA and no endoleak at 2 years later died of a ruptured AAA (RAAA) after uncomplicated surveillance at 3 years without a CTA or autopsy confirmation, lowering the NPV from 100% to 98.2%.

Complications and reinterventions. During the surveillance, 23.2% of the patients (n = 101) underwent reinterventions for graft-related complications (Zenith: n = 52, 24.8%; Excluder: n = 33, 22.0%; and Endurant: n = 16, 21.3%) (Table III). These included 11 RAAAs (2.5%). Nine of the ruptures were confirmed in CTA, and two had a clinical diagnosis without an autopsy. These latter two

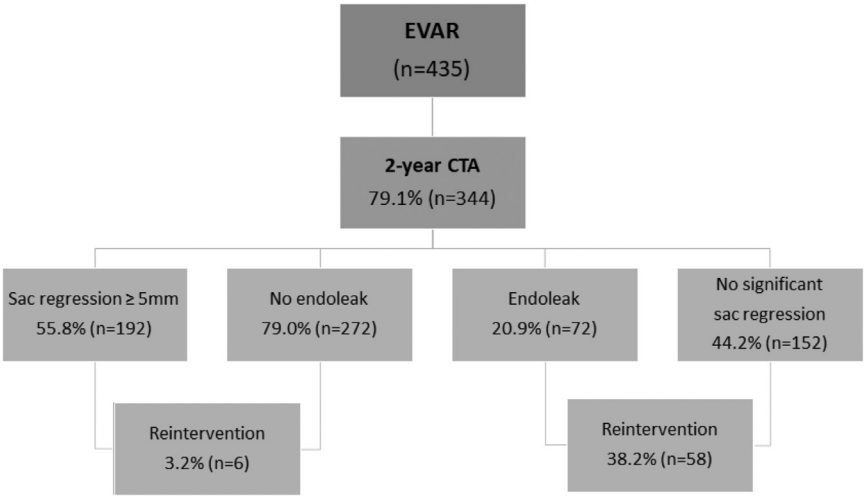

Fig 1. A retrospective analysis of post-endovascular aneurysm repair (*EVAR*) reinterventions in long-term surveillance according to categorization based on abdominal aortic aneurysm (*AAA*) sac shrinkage and endoleak findings in the 2-year computed tomography angiography (*CTA*).

patients had uncomplicated surveillance. Reinterventions and aneurysm ruptures in every post-EVAR year are presented in Fig 2.

In six RAAA cases, a persistent type II endoleak, combined in four of them with sac expansion, led to loss of proximal sealing and further type 1A endoleak. In two cases, a persistent type II endoleak caused sac expansion, but no treatment was offered because of patients' high age and dementia. One patient had primary type II endoleak, but he was not under surveillance because of widespread cancer. In one case, significant sac expansion was noted before RAAA without a detectable endoleak, but this patient was considered a poor candidate for open conversion, and no treatment was offered. In one case, both type IA and IB led to RAAA without previous type II endoleak or significant sac expansion. Endoleaks were confirmed 7 months before rupture, but patients refused further procedures.

DISCUSSION

The current study showed that there are significant differences after EVAR in the prevalence of endoleaks between devices at 30 days and 2 years. Furthermore, according to our results, more than one-half of the patients showed sac regression of at least 5 mm at 2 years, with no significant differences between the devices.

Our study confirms earlier findings suggesting that significant sac shrinkage during early surveillance is the key factor to predicting reintervention-free long-term surveillance.[14-18] Only 5.7% of these patients require reinterventions during long-term surveillance. A previous study demonstrated that persisting sac regression is significantly and positively associated with new-generation devices when compared with older devices, and based on our results, there is no significant difference at least between these three new-generation devices included in the current study.[17]

The NPV in this context allows us to estimate the safety of patient categorization for less frequent surveillance after EVAR. The higher the NPV, the higher the probability of uneventful follow-up after the time of evaluation. The highest NPV was achieved when we combined sac regression (≥5 mm) with an endoleak-free status at the 2-year CTA. Those who met these criteria had a probability of 95.6% of having a reintervention-free long-term surveillance. The NPV was high regardless of the device used (Table II). This is emphasized by the fact that only 3.2% of all patients with sac regression and no endoleak at 2 years eventually had a graft failure during long-term surveillance (Fig 1). These criteria (≥5 mm sac regression combined with no endoleak at 2 years) were particularly predictive of uneventful long-term surveillance with the Excluder device, as none of the patients who had received this device underwent reinterventions during later surveillance.

As there was a wide variety and a significant difference in endoleak finding between the devices at 30 days and 2 years, there was also wide variety between the devices in the sensitivity, specificity, and NPV of endoleak findings to predict reintervention-free long-term surveillance. Moreover, most patients with an early endoleak did not ultimately turn out to be the ones who required future reinterventions. Therefore, the categorization based on endoleak status is not suitable for all devices and performs poorly in identifying those patients who eventually require reinterventions in long-term surveillance. The difference in the rate of type II endoleaks between the devices in early surveillance is not a novel finding. A high rate of type II endoleaks has been associated with polytetrafluoroethylene-based stent grafts, especially with Excluder.[24]

Table III. Number of patients with endovascular aneurysm repair (EVAR)-related complications requiring reinterventions stratified by stent grafts

	Zenith (n = 210)	Excluder (n = 150)	Endurant (n = 75)
Complication	**52 (24.8)**	**33 (22.0)**	**16 (21.3)**
Endoleak			
Type IA	15 (7.1)	7 (4.7)	4 (5.3)
Type IB	13 (6.2)	6 (4.0)	6 (8.0)
Type II	22 (10.5)[a]	25 (16.7)	4 (5.3)[a]
From IMA	5 (2.4)	1 (0.7)	2 (2.7)
From other aortic branches	18 (8.6)	24 (16.0)	3 (4.0)
Type III	1 (0.5)	0	1 (1.3)
Type IV	0	0	0
Endotension ≥5 mm	0	0	5 (6.7)
Thrombosis	6 (2.9)	1 (0.7)	3 (4.0)
Migration	3 (1.4)	1 (0.7)	1 (1.3)
Kinking	2 (1.0)	0	0
RAAA	7 (3.3)	3 (2.0)	1 (1.3)
Reintervention	**52 (24.8)**	**33 (22.0)**	**16 (21.3)**
Proximal cuff	15 (7.1)	3 (2.0)	4 (5.3)
Infrarenal	15 (7.1)	3 (2.0)	3 (4.0)
Suprarenal (fenestrated)	0	0	1 (1.3)
Limb graft repair	18 (8.6)	7 (4.7)	9 (12.0)
Embolization	24 (11.4)	23 (15.3)	4 (5.3)
PTA	2 (1.0)	0	0
Laparotomy with ligation of the side branch	1 (0.5)	0	0
Femoro-femoral bypass	6 (2.9)	1 (0.7)	3 (4.0)
Conversion	2 (1.0)	2 (1.3)	0
For rupture	1 (0.5)	0	0
For repeated endovascular procedures	1 (0.5)	2 (1.3)	0

IMA, Inferior mesenteric artery; *PTA*, percutaneous transluminal angioplasty; *RAAA*, ruptured abdominal aortic aneurysm.
Data are presented as number (%).
[a]One patient had embolization of IMA and lumbar artery due to type II endoleak.

We also demonstrated that complications were particularly common during the first 2 years after EVAR, a fact that can serve as a rationale for surveillance categorization. The reintervention peak was reached in the third post-EVAR year, which can be explained by the routine CTA scan at 2 years (Fig 2). Had the patients had a control CTA at 1 year, some of the reinterventions may have already been performed during the second post-EVAR year. Despite the early complications and reinterventions, the long-term outcome of EVAR patients seems to be favorable. However, some type I endoleaks and ruptures continue to occur as late as more than 10 years after the primary procedure.[25] This finding was also confirmed in our study, supporting the importance of life-long surveillance.

Sac regression during follow-up has been shown to be the best predictor of a low risk of late EVAR failure.[14,16] Furthermore, sac shrinkage is more likely to occur in patients with favorable aneurysm anatomy and adequate sealing, as well as in those with no endoleak.[16] This has, perhaps, led to the clinical misinterpretation that patients with no endoleaks, combined with a favorable anatomy and adequate sealing, have a low risk of reinterventions despite the sac regression.[15,23] There is one study supporting this finding, consisting only of Excluder devices.[15] In our study, patients with an Excluder device had a particularly high rate of type II endoleak, leading to at least one-third of the patients remaining under frequent surveillance based on this categorization. Moreover, early categorization underestimates the natural history of type II endoleaks, which mostly seal spontaneously during early surveillance. It also overestimates the power of CTA to find all endoleaks, as this ability is highly dependent on the timing and the quality of the scan. Also, it has been reported that over 10% of the patients can develop a new-onset type II endoleak during the surveillance.[21] In our study, almost one-half of the type II endoleaks at 2 years were new-onset, and the other one-half were persistent. Late-onset and persistent type II endoleaks, in particular, have been related to a

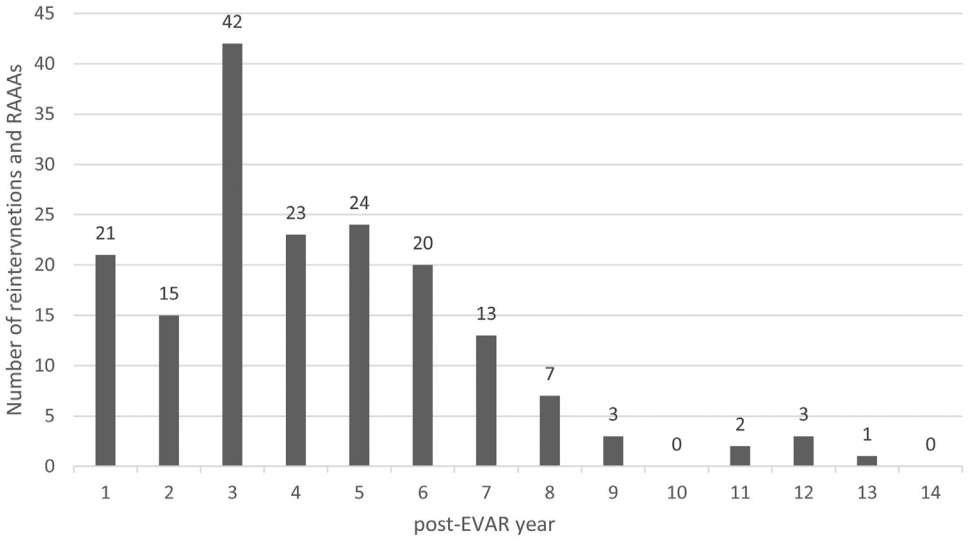

Fig 2. Number of reinterventions and aneurysm ruptures in every post-endovascular aneurysm repair (*EVAR*) year. *RAAA*, Ruptured abdominal aortic aneurysm. Includs embolization attempts.

poorer outcome after EVAR.[10,26] This confirms the importance of late categorization for surveillance.

Two decades have passed since the results of the EVAR-1 trial were published, showing a superior early outcome of EVAR compared with open repair.[27] The postoperative later surveillance in the trial was suboptimal, and the importance of sac growth as a predictor of graft failure was probably overlooked. Since then, the significance of surveillance has been demonstrated, but there remains heterogeneity in guidelines and the real-world implementation of post-EVAR surveillance.[4,5,21-23] For example, some of the current grafts' IFUs recommend regular surveillance, with up to five examinations during the first post-EVAR year, which is quite excessive.[28] Indeed, real-world experience shows that patients tend to skip the surveillance despite recommendations.[29] Incomplete surveillance is associated with male sex, age, a lack of a primary health care provider, longer driving distance, and patients who initially presented with an RAAA.[29,30] A study by Garg et al reported that only 43% of patients had a complete surveillance.[31] Optimized follow-up plans with less frequent visits and examinations may lead to better patient adherence. Based on our findings, less frequent surveillance could be safely offered to over one-half of the patients after 2 years. There are no studies comparing different surveillance protocols to determine the optimal and safe intervals, and due to the low frequency of complications, we could also not identify the optimal interval for surveillance after 2 years.

This study has its limitations. The distribution of different stent grafts during the study period was not even. At the beginning of the study, the most used device was Zenith, whereas Excluder became the most popular device by the end of the study, which might influence the results. The device was selected based on the patient's anatomy and the surgeon's preference for the selected patient, and we cannot evaluate the effect of anatomical differences on the results. The device-specific difference in endoleaks was interesting, but owing to the lack of some data, such as the number of side branches or the use of an anticoagulant or antiplatelet, we cannot state that type II endoleaks are device-dependent. Furthermore, as our study included color Doppler ultrasonography at 1 year, it is impossible to evaluate type II endoleaks at that point, but it is possible that optimal categorization could be done as early as at 1 year. At the time of the study, the applied threshold for reinterventions was 5 mm regarding type II endoleaks, and the currently recommended limit is higher. A higher threshold probably lowers the rate of reinterventions for type II endoleaks. IMA was routinely embolized regardless of size during the study, and the results may not be comparable with centers with other strategies. At the same time, most of the type II endoleaks presented in the study were of lumbar origin. Therefore, management strategy of patent IMA may not be of substantial importance. IFU adherence was high compared with previous studies, making the results reliable and generalizable.[32]

Our study shows a high NPV for all three devices when sac regression (≥5 mm) was combined with endoleak-free status at the 2-year CTA. However, there was a slightly significant difference between the devices ($P = .023$) regarding this combination. With the Endurant device, the NPV was significantly lower, but still high (86.67%), implying that some other categorization criteria could possibly be superior, particularly for this device.

CONCLUSIONS

There are significant differences in the prevalence of endoleaks between devices at 30 days and 2 years, but there is no difference in sac regression. Patients with AAA sac regression of at least 5 mm and no endoleak at the 2-year CTA can be safely categorized for infrequent surveillance regardless of the stent graft model that has initially been used. Conversely, patients in whom early shrinkage does not occur are at a higher risk of complications and more often require secondary interventions.

AUTHOR CONTRIBUTIONS

Conception and design: SV
Analysis and interpretation: SV, IU, VS
Data collection: SV, IU
Writing the article: SV
Critical revision of the article: SV, IU, VS
Final approval of the article: SV, IU, VS
Statistical analysis: SV, VS
Obtained funding: SV, VS
Overall responsibility: SV

REFERENCES

1. DeBruin JL, Baas AF, Buth J, et al; DREAM Study Group. Long-term outcome of open or endovascular repair of abdominal aortic aneurysm. N Engl J Med 2010;362:1881-9.
2. Reimerink JJ, Hoornweg LL, Vahl AC, et al; Amsterdam Acute Aneurysm Trial Collaborators. Endovascular repair versus open repair of ruptured abdominal aortic aneurysms: a multicenter randomized controlled trial. Ann Surg 2013;258:248-56.
3. Patel R, Sweeting MJ, Powell JT, Greenhalgh RM; EVAR trial investigators. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. Lancet 2016;388:2366-74.
4. Karthikesalingam A, Page AA, Pettengell C, et al. Heterogeneity in surveillance after endovascular aneurysm repair in the UK. Eur J Vasc Endovasc Surg 2011;42:585-90.
5. Patel A, Edwards R, Chandramohan S. Surveillance of patients post-endovascular abdominal aortic aneurysm repair (EVAR). A web-based survey of practice in the UK. Clin Radiol 2013;68:580-7.
6. de Mik SML, Geraedts ACM, Ubbink DT, Balm R. Effect of imaging surveillance after endovascular aneurysm repair on reinterventions and mortality: a systematic review and meta-analysis. J Endovasc Ther 2019;26:531-41.
7. Suckow B, Goodney P, Columbo A, et al. National trends in open surgical, endovascular, and branched-fenestrated endovascular aortic aneurysm repair in Medicare patients. J Vasc Surg 2018;67:1690-7.
8. Dutch Institute for Clinical Auditing. Annual reports 2016. https://dica.nl/media/993/DICA-2016-jaarverslag.pdf.
9. Baderkhan H, Haller O, Wanhainen O, Björck M, Mani K. Follow-up after endovascular aortic aneurysm repair can be stratified based on first postoperative imaging. Br J Surg 2018;105:709-18.
10. Seike Y, Matsuda H, Shimizu H, et al; Japanese Committee for Stentgraft Management (JACSM). Nationwide analysis of persistent type II endoleak and late outcomes of endovascular abdominal aortic aneurysm repair in Japan: a propensity-matched analysis. Circulation 2022;145:1056-66.
11. Hahl T, Protto S, Järvenpää V, Uurto I, Väärämäki S, Suominen V. Long-term outcomes of endovascular aneurysm repair according to instructions for use adherence status. J Vasc Surg 2022;76:699-706.
12. Lo RC, Buck DB, Herrmann J, et al. Risk factors and consequences of persistent type II endoleaks. J Vasc Surg 2016;63:895-901.
13. Väärämäki S, Salenius JP, Pimenoff G, Uurto I, Suominen V. Systematic long-term follow up after endovascular abdominal aortic aneurysm repair with the Zenith stent graft. Eur J Vasc Endovasc Surg 2019;58:182-8.
14. Bastos Goncalves F, Baderkhan H, Verhagen HJ, et al. Early sac shrinkage predicts a low risk of late complications after endovascular aortic aneurysm repair. Br J Surg 2014;101:802-10.
15. Bastos Goncalves F, van de Luijtgaarden KM, Hoeks SE, et al. Adequate seal and no endoleak on the first postoperative computed tomography angiography as criteria for no additional imaging up to 5 years after endovascular aneurysm repair. J Vasc Surg 2013;57:1503-11.
16. Väärämäki S, Uurto I, Suominen V. Postoperative imaging follow-up at 2 years as a predictor of long-term outcomes after endovascular aneurysm repair. J Vasc Surg 2021;74:1853-60.
17. Cieri E, De Rango P, Isernia G, et al. Effect of stentgraft model on aneurysm shrinkage in 1450 endovascular aortic repairs. Eur J Vasc Endovasc Surg 2013;46:192-200.
18. Houbballah R, Majewski M, Becquemin JP. Significant sac retraction after endovascular aneurysm repair is a robust indicator of durable treatment success. J Vasc Surg 2010;52:878-83.
19. Karthikesalingam A, Holt PJE, Hinchliffe RJ, Nordon IM, Loftus IM, Thompson MM. Risk of reintervention after endovascular aortic aneurysm repair. Br J Surg 2010;97:657-63.
20. Barnes M, Boult M, Maddern G, Fitridge R. A model to predict outcomes for endovascular aneurysm repair using preoperative variables. Eur J Vasc Endovasc Surg 2008;35:571-9.
21. Chaikof EL, Dalman RL, Eskandari MK, Jackson BM, Lee WA, Mansour MA. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. J Vasc Surg 2018;67:2-77.
22. Isselbacher EM, Preventza O, Hamilton Black J 3rd, et al. 2022 ACC/AHA guideline for the diagnosis and management of aortic disease: a report of the American Heart Association/American College of Cardiology Joint Committee on clinical practice guidelines. Circulation 2022;146:e334-482.
23. Wanhainen A, Verzini F, Van Herzeele I, et al. European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. Eur J Vasc Endovasc Surg 2019;57:8-93.
24. Sheehan MK, Ouriel K, Greenberg R, et al. Are type II endoleaks after endovascular aneurysm repair endograft dependent? Vasc Surg 2006;43:657-61.
25. Zhou W, Blay E Jr, Varu V, et al. Outcome and clinical significance of delayed endoleaks after endovascular aneurysm repair. J Vasc Surg 2014;59:915-20.
26. Lal BK, Zhou W, Li Z, et al; OVER veterans affairs Cooperative study group. Predictors and outcomes of endoleaks in the veterans affairs open versus endovascular repair (OVER) trial of abdominal aortic aneurysms. J Vasc Surg 2015;62:1394-404.
27. Greenhalg RM, Brown LC, Kwong GPS, Powell JT, Thompson SG. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. Lancet 2004;364:843-8.
28. Medical Cook. Zenith flex AAA endovascular graft physician reference manual 2008. Available at: cookmedical.com. Accessed August 9, 2023.
29. Schanzer A, Messina LM, Ghosh K, et al. Follow-up compliance after endovascular abdominal aortic aneurysm repair in Medicare beneficiaries. Vasc Surg 2015;61:16-22.
30. Spanos K, Karathanos C, Athanasoulas A, Sapeltsis V, Giannoukas AD. Systematic review of follow-up compliance after endovascular abdominal aortic aneurysm repair. J Cardiovasc Surg 2018;59:611-8.
31. Garg T, Baker LC, Mell MW. Postoperative surveillance and long-term outcomes after endovascular aneurysm repair among Medicare beneficiaries. JAMA Surg 2015;150:957-63.
32. Antoniou GA, Juszczak MT, Nasr H, et al. Prognosis review and time-to-event data metaanalysis of endovascular aneurysm repair outside versus within instructions for use of aortic endograft devices. J Vasc Surg 2020;71:1415-31.

Submitted Apr 17, 2023; accepted Jul 4, 2023.