

Open Surgical Conversion After Failed Endovascular Aneurysm Sealing

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Objective: The aim of this study was to investigate the early and late outcomes of Open Surgical Conversion (OSC) following the failure of Endovascular Aneurysm Sealing (EVAS) endografts, regarding surgical technique, morbidity and mortality.

Method and Material: A single center retrospective observational cohort of 46 patients undergoing OSC after EVAS failure. Primary endpoints were primary technical procedural success and 30-day mortality. Secondary endpoints were complications and primary prosthesis patency.

Results: Primary technical procedural success was 97.8% (45/46). Elective 30-day mortality for OSC was 10.9% (5/42) and 75% (3/4) for acute OSC procedures. Median survival after OSC was 4.2 years (IQR 1.0, 4.9 years). Four peri-operative and 17 post-operative complications were registered. Major complications included bleeding, myocardial infarction, acute renal failure and splenectomy. Primary prosthesis patency was 82.6% (38/46) at 30-days. At median follow-up of 4.7 years (IQR 3.9, 5.3 years) 69.6% (32/46) of the patients are still alive with patent vascular prostheses.

Conclusion: Open surgical conversion achieved acceptable technical success rate for failed EVAS, with better outcomes in elective versus emergency procedures. Enhanced surveillance with timely interventions before rupture and careful patient selection through multidisciplinary evaluation are essential for optimizing surgical outcomes.

Keywords: EVAS failure, open surgical conversion, EVAS, endoleak, secondary intervention, secondary AAA rupture

Objectives

The Endovascular Aneurysm Sealing (EVAS) stent graft (Endologix Inc. Nellix, Irvine, CA, USA) was introduced as a new and revolutionary sac-anchoring prosthetic device in 2013.^{1,2} EVAS was designed to be superior to the endograft fixation provided by conventional Endovascular Aneurysm Repair (EVAR).^{3,4} The specific advantages of EVAS design were: fewer components, reduced procedure time and radiation, shorter hospital stays, applicability on adverse anatomy (short, conical or angulated proximal abdominal aortic aneurysms (AAA) necks and fewer endoleaks.⁵⁻⁸

Despite encouraging early results, a gradual distal migration and separation of stent graft components led to development of endoleak type 1a (EL 1a) in many patients, subsequently causing aneurysm sac enlargement.⁹ A voluntary recall of the Nellix device was initiated in 2019 and the CE mark was suspended.^{10,11} EVAS failure necessitated treatment either with endovascular procedures, such as proximal embolization or Nellix-In-Nellix Extension (NINE), or open surgical conversion (OSC).^{8,11}

OSC of elderly and frail patients is more challenging and associated with higher morbidity and mortality than primary elective AAA surgery. The aim of this study was to investigate the early and late results of the OSC after failed EVAS endografts, regarding surgical technique, morbidity and mortality.

Materials and Methods

This is a retrospective observational cohort of patients undergoing OSC following EVAS failure. The data originates from a single-center and a secondary referral center for Vascular Surgery covering the period from 2014 to 2023. Data

has been registered prospectively in our internal quality control registry (IQCR). Early and late results of 46 patients treated with OSC for failing EVAS stent grafts are presented.

Indications for Open Surgical Conversion Post EVAS

Patients treated with EVAS were surveyed with computer tomography angiography (CTA) at one and six months, and annually thereafter. In case of chronic renal disease, a CT without contrast and a contrast enhanced ultrasound (CEUS) was performed. EVAS failure was defined by Harrison et al as a combination of (a) > 5 mm distal migration, > 5 mm increase in aneurysm diameter and > 5 mm separation of the stent components with or without a visible endoleak, (b) a secondary aneurysm rupture, (c) an open surgical conversion for any reason or any endovascular procedure for EL 1a.⁸

An endovascular-first approach was initially used for EL 1a in the first EVAS failures.

However, after multiple unsuccessful endovascular attempts, this strategy was abandoned, and OSC became the primary treatment method. The indication for OSC was secondary aneurysm rupture, any combination of increasing aneurysm diameter > 5 mm, distal migration > 5 mm or separation > 5 mm of the stent graft components or EL 1a based on CTA measurements.

Patients with failing EVAS underwent a clinical evaluation including physical and mental status, in addition to a cardio-pulmonary work-up to assess surgical fitness. Patients deemed fit for surgery were scheduled for OSC. Frail, elderly, or dementia patients were deemed unfit for surgery. All 46 patients who underwent EVAS explant during the follow-up period were included in this study.

Endpoints

Primary endpoints were Primary Technical Procedural Success and 30-day mortality.

Primary Technical Procedural Success was defined as successful explant of the EVAS stent graft and implantation of a new prosthetic graft. The secondary endpoints were complications and primary prosthetic patency of the reconstruction.

Surgical Technique

The surgical technique was done in general anesthesia with a midline laparotomy or a thoraco-laparotomy in case of difficult proximal aneurysm neck anatomy requiring reimplantation of visceral vessels. The EVAS stent graft was removed and replaced with an aorta tube graft or an aorto-bi-iliac bifurcated Dacron silver coated vascular prosthesis.

Statistical Analysis

Continuous variables with normal distribution are expressed as means \pm Standard Deviation (SD), and skewed data as median and interquartile range (IQR). Categorical variables are expressed as numbers and percentages. Kaplan-Meier curves were generated with the Log rank test. Statistical analysis was performed in SPSS, Software (Version 29.0 IBM, IL, USA). The Follow-up index was also calculated.

Ethics

The Data Protection Officer (DPO) at our hospital ethical committee (Innlandet Hospital Trust, Postboks 104, 2381 Brumunddal, Norway) has approved the use of this de-identified and anonymous data aggregate to organize the study data and publish the results (DPO reference #12404645/2021). The regional ethical committee (REC south-east, 1130 Blindern, 0318 Oslo, Norway) has approved the publication of the data (REC reference #551836/2022). This study is retrospective and many of the patients were dead or elderly and with cognitive decline. The study was deemed to be of vital interest to the general population and the scientific community, and hence the requirement of written patient consent was waived. This was based on The Norwegian Healthcare Personnel Law §29, first section, in accordance with regulation of May 27, 2021, nr. 1725. This manuscript complies with the Declaration of Helsinki 2024.

Results

From 2013 to 2016, 137 patients were treated with EVAS. The median age of the study population at the time of EVAS was 71.5 years (IQR 68.0, 75.4 years, $n = 46$), and the median age at time of OSC was 76.0 years (IQR 71.0, 78.8 years,

n = 46). In this study 82.6% (38/46) of the patients were male. The median follow-up after OSC was 4.7 years (IQR 3.9, 5.3 years). Demographic data can be found in Table 1. The first OSC was performed in 2014. The median time from EVAS implantation to OSC conversion was 3.4 years (IQR 2.9, 4.5 years). Freedom from OSC for the entire population (n = 137) at three and five years was 88% (95% CI 85, 91%) and 63% (95% CI 58, 68%) respectively.¹²

Of the 137 patients treated for AAA with the EVAS stent graft, OSC was performed in 33.6% (n = 46) of the patients. The conversion was elective in 91.3% (n = 42) and acute in 8.7% (n = 4) due to acute rupture of the aneurysm sac despite the EVAS stent graft. The median anteroposterior diameter of the AAA at time of the EVAS stent graft procedure was 58 mm (IQR 54, 64 mm). For aortic anatomy and CTA measurements prior to EVAS see Table 2. At the time of OSC the median diameter had increased to 64.5 mm (IQR 60, 74 mm). Most remaining patients had CTA findings not requiring OSC, but enhanced follow-up was implemented.¹³

Endovascular treatment modalities were attempted to treat EL 1a in the first five patients with EVAS failure. Two patients received proximal embolization with Onyx (Medtronic, Irvine, CA, USA) and three patients were treated with NINE. Two of patients treated with embolization later required an OSC. The remaining three patients died of unrelated

Table 1 Demography Preoperatively, Medication and ASA Score (n = 46)

Comorbidity	Number of Patients (Percent)
Hypertension	28 (60.9%)
Angina Pectoris	5 (10.9%)
Myocardial infarction	12 (26.1%)
PCI/CABG	12 (26.1%)
Atrial fibrillation	6 (13.0%)
Cerebral infarction/Stroke	8 (17.4%)
COPD	12 (26.1%)
DM	4 (8.7%)
Chronic Renal Failure	5 (10.9%)
Previous Laparotomy	8 (17.4%)
Tobacco: smoker	20 (43.5%)
previous smoker	17 (37.0%)
Medication	
Oral anticoagulation	6 (13.0%)
Acetylsalicylic acid	27 (58.7%)
Clopidogrel	1 (2.2%)
Statin	33 (71.7%)
Beta-blocker	28 (60.9%)
ASA* Score	
2	11 (23.9%)
3	33 (71.7%)
4	2 (4.4%)

Note: *American Society of Anesthesiology.

Abbreviations: PCI, Percutaneous coronary intervention; CABG, Coronary artery bypass graft; COPD, Chronic obstructive pulmonary disease; DM, Diabetes mellitus.

Table 2 Abdominal Aortic Aneurysm (AAA) Anatomy Prior to Endovascular Aortic Sealing (EVAS) (n = 46)

Description	Median, IQR
Diameter proximal infrarenal neck distally to lowest renal artery	24 mm, (IQR 21, 25 mm)
Diameter proximal neck 15 mm distally to lowest renal artery	25 mm, (IQR 22, 27 mm)
Length of proximal neck	28.5 mm, (IQR 23, 39.5 mm) (R 10–71)
Diameter of AAA	58 mm, (IQR 54, 64 mm) (R 45–98)
Proximal aortic neck angle > 60 degrees	32.6% (15/46)
Conicity: proximal aortic neck change in diameter > 10%	23.9% (11/46)
Diameter of right common iliac artery	13 mm, (IQR 11, 18 mm)
Diameter of left common iliac artery	13.5 mm, (IQR 10, 16 mm)

Abbreviations: AAA, abdominal aortic aneurysm; IQR, Inter-Quartile Range; mm, millimeters.

causes or were lost to follow-up. The surgical community was at the time divergent, some opted for endovascular intervention of failing EVAS stent grafts while others found it more advantageous to remove the failing EVAS stent graft and replace it with a vascular prosthesis with an OSC. Following poor results of an endovascular first approach, this strategy was abandoned in favor of OSC.

Indication for Conversion

The indication for conversion was increasing diameter, distal migration, separation, secondary AAA rupture, EL 1a, or any combination of these in all 46 patients.⁸ In Figure 1 the type of endoleak is presented.

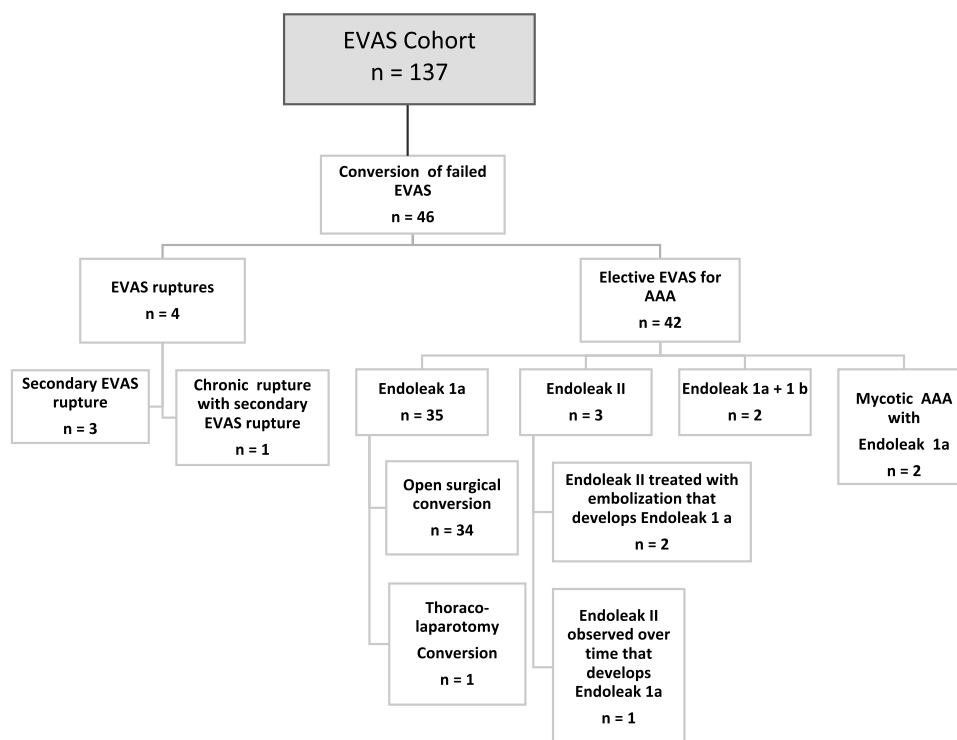


Figure 1 Patient Flowchart. Indication for open surgical conversion (OSC) of 46 patients from a cohort of 137 patients treated with endovascular aortic sealing (EVAS) for abdominal aortic aneurysm (AAA).

Indication for OSC could be one or several of the CTA findings at follow-up. 47.8% (22/46) had increased diameter, distal migration and contrast leakage, 26.1% (12/46) had increased diameter and distal migration, 8.7% (4/46) had increased diameter and contrast leakage, 6.5% (3/46) had distal migration and contrast leakage, 4.5% (2/46) had only increased diameter, and 6.5% (3/46) had only distal migration. In addition, 43.5% (20/46) had separation of the components and 21.7% (10/46) had bowing as well (Table 3). Secondary aneurysm rupture was an emergency indication present in four (8.7%) of the patients presented with an acute rupture, where one was an acute-on-chronic rupture. The median time from EVAS to secondary EVAS rupture was 1.9 years (IQR 1.1, 3.0 years) for the four acute patients.

In addition to the 46 converted EVAS patients, eight patients had an indication for OSC with EVAS stent graft failure but did not undergo surgery. Seven were deemed unfit for OSC due to frailty and dementia, these received conservative management with best medical therapy and palliation when appropriate. One patient declined treatment.

Of all EVAS treated patients ($n=137$), 74% were within 2013 instruction for use (IFU). Of patients undergoing OSC ($n=46$), 43.5% (20/46) were within 2013 IFU and 21.8% (10/46) were within the revised 2016 IFU. However, being within both IFU's did not prevent the development of EVAS failure.

Surgical Technique

All the OSC procedures were done under general anesthesia and with prophylactic antibiotics and heparin bolus. All the 46 EVAS explants were with complete removal of both prosthetic limbs. In three cases an embolectomy due to thrombotic occlusion was performed through the common femoral artery. None of the patients experienced worsening of claudication after the procedure. There was no deterioration of the mesenteric circulation during the OSC, as the inferior mesenteric artery in all cases were previously occluded by the EVAS stent graft. However, one patient did develop non-occlusive mesenteric ischemia in combination with acute pancreatitis and sepsis.

Forty-five patients had a mid-line laparotomy, and one patient required a thoraco-laparotomy (treated at a tertiary referral center, Oslo University Hospital, Rikshospitalet, Norway).

Infrarenal clamping was performed in 71.7% (33/46) of the explants, 13.4% (6/46) with oblique clamping over one renal artery, and 15.2% (7/46) over both renal arteries. Of the patients requiring suprarenal clamping 42.9% (3/7) died within 30-days.

When the aneurysm sac was opened each stent graft limb was clamped to prevent retrograde bleeding. Proximal removal of the device was uneventful due to the lack of suprarenal and hook fixation and the stent graft had in most cases shifted distally, creating additional space just below the renal arteries. The common iliac artery (CIA) was then clamped after removal of the distal EVAS stent grafts, if possible. Removal of the iliac portion of the EVAS stent graft could be challenging and might necessitate some force and even traction. The iliac artery was not incised in the early cases, and removal of the stent graft limbs was performed

Table 3 CTA Follow-up Findings Used as Indicators for EVAS OSC (Pre-OSC)

Type of Anatomical EVAS Failure	Percentage (Number)
Increasing AAA diameter, distal migration, and contrast leakage	47.8% (22/46)
Increasing AAA diameter and distal migration	26.1% (12/46)
Increasing AAA diameter and contrast leakage	8.7% (4/46)
Distal migration and contrast leakage	6.5% (3/46)
Increasing diameter only	4.4% (2/46)
Distal migration only	6.5% (3/46)
Total	100.0% (46/46)
Percent of patients with distal migration that had separation of the stent grafts	43.5% (20/46)
Percent of patients with distal migration that had bowing of the stent grafts.	21.7% (10/46)

Notes: Rate and size of increasing diameter and distal migration were the most significant factors. Contrast leakage was a sign of an active endoleak that increases the pressure in the AAA and causes increasing diameter. Millimeter increase over 5 mm was significant.

with just external visualization of the vessel. Removal was further complicated in the presence of a prior elongation of the distal stent graft limb with an open stent or stent graft which led to further adherence of the stent graft to the vessel wall. Following the initial experience, an inflammatory reaction around the distal portion of the stent graft limbs was recognized. Attempts to remove the stent graft limbs with force led to an intimal tear distal to the intended landing zone for the new aorto-bi-iliac prosthetic graft. This resulted in thromboembolic complications in three patients due to an intimal tear and subsequent dissection. Considering this, the distal anastomosis was in subsequent patients moved to a position distal to the landing zone of the EVAS stent graft.

The EVAS explants was replaced with a silver coated Dacron vascular tube prosthesis (Uni-Graft, B Braun, Berlin, Germany) was used in 11 (23.9%) patients. One patient requiring thoraco-laparotomy received a 25 mm Gelweave Vascular Prosthesis (Terumo Corporation, Bolton Medical, Inc., Inchinnan, Great Britain) with visceral branches and reimplantation of intercostal arteries. A bifurcated vascular prosthesis (Uni-graft) was used in 33 (71.7%) patients. In addition, two (4.4%) autologous reversed femoral vein prosthesis (using the technique described by Dr. Nevelsteen) were required because of infected vascular prostheses.^{14–16} They were applied as tube grafts where one was completed with a femoral-femoral crossover bypass with a silver coated Dacron 8 mm vascular prosthesis (Uni-graft), due to occlusion of one of the common Iliac arteries. In patients with an anastomosis distal to the internal iliac artery, retrograde flow to the internal iliac arteries (hypogastric) was preserved by ligating the common iliac artery instead of ligating just proximal to the anastomosis of the external iliac artery. An example of Nellix stent graft explant is found in Figure 2.



Figure 2 EVAS Nellix stent graft explant. The left specimen is placed correctly, the right specimen is regrettably rotated 180 degrees in this photo. EVAS: Endovascular Aortic Sealing.

The median procedure time for OSC was 237 minutes (IQR 207, 299 minutes) with a peri-operative median blood-loss of 1350 mL (IQR 1000, 1800), and a diuresis of 200 mL (IQR 80, 315 mL). Patients were transfused with a median of two units (IQR 2, 3,5) red blood cells, and one unit (IQR 0, 2.5 units) plasma.

Peri- and Post-Operative Results and Complications

The median length of stay on the intensive care unit was two days (IQR 1, 3 days) and the median length of hospitalization was ten days (IQR 8, 13 days). Complications occurred in 16 patients, with a total of 21 complications recorded. Four complications occurred during surgery and 17 were postoperative (Table 4).

A univariate regression analysis has been performed but did not identify any risk- factors for primary outcomes with significant impact. Our records of patients treated with OSC are complete with no loss to follow-up, and the follow-up index was 1.0.¹⁷

Primary technical procedural success was attained in 97.8% (45/46) of the patients. In one patient with a secondary sac rupture, the EVAS stent graft was successfully explanted, and a vascular prosthesis was reimplanted. However, excessive blood loss resulted in the patient's death on the operating table. The 30-day mortality rate for the elective OSC was 10.9% (5/42), whereas for acute OSC following secondary ruptured AAA the 30-day mortality was 75.0% (3/4). For cause of death see Table 5.

Median survival after OSC was 4.2 years (IQR 1, 4.9 years), and the median survival from EVAS in the OSC cohort was 8.1 years (IQR 7.2, 8.7 years) (n = 46). The median age at the time of death was 79.2 years (IQR 75.3, 8.7 years) (n = 14). Kaplan-Meier estimate and life table analysis for survival after OSC is found in Figure 3.

Table 4 Complications to Open Surgical Conversion (OSC) After Endovascular Aortic Sealing (EVAS) Failure

Type (n = 21)	Description	Time Days After OSC (Days)	Early ≤ 30 Days	Late > 30 Days
Cardiac (n = 3)	Myocardial Infarction Arrhythmia (2)	5 8 30	X X X	
Hemorrhage (n = 3)	Perioperative: Venous Perioperative: Arterial - EVAS rupture Relaparotomy – due to bleeding	0 0 1	X X X	
Thrombo-Emboloc Occlusive (n = 3)	Perioperative: Groin embolectomy (2) Groin embolectomy	0 0 1	X X X	
Stenosis (n = 1)	PTA- and stent due to stenosis caused by EVAS distal stent graft limb in the iliac artery	10	X	
Renal (n = 3)	Acute renal failure with dialysis (3)	8 17 21	X X X	
Gastro-intestinal (n = 8)	Aorto-enteric fistulae Hematemesis / Melena Peptic Ulcer Splenectomy Acute Pancreatitis, Colon Ischemia, Sepsis Incisional wound rupture (3) Ventral hernia	730 1 4 7 4 5 6 182	 X X X X X X	X X
Total			19	2

Abbreviation: EVAS, endovascular aneurysm sealing.

Table 5 Cause of Death After Open Surgical Conversion (OSC)

Cause of Death	Early \leq 30 Days (Days)	Late > 30 Days (Years)
Sepsis (n = 2)		3 4
Multi Organ Failure after EVAS rupture treated with OSC (n = 3)	1 7 14	
Cardiac arrest (n = 2)	8 30	
Myocardial infarction	5	
Rupture of Lusoria artery with bacterial pneumonia		5
Respiratory arrest	9	
Multi-organ failure after thoraco-laparotomy	7	
Chronic renal failure		2
AML		7
Heart failure with Chronic obstructive pulmonary disease		5
Total number of patients	8	6

Abbreviations: EVAS, Endovascular Aortic Sealing; OSC, Open Surgical Conversion. AML, Acute Myeloid Leukemia

Complications and Patency

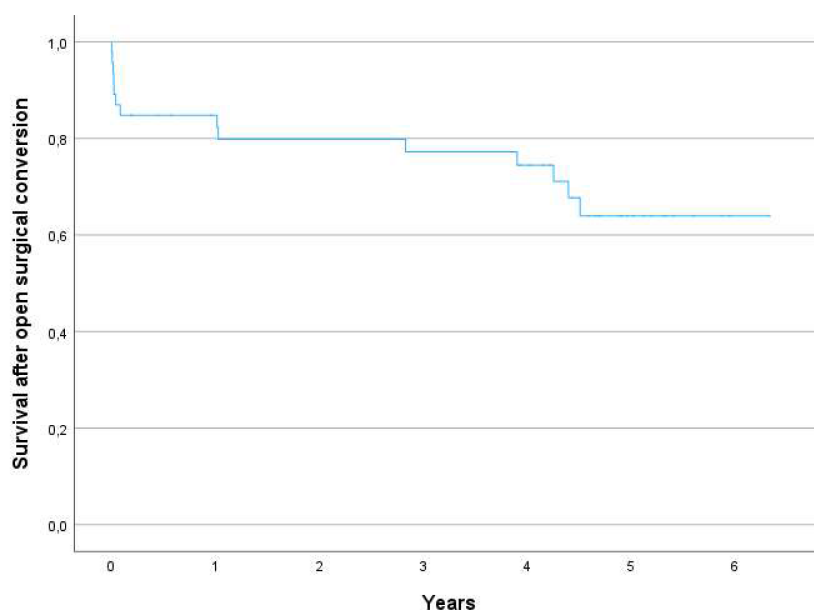
Major complications included bleeding, myocardial infarction, acute renal failure and splenectomy, (Table 4) 30-day primary prostheses patency was 82.6% (38/46) at 30 days. At median follow-up of 4.7 years (IQR 3.9, 5.3 years) 69.6% (32/46) of the patients had patent vascular prostheses.

Discussion

The primary technical procedural success of OSC after failed EVAS stent graft treatment at our institution was good. One secondary procedural intervention has been necessary due to a stenosis in the common iliac artery after the distal EVAS stent (Table 4).

30-day mortality following OSC after EVAS failure was very high in the patient cohort. A 75% (3/4) 30-day mortality in patients with secondary aneurysm sac rupture followed by an emergency explant reflects the challenges of hemostatic control and technical difficulties with device explant in an acute setting. Several case series have shown a high 30-day mortality after acute OSC in patients with EVAS and ruptured AAA has in general a very high mortality.^{18,19} The outcomes after elective conversions were much better, although a 30-day mortality of 10.9% (5/42) remains high as compared to primary elective open AAA surgery, with a mortality rate of 1–2% in Norway.²⁰ EVAR conversions are also known to have high mortality rates; Moulakakis et al reported a 30-day mortality rate for elective EVAR conversion of 12.4%.²¹ Espada et al found a 30-day elective and acute mortality of 6.1% and 25.5%, respectively in 348 stent graft explants, including 39 EVAS.²² Although mortality rates are very high also in primary ruptured AAA, the major disadvantage of patients with secondary aneurysm rupture after EVAS or EVAR is the additional difficulty with explant removal and bleeding control with stent grafts in place. The lack of proximal fixation should, nonetheless, make EVAS removal more straightforward compared to EVAR explant with suprarenal fixation.

Complications in this study reflect the frailty and comorbidity of patients in need of OSC after EVAS failure. Many of the patients were initially considered unfit for open surgical repair and hence received an endovascular treatment for their AAA. This makes comparison of OSC in this cohort to primary elective treatment of AAA futile.



Interval start time	0	1	2	3	4	5	6
Number at risk	46	34	32	29	25	10	1
Deaths	7	2	1	1	3	0	0
Proportion surviving (%)	84	94	97	96	84	100	100
Cumulative proportion surviving at end of interval (%; 95 % CI)	84 (78 - 90)	79 (73 - 85)	76 (69 - 83)	74 (67 - 81)	62 (54 - 70)	62 (54 - 70)	62 (54 - 70)

Figure 3 Kaplan Meier survival curve of patients treated with open surgical conversion (OSC) after failed endovascular aneurysm sealing (EVAS). Numbers at risk shown in the table under, with number of deaths per interval and proportion surviving each interval, and cumulative proportion surviving with 95% confidence Intervals (CI).

A Cambridge study of 161 EVAS patients, with a comparable failure rate at four years of 36.5% (42/115) in elective EVAS, only mounted to 8.7% (10/115) device explants with no 30-day mortality.⁸ In comparison, the current study reports a device explant of 33.6% (46/137) for both acute and elective OSC, suggesting a more liberal use of the OSC procedure with subsequent higher mortality rates.

Singh et al advocate early discussion of conservative approaches for those unsuitable for intervention, as determined by a multidisciplinary team.²³ The high mortality rate after OSC in the current study may indicate inadequate pre-operative screening, where more patients should have been considered for palliative treatment. The significantly better survival for elective OSC compared to acute conversion, however, highlights the importance of post-market surveillance after taking new prosthetic devices into clinical use, as outlined by Boyle et al.¹³

The median time to OSC after EVAS at our institution was 3.4 years (IQR 2.9, 4.5 years) with a conversion rate of at five years of 27.7% (38/137). In comparison, Harrison et al reported a five-year conversion rate of 8.7% (14/161).⁸ This is a much lower conversion rate as compared to the present study. In part this may be accounted for by a high number of patients being considered for explant or NINE but found unfit for surgery. The current study's conversion rate at seven years follow-up was 29.0% (39/137), increasing to 33.6% (46/137) at nine-year follow-up. Prior to the introduction of EVAS in this study institution, the conversion rate was 2.1% for EVAR. Again, this highlights the necessity for vigilant post-marked surveillance of new prosthetic devices.

Regarding treatment options, the study institution modified the approach from endovascular with proximal Onyx embolization and NINE to OSC due to rapid reoccurrence of EL 1a for the entire cohort ($n = 137$).^{24,25} This shift to OSC was later also advocated by Mortola L, Singh AA, and Quaglino S.^{11,23,26}

Zerwes et al found an incidence of endoleaks after EVAS of 12% of the patients treated within the 2016 IFU, compared to 26% of patients treated outside of 2016 IFU.²⁷ In this paper 43.5% (20/46) of the converted patients were within the 2013 IFU. If we were to retrospectively deploy the revised 2016 IFU on the cohort, IFU's with significantly limited applicability as compared to the initial IFU, only 21.7% (10/46) would have been within IFU. Ten of the patients in this study were within both IFU's and despite this developed EVAS failure and requiring OSC. In comparison, the VASCUNExplant Project reports 62.2% (216/348) of EVAR to be within IFU.²²

Najafi et al and Choo et al stated that strict adaptation to the original and revised IFU did not seem to reduce the failure of the Nellix stent graft.^{28,29} Furthermore Yafawi et al found that 100% of the Nellix stent graft patients were at risk of EVAS sac rupture after four years follow-up regardless of whether the AAA sac anatomy was within IFU compliance.³⁰

Alternative endovascular procedures have been suggested to treat EVAS failure. Pleben et al introduced the Colt multibranch device (Jotec, Germany) for treating failed EVAS stent grafts.³¹ While Kasprzak et al have suggested a 5-branched device (Cook Zenith, USA).³² These studies are in the preliminary stages and may prove effective for the treatment of failed EVAS, especially if the patient is old and frail and not a candidate for OSC.

With regards to the surgical technique, early peri-operative thromboembolic complications led to modification of the approach. The distal anastomosis of the new vascular prosthesis was placed one level below the inflammatory response where intima dissection was observed after removal of the distal legs of the EVAS stent graft. Few peri-operative complications were observed after adjustment of the surgical approach from straight interposition tube prostheses to the aortic bifurcation aorto-bi-iliac prostheses.

Limitations of This Study

This is a retrospective study of a single-center experience on a non-randomized patient cohort. The authors acknowledge that a learning curve with new devices like EVAS deployment is to be expected.

Many patients were elderly with comorbidities and adverse proximal AAA neck anatomies, some over 60 degrees, bellowed and short < 10 mm. This selection bias may have resulted in both increased conversion rates and mortality rates after OSC for failed EVAS stent grafts.

A learning curve is also to be expected with the OSC procedure, which may also have influenced the outcomes after conversion.

Proximal aorta clamping times were not recorded, nor retrievable later.

Conclusion

Open surgical conversion achieved acceptable technical success rate for failed EVAS, with better outcomes in elective versus emergency procedures. Enhanced surveillance with timely interventions before rupture and careful patient selection through multidisciplinary evaluation are essential for optimizing surgical outcomes.

Disclosure

The authors report no conflicts of interest in this work.

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