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research article

Single centre experience with Excluder® stent graft; 17-year outcome

Ziga Snoj[1,2,*], Tjasa Tomazin[1*], Vladka Salapura[1,2], Dimitrij Kuhelj[1]

[1] Radiology Institute, University Medical Centre Ljubljana, Ljubljana, Slovenia
[2] Faculty of Medicine, University of Ljubljana, Ljubljana, Slovenia

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Correspondence to: Assoc. Prof. Dimitrij Kuhelj, M.D., Ph.D., Radiology Institute University Medical Centre Ljubljana, SI-1000 Ljubljana, Slovenia. Phone: +386 1 522 8530; E-mail: dimitrij.kuhelj@guest.arnes.si

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* These authors contributed equally to this work; shared authorship.

Background. Endovascular abdominal aortic aneurysm repair (EVAR) has become a mainstay of abdominal aorta aneurysm treatment. Long term follow-up on specific stent grafts is needed.

Patients and methods. This study included 123 patients (104 men; mean age 73.0 years, range 51–89) with abdominal aorta aneurysm, treated with Excluder® stent graft between October 2002 and June 2008. Periprocedural and follow-up data were retrieved by reviewing the records of our institution, while time and cause of death were retrieved from the National Institute of Public Health. If an abdominal aortic aneurysm rupture was listed as the cause of death, records were retrieved from the institution that issued the death certificate. Our primary goal was to assess the primary technical success rate, type 1 and type 2 endoleak, reintervention free survival, 30-day mortality, the overall survival and aneurysm rupture-free survival.

Results. The median follow-up was 9.7 years (interquartile range, 4.6–13.8). The primary technical success was 98.4% and the 30-day mortality accounted for 0.8%. Secondary procedures were performed in 29 (23.6%) patients during the follow-up period. The one-, five-, ten-, fifteen- and seventeen-year overall survival accounted for 94.3%, 74.0%, 47.2%, 35.8% and 35.8%, while the aneurysm-related survival was 98.4%, 96.3%, 92.6%, 92.6%, 92.6%. In seven (5.7%) patients, abdominal aortic rupture was found as the primary cause of death during follow-up.

Conclusions. Our data showed that EVAR with Excluder® stent graft offers good long-term results. More than 75% of patients can be treated completely percutaneously. Late ruptures do occur in the first ten years, raising awareness about regular medical controls.

Key words: EVAR; long-term experience; Excluder® stent graft

Introduction

Endovascular management of the aorta with stent grafts (SG) was introduced in the late 1980 and early 1990's[1-3] with the intention of reducing mortality originating from aortic rupture by using a less invasive method as open surgery repair (OSR). In the last decades, endovascular abdominal aortic aneurysm repair (EVAR) has been expanding, surpassing OSR in the USA by 2003.[4]

Large series have already reported good short- and mid-term results after EVAR with a decreased 30-day mortality compared to OSR[4-6], while long-term studies revealed no difference in long-term survival and reported a higher reintervention rate in the EVAR as opposed to the OSR group.[7-9]

While large series studies provide a great overview on success and outcome, they provide little data and outcomes on specific SG. Such information plays a crucial role in the modification and

evolution of SGs.[10] Thus, information on specific SG should be gathered to contribute to the ongoing evolution of SGs. Several SGs are used in Europe, and some were modified throughout the years, while others were newly designed.[9,11,12] So far, SGs show excellent medium-term results, whereas their long-term efficacy and durability have not yet been proven.[9] Excluder® SG (W.L. Gore & Associates, Flagstaff, AZ, USA) was introduced in 1997 and remains one of the most used devices for abdominal aortic aneurysm (AAA) management. Regular modifications and improvements help to maintain Gore Excluder as a safe and durable treatment choice.[13] Only a handful of studies reported outcomes on the first two generations of Excluder® SG.[13-15] The longest follow-up reported for Excluder® SG is ten years.[13] With the increasing life span of the general population, many patients live as far as decades after aneurysmal management. Detailed evaluation of long-term results, even beyond ten years, should therefore be conducted.

The aim of our study was to present a long-term single centre experience with Excluder® SG. In detail, all-cause mortality, aneurysm-related mortality, incidence of complications and re-interventions have been reported.

Patients and methods

The National Medical Ethics Committee approved the study (number 0120-120/2015-2). Between October 2002 and June 2008, 130 consecutive patients with AAA were treated with Excluder® (W.L. Gore & Associates, Flagstaff, AZ, USA). As seven patients were lost to follow-up, our study included 123 patients (104 men; mean age 73.0 years, range 51–89).

EVAR procedure and follow-up

The decision for endovascular management was made by a multidisciplinary board of vascular surgeons, interventional radiologists, and angiologists. Treatment was considered if the maximal diameter of AAA surpassed 5.5 cm or if it grew more than 5 mm in six months. OSR in Slovenia is less expensive than endovascular management, so the consensus was made that mainly patients older than seventy, would be treated by EVAR if that proved to be technically feasible. Since this was the only treatment option for many of them, some were treated outside the instructions for use. Due to comorbidities that affected many of our patients, also those unsuitable for OSR (polymorbid, those having previous abdominal surgeries, etc.) received EVAR. Emergency EVAR was performed in cases of anatomically suitable AAA rupture and in hemodynamically stable patients.[16] The decision in these cases was left to the interventional radiologist on duty.

The procedures were performed by an experienced team of seven interventional radiologists with surgical back-up in case of failed percutaneous access site or calcified access arteries. The standard follow-up protocol in our institution was CT angiography (CTA) at 3 and 12 months, and yearly thereafter, however the protocol was impacted with patients' compliance. All proximal and distal type 1 endoleaks were treated; type 2 endoleaks were treated only in cases of > 5 mm aneurysm growth.

Data retrieval

The follow-up extended until January 2021. The periprocedural and follow-up data were retrieved by reviewing the records of our institution. The time of death and International Classification of Diseases (ICD), 10th Revision, diagnosis with procedure codes were retrieved from the Slovenian National Institute of Public Health. To ensure the maximal accuracy in patients assigned with ICD code I71.3 (AAA, ruptured), death records were retrieved from the institution that issued the death certificate, followed by a detailed examination of the records. Based on the findings, the consensus on the cause of death was made (Table 1).

The primary technical success was defined as a successful introduction and deployment of the device without the need for secondary procedure within 24 hours after EVAR.[13,17]

A secondary procedure was defined as any endovascular or surgical procedure related to failure or complication of EVAR.[17] Endoleak has been described in publications by Chaikof *et al*.[17] Post-implantation syndrome was considered if the clinical and biochemical expression of an inflammatory response following EVAR expressed C-reactive protein (CRP) > 8 mg/L and body temperature of ≥ 38.0°C.[18] The drop of hemoglobin (Hb) was considered if the values were reduced ≥ 15.0% from the baseline value and/or ≤ 120 g/L after the procedure.[19]

The primary objective was to assess the primary technical success rate, type 1 and type 2 endoleak, reintervention free survival, 30-days mortality,

TABLE 1. Brief presentation of patients with retrieved I71.3 ICD codes from the National Institute of Public Health and assigned code after revision

Patient No.	Time after EVAR	Reported History	Retrieved ICD-10 Code	ICD-10 Code after Revision
1	51 months	Rupture of AAA and unsuccessful aortobifemoral bypass	I71.3	I71.3
2	2 days	Rupture of AAA after EVAR	I71.3	I71.3
3	72.5 months	Rupture of AAA and unsuccessful resuscitation	I71.3	I71.3
4	16.5 months	Succumbed to high fever due to prolonged and unsuccessful treatment of spondylodiscitis; graft showed imaging findings consistent with infection	I71.3	M46.4
5	50.1 months	AAA rupture and placement of proximal extension cuff; 2 months after secondary procedure AAA rupture and exsanguination to peritoneal cavity	I71.3	I71.3
6	1.5 months	Succumbed to nosocomial pneumonia and sepsis	I71.3	J18.9
7	117.4 months	Graft extension 36.7 months after EVAR; 64.2 months after EVAR control CT scan	I71.3	I71.3
8	3.4 months	1.2 months after EVAR CTA scan and right stent graft limb lysis; additional 2.2 months later sudden severe abdominal pain and unsuccessful resuscitation	I71.3	I71.3
9	18,9 months	Cardiorespiratory arrest, no history of abdominal pain.	I71.3	I46.9
10	2 months	Succumbed to sepsis due to septic arthritis, CT and scintigraphy excluded stent graft infection	I71.3	M00.8
11	21.9 months	11.4 months after EVAR leak type 2 on control CT scan	I71.3	I71.3

AAA = abdominal aortic aneurysm; CTA = CT angiography; EVAR = endovascular abdominal aortic aneurysm repair

overall survival and aneurysm rupture free survival.

Statistical analysis

To calculate the patients' survival, the Kaplan-Meier method was used (any cause and aneurysm related survival). The influence of age and gender on the outcome was assessed with the Cox regression model to calculate hazard ratios with 95% confidence intervals. The statistical significance was set at $p < 0.05$. Data analysis was performed with SPSS v.22.0 (SPSS Inc., Chicago, Illinois, USA).

Results

The median follow-up was 9.7 years (interquartile range, 4.6 - 13.8). Patients were followed-up for up to seventeen years.

The comorbidities of this cohort are shown in Table 2. The emergency repair was performed in five (4.1%) patients. One of them later died due to a recurrent AAA rupture, while the other causes of death were trauma and Alzheimer disease. Two of these patients are still alive more than twelve years after the aneurysmal rupture.

Technical success rate

The primary technical success rate was 98.4% on account of 2 complications; in one patient, the posterior tibial artery was occluded due to coil dislocation during inferior mesenteric artery embolization and in another patient, a stent was implanted in subclavian artery after failed transaxillary renal stenting.

Endoleak was observed in thirty-five (28.5%) patients, type 1 in thirteen (10.0%) patients, and type 2 in twenty-four (18.5%) patients. Two patients had both type 1 and type 2 endoleak. No other type of endoleak was found in the members of the cohort.

In five (4.1%) patients a renal stent was implanted during EVAR due to stenosed renal artery.

TABLE 2. Comorbidities in patients with abdominal aortic aneurysm

Comorbidity	Number of patients
Hypertension	103 (83.7%)
Dyslipidemia	70 (56.9%)
History of smoking	57 (46.3%)
PAOD	32 (26.0%)
History of MI	17 (13.8%)
Diabetes mellitus	16 (13.0%)
Carotid disease	11 (8.9%)
History of CABG	9 (7.3%)
History of CVI/TIA	6 (4.9%)

CABG = coronary artery bypass graft; CVI = cerebrovascular infarction; MI = myocardial infarction; PAOD = peripheral artery occlusive disease; TIA = transitory ischemic attack

A percutaneous hemostasis was achieved in ninety-four (76.4%) patients (completely percutaneous EVAR), surgical hemostasis in thirteen (10.6%) patients and combined in sixteen (13.0%) patients.

Thirty-seven secondary procedures were performed in twenty-nine (23.6%) patients during the follow-up period, the majority being endovascular (Table 3). Mean time to secondary intervention was 36.4 ± 31.1 months. In nearly half of the cases (fourteen patients), SG extensions, seven proximal and seven distal, were implanted (Table 3). In fourteen (11.4%) patients, two secondary procedures were performed; the most frequently repeated ones being translumbar sac embolization (five patients), followed by SG extension, and later translumbar sac embolization (four patients).

Two aortobifemoral bypasses were performed as an emergency procedure due to aneurysm rupture, and two as an elective procedure due to SG infection (Table 3).

24-hour morbidity

In the first twenty-four hours after EVAR, 13 (10.6%) patients showed signs of an inflammatory reaction (CRP: 114.9 ± 54.2 mg/L, range 50–234; increased body temperature). The average hospitalization period for patients who developed post-implantation syndrome was 3.8 days (range 3–8 days). Ten (8.1%) patients received antibiotic treatment; two (1.6%) had X-ray proven pneumonia. In one case, pneumonia was the cause of definitive deterioration and death as well as the cause of the longest hospital stay (45 days). In twelve (9.8%) patients, a drop of Hb was observed; four (3.3%) received blood transfusion due to a significant drop caused by hemostatic problems at the vascular access site. In twelve patients (9.8%), a groin hematoma was detected.

30-day mortality and long-term survival

The 30-day mortality was 0.8% due to AAA rupture in one patient on the second day. The average length of hospital stay was 4.3 days (range 2–45 days). Long-term survival is shown in Figure 1. Younger patients (≤ 69 years old) lived longer than older patients (≥ 70 years old) (Hazard Ratio = 1.34; 95% confidence interval: 1.14–2.23; P = 0.02). However, when a division in the same age groups was performed for aneurysm-related survival, no such difference was observed (P > 0.05). Gender did not affect any cause of survival or aneurysm rupture related survival (both P > 0.05).

TABLE 3. Secondary procedures

Type of treatment		Number of patients treated	Time form EVAR to treatment (months)
Interventional procedure	Stent graft extension	14 (11.4 %)	31.8 ± 35.7
	Translumbar sac embolisation	13 (10.6 %)	60.2 ± 35.6
	Thrombolysis of iliac limb	3 (2.4 %)	1.9 ± 1.4
Surgery	4 aortobifemoral bypass 1 thrombectomy 2 hemicolectomy	7 (5.7 %)	48.5 ± 47.9

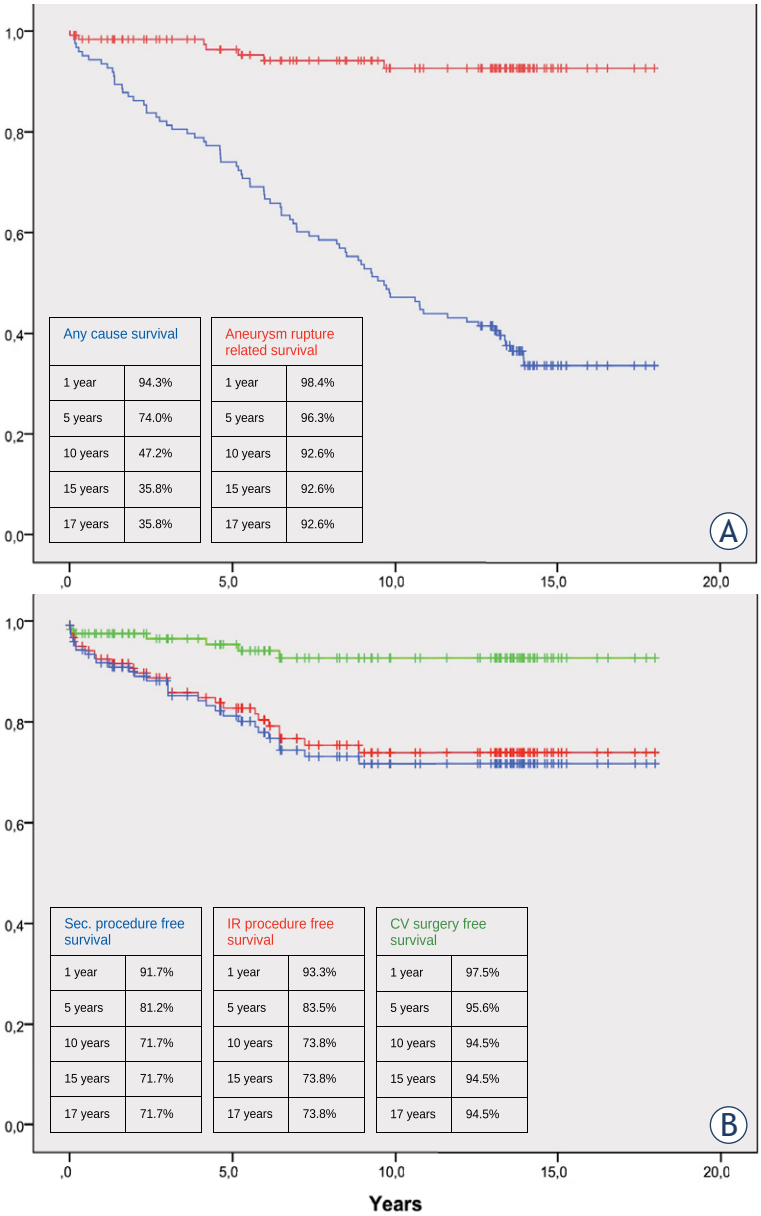

FIGURE 1. (A) Long-term survival; **(B)** survival without secondary procedure with subdivision according to the type of secondary procedure.

CV = cardiovascular; IR = interventional; Sec. = secondary

The one-, five-, ten-, fifteen- and seventeen-year overall survival was 94.3%, 74.0%, 47.2%, 35.8% and 35.8%, while aneurysm-related survival was 98.4%, 96.3%, 92.6%, 92.6%, 92.6% (Figure 1).

Causes of deaths

We identified seventy-nine deaths (64.2%) after the median follow-up of 9.7 years (Figure 1). In eleven (8.9%) patients the ICD-10 diagnosis code I71.3 (AAA, ruptured) was retrieved from the National Institute of Public Health (Table 1). However, after a revision, AAA rupture was assigned as the primary cause of death in only seven (5.7%) patients. They all died within the first ten years following the procedure. After the revision, the adjusted causes of deaths were as follows: twenty-nine (36.7%) patients died of cardiovascular related causes, twenty-five (31.6%) died due to malignancy related causes, eight (10.1%) died of infectious related causes, seven (8.9%) died due to respiratory related causes, and three (3.8%) died because of trauma. The average time of death due to cancer was 5.4 years (range 1.0–14.0 years) after EVAR. The most commonly diagnosed causes of death were pulmonary cancer (7 patients), abdominal cancer (5), prostate cancer (4), breast cancer (3) and plasmocytoma (3).

Discussion

Our cross-sectional study presents a cohort of patients with long-term follow-up, up to 17 years, after EVAR treatment with Excluder® SG.

More than three quarters of our patients were successfully treated completely percutaneously, confirming the minimal invasiveness of EVAR, which is one of the key benefits of endovascular management. Still, surgical backup is essential in centres using percutaneous sutures, since the conversion rate in the previous series was nearly 10%.[20] A good primary technical success rate was achieved and is comparable to the previously published paper on Excluder® SG.[13] In the first twenty-four hours after EVAR, one in ten patients showed signs of inflammatory reaction. These features of systemic inflammatory response are known as post-implantation syndrome, which is reportedly associated with prolonged hospitalization.[18] However, our data did not confirm this, since the average length of hospital stay in our patients was 4.3 days.

In the EUROSTAR registry (one of the first large series dated in 1996), the reported 30-day mortality was 3.4%.[21] In more recent large series of studies, the reported 30-day mortality ranges from 1.2% to 2.6%.[7,22-24] These rates are even lower in studies reporting outcomes on Excluder® SG.[13-15] The excellent results were confirmed by our data, observing less than 1% 30-day mortality. The decreasing number of deaths in the first thirty days can probably be attributed to technical improvements, as first-generation devices were more robust, as well as to superior operators' experience.[25]

The most common secondary procedures were interventions treating endoleaks, namely SG extensions and translumbar sac embolizations.[26] This is consistent with the previously published data, since endoleak is common and EVAR-specific complication that occurs in up to 30% of cases using early-generation SG.[27,28] Newer studies report a 19–33% reintervention rate in the follow-ups for up to fifteen years after EVAR.[29-32] The results of our study are within the reported range with nearly a quarter of patients needing a secondary procedure. A study on Excluder® SG with a ten-year follow-up period reported 85% secondary procedure free survival, a result that exceeds ours.[13] The recently published multicenter study by Geraedts *et al*.[33] reported a mean time of twenty-eight months before a secondary procedure, a time frame that is 8 months shorter than ours. The differences in secondary procedure free survival and mean time to secondary procedure can be attributed to indications which may vary between institutions as the rates of endoleaks are comparable in the studies, while the rates of secondary procedures differ.[13-15,33] Overall, relatively high reintervention rates persist despite the surgeon's experience, graft technology and imaging improvements[34], emphasizing the importance of lifelong imaging surveillance in correlation with clinical examinations.[35]

Since the life expectancy of the general population has been increasing, the optimal treatment choice of AAA is essential for long-term survival. A recent systematic review[7] confirmed the superiority of the 30-day survival rate after EVAR as opposed to OSR and indicated a similar long-term survival after ten years. The study with the longest follow-up on Excluder® to our knowledge followed patients for up to ten years.[13] The results of the overall survival reported in our study coincide with the previously published time points in research on Excluder®.[13-15] Our study, on the other hand, also provides an insight into the outcome even beyond a time point of ten years. Long-term survival is also affected by the patients' age at the time of the procedure, since the life expectancy of

older patients is shorter than that of younger ones. In accordance with the findings of several studies, our results confirmed that patients' age significantly influenced overall survival.[36-38] However, in cases of unfavorable anatomy, OSR has been proven superior to EVAR regarding the long-term survival.[39] Additional caution should therefore be taken when considering the standard EVAR procedure for patients with anatomy outside the instructions.[39] Within our institution, each patient was examined by a multidisciplinary board to ensure the optimal treatment regime. Patients who were unfit for OSR were sometimes treated outside the instructions for use, since EVAR was the only treatment option for them. The risk of an aneurysmal rupture in these patients was equivalent to the possibility of a suboptimal procedure.

Similar results to ours on aneurysm rupture related survival after EVAR were published by Verzini *et al*., however Zenith SG was used.[9] Studies on Excluder® SG even reported zero aneurysm-related deaths up to ten years[13,14], while one study stressed a potential bias on aneurysm-related deaths due to retrospective data collection.[13] Based on our results as well as those previously published, patients' surveillance is most important in the first ten years after EVAR, although opposing conclusions have been drawn in some other studies where secondary aneurysm rupture occurred at any period beyond ten years after EVAR.[40,41] This is probably caused by the progression of the disease as well as by material failure due to constant forces present in the aorta, distortion of anatomy due to new hemodynamics, dilatation of the common iliac arteries or progress of previous iliac arteries ectasia.[42-44] The follow-up protocol should be carefully adjusted since higher post-EVAR imaging frequency has been associated with a lower risk of death but attributed to higher cost and irradiation dose.[4,24,45] The current recommendations propose imaging at 30 days after the procedure and yearly thereafter if no complications are detected.[46] The imaging modalities used for surveillance include CT angiography considered as the gold standard modality, duplex ultrasonography and magnetic resonance angiography. A large-scale study based on the nationwide English Hospital Episode Statistics database showed an increased risk of postoperative abdominal and all cancers in patients after EVAR in comparison to OSR.[47] However, the meta-analysis dating from the same year[48] reported no significant difference in the risk of death due to cancer between the EVAR and the OSR group. This report draws similar conclusions to our findings, as cancer-related mortality in Slovenia accounts for approximately 30%[49,50], and as a similar rate of cancer-related deaths has also been observed in our study.

The most important limitation of our study is the retrospectivity and, consequently, the limitation in data acquisition. No aneurysm specific parameters could therefore be determined, and a potential sac growth could not be evaluated. The biases may be anticipated in retrospective research and should be carefully interpreted as noted in previous studies on Excluder® SG.[13,14] However, our results were acquired by real-life data in consecutive patients. Additionally, the research thoroughly examined aneurysm-related deaths to maximize the accuracy of data in our study. To reduce follow-up biases and to be able to process reliable data, we included only patients with obtainable data in the follow-up period. Since only a handful of emergency EVAR repairs were performed in the cohort, only descriptive information is provided.

Conclusions

Our data proved that EVAR with Excluder® offers good long-term results. More than 75% of patients can be treated completely percutaneously. No late ruptures occur within the first ten years, raising awareness of the importance of regular medical controls.

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