

Systematic Long-term Follow Up After Endovascular Abdominal Aortic Aneurysm Repair With the Zenith Stent Graft

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WHAT THIS PAPER ADDS

This paper reports the 16 year outcomes of elective endovascular aneurysm repair (EVAR) with the Zenith stent graft. The results indicate that graft related complications keep appearing years after the primary procedure, suggesting mandatory lifelong surveillance. Abdominal aortic aneurysm rupture is rare after EVAR, with a mean annual risk of 0.5%, and is not prevented by regular follow up.

Objective/Background: Although endovascular aneurysm repair (EVAR) has been widely adopted, long-term data remain limited. This study analyses the long-term outcome (16 years) after EVAR with the Zenith stent graft in a single academic centre.

Methods: From 2000 to 2010, 282 patients with an abdominal aortic aneurysm (AAA) were treated electively and monitored annually. Primary outcomes were overall and AAA rupture free survival; the secondary outcomes were complication and re-intervention free survival. Kaplan–Meier analysis was used to examine survival.

Results: The median patient age was 76 years (range 49–92 years) and mean aneurysm diameter 61 mm (range 40–110 mm). Patients were followed for a median of 76 months (range 0–201 months). Overall survival was 93% (SE 0.02), 61% (SE 0.08), 25% (SE 0.16), and 9% (0.19) at 1, 2, 5, 10, and 16 years, respectively. Ten (3.5%) AAA ruptures occurred, and the cumulative AAA rupture free survival was 100%, 98% (SE 0.01), 96% (SE 0.02), and 79% (SE 0.12) at 1, 5, 10, and 16 years, respectively. The mean annual AAA rupture rate was 0.5%. Freedom from any stent graft related complications was 68% (SE 0.03), 58% (SE 0.09), 54% (SE 0.17), and 52% (SE 0.21), respectively; freedom from graft related re-interventions was 95% (SE 0.01), 80% (SE 0.08), 73% (SE 0.11), 70% (SE 0.16), at 1, 5, 10, and 16 years, respectively. Five (1.8%) late conversions were required during follow up. The variables that significantly and independently correlated with ruptured AAA were pre-operative aneurysm size and primary type II endoleak. The latter was the only independent significant factor to increase the risk of re-intervention.

Conclusion: The number of graft related complications is high after EVAR, and new complications keep appearing years after the initial procedure. Even though fatal AAA rupture after EVAR is rare, it cannot be totally avoided despite systematic follow up.

Keywords: AAA, Complication, EVAR, Long-term, Re-intervention

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INTRODUCTION

Endovascular aneurysm repair (EVAR) has become the method of choice for the treatment of abdominal aortic aneurysms (AAA).¹ Since the introduction of EVAR over 20 years ago, many successful short-term results have been

reported, but long-term data are still limited.^{2–5} Furthermore, the inconsistency in reporting the results of individual studies makes the interpretation of the findings troublesome. This is true especially when a cohort consists of patients treated with multiple devices with different technical qualities. Consequently, this may carry the risk of underestimating the long-term durability of a particular device.^{2,4,6–10}

Despite all the advances of endovascular techniques and graft materials, the late failure of endovascular repair due to endoleaks persists.^{10,11} Even though awareness of the

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nature of different types of endoleak and their treatment options is increasing, the re-intervention rate remains higher than following open repair.^{2,4,8–10}

According to the available data, the number of necessary re-interventions after the primary procedure does not seem to have a negative effect on the AAA related mortality after EVAR; the treatment modality therefore provides effective protection against AAA rupture.^{2,3,12} At the same time, a similar positive impact on overall mortality has not been demonstrated.^{2,8–10,13} There are several reasons for this. Firstly, as the population is ageing and the prevalence of AAA has been shown to be highest among those over 80 years of age, elderly patients with AAA and multiple comorbidities are increasingly being treated.¹³ Secondly, it has been implied in the literature that EVAR may be associated with increased cancer mortality vs. open repair.² The justification for treatment must therefore always be carefully considered, despite the minimally invasive nature of the modality.

The purpose of this study was to report the 16 year overall survival, as well as AAA rupture, complication, and re-intervention free survival after elective EVAR with a Zenith stent graft at an academic institution.

MATERIAL AND METHODS

Between 2000 and 2010, 282 patients, constituting the study group, underwent elective EVAR with the Zenith stent graft (Cook, Bloomington, IN, USA) at a single academic institution. Patients with an isolated iliac artery aneurysm or previous open aortic surgery were excluded from the study. The indication for initial treatment was an aneurysm with a diameter of ≥ 55 mm in men and ≥ 50 mm in women. Patients with an increase in AAA diameter of ≥ 5 mm over a six month period, as well as those in whom the AAA became symptomatic, were also treated. All procedures were performed by a vascular surgeon together with an interventional radiologist in a hybrid suite. The patients were mainly treated under spinal anaesthesia, and the stent grafts were implanted through the common femoral artery. Bifurcated grafts were used in most of the EVAR procedures, but an

aorto-uni-iliac graft was employed if one of the iliac arteries was occluded or severely stenosed. An attempt to embolise a patent inferior mesenteric artery (IMA) was always made prior to stent graft placement.

The patients were systematically followed after the procedure according to the protocol in Table 1. Based on the available data and the authors' experience at the time, the initial surveillance protocol was modified by replacing the annual computed tomography angiography (CTA) scan with a colour duplex ultrasonography (CDUS) in 2005. Thereafter, all CDUS examinations were performed by experienced vascular surgeons. The CTA scans were continued for all patients, if not contraindicated, 24 months after the initial procedure to confirm the reliability of the CDUS examinations. For obese individuals and for patients with a suspected complication at CDUS, an additional CTA scan was performed. A plain abdominal Xray was taken annually up until 2013. The patients were followed annually until the end of March 2017. At the end of follow up, the status of each patient was confirmed (i.e., dead or alive), in addition to obtaining information on possible EVAR related re-interventions up until the end of the follow up. For some individuals, long-term surveillance was carried out in the referring hospitals they had initially visited prior to the endovascular AAA treatment. The referring vascular colleagues were contacted accordingly to obtain follow up data. Patients were contacted if a delay in a follow up examination was noted. All CTAs were re-analysed for the study.

The primary outcomes were overall and AAA rupture free survival, while the secondary outcomes included graft related complication free and re-intervention free survival. 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.

SPSS 22.0 for Windows was used for statistical analysis (IBM, Armonk, NY, USA). Kaplan–Meier survival analysis was used to examine survival. Uni- and multivariable analyses were used to assess the effect of age, sex, AAA diameter, neck diameter, neck length, neck angulation,

Table 1. Changes in follow up protocol of patients with an abdominal aortic aneurysm treated with endovascular aneurysm repair over the study period

	2000	2001	2003	2005	2010	2013
2–3 d	Computed tomography angiography (CTA)	CTA	CTA ^a	CTA ^a		
1 mo	CTA	CTA	CTA ^b	Colour duplex ultrasonography (CDUS) ^b	CTA ^a	CDUS, CTA
3 mo	CTA	CTA				
6 mo	CTA, aortography	CTA	CTA ^b			
12 mo	CTA	CTA ^a	CTA	CDUS	CDUS	CDUS
24 mo	CTA	CTA ^a	CTA ^a	CDUS, CTA ^a	CDUS, CTA ^a	CDUS, CTA
Annually thereafter	CTA	CTA ^a	CTA ^a	CDUS ^{a,c}	CDUS ^{a,c}	CDUS ^c

CTA = computed tomography angiography; CDUS, colour duplex ultrasonography.

^a An additional plain abdominal Xray was taken.

^b CTA if previous CTA showed signs of an endoleak.

^c CTA if a complication was suspected in CDUS.

patent IMA, primary type II endoleak, following the instructions for use (IFU), and of being lost to follow up on any stent graft related re-intervention (defined later in Table 5) and AAA rupture. A primary endoleak was defined as an endoleak observed in the primary procedure or in the first post-operative CTA on the second or third day. Statistical significance was indicated by a p value $\leq .05$.

RESULTS

The median age of the cohort was 76 years (interquartile range [IQR] 11; range 49–92 years) and mean aneurysm diameter was 61 mm (range 40–110 mm) at the time of the treatment. The IFU issued for the implantation of the stent graft were followed in 90% of the patients. Patient characteristics are presented in Table 2. The median follow up was 76 months (IQR 69; range 0–201 months). The status of each patient was confirmed at the end of the follow up (i.e., dead or alive). For each patient, information was available regarding the latest annual follow up examination and possible EVAR related re-interventions after that up to the end of follow up. In some cases, the follow up interval was prolonged, or the surveillance discontinued after uncomplicated surveillance, if the patient was physically frail or if life expectancy short. These patients were reported as lost to follow up.

Spinal anaesthesia was used in most cases ($n = 271$; 96%). A bifurcated stent graft was employed in 268 patients (95%) and a uni-iliac stent in 14 cases (5%). The IMA was patent in 186 patients, and was successfully embolised during the initial procedure prior to the stent graft placement in 147 cases (79%). There were no intra-operative deaths or primary conversions. The thirty day mortality was 1.8% ($n = 5$), and the causes of death were brainstem infarction ($n = 1$), cardiac failure ($n = 3$), and cardiac arrest due to total stent graft thrombosis ($n = 1$). There was no

significant difference in 30 day mortality between patients under and over 80 years of age (1.5% vs. 2.3%; $p = .500$).

The overall survival rates were 93% (SE 0.02), 83% (SE 0.03), 61% (SE 0.08), 25% (SE 0.16), and 9% (SE 0.19) at 1, 2, 5, 10, and 16 years, respectively (Fig. 1). The corresponding figures for those aged ≥ 80 years were 93% (SE 0.03), 80% (SE 0.04), 46% (SE 0.19), and 4% (SE 0.42) at 1, 2, 5, and 10 years, respectively. There was no significant difference in survival between patients under and over 80 years of age at two years of surveillance ($p = .529$). The most common causes of death were a cardiac event ($n = 70$; 32%) and cancer ($n = 48$; 22%). The autopsy rate was 26%.

There were 10 (3.5%) AAA ruptures during follow up (Table 3). All ruptures were confirmed by CTA ($n = 8$) or autopsy ($n = 2$). Mean time to rupture was 81 months (range 22–173 months). Consequently, the cumulative AAA rupture free survival was 100%, 98% (SE 0.01), 96% (SE 0.02), and 79% (SE 0.12) at 1, 5, 10, and 16 years, respectively. Eight of the 10 patients with a ruptured AAA (RAAA) reached the hospital, and two of them underwent an emergency open repair. One of these patients died in the intensive care unit two days after the procedure, and the other was still alive at the end of the follow up. In three RAAA cases, an additional proximal cuff was placed during an emergency procedure, but adequate proximal sealing was not achieved, and the patients died post-operatively. They were not considered candidates for open conversion. In the remaining three cases, endovascular repair was not considered technically possible and open repair was refused owing to the patients' high age and multiple comorbidities.

During surveillance, one patient with a RAAA was found to have a type IB endoleak, but, at the age of 90 years, he was severely demented and no further procedures were

Characteristics	n (%)
Age	75 (49–92)
Sex	
Male	249 (88)
Female	33 (12)
Coexisting conditions	
Hypertension	138 (49)
Coronary heart disease	148 (52)
Hypercholesterolaemia	66 (23)
Diabetes	41 (15)
Chronic renal insufficiency	28 (10)
Cigarette smoking	57 (20)
Cerebrovascular disease	46 (16)
Respiratory disease	81 (29)
Previous arterial reconstruction or amputation	10 (3.5)
No risk factors	26 (8.8)
Size of aneurysm – mm	61 (40–110)

Data are n (%) or mean (range) unless otherwise indicated.

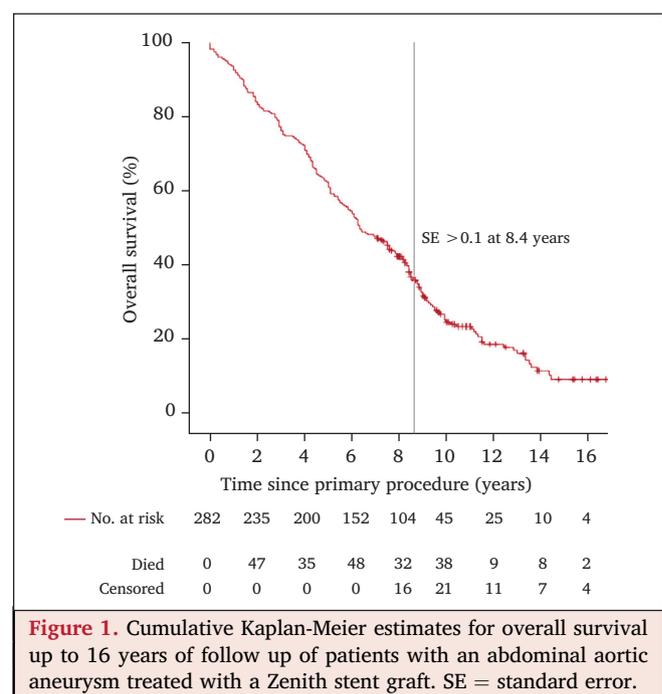


Figure 1. Cumulative Kaplan-Meier estimates for overall survival up to 16 years of follow up of patients with an abdominal aortic aneurysm treated with a Zenith stent graft. SE = standard error.

performed. In one case, the rupture was unexpectedly found at autopsy 14 years after the primary treatment. This female patient had refused further follow up after 9 years of uncomplicated surveillance, with a shrunken AAA diameter of 30 mm. The nine other patients were under surveillance at the time of the RAAA.

Seven of the 10 AAA ruptures were due to type I endoleak (IA: $n = 5$; IB: $n = 2$). Six of these patients had a persistent primary type II endoleak in early surveillance prior to the development of the type I endoleak. In three of these cases, as the aneurysm sac showed enlargement in surveillance, repeated unsuccessful attempts to embolise the type II endoleak were made. In three cases, however, the type II endoleak seemed stable, with no detectable change in aneurysm sac size during early surveillance, but AAA enlargement was noted approximately three years after the primary treatment. By that time, these patients had also developed a type I endoleak before AAA rupture. One rupture patient refused further procedures for the type IA endoleak and died three years after the initial procedure.

In the case of three of the 10 ruptures, no significant endoleak had been noted during surveillance. One patient with a primary type II endoleak showed clear shrinkage of the aneurysm sac during the early surveillance. However, at 22 months, the aneurysm ruptured. Another patient was followed for endotension, with no signs of an endoleak, and he died of a RAAA five years after the primary procedure. One rupture, as mentioned earlier, was found at autopsy with no prior history of an endoleak. The univariable analysis showed a significant association between primary type II endoleak and AAA rupture (odds ratio [OR] 4.09, 95% CI 1.12–14.9; $p = .033$). An even more significant association was found between pre-operative aneurysm size and late AAA rupture (OR 1.06, 95% CI 1.02–1.11; $p = .007$). These results also remained constant in the multivariable analysis, with an OR of 4.65 (95% CI 1.14–18.9; $p = .032$) for type II endoleak and 1.07 (95% CI 1.02–1.13; $p = .009$) for pre-operative aneurysm size. Consequently, at the end of the 16 year follow up, the mean annual aneurysm rupture rate was 0.49% (Table 4).

Table 3. Graft related complications during long-term surveillance in 282 patients with an abdominal aortic aneurysm treated with a Zenith stent graft

Complication	Events n	Patients n (%)
Endoleak	120	117 (41)
Type I	39	37 (13)
Type II	79	79 (28)
Type III	2	2 (1)
Thrombosis	15	14 (5)
Endotension (≥ 5 mm)	13	13 (5)
Migration (≥ 5 mm)	6	5 (2)
Stent fracture	2	2 (1)
Kinking	2	2 (1)
Abdominal aortic aneurysm rupture	10	10 (4)

Table 4. Annual rupture rate of abdominal aortic aneurysms treated with a Zenith stent graft according to year of follow up

Year of follow up	Combined follow up y^a	Ruptures n	Annual rupture rate %
1	261	0	0
2	235	1	0.4
3	215	1	0.5
4	200	0	0
5	172	2	1.2
6	152	1	0.7
7	135	2	1.5
8	104	0	0
9	66	0	0
10	45	0	0
11	34	0	0
12	25	0	0
13	20	2	10.0
14	10	0	0
15	7	1	14.3
16	4	0	0

^a Combined follow up years were calculated for each interval.

A total of 168 graft related complications were seen in a total of 119 patients (42%). All primary type II endoleaks were taken into account, even if they were detected only in the peri-operative angiogram or on the first CTA. All complications are listed in Table 3. The freedom from any stent graft related complication was 68% (SE 0.03), 63% (SE 0.05), 58% (SE 0.09), 54% (SE 0.17), and 52% (SE 0.21) at 1, 2, 5, 10, and 16 years, respectively (Fig. 2). Complications seemed to accumulate during the early years of surveillance but were encountered up to 14 years after the primary procedure. A type II endoleak was the most common complication ($n = 79$; 28%), with almost half (48%) of them

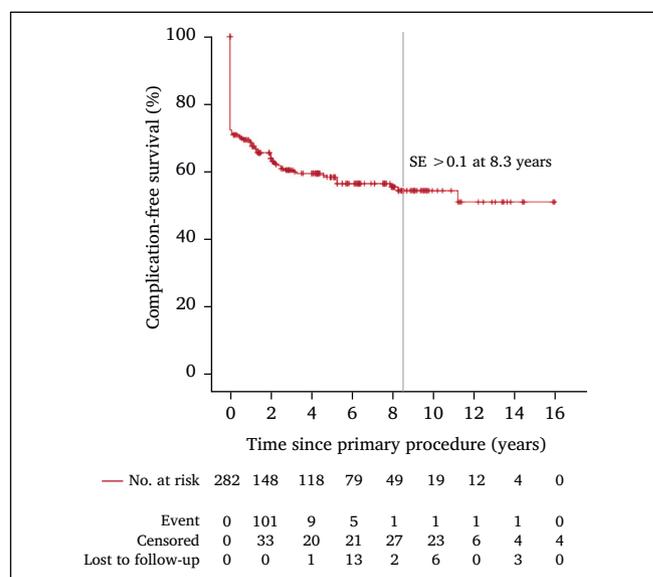


Figure 2. Cumulative Kaplan-Meier estimates for complication free survival up to 16 years of follow up of patients with an abdominal aortic aneurysm treated with a Zenith stent graft. SE = standard error.

sealing spontaneously and the vast majority (89%) occurring during the first two years of follow up. Of those with a patent IMA (39 patients) after the initial procedure, 18 (46%) developed either a type II endoleak ($n = 14$) or endotension ($n = 4$). Most of these patients (88%) with either a type II endoleak or endotension also had a patent IMA on surveillance, and only two of them required later embolisation. In all, only 26 (33%) of all type II endoleaks required endovascular treatment due to aneurysm sac enlargement over the study period. The primary embolisation strategy was coil embolisation; if that proved unsuccessful, a secondary attempt was made with glue.

A total of 13 patients were diagnosed with endotension (≥ 5 mm) without a detectable endoleak during the surveillance. For one patient, there was an attempt to treat the endotension by relining the old graft, while the rest were followed carefully. Two of these patients later developed a type I endoleak, and they were treated at that point with an additional cuff and limb graft. None of the patients with endotension suffered a RAAA.

Re-intervention for a graft related complication was required for 61 patients (22%). All additional procedures are listed in Table 5. The rate of freedom from graft related re-interventions was 95% (SE 0.01), 91% (SE 0.03), 80% (SE 0.08), 73% (SE 0.11), and 70% (SE 0.16) at 1, 2, 5, 10, and 16 years, respectively (Fig. 3). Only five (1.8%) late conversions to open repair were required, two as an emergency repair of a rupture as mentioned earlier. Two patients had a persistent type I endoleak despite the placement of an extra proximal cuff, and conversions were performed at 12 and 27 months, respectively. One patient had a stent fracture and type III endoleak 149 months after the primary treatment. The other case of type III endoleak developed as a result of limb graft migration and was successfully treated with an additional limb graft at 47 months. All elective conversions were uncomplicated. A primary type II endoleak was found to be the only independent significant factor to increase the risk of any late re-intervention (OR 6.79, 95% CI 3.61–12.79; $p < .001$).

During follow up, aneurysm sac shrinkage of ≥ 5 mm was seen in 61% of the cases, with at mean decrease of 18 mm (range 5–41 mm) in maximum diameter.

Table 5. Secondary procedures during long-term surveillance in 282 patients with abdominal aortic aneurysms treated with a Zenith stent graft

Additional procedures	<i>n</i>
Limb repair	18
Infrarenal cuff	19
Embolisation ^a	53
Percutaneous transluminal angioplasty	5
Thrombolysis	3
Femorofemoral bypass	10
Amputation	1
Conversion to open repair	5

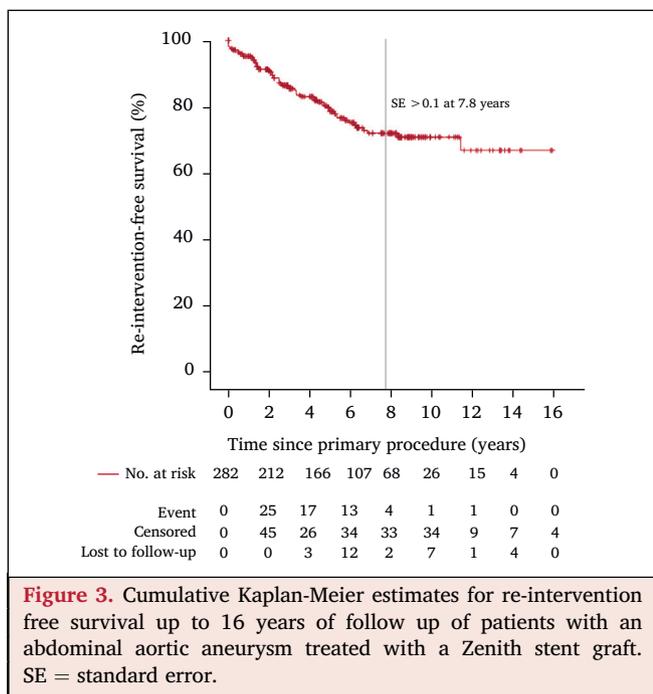
^a An additional seven angiograms with no further interventions.

DISCUSSION

This study confirms earlier findings suggesting that EVAR is a safe treatment method for AAA in both the short and long-term.^{2,3,5,14} Fatal AAA ruptures after EVAR are sparse, and patients with an AAA mostly die due to the sequelae of other comorbidities. Rupture free survival remained high during follow up, but a 0.49% annual rupture rate persists. A recent meta-analysis on the topic proposed that rupture after EVAR predominantly occurs in patients who are not under surveillance.¹¹ The present results are not in line with this finding as nine of the 10 patients with a RAAA were under regular surveillance. The annual rupture rate was lower than those published previously (0.6–1.1%).^{7,15,16} This might be explained by the patients' commitment to the regular follow up and the fact that being compared are the results of older, first generation stent grafts with a newer device. This is further emphasised by the fact that the current results concern only the Zenith stent graft, which is known to have a particularly low rupture rate.^{3,17,18}

In the current study, 61% of patients survived for >5 years, while 25% survived >10 years after the primary treatment. These figures are somewhat lower than those published in other long-term series.^{2,3} Possible explanations for this difference could be the higher mean age and the higher prevalence of coronary artery disease in the present study population than in those published previously. Furthermore, in the authors' practice, during the period in question, younger patients (those < 70 years of age) with no significant comorbidities were primarily offered open repair, while those with significant comorbidities were treated endovascularly regardless of age. In general, octo- and nonagenarians seemed to tolerate the procedure well, as their overall survival rate was similar to that of those < 80 years of age at two years and almost half of them were still alive at five years. According to a recent meta-analysis, however, the 30 day mortality was significantly higher among octogenarians, despite the minimally invasive nature of EVAR.¹⁹ Even though our study does not support this finding, the risks related to the procedure must be borne in mind, despite its minimally invasive nature.

The most common cause of death among the patients was a cardiac event (32%), thus mirroring the results of previous studies on EVAR.^{2,3} Cancer was the second most common cause of death (22%). It has been suggested by the investigators of the EVAR 1 trial that patients treated by EVAR have a higher cancer mortality in the long term than those treated by open repair, raising the question of the effect of the stent grafts and radiation on patient health.² When comparing the cancer death rate among the study population and the age matched general population in Finland during the study period, higher cancer death rates among those treated with EVAR were not found (22% vs. 17–22%).²⁰ The figures were similar even when the deaths were compared separately during the first five years (22% vs. 24–30%) and thereafter (20% vs. 17–22%). Convincing conclusions about the possible effect of EVAR on cancer incidence and death cannot however be made based on the



EVAR1 trial results and the present findings. Further studies are needed to clarify this matter.

The number of graft related complications was relatively high in the present cohort compared with other long-term studies.²⁻⁴ This could be explained by the patients' high compliance with the surveillance protocol and the complete, systematic follow up data available for analysis. Furthermore, all available CTAs were re-analysed in order to avoid any complication being missed. At the same time, the re-intervention free survival was similar to the rates reported in previous studies.^{3,7,11,21} This finding may suggest that not all detected complications require re-intervention but can be followed safely. A conversion to open repair is rarely needed, and most of the complications can be treated by endovascular means.

The most common reported complication is a type II endoleak, and the majority of them seal spontaneously during early surveillance or require no treatment, a phenomenon also seen in the present study.²² Seven of 10 ruptures were caused by a type I endoleak, and its significance as the main risk factor for RAAA is indisputable.^{16,23} The natural progression of the aneurysmal disease of the aorta, especially at the proximal sealing zone, is the most likely cause of a late type I endoleak. However, six of the RAAA cases in the current cohort had a persistent type II endoleak in conjunction with a type I endoleak, and therefore it is possible that sac enlargement caused by the type II endoleak resulted in inadequate sealing at the landing zones and eventually, a type I endoleak. This might suggest that type II endoleaks are not as benign as assumed after all. Also, the multivariable analysis showed a primary type II endoleak to be the only independent significant factor increasing the risk of any late re-intervention or RAAA. The new European Society for Vascular Surgery Guidelines on the Management of Abdominal Aorto-iliac

artery Aneurysms also highlights the meaning of any type of early endoleak in post-operative surveillance.²⁴ Moreover, a significant association was found between pre-operative aneurysm size and RAAA, but the reason for this is not clear, even though it has also been repeatedly established in previous studies.²⁵

In the Western world, the life expectancy is rising. In Finland, almost 21% of the current population is > 65 years old, and according to the country's population prospects, over a quarter of the population will be > 65 years in 2030.²⁰ At the beginning of the current study, the life expectancy of a 65 year old man in Finland was 16 years and, at the end of the study, it was 18 years.¹⁹ Therefore, the long-term durability of the chosen treatment method for AAA plays an increasing role in patients' wellbeing. Based on the present results, the durability of EVAR with a Zenith stent graft is good, as the re-intervention free survival was 70% at 16 years, which is in concordance with another long-term study on the Zenith stent graft.³ Additionally, as the number of patients treated endovascularly continuously increases, the workload caused by the surveillance will become unbearable for healthcare providers in the future. In the current study, most of the patients (58%) experienced an uncomplicated surveillance and the aneurysm shrank in 61% of the cases during long-term follow up, suggesting that annual follow up may not be necessary for all patients, although lifelong surveillance is probably still required for all. Further investigations are needed to identify those who may not require annual surveillance without any additional risks to the patient. Additionally, the first complication occurring after two years of surveillance is a rare finding, and the long-term follow up should probably focus on patients with complications in early surveillance.

The study is limited by several factors. Firstly, the retrospective nature of the study is a drawback. However, the introduction of a new treatment method also requires retrospective analysis, as not all possible problems can be predicted at the beginning of the novel era. In the current study, the data were collected prospectively, thus making the results more robust and generalisable. Secondly, overall knowledge regarding the endovascular treatment method for AAA increased during the study period, thus allowing modification of the follow up protocol. It is believed this has had little impact on the findings, even though it may have led to some complications being omitted, especially when it comes to type II endoleaks. Thirdly, the current results concern only the Zenith AAA endograft and should be interpreted as such.

CONCLUSION

EVAR is an effective treatment for preventing RAAA, but despite careful surveillance, the risk of a late rupture remains. Furthermore, prevention requires a considerable volume of secondary procedures, but open conversion is rarely needed. New complications keep appearing years after the initial procedure, suggesting that lifelong

surveillance is mandatory. More long-term studies are needed to determine the most effective surveillance protocol for this rapidly increasing patient group.

CONFLICT OF INTEREST

None.

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REFERENCES

- Chaikof EL, Dalman RL, Eskandari MK, Jackson BM, Lee WA, Mansour MA, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *J Vasc Surg* 2018;**67**:2–77.
- 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.
- Verzini F, Romano L, Parlani G, Isernia G, Simonte G, Loschi D, et al. Fourteen-year outcomes of abdominal aortic endovascular repair with the Zenith stent graft. *J Vasc Surg* 2017;**65**:318–29.
- Schermerhorn ML, Buck DB, O'Malley AJ. Long-term outcomes of abdominal aortic aneurysm in the Medicare population. *N Engl J Med* 2015;**373**:328–38.
- Brewster DC, Jones JE, Chung TK. Long-term outcomes after endovascular abdominal aortic aneurysm repair: the first decade. *Ann Surg* 2006;**244**:426–38.
- Powell JT, Sweeting MJ, Ulug P, Blankensteijn JD, Lederle FA, Becquemin JP, et al. Meta-analysis of individual-patient data from EVAR-1, DREAM, OVER and ACE trials comparing outcomes of endovascular or open repair for abdominal aortic aneurysm over 5 years. *Br J Surg* 2017;**104**:166–78.
- Koole D, Moll FL, Buth J, Hobo R, Zandvoort HJ, Bots ML, et al. Annual rupture risk of abdominal aortic aneurysm enlargement without detectable endoleak after endovascular abdominal aortic repair. *J Vasc Surg* 2011;**54**:1614–22.
- Becquemin JP, Pillet JC, Lescalie F, Sapoval M, Goueffic Y, Lermusiaux P, et al. A randomized controlled trial of endovascular aneurysm repair versus open surgery for abdominal aortic aneurysms in low- to moderate-risk patients. *J Vasc Surg* 2011;**53**:1167–73.
- Lederle FA, Freischlag JA, Kyriakides TC, Matsumura JS, Padberg Jr FT, Kohler TR, et al. Long-term comparison of endovascular and open repair of abdominal aortic aneurysm. *N Engl J Med* 2012;**367**:1988–97.
- Blankensteijn JD, de Jong SE, Prinssen M, van der Ham AC, Buth J, van Sterkenburg SM, et al. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. *N Engl J Med* 2005;**352**:2398–405.
- Antoniou GA, Georgiadis GS, Antoniou SA. Late rupture of abdominal aortic aneurysm after previous endovascular repair: a systematic review and meta-analysis. *J Endovasc Ther* 2015;**22**:734–44.
- Steinmetz E, Rubin BG, Sanchez LA, Choi ET, Geraghty PJ, Baty J, et al. Type II endoleak after endovascular abdominal aortic aneurysm repair: a conservative approach with selective intervention is safe and cost-effective. *J Vasc Surg* 2004;**39**:306–13.
- Khashram M, Jones GT, Roake JA. Prevalence of abdominal aortic aneurysm (AAA) in a population undergoing computed tomography colonography in Canterbury, New Zealand. *Eur J Vasc Endovasc Surg* 2015;**50**:199–205.
- Stather PW, Sidloff D, Dattani N. Systematic review and meta-analysis of the early and late outcomes of open and endovascular repair of abdominal aortic aneurysm. *Br J Surg* 2013;**100**:863–72.
- Franks SC, Sutton AJ, Bown MJ, Sayers RD. Systematic review and meta-analysis of 12 years of endovascular abdominal aortic aneurysm repair. *Eur J Vasc Endovasc Surg* 2007;**33**:154–71.
- Harris PL, Vallabhaneni SR, Desgranges P. Incidence and risk factors of late rupture, conversion, and death after endovascular repair of infrarenal aortic aneurysms: the EUROSTAR experience. European collaborators on stent/graft techniques for aortic aneurysm repair. *J Vasc Surg* 2000;**32**:739–49.
- Greenberg RK, Chuter TA, Cambria RP, Sternbergh 3rd WC, Fearnot NE. Zenith abdominal aortic aneurysm endovascular graft. *J Vasc Surg* 2008;**48**:1–9.
- Iwakoshi S, Ichihashi S, Higashiura W, Itoh H, Sakaguchi S, Tabayashi N, et al. A decade of outcomes and predictors of sac enlargement after endovascular abdominal aortic aneurysm repair using zenith endografts in a Japanese population. *J Vasc Interv Radiol* 2014;**25**:694–701.
- Han Y, Zhang S, Zhang J, Ji C, Eckstein HH. Outcomes of endovascular abdominal aortic aneurysm repair in octogenarians: meta-analysis and systematic review. *Eur J Vasc Endovasc Surg* 2017;**54**:454–63.
- Statistics Finland. Available at: <http://www.stat.fi/index>.
- Prinssen M, Verhoeven EL, Buth J. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. *N Engl J Med* 2004;**351**:1607–18.
- Tolia AJ, Landis R, Lamparello P, Rosen R, Macari M. Type II endoleaks after endovascular repair of abdominal aortic aneurysms: natural history. *Radiology* 2005;**235**:683–6.
- van Marrewijk C, Buth J, Harris PL, Norgren L, Nevelsteen A, Wyatt AG. Significance of endoleaks after endovascular repair of abdominal aortic aneurysms: the EUROSTAR experience. *J Vasc Surg* 2002;**35**:461–73.
- Wanhainen A, Verzini F, Van Herzele I, Allaire E, Bown M, Cohnert T, et al. Editor's choice - 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.
- Patel SR, Allen C, Grima MJ, Brownrigg JRW, Patterson BO, Holt PJE, et al. A systematic review of predictors of reintervention after EVAR: guidance for risk-stratified surveillance. *Vasc Endovascular Surg* 2017;**51**:417–28.