Open conversion after endovascular aneurysm sealing: technical features and clinical outcomes in 44 patients

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Open Conversion After Endovascular Aneurysm Sealing: Technical Features and Clinical Outcomes in 44 Patients

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Abstract

Purpose: To evaluate the technical features and clinical results after open conversion for complications following endovascular aneurysm sealing (EVAS). **Materials and Methods:** From July 2013 to February 2020, 44 patients (mean age 72±8 years; 36 men) underwent an open conversion due to EVAS complications in a single center. Data were collected on patient characteristics, reasons for conversion, characteristics and duration of the procedure, condition of the polymer, blood loss, time in the intensive care unit (ICU), and intra/postoperative complications. The main outcome measure was mortality at 30 days and in follow-up. Data are presented as the median (IQR) and absolute range. **Results:** On average, the open conversion took place 3 years after the initial EVAS implantation [median 37 months (IQR 23, 50); range 0–64]. Most patients were converted due migration (82%), aneurysm growth (77%), and/or endoleak (75%), with 21 patients (48%) having all 3 events. Less frequent diagnoses were aneurysm rupture (n=7), aortic infection (n=3), technical failure during implantation (n=2), and graft thrombosis (n=1). The majority of patients (n=26) were asymptomatic and converted electively, but 9 were operated on urgently and 9 emergently (7 late rupture and 2 due to technical failure). The median procedure duration was 178 minutes (IQR 149, 223; range 87–417), the median blood loss was 1100 mL (IQR 600, 2600; range 300–5000). Polymer degradation was mentioned in the operative reports of 18 cases (41%). Patients stayed a median of 3 days (IQR 2, 7; range 1–35) in the ICU, while the median length of stay in the hospital was 14 days (IQR 10, 20; range 0–93). The 30-day mortality was 23% (n=10). During a median follow-up of 3 months (IQR 0, 11; range 0–38), no additional deaths occurred, but 12 patients suffered from an adverse event. There were 3 cases of wound dehiscence after laparotomy, 2 cases of leg ischemia, 2 cases of renal failure, and individual cases of urinary obstruction, urinoma, paralytic ileus, gastrointestinal bleeding, and postoperative delirium. A non-elective setting was associated with a significantly increased mortality of 33% in urgent cases and 56% in emergent cases (p=0.007). Based on these results an algorithm for the management of EVAS complications was developed. **Conclusion:** The significantly increased mortality associated with nonelective conversions highlights the need for active surveillance. The presented algorithm offers a structured tool to avoid emergency conversions.

Introduction

When endovascular aneurysm sealing (EVAS) was introduced in 2011, it represented a truly novel technique, as it circumvented the fundamental principles of endovascular aneurysm repair (EVAR), namely, proximal and distal fixation through radial force.[1–3] Instead, 2 balloon-expandable EVAS endografts surrounded by endobags filled the aneurysm sac, supposedly providing both

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fixation of the endografts and exclusion of the aneurysm from blood flow, hence minimizing the chance of type II endoleak.[1,2,4,5] Initial results were promising with regard to perioperative outcomes and complications; the device seemed to perform well in a broad range of patients and associated morphologies, including those treated outside of the instructions for use (IFU).[6,7] However, as experience grew, midterm follow-up started to reveal durability issues of this new endovascular therapy, presenting higher than anticipated rates of endoleak and migration.[8] This first led to the updated IFUs in 2016,[9] but as reports of unfavorable outcomes after EVAS increased,[3,10] the manufacturer eventually voluntarily withdrew the device from the market in early 2019.[11]

While the device may no longer be available, dealing with EVAS complications is of major importance. Options range from endovascular approaches, such as coil embolization of endoleaks[12–14] and Nellix-in-Nellix applications,[15] to conversion to open surgery.[16] Naturally, publications on the frequency and prognostic implications of performing the aforementioned techniques are limited to small retrospective series.

The present study reviews a single-center experience of 44 conversions to open surgery after EVAS, discussing distinctive technical features of the procedures, as well as evaluating initial postoperative outcomes that may influence clinical management of EVAS complications.

Materials and Methods

Study Design

A retrospective review was conducted of all consecutive open conversions after failed EVAS (elective and non-elective for symptomatic and/or ruptured aneurysms) between June 2013 and February 2020 at a single center. During this period, 253 patients were treated with EVAS at this institution, including 189 elective and 17 nonelective standard EVAS procedures and 47 chimney EVAS (chEVAS) procedures (36 elective and 11 nonelective). The standard followup protocol called for contrast-enhanced ultrasound scans at 3 and 6 months and computed tomography at 12 months and annually thereafter.

All data were collected from the electronic patient files and entered into an Excel database (Microsoft, Redmond, WA, USA). Characteristics of the conversion procedure included the type of approach (transperitoneal, retroperitoneal, or thoracoabdominal); type of clamping (infrarenal, interrenal, suprarenal, or supraceliac); type of repair (bifurcated or tube graft); revascularization of visceral or renal vessels (renal bypass or complete renovisceral debranching); blood loss; and whether the procedure was successfully concluded. Whenever available in the operative report, information regarding potential inflammation of the aortic

wall, as well as the condition of the polymer (intact or disrupted), was recorded.

Available imaging was used to analyze preoperative anatomical features of the aneurysms both at the time of the initial implantation and at conversion, including the indications for the procedure. The status according to the IFU in effect at the time of implantation was evaluated: the IFU 2013[17] for all grafts implanted before October 2016 and the updated IFU 2016[18] for all grafts implanted starting October 2016. In a second step, the IFU 2016 were retrospectively applied to the entire conversion cohort. Migration was defined as any stent-graft movement ≥4 mm related to a predefined reference vessel or any migration leading to an endoleak.[19]

The local ethics committee waived the need for ethics approval or patient consent for the collection, evaluation, and publication of retrospectively collected and anonymized data used in this analysis.

Outcome Measures

The main outcome measure was mortality at 30 days post conversion and during follow-up. Secondary outcome measures were indications for conversion, morbidity, length of intensive care unit (ICU) stay, total length of hospital stay, and postoperative complications (bleeding, respiratory, renal, cardiac, neurologic, gastrointestinal, urinary, limb ischemia, and wound infections). Complications were collected both during and after the hospital stay. Discharged patients were seen for routine postsurgical follow-up and returned to the care of their attending physician. All surviving patients were contacted in February 2020 to check on their status relative to the primary outcome measure.

Patient Sample

During the observation period, 44 patients (mean age 72 ± 8 years; 36 men) underwent an open conversion due to EVAS complications. Forty-one implantations were originally performed at this center; 3 patients were referred from other institutions, resulting in a conversion proportion of 16% (41/253) for the site. Of the 41 patients initially treated at our institution, the technical success during the initial implantation was 95% (39/41); 2 patients experienced technical failures during endograft deployment and underwent immediate conversion. Patient characteristics and anatomical features at the initial EVAS implantation can be found in Tables 1 and 2, respectively.

Statistical Analysis

Continuous data are given as the means ± standard deviation or median, interquartile range (IQR) Q1, Q3, and absolute range; categorical data are presented as the counts

Table 1. Demographics and Comorbidities of the 44 Patients in the Study.[a]

Age, y	72 (51–89)
Men	36 (82)
Comorbidities	
BMI >30 kg/m^2	11 (25)
Hypertension	38 (86)
CAD	18 (41)
Arrhythmia	9 (20)
Valvular heart disease	4 (9)
CABP	3 (7)
COPD	19 (43)
Stroke	8 (19)
PVD	12 (28)
Diabetes	10 (23)
Smoking (≤10 years)	29 (74)
Smoking current	20 (51)
Renal insufficiency[b]	13 (30)
Hyperlipidemia	32 (76)
Abdominal surgery/trauma	10 (23)
ASA	
III	29 (66)
IV	6 (14)
V	9 (20)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; PVD, peripheral vascular disease.
[a]Continuous data are presented as the median (range); categorical data are given as the counts (percentage).
[b]Creatinine >2.0 mg/dL.

Results

The median follow-up of the overall EVAS cohort was 44 months (IQR 19, 57; range 0–79); 4 of 253 patients were lost to follow-up. On average, the open conversion took place 3 years after the initial EVAS implantation [median 37 months (IQR 23, 50); range 0–64]. Of the 206 standard EVAS procedures, 127 of the 206 procedures (62%) met the original IFU (2013),[17] while only 58 (28%) met the updated IFU 2016.[18] All chEVAS procedures fell outside IFU 2013/2016 (Table 3).

Most patients had multiple reasons for conversion (Table 4), including 36 cases of migrations (82%), 34 cases of aneurysm growth (77%), and 33 endoleaks (75%), with a combination of all 3 present in almost half (48%) of the patient cohort. The endoleaks consisted of 27 type Ia endoleaks (3 in combination with type Ib), 8 type Ib endoleaks (3 combined with type Ia), and 1 isolated type II endoleak.

Other less frequent reasons for conversion to open surgery were 7 cases of aneurysm rupture, 3 cases of aortic infection (autoimmune in 2 patients and infectious per continuitatem in the setting of perforated diverticulitis in the other), 2 technical failures during implantation, and 1 graft thrombosis and migration (Table 4).

The majority of patients (n=26) were asymptomatic at the time of conversion (Table 4), hence the procedure was carried out in an elective setting. Of the remaining patients, 9 were operated on urgently and 9 emergently (7 in the setting of late rupture and 2 due to technical failure during the primary implantation as mentioned above).

During the conversion, a transperitoneal approach (89%) was chosen most frequently, while a retroperitoneal or

(percentage). Nominal variables were analyzed using the Fisher exact test, while numeric variables were compared with the Mann-Whitney U test due to the mostly nonnormal distributions; 95% confidence intervals (CI) were calculated. The threshold of statistical significance was set at p<0.05.

Table 2. Anatomical Characteristics of the Aneurysm at the Time of Implantation and Explantation.[a]

Characteristics	Implantation	Explantation
Aneurysm diameter, mm	60 [54, 65] (45–106)	69 [58, 75] (45–145)
Proximal neck diameter, mm	24 [22, 27] (20–38)	25 [23, 28] (14–46)
Proximal neck length, mm	25 [9, 36] (0–65)	9[b] [3, 17] (0–45)
Proximal neck angulation, deg	30.5 [17, 50] (0–134)	45 [26, 64] (15–130)
Right CIA diameter, mm	17 [13, 26] (10–54)	16 [13, 28] (11–63)
Left CIA diameter, mm	15 [13, 19] (10–47)	17,5 [13, 22] (10–48)
Right CIA length, mm	39 [30, 52] (19–76)	47 [39, 58] (23–89)
Left CIA length, mm	47 [42, 66] (14–84)	47 [40, 55] (17–71)
Thrombus ratio	1.43 [1.24, 1.55] (1.03–3.08)	1.37 [1.23, 1.58] (1.05–2.15)
Migration, mm (n=36)	—	7 [2, 20] (0–30)

Abbreviations: CIA, common iliac artery.
[a]Data are presented as the median [Q1, Q3] (absolute range).
[b]Length for clamping between the top of the upper stent-graft and the lowest renal artery.

Table 3. Compliance With the Anatomical Criteria in the Instructions for Use.[a]

	Overall	At Initial Implantation			Retrospectively Applied IFU 2016	
		Within IFU 2013/2016	Outside IFU 2013/2016	Unknown IFU Status	Within	Outside
All EVAS	44 (100)	25 (57)	15 (34)	4 (9)	7 (16)	33 (75)
According to type of EVAS						
Standard bilateral	37 (84)	25 (68)	8 (22)	4 (11)	7 (19)	26 (70)
Unilateral	1 (2)	0	1 (2)	0	0	1 (2)
Chimney	6 (14)	0	6 (100)	0	0	6 (100)

Abbreviations: EVAS, endovascular aneurysm sealing; IFU, instructions for use.
[a]Data are given as the counts (percentage).

Table 4. Case Status, Indication for Conversion, Type of Approach/Clamping/Repair, and Associated 30-Day Mortality.[a]

	Overall (n=44)	30-Day Mortality (n=10)
Case status		
Elective (asymptomatic)	26 (59)	2
Urgent/symptomatic	9 (20)	3
Emergent/ruptured	9 (20)	5
Indication for conversion to open surgery		
Endoleak, migration, and aneurysm growth	21 (48)	3
Migration and aneurysm growth	5 (11)	0
Endoleak, migration, aneurysm growth, and rupture	4 (9)	3
Endoleak and migration	4 (9)	0
Endoleak and technical failure during implantation	2 (5)	1
Endoleak, aortitis (autoimmune), aneurysm growth, and rupture	1 (2)	0
Endoleak, aortitis (autoimmune) and aneurysm growth	1 (2)	1
Infectious aortitis (per continuitatem through perforated diverticulitis)	1 (2)	1
Aneurysm rupture	1 (2)	1
Aneurysm growth without endoleak or migration	1 (2)	0
Aneurysm growth and rupture	1 (2)	0
Graft thrombosis and migration	1 (2)	0
Migration	1 (2)	0
Type of approach		
Transperitoneal	39 (89)	9
Retroperitoneal	4 (9)	1
Thoracoabdominal	1 (2)	0
Type of clamping		
Infrarenal	32 (73)	6
Interrenal	1 (2)	0
Suprarenal	5 (11)	2
Supraceliac	6 (14)	2
Type of repair		
Bifurcated graft	39 (89)	9
Tube graft	1 (2)	0
Bifurcated graft and additional renal bypass	2 (5)	0
Tube graft with complete renovisceral debranching	1 (2)	0
None due to intraoperative death	1 (2)	1

[a]Data are given as the counts (percentage).

thoracoabdominal approach took place in 4 cases and 1 case, respectively. The majority of aortas (73%) were clamped infrarenally (vs 1 interrenal, 5 suprarenal, and 6 supraceliac). No cold perfusion of the renal arteries or extracorporeal perfusion was performed during supraceliac clamping. In 43 of the 44 cases (98%), the procedure was
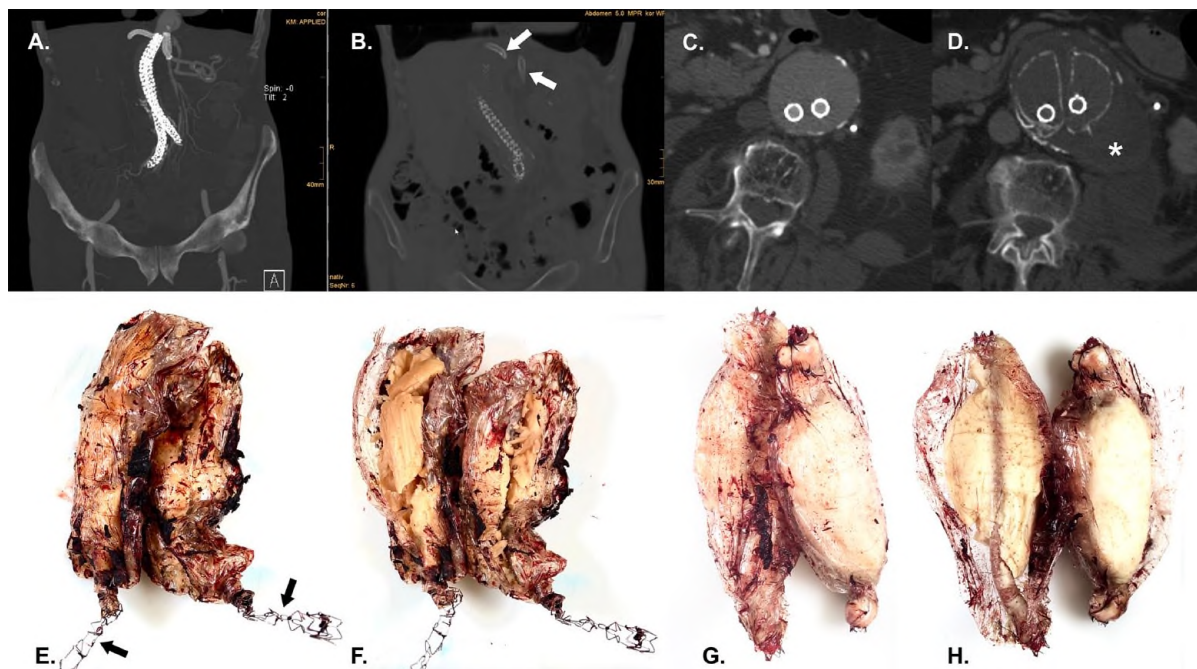
Figure 1. (A) A 3-vessel chimney endovascular aneurysm sealing (EVAS) case. (B) Massive migration with free-floating chimney grafts (white arrows). (C) An axial view of another EVAS case with (D) a contained rupture (white asterisk) and endobag separation. (E) An explanted EVAS graft before opening the endobags (black arrows pointing to the disrupted stents distally) and (F) the fragmented polymer seen after opening the endobags. Another EVAS graft with relatively intact polymer (G) before and (H) after opening the endobags.

terminated successfully; 1 patient died intraoperatively due to cardiac arrest before the aortic reconstruction could be completed. A bifurcated graft was used in 41 cases (93%), while a tube graft was used in 2 patients. Three patients required renovisceral bypasses for a single renal artery and 2 for complete debranching. All renovisceral bypasses were performed in an elective setting.

In 6 operative reports, surgeons subjectively noted that the aortic wall that had been in contact with the EVAS endografts/endobags seemed inflamed and vulnerable. Also, the distal portion of the EVAS stents, which had no endobag attachment in the early-generation device, tended to be more difficult to remove from the common iliac arteries (CIAs), resulting in stent disruptions as shown in Figure 1. Still, all EVAS endografts were removed in toto. In 18 cases (41%), visible fracture (degradation) of the polymer (Figure 1) was mentioned in the operative reports. The surgeries lasted a median of 178 minutes (IQR 149, 223; range 87–417), with a median blood loss of 1100 mL (IQR 600, 2600; range 300–5000). Patients stayed a median of 3 days (IQR 2, 7; range 1–35) in the ICU, while the median length of stay in the hospital was 14 days (IQR 10, 20; range 0–93).

Postoperative Mortality, Morbidity, and Secondary Procedures

The 30-day mortality was 23% (95% CI 11% to 38%). One patient died intraoperatively due to cardiac arrest. Two patients died postoperatively from uncontrollable bleeding: one before a surgical reintervention could take place and the other from hemorrhagic shock after coil embolization of an insufficiently sutured CIA. One patient died from respiratory failure. The remaining 6 patients died due to multiple organ failure, including 1 patient who suffered from a stroke and 2 patients who developed ischemic colitis.

A nonelective surgery setting was associated with significantly increased mortality in 33% of urgent cases and 56% of emergent conversions (p=0.007). The patients who died had a median age of 75 years (IQR 71, 79; range 67–83) compared with a median age of 71 years (IQR 64, 76; range 51–89) for the patients who survived the conversion (p=0.096). Furthermore, the group of patients who died included 5 ruptures and 2 cases of aortitis (1 autoimmune and 1 infectious). There were no further deaths during a median follow-up of 3 months (IQR 0, 11; range 0–38).

Apart from the fatal complications mentioned above, 11 patients (25%) suffered from an adverse event within 30 days of surgery. Three patients had wound dehiscence after laparotomy, which was surgically treated and had resolved at the time of discharge. Two patients developed ischemia of the right leg; both were successfully treated [transfemoral embolectomy/stenting of the external iliac artery (EIA) and recanalization of an anastomotic stenosis of the EIA, respectively]. Two patients developed renal failure with the continued need for dialysis; both had undergone a chEVAS procedure initially. One patient had a urinary obstruction due to retroperitoneal hematoma, which was surgically removed with the additional insertion of a double J urinary catheter. The adverse event was resolved at discharge. One patient had gastrointestinal bleeding (without the need for reintervention), 1 patient had paralytic ileus, and 1 patient had postoperative delirium, all of which resolved spontaneously. As a late complication (>30 days after surgery) 1 patient presented with urinoma, which was treated surgically with creation of a renal fistula; the cyst is currently decreasing in size.

Discussion

This single-center experience demonstrates the possible outcome when a new technology is adopted too rapidly. EVAS was first used at our service in 2013. With promising early EVAS results both in standard and challenging morphologies and the broad initial IFU 2013, the aneurysm sealing system soon became our workhorse for endovascular aneurysm repair. This was due to the belief that EVAS might have significant benefits over conventional EVAR, especially with regard to freedom from reintervention.[20,21] In the early days, we used EVAS in cases that were outside the IFU of other manufacturers but within the IFU 2013 for EVAS. With growing confidence, the EVAS system was also increasingly used outside its IFU, including in patients who were deemed unfit for open surgery. As with other physicians, we were lured into the assumption that the active sac management abolished the imperative need for a healthy neck.[22,23] In retrospect, this enthusiasm should have been countered by the lack of long-term data regarding the durability of the device, especially as the EVAS system was used in cases that would have been suitable for other endovascular options.[20] We thus agree with Harrison et al,[20] who suggested that all new grafts should be considered "experimental" until there are long-term data to support routine usage.

The impact of the updated IFU 2016 has previously been published[3] and is also evident when analyzing the IFU status of the patients who required conversion (Table 3). While close to 60% of the explanted patients were within the IFU at the time of implantation, <20% would have met the updated IFU 2016. This leads to the noteworthy observation that being within the updated IFU 2016 did not protect patients from needing a conversion to open surgery over the course of time. Hence, even EVAS patients who were within the IFU 2016 must be closely monitored.

Technical and Operative Aspects

While there are many endovascular treatment options available before a failed EVAR stent-graft needs be removed, the EVAS system behaves quite differently. Due to its unique design of 2 balloon-expandable endografts, each measuring approximately 10 mm in diameter, endovascular bailout procedures are sparse. In the setting of endoleak, one endovascular option is coil embolization. Experience is very limited, and the technique is only advisable in cases of minor type I endoleaks.[12,13]

Another option is the proximal extension of the existing EVAS graft using the Nellix-in-Nellix technique. Once again, there is only preliminary experience with this procedure,[15,24] while mid- and long-term follow-ups are still missing. However, repairing an EVAS endograft that presents with a failed sealing mechanism by implanting yet another EVAS endograft that uses exactly the same sealing mechanism seems to be debatable at least. After all, it feels like fixing a sunken house that was built on unstable ground (thrombus) by putting another story on top: might work in the short term but literally does not eliminate the underlying problem.

A closer look at the diagnoses leading to conversion reveals that most of the patients presented not with a single complication but rather with a set of diagnoses, the most frequent combination being aneurysm growth in the presence of migration and endoleak. While the combination of endoleak, migration, and aneurysm growth is a phenomenon described by many studies, it is not clear which component of the composite event occurs first. Is it the loss of proximal sealing that leads to migration and subsequent aneurysm growth? Or rather the migration leading to loss of proximal sealing, endoleak, and subsequent aneurysm growth?[3,20,25,26] We believe that the latter is more likely the failure mechanism, as many patients (41%) presented intraoperatively with degraded polymer, making proper sac anchorage impossible. Why and how the polymer degrades was not the subject of the present study, however. Furthermore, due to the retrospective nature of the present study, the actual number of cases with degraded polymer might be higher.

Hence, taking the aforementioned considerations into account, conversion to open surgery seemed to be the best option for elective patients fit enough for surgery and the only option for those presenting in acute rupture. This strategy is in line with a recent publication by Stenson et al[10] describing how EVAS failures are managed at their vascular unit. Based on these findings and the results of the present

study, we developed a possible algorithm for dealing with EVAS complications (Figure 2). Please note that this algorithm was not established at the beginning but rather at the end of the study after analysis of the results.

From a technical standpoint, the EVAS endograft and its surrounding endobags lack proximal fixation through radial force within the aorta, thus facilitating proximal endograft removal. This may have had a positive impact on the duration of the conversion procedures. Compared to a report by Ultee et al[27] containing 300 conversions with a mean operative time of 275 ± 124 minutes, the median operative time in the present study was only 178 minutes. However, special attention must be paid to the distal landing zone. Since the early-generation devices had the distal portion of the stent-graft system not connected to the endobags, the bare metal stents tend to grow into the CIAs, making the distal removal of the endografts more challenging, while potentially injuring the arterial wall. Also, the endobags themselves might cause inflammation of the aortic wall. For this reason, a bifurcated graft, with anastomosis in a "virgin" zone of the distal CIAs/EIAs was used in over 90% of the patients.

Infrarenal clamping was performed in the majority of cases (73%). One explanation for that was the high number of migrations, making infrarenal clamping possible in the first place. In contrast to previously published data, the results showed no significant association between the height of clamping and mortality.[28] Still, both suprarenal and supraceliac clamping presented increased mortality rates (see Table 4), but the differences were not significant. A potential explanation why none of the patients with renovisceral debranching died might be the fact that all were carried out in an elective setting. Other intraoperative aspects of our series, such as the operative approach and the type of aortic reconstruction, were similar to a recently published meta-analysis of secondary open aortic procedures after EVAR.[29]

Case Status and Diagnosis: Impact on Mortality and Surveillance

Mortality rates for open conversions after EVAR range from 0% to 27% as described in the meta-analysis by Gambardella et al.[29–32] Contrarily, reports of open aortic repair after EVAS are limited to single cases or small series,[10,16,26,33] making a direct comparison to the present study somewhat difficult. While the observed mortality rate of 23% in the present cohort had a wide confidence interval, it warrants careful analysis nonetheless. First of all, it is important to evaluate the mortality according to the case status (see Table 4). The lowest mortality of the cohort (8%, 2/26) was recorded in the elective conversion setting. This outcome is in line with previous studies[34,35] that found that while elective conversions after EVAR present with higher mortality rates than primary open aneurysm repair, they are also associated with lower mortality than nonelective conversions.

Regarding the nonelective cases, it is no surprise that the patients undergoing an emergent conversion in the setting of rupture experienced the highest mortality (56%, 5/9). This finding is in line with previous studies that found high mortality rates for patients presenting with ruptured aneurysms regardless of whether they received a primary open repair or an open conversion after previous EVAR.[31,36]

This leaves the nonelective patients who were urgently converted to open surgery. Startlingly, their mortality rate was 33% (3/9). While this is higher than one would expect, it must be taken into consideration that 2 of those patients were diagnosed with aortitis, a condition that is associated with unfavorable outcome.[37]

Generally speaking, the patients who died tended to be older than the survivors. While this finding was not significant, it might help to explain why more than a fifth of patients died after conversion. Also, the fact that the group of deceased patients contained 5 ruptures and 2 cases of aortitis might add a potential explanation.

In addition to the fact that the EVAS endografts were explanted an average of 3 years after implantation, the significantly increased mortality in nonelective cases emphasizes the importance of continued surveillance to avoid urgent/emergent conversion and the associated increased mortality. Consequently, at our service we now adhere to an algorithm for dealing with EVAS complications. In addition, we have a study nurse actively calling all patients who had an EVAS implantation at our clinic to help us detect potential endograft complications early on and facilitate individualized patient treatment.

Limitations

This was a single-center experience that included 44 consecutive patients. While representing a relatively large series in the still new field of dealing with EVAS complications, only limited conclusions can be drawn from such a small sample. Also, due to the fact that this was a retrospective study, the algorithm for dealing with EVAS complications did not exist at the start. Hence, no data are available on how many patients were declined an open conversion, resulting in a potential bias. Another drawback of the retrospective nature of the present cohort is that the clamping time was not reported in a consistent manner, allowing no conclusion regarding a correlation between clamping time and clinical outcome. Also, no wall specimens were taken to confirm inflammation of the portions of the aortic wall that had been in contact with the EVAS endografts. In addition, the status of the polymer and the description of potentially inflamed aortic wall were not consistently reported. Consequently, further data and prospective collection are needed to gain a better
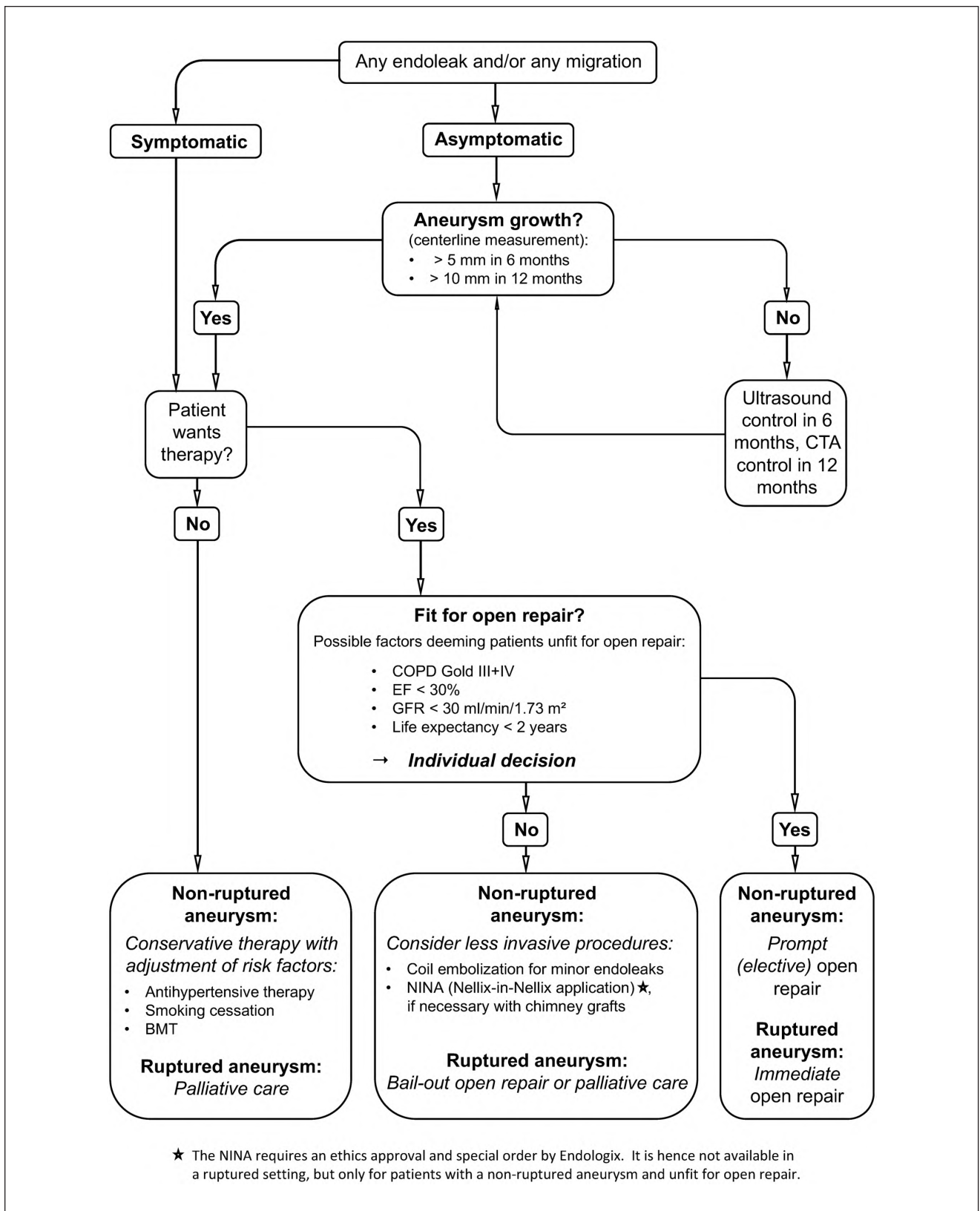
Figure 2. Algorithm for dealing with endovascular aneurysm sealing complications. BMT, best medical therapy; COPD, chronic obstructive pulmonary disease; CTA, computed tomography angiography; EF, ejection fraction; GFR, glomerular filtration rate.

understanding of the underlying mechanisms of EVAS failures and to individually determine the most suitable therapy for affected patients.

Conclusion

To the best of our knowledge, no larger single-center EVAS conversion experience has been reported. The fact that the majority of the explants took place beyond 3 years after the initial implantation coupled with the significantly increased mortality after the nonelective conversions highlight the need for active surveillance. The presented algorithm helps in dealing with EVAS complications and offers a structured tool to avoid emergency conversion procedures, hence maximizing patient safety. The conversion itself remains a high-risk procedure. Although the EVAS endobags and the lack of radial force fixation make it relatively easy to remove the stent-graft proximally, special attention must be paid to the distal landing zones.

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References

1. Donayre CE, Zarins CK, Krievins DK, et al. Initial clinical experience with a sac-anchoring endoprosthesis for aortic aneurysm repair. *J Vasc Surg*. 2011;53:574–582.
2. Krievins DK, Holden A, Savlovskis J, et al. EVAR using the Nellix Sac-anchoring endoprosthesis: treatment of favourable and adverse anatomy. *Eur J Vasc Endovasc Surg*. 2011;42:38–46.
3. Zerwes S, Bruijnen HK, Gosslau Y, et al. Influence of the revised Nellix instructions for use on outcomes after endovascular aneurysm sealing. *J Endovasc Ther*. 2018;25: 418–425.
4. Kisis K, Krievins D, Naskovica K, et al. Quality of life after endovascular abdominal aortic aneurysm repair: Nellix sac-anchoring endoprosthesis versus open surgery. *Medicina (Kaunas)*. 2012;48:286–291.
5. Karthikesalingam A, Cobb RJ, Khoury A, et al. The morphological applicability of a novel endovascular aneurysm sealing (EVAS) system (Nellix) in patients with abdominal aortic aneurysms. *Eur J Vasc Endovasc Surg*. 2013;46:440–445.
6. Thompson MM, Heyligers JM, Hayes PD, et al. Endovascular aneurysm sealing: early and midterm results from the EVAS FORWARD Global Registry. *J Endovasc Ther*. 2016;23:685–692.
7. Zerwes S, Nurzai Z, Leissner G, et al. Early experience with the new endovascular aneurysm sealing system Nellix: first clinical results after 50 implantations. *Vascular*. 2016; 24:339–347.
8. Carpenter JP, Cuff R, Buckley C, et al. Results of the Nellix system investigational device exemption pivotal trial for endovascular aneurysm sealing. *J Vasc Surg*. 2016;63: 23–31.e1.
9. Endologix. Important field safety notice: Updated instructions for use (IFU). 2016.
10. Stenson KM, de Bruin JL, Loftus IM, et al. Migration and sac expansion as modes of midterm therapeutic failure after endovascular aneurysm sealing: 295 cases at a single center. *J Vasc Surg*. 2020;71:457–469.e1.
11. Endologix. Endologix provides update on previously announced voluntary Nellix System recall. 2019. https:// endologixcom/wp-content/uploads/2019/01/20190122-Press-Release-Nellix-CE-Mark-FINALpdf
12. Ameli-Renani S, Morgan RA. Percutaneous interventions following endovascular aneurysm sac sealing: endoleak embolization and limb-related adverse events. *Semin Vasc Surg*. 2016;29:135–141.
13. Ameli-Renani S, Morgan RA. Secondary interventions after endovascular aneurysm sac sealing: endoleak embolization and limb-related interventions. *Semin Vasc Surg*. 2016;29:61–67.
14. Harvey JJ, Stefan B, Hill A, et al. Transcatheter embolization of type Ia endoleak after Nellix endovascular aortic aneurysm sealing with n-butyl cyanoacrylate: technique in three patients. *J Vasc Interv Radiol*. 2016;27:194–199.
15. Zoethout AC, Zerwes S, Zeebregts C, et al. Preliminary outcome of Nellix-in-Nellix extensions in patients treated with failed endovascular aneurysm sealing. *J Vasc Surg*. 2019;70: 1099–1106.
16. Tolenaar JL, van den Ham LH, Reijnen MM, et al. Late conversion after sac anchoring endoprosthesis for secondary aortic aneurysm infection. *J Endovasc Ther*. 2015;22:813–818.
17. Endologix. Nellix EndoVascular Aneurysm Sealing System instructions for use. 2013.
18. Endologix. Nellix EndoVascular Aneurysm Sealing System instructions for use. 2016.
19. England A, Torella F, Fisher RK, et al. Migration of the Nellix endoprosthesis. *J Vasc Surg*. 2016;64:306–312.
20. Harrison SC, Winterbottom AJ, Coughlin PA, et al. Editor's Choice. Mid-term migration and device failure following endovascular aneurysm sealing with the Nellix Stent Graft System—a single centre experience. *Eur J Vasc Endovasc Surg*. 2018;56:342–348.
21. Bockler D, Holden A, Thompson M, et al. Multicenter Nellix EndoVascular Aneurysm Sealing system experience in aneurysm sac sealing. *J Vasc Surg*. 2015;62:290–298.

22. Zerwes S. Commentary: Seduction and its impact on instructions for use. *J Endovasc Ther*. 2016;23:693–694.

23. Hoksbergen AW. Commentary: endovascular aneurysm sealing with the Nellix device: a panacea for ruptured aneurysms? *J Endovasc Ther*. 2015;22:288–290.

24. Donselaar EJ, Holden A, Zoethout AC, et al. Feasibility and technical aspects of proximal Nellix-in-Nellix extension for late caudal endograft migration. *J Endovasc Ther*. 2017;24: 210–217.

25. van den Ham LH, Holden A, Savlovskis J, et al. Editor's Choice. Occurrence and classification of proximal type I endoleaks after endovascular aneurysm sealing using the Nellix device. *Eur J Vasc Endovasc Surg*. 2017;54: 729–736.

26. Martinelli O, Fresilli M, Irace L, et al. Nellix endovascular aortic sealing endoprosthesis late explant for concomitant type I endoleak and stent frames proximal caudal migration. *Ann Vasc Surg*. 2019;60:478.e7–478.e14.

27. Ultee KH, Soden PA, Zettervall SL, et al. Conversion from endovascular to open abdominal aortic aneurysm repair. *J Vasc Surg*. 2016;64:76–82.

28. Sarac TP, Clair DG, Hertzer NR, et al. Contemporary results of juxtarenal aneurysm repair. *J Vasc Surg*. 2002;36: 1104–1111.

29. Gambardella I, Antoniou GA, Gaudino M, et al. State of the art and meta-analysis of secondary open aortic procedure after abdominal endovascular aortic repair. *J Vasc Surg*. 2019; 70:1341–1350e4.

30. Ferrero E, Ferri M, Viazzo A, et al. Open conversion after endovascular aortic aneurysm repair: a single-center experience. *Ann Vasc Surg*. 2013;27:856–864.

31. Gambardella I, Antoniou GA, Torella F, et al. Secondary open aortic procedure following thoracic endovascular aortic repair: meta-analytic state of the art. *J Am Heart Assoc*. 2017; 6:e006618.

32. Turney EJ, Steenberge SP, Lyden SP, et al. Late graft explants in endovascular aneurysm repair. *J Vasc Surg*. 2014;59:886–893.

33. Ascoli Marchetti A, Oddi FM, Vacca F, et al. The safety of EVAS surgical conversion in a comparative monocentric analysis. *Ann Vasc Surg*. 2020;68:310–315.

34. Perini P, Gargiulo M, Silingardi R, et al. Twenty-two year multicentre experience of late open conversions after endovascular abdominal aneurysm repair. *Eur J Vasc Endovasc Surg*. 2020;59:757–765.

35. Scali ST, Beck AW, Chang CK, et al. Defining risk and identifying predictors of mortality for open conversion after endovascular aortic aneurysm repair. *J Vasc Surg*. 2016;63: 873–881.e1.

36. Karthikesalingam A, Holt PJ, Vidal-Diez A, et al. Mortality from ruptured abdominal aortic aneurysms: clinical lessons from a comparison of outcomes in England and the USA. *Lancet*. 2014;383:963–969.

37. Shiraev T, Barrett S, Heywood S, et al. Incidence, management, and outcomes of aortic graft infection. *Ann Vasc Surg*. 2019;59:73–83.