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Five-year survival after elective open and endovascular aortic aneurysm repair

Jüri Lieberg, Karl G. Kadatski, Mart Kals, Kaido Paapstel and Jaak Kals

Abstract

Background and objective: Current evidence suggests short-term survival benefit from endovascular aneurysm repair (EVAR) versus open surgical repair (OSR) in elective abdominal aortic aneurysm (AAA) procedures, but this benefit is lost during long-term follow-up. The aim of this study was to compare short- and mid-term all-cause mortality in patients with non-ruptured aneurysm treated by OSR and EVAR; and to assess the rate of complications and reinterventions, as well as to evaluate their impact on survival.

Methods: The medical records of the non-ruptured AAA patients undergoing OSR or EVAR between 1 January 2011 and 31 December 2019 at Tartu University Hospital, Estonia, were retrospectively reviewed. We gathered survival data from the national registry (mean follow-up period was 3.7 ± 2.3 years).

Results: A total of 225 non-ruptured AAA patients were treated operatively out of whom 95 (42.2%) were EVAR and 130 (57.8%) were OSR procedures. The difference in estimated all-cause mortality between the OSR and EVAR groups at day 30 was statistically irrelevant (2.3% vs 0%; p = 0.140), but OSR patients showed statistically significantly higher 5 year survival compared with EVAR patients (75.3% vs 50.0%, p = 0.002). Complication and reintervention rates for the EVAR and OSR groups did not differ statistically (26.3% vs 16.9%, p = 0.122; 10.5% vs 11.5%, p = 0.981, respectively). Multivariate analysis revealed that greater aneurysm diameter (p = 0.012), EVAR procedure (p = 0.016), male gender (p = 0.023), and cerebrovascular diseases (p = 0.028) were independently positively associated with 5-year mortality.

Conclusions: Thirty-day mortality, and complication and reintervention rates for EVAR and OSR after elective AAA repair were similar. Although the EVAR procedure is an independent risk factor for 5-year mortality, higher age and greater proportion of comorbidities among EVAR patients may influence not only the choice of treatment modality, but also prognosis.

Keywords

Abdominal aortic aneurysm, open surgical repair, endovascular aneurysm repair, survival, complications

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Introduction

Abdominal aortic aneurysm (AAA) is clinically defined as abnormal and permanent dilation of the infra-renal abdominal aorta ⩾ 3 cm.[1] The prevalence of AAA in the Western population is 2%–5% in men ⩾ 65 years of age, with very high mortality rates related to AAA rupture.[2] AAA is also among the most expensive cardiovascular diseases to treat while it significantly reduces patients' life expectancy.[3] Furthermore, current evidence suggests growing trends for

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AAA morbidity, which emphasizes the necessity to improve and optimize its management.

Treatment of AAA has profoundly changed after the introduction of endovascular treatment solutions. Endovascular aneurysm repair (EVAR) has become standard therapy alongside open surgical repair (OSR) for AAA and evidently there has been a change in the demographics of the population treated for AAA as a consequence of EVAR.[1] Current evidence suggests also significant short-term survival benefit from EVAR versus OSR in elective AAA repair, but this benefit is lost during mid- and long-term follow-up.[4–9]

Patients treated by EVAR are more likely to experience aortic complications and reinterventions compared with those treated by OSR.[10] The main complication, endoleak, that is, presence of flow in the aneurysm sac outside the graft after EVAR, occurs in up to one third of cases.[11] However, type 2 endoleak is not always considered as a complication as far as the aneurysm is not growing. Besides persistent endoleak repair, reinterventions after EVAR procedures, performed mainly with older-generation devices, are often needed because of stent graft thrombosis or stenosis, infection, and late AAA rupture.[1] However, improvements in the design and delivery of modern stent grafts have reduced the frequency of those adverse events over 5 years and beyond.[12,13]

Although EVAR has been widely adopted and the initial results have been promising, comparison of its long-term efficacy against OSR still remains elusive, and late-onset aortic complications need to be systematically evaluated. Usage of older-generation stent grafts on the on hand, and the relatively small number of patients in controlled trials with long-term results on the other hand, are the limitations to comparison of long-term survival after elective OSR and EVAR. The aim of this study was to compare time-dependent short- and mid-term survival with a cut-off of 5 years for follow-up in patients with non-ruptured aneurysm treated by OSR and EVAR; and to assess the rate of complications and reinterventions after the procedures, as well as to evaluate their impact on survival.

Patients and methods

Subjects and study design

The medical records of the non-ruptured AAA patients undergoing OSR or EVAR between 1 January 2011 and 31 December 2019 at Tartu University Hospital, Estonia, were retrospectively reviewed. We gathered survival data (i.e. the time and place of death) from the national Population Registry (Ministry of the Interior, Republic of Estonia). In addition, clinical data from the records about AAA patients, and OSR and EVAR procedures, stored within the hospital's online system, were collected and analyzed. This study was carried out in accordance with the Declaration of Helsinki of the World Medical Association and the Ethics Committee on Human Research of the University of Tartu (License No. 307/T-20).

All operations were performed at a single institution by fellowship-trained vascular surgeons; the EVAR procedures were performed by interventional teams consisting of a fellowship-trained vascular surgeon and an interventional radiologist. Patients were considered to meet the criteria for surgical treatment if the maximum AAA diameter was ⩾5.5 cm for men and ⩾5.2 cm for women, if AAA had grown ⩾0.5 cm during the past 6 months, or if the patient had symptomatic non-ruptured AAA. EVAR procedures were usually assigned to patients with several comorbidities and high surgical risk, suitable aortic anatomy and advanced age. Patients were treated by EVAR under general anesthesia, and stent grafts were implanted through the common femoral artery by puncture or through surgical exploration (mainly in the first years). Bifurcated graft devices (W.L. Gore & Associates, Inc., Newark, Delaware, USA; Cook, Bloomington, IN, USA; Medtronic Inc., Santa Rosa, CA, USA) were used for all EVAR procedures. Patients were treated by OSR under general anesthesia, and a tube graft or a bifurcated aorto-bi-iliac of aorto-bi-femoral graft was employed if the iliac arteries were occluded or severely stenosed. All EVAR patients were recommended to attend follow-up within 30 days following intervention, then at 6 months and 1 year, and henceforth annually over 5 years. Clinical and radiological follow-up was conducted according to standard practice and included assessment of AAA by either abdominal plain X-ray, computed tomography, or magnetic resonance angiography.

The primary outcome measure of the study was time-dependent short- and mid-term all-cause mortality rates with a cutoff of 5 years for follow-up after OSR and EVAR in patients with non-ruptured AAA. The secondary outcome measure was the number of complications and reinterventions following OSR and EVAR procedures and their effect on survival.

Statistical analysis

Data were collected and analyzed using the software R, version 3.6 (R Core Team; R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria). All continuous variables were compared with the Mann–Whitney U test except for age where an unpaired t-test was used to compare the OSR and EVAR patient groups. Continuous variables are described by medians (interquartile range (IQR)) except for age and hemoglobin value, which are expressed as mean (standard deviation). Categorical data are presented as the number (%) of patients and was analyzed using the chi-square test. The Kaplan–Meier estimate was used to assess the difference in the survival curves between the OSR and EVAR patients as based on the log-rank test. Univariate Cox

Table 1. Baseline characteristics of the study population.

Parameters	EVAR (n=95)	OSR (n=130)	p values
Age, years (±SD)	77 ± 6.6	69 ± 7.7	<0.001
Male gender, n (%)	78 (82)	113 (87)	0.419
Comorbidities, n (%)			
Cardiovascular diseases	88 (94)	113 (87)	0.160
Pulmonary diseases	23 (25)	21 (16)	0.169
Renal diseases	23 (25)	16 (12)	0.03
Malignancies	19 (20)	15 (12)	0.110
Cerebrovascular diseases	20 (21)	13 (10)	0.03
Diabetes	14 (15)	20 (15)	1.000
Other diseases	61 (65)	81 (62)	
Medications, n (%)			
Antithrombotic therapy	59 (62.1)	53 (40.8)	0.002
Heart medications	86 (90.5)	101 (77.7)	0.018
Statins	32 (33.7)	45 (34.6)	0.997
Antidiabetic medications	14 (14.7)	19 (14.6)	1.000
Smoking, n (%)	14 (15)	69 (56)	<0.001
Maximal diameter of the aneurysm in cm, median (IQR)	6.0 (5.4–6.8)	6.3 (5.7–7.5)	0.012

SD: standard deviation; IQR: interquartile range; EVAR: endovascular aneurysm repair; OSR: open surgical repair.

proportional hazard models were used to determine the potential risk factors related to the prognosis of AAA repair. To determine independent risk factors for 5-year survival, multivariate age-adjusted Cox models were estimated. All variables with $p < 0.10$ from the univariate model were implemented to the multivariate Cox model to find out independent risk factors. The assumption of proportional hazards was assessed based on the scaled Schoenfeld residuals. The results of the Cox models were presented as hazard ratios (HRs) with the 95% confidence intervals (CIs); $p < 0.05$ was considered statistically significant.

Results

A total of 225 non-ruptured AAA patients were treated operatively, out of whom 95 (42.2%) were EVAR and 130 (57.8%) were OSR procedures. The follow-up period ended on 1 August 2020 (mean follow-up for all patients was 3.7 ± 2.3 years; for EVAR, 3.6 ± 2.0 and for OSR, 3.8 ± 2.4 years). The baseline characteristics of the EVAR and OSR patients are presented in Tables 1 and 2. Comparison of the patients' baseline characteristics revealed that significantly lower preoperative hemoglobin, haematocrit, platelet and white blood cell values, smaller maximum diameter of AAA, and fewer current smokers were associated with the EVAR group. The OSR patients were associated with statistically younger age, lower creatinine and urea levels, and with less renal and cerebrovascular system comorbidities, and less frequent usage of antithrombotic and heart medications.

Table 2. Preoperative markers of the study population.

Parameters	EVAR (n=95)	OSR (n=130)	p values
Biochemical markers			
Hemoglobin (g/L) (SD)	135 ± 16	148 ± 18	<0.001
Haematocrit (%) (IQR)	41 (38–44)	43 (40–46)	0.001
Platelet count (10^9/L) (IQR)	197 (156–235)	218 (185–251)	0.002
White blood cell count (10^9/L) (IQR)	6.7 (5.8–8.1)	7.4 (6.4–8.7)	0.005
P-Glucose (mmol/L) (IQR)	6.0 (5.5–6.5)	5.8 (5.4–6.5)	0.840
S-C-Reactive protein (mg/L) (IQR)	3.0 (2.0–7.0)	4.0 (1.0–11.0)	0.385
P-Sodium (mmol/L) (IQR)	141 (139–143)	140 (138–142)	0.036
P-Potassium (mmol/L) (IQR)	4.4 (4.1–4.7)	4.3 (4.0–4.5)	0.161
S-Urea (mmol/L) (IQR)	7.3 (6.0–9.2)	6.1 (5.0–8.2)	0.001
S-Creatinine (μmol/L) (IQR)	95 (82–118)	84 (71–103)	0.001
Systolic blood pressure (mmHg) (IQR)	132 (120–146)	134 (124–145)	0.308
Diastolic blood pressure (mmHg) (IQR)	81 (76–89)	80 (76–88)	0.578

SD: standard deviation; IQR: interquartile range; EVAR: endovascular aneurysm repair; OSR: open surgical repair.

For EVAR patients, 30-day, 90-day, and 5-year all-cause mortality was 0% (95% CI 0%–0%), 1.1% (95% CI 0%–3.1%) and 50.0% (95% CI 37.0%–60.3%), respectively. Thirty-day, 90-day, and 5-year all-cause mortality for OSR patients was 2.3% (95% CI 0%–4.9%), 2.3% (95% CI 0%–4.9%), and 24.7% (95% CI 14.9%–33.4%), respectively (Fig. 1). The corresponding values for all elective AAA cases (EVAR and OSR combined) were 1.3% (95% CI 0%–2.8%), 1.8% (95% CI 0%–3.5%), and 36.8% (95% CI 28.7%–44.1%). The differences in the survival estimates between the OSR and EVAR groups at 30-day and 90-day points were statistically irrelevant ($p=0.140$, $p=0.480$, respectively), but OSR patients showed statistically significantly higher 5-year survival ($p=0.002$).

Endoleaks were detected in 47 cases (49.5%) and arterial/graft thrombosis, in five cases (5.3%) among the EVAR patients. Type II endoleaks were considered a complication only in case the aneurysm was growing more than 5 mm and/or endoleak needed specific reintervention. Totally 25 type II endoleaks were detected on the peri-operative angiogram or on the first follow-up CTA, but only 2 of them were considered a clinically relevant complication. EVAR patients had no significantly higher complication risk compared with OSR patients: a total of 29 postoperative graft related complications were seen in 25 EVAR patients and a total of 22 postoperative complications occurred in 22 OSR patients (26.3% vs 16.9%, $p=0.122$). All endoleaks, postoperative complications, and reinterventions in EVAR and OSR patients are listed in Table 3. Out of the 95 EVAR patients, 10 (10.5%) required reinterventions: two inferior mesenteric artery

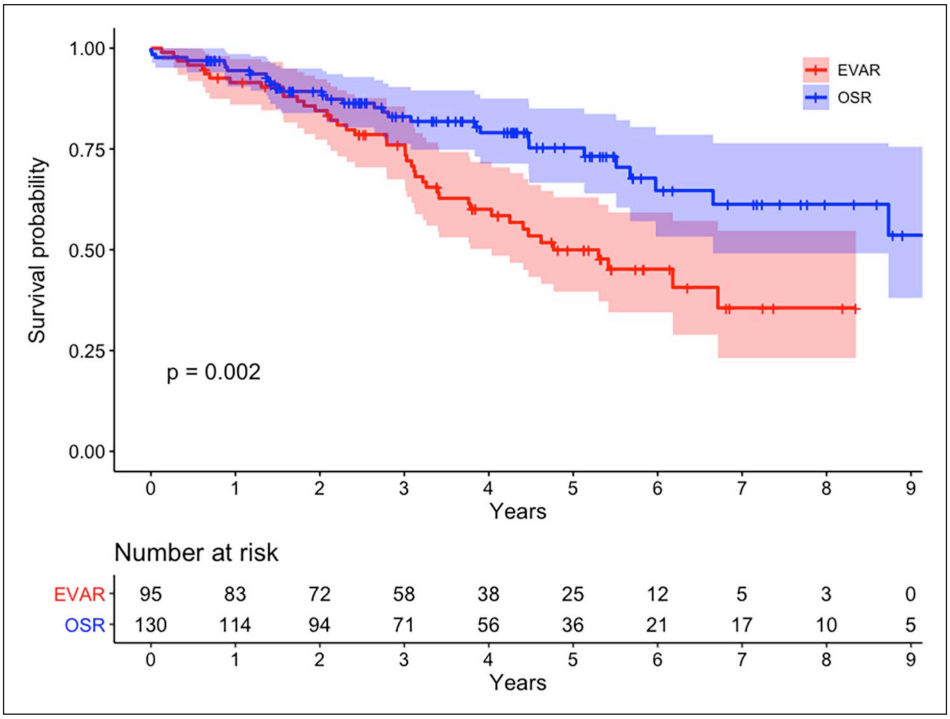

Fig. 1. Kaplan–Meier plots showing the 5-year survival after OSR and EVAR.

embolizations (due to type II endoleak), two aortic extender implantations (due to type Ia endoleak), one iliac extender insertion (due to type Ib endoleak), four femoro-femoral cross-over bypasses, and two intra-arterial thrombolyses. One patient required femoro-femoral bypass after the insufficient result of thrombolysis. Fifteen (11.5%) out of the 130 OSR patients required reinterventions: six abdominal wall repairs and debridement (due to dehiscence/infection of aponeorosis and/or incisional hernias), five revascularisations (open thrombectomy or bypass surgery, endovascular angioplasty/stenting), three surgical haemostases, and one surgical abdominal adhesiolysis. Reintervention rates for the EVAR and OSR groups did not differ statistically (10.5% vs 11.5%, $p=0.981$).

According to Cox univariate analysis, renal diseases (HR=2.340, 95% CI 1.362–4.020, $p=0.002$), comorbid malignancies (HR=3.287, 95% CI 1.871–5.775, $p<0.001$), cerebrovascular diseases (HR=1.939, 95% CI 1.068–3.518, $p=0.029$), and EVAR *versus* OSR procedure (HR=2.155, 95% CI 1.296–3.584, $p=0.003$) were significantly associated with poorer 5-year survival. Postoperative graft related complications and reinterventions did not show an increase in 5-year total mortality risk in EVAR patients ($p=0.893$ and $p=0.124$, respectively). In OSR patients, postoperative complications, but not reinterventions, increased 5-year mortality risk ($p=0.034$, $p=0.254$, respectively).

Multivariate analysis showed that greater aneurysm diameter, EVAR procedure, male gender, and cerebrovascular diseases were independently positively associated with 5-year mortality (Table 4). Postoperative complications, as well as reinterventions, did not independently increase 5-year total mortality risk in AAA patients.

Discussion

This study is the first to compare 30-day and 5-year all-cause mortality of OSR and EVAR procedures in non-ruptured AAA patients and the incidence of postoperative complications and reinterventions associated with open and endovascular aortic surgery in Estonia. The first EVAR at our center was performed in 2011 and the current study includes all EVAR procedures performed since the introduction of endovascular aortic procedures at Tartu University Hospital (service area is mainly Southern Estonia). The second center in Estonia, where EVAR procedures were performed, is the North Estonian Medical Centre in Tallinn (service area is mainly Northern Estonia).

We found non-significant differences in 30-day postoperative all-cause mortality rates after OSR and EVAR procedures (2.3% vs 0%, respectively). However, at 5 years the OSR patients' survival was significantly better compared with EVAR patients' survival (81.5% vs 58.9%, respectively). Our better mid-term results after OSR versus EVAR are similar to previous data from different countries. EVAR has been shown to be less invasive than OSR, and 30-day all-cause mortality rates are significantly lower for EVAR compared with OSR (1.6% vs 4.8%, respectively). Despite this

Table 3. Endoleaks, complications, and reinterventions during 5-year surveillance in elective AAA patients.

Endoleak and complication	Successful EVARs completed (n = 95)		Open repairs completed (n = 130)	
	Number of patients with endoleak and complication	Number of patients with reintervention	Number of patients with complication	Number of patients with reintervention
Endoleak	47			
Type Ia	15	2		
Type Ib	5	1		
Type II	25[a]	2		
Type III	1			
Endotension	1			
Arterial or graft thrombosis	5[b]	5	5	5
Incisional hernia, wound dehiscence, or infection			8	6
Other (postoperative ileus, bleeding, pneumonia, myocardial infarction)			9	4
In total 79 endoleaks and complications in 70 patients	48 of 95 (50.5%; 95% CI 40.1–60.9%)	10 of 95 (10.5%; 95% CI 5.2–18.5%)	22 of 130 (16.9%; 95% CI 10.9–24.5%)	15 of 130 (11.5%; 95% CI 6.6–18.3%)

AAA: abdominal aortic aneurysm; EVAR: endovascular aneurysm repair; OSR: open surgical repair; CI: confidence interval.
[a]Primary type II endoleaks detected on the peri-operative angiogram or on the first follow-up computed tomography angiogram.
[b]Four patients with arterial/graft thrombosis and concomitant endoleak.

Table 4. Multiple regression analysis of the variables associated with 5-year mortality of AAA patients.

	HR (95% CI)	p value
Aneurysm diameter	1.218 (1.045–1.421)	0.012
AAA procedure: EVAR	2.184 (1.158–4.120)	0.016
Sex: Male	2.924 (1.157–7.388)	0.023
Cerebrovascular diseases	2.033 (1.078–3.833)	0.028
Age	1.037 (0.995–1.081)	0.085

AAA: abdominal aortic aneurysm; HR: hazard ratio; EVAR: endovascular aneurysm repair; CI: confidence interval.
$R^2 = 0.30$, concordance = 0.68 (SE = 0.04).

short-term benefit, studies have failed to show long-term benefit from EVAR versus OSR after 2 years.[14,15] In a recent meta-analysis comparing 151.092 EVAR and 148.692 OSR patients, EVAR was associated with higher long-term all-cause mortality, and higher reintervention and secondary rupture rates.[8] Another meta-analysis revealed significantly lower 30-day mortality for EVAR compared with OSR (1.2% vs 3.3%, respectively), but equivalent 5-year mortality for both EVAR and OSR.[16] In our previous analysis of AAA repair conducted between 2004 and 2015, we enrolled 228 elective AAA patients of whom 50 (22%) were treated by EVAR; 30-day all-cause mortality rate was 0.9% and the 5-year all-cause mortality rate was 32% in all elective cases.[17] In the current study, we included all EVAR procedures performed at our center (up to 2019); the 5-year mortality rate for all elective AAA cases was 36.8%, which remains almost constant. Also, the low 30-day mortality rate in OSR patients indicates the high quality of the patient selection process, as well as sufficient surgical skills and postoperative care at our center, despite the relatively small case load.

According to our data, the number of graft and surgery related complications and necessary reinterventions after the primary procedure does not seem to have a negative effect on total mortality following EVAR and OSR in multiple regression analysis. This confirms the findings of previous studies that EVAR provides effective protection against AAA rupture.[18,19] Our study showed significantly increased mortality in the EVAR group 5 years after the procedure, compared with OSR, and the 5-year overall survival of EVAR patients was somewhat lower than the data reported by others.[13,18,19] Although the EVAR procedure is an independent risk factor for 5-year mortality, we cannot ignore the imbalance in the baseline characteristics between the EVAR and OSR groups. Significantly higher mean age and greater proportion of renal and cerebrovascular comorbidities among EVAR patients may influence not only the choice of treatment modality, but also prognosis. Moreover, higher cardiovascular disease mortality in East Europe has been reported recently.[19] A meta-analysis indicates a significant reduction in mortality risk among AAA patients receiving statin therapy compared with non-users.[20] Yet only one third of the AAA patients treated by EVAR in our center received statins, which is lower than the proportion reported in the above analysis. In our center's practice, younger patients (<70 years of age) without significant surgical risk were primarily offered OSR, while those with significant comorbidities were treated by EVAR regardless of age.

The number of endoleaks and graft related complications in EVAR patients was relatively high in the present cohort compared with other long-term studies.[18,21] This could indicate the patients' compliance with the surveillance protocol and the availability of systematic follow-up data for analysis. At the same time, a minority of patients (10.5%) in whom graft related complications were detected required reintervention, and only half of the reinterventions were performed due to treatment of endoleak. The reintervention rate was quite similar[4,22] or even lower than that reported by others.[7,23] Moreover, there was no need for conversion to open repair. Nor were there secondary sac ruptures diagnosed during lifetime and almost all complications could be treated by the endovascular technique. In our study, the reintervention rate for graft limb thrombosis was 5.3%, which is comparable to previous reports where post-EVAR reintervention due to limb occlusion or kinking occurred in 1.4%–8% of patients.[24,25] The complications and the number of reinterventions after the primary procedure did not increase mortality following EVAR treatment in our study. The devices used in earlier trials were mainly first- or second-generation EVAR devices. It is possible that currently used newer devices and advanced techniques may provide improved long-term outcomes; in this regard, only systemic short-term results are so far available.

Based on our results, postoperative complications after OSR occurred in 16.9% of the patients and thrombosis after OSR occurred in 5 (3.8%) patients, which is acceptable considering the results from other centers. Following open aortic surgery with a bifurcated prosthesis, limb occlusion develops in 1%–5%,[26,27] leading to acute or chronic limb ischemia. It has previously been established that patients with aneurysmal disease have higher incidence of incisional hernias after surgical aneurysm repair (11%–37%) compared with other patients undergoing abdominal surgery.[28] We found incisional hernias and/or dechisceses/infection of aponeurosis in 8 patients (6.2%) of whom 6 (4.6%) needed surgical repair. Postoperative complications and reinterventions were shown not to independently increase 5-year total mortality risk in AAA patients.

In a meta-analysis of survival after elective AAA repair, based on 36 studies including 107,814 patients, the 5-year survival rate was 69%,[29] which is comparable to our results (survival was 72% for all elective AAA cases). Our findings that mid-term survival after AAA repair is independently affected by AAA size, male gender, and comorbidities are supported by other studies and by a recent guideline.[1,14,30]

The limitations of this study are its retrospective nature and non-randomized design. Because it is a single-center study, the case load was relatively small. This sample size may affect a multivariate analysis with the tested number of confounders. Regrettably, data about aneurysm-related mortality and other causes of death were not available. Since the majority of deaths occurred outside hospitals and autopsies are rarely performed in Estonia, we were unable to establish the cause of death. The recent European Vascular Surgery AAA guideline[1] also underlines that the risk of late aneurysm-related death is difficult to assess due to inconsistencies in the registration of the cause of death and the lack of adequate long-term cohorts. Our study demonstrated significantly lower mortality in the OSR group 5 years after the procedure in comparison with EVAR. However, the EVAR procedure was performed only to older patients who were too frail for OSR, which could be a selection bias.

In conclusion, 30-day mortality rates for EVAR and OSR after elective AAA repair in our study were similar. Diminished EVAR survival at 5 years is probably related to the poorer population. Still, the EVAR population was not associated with more complications and reinterventions compared with OSR patients. Aggressive follow-up after EVAR enables to timely intervene in aortic complications and thus prevent late AAA sac ruptures and reduce AAA-related mortality.

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