Journal Pre-proof

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PII: S0890-5096(24)00215-2

DOI: https://doi.org/10.1016/j.avsg.2024.02.028

Reference: AVSG 7156

To appear in: *Annals of Vascular Surgery*

Received Date: 11 October 2023

Revised Date: 20 February 2024

Accepted Date: 24 February 2024

Please cite this article as: Becker D, Riggi M, Wyss TR, Jungi S, Weiss S, Kotelis D, Schmidli J, Bosiers MJ, Makaloski V, Indication and outcome of late open conversion after abdominal endovascular aortic repair, *Annals of Vascular Surgery* (2024), doi: https://doi.org/10.1016/j.avsg.2024.02.028.

Indication and outcome of late open conversion after abdominal endovascular aortic repair

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Word count: 3108

Keywords: EVAR, late open conversion, Endoleaks, rupture

Running title: Late open conversion after EVAR.

Abstract

Objective: Endovascular aortic repair (EVAR) has become the standard of care for patients with infrarenal aortic aneurysms over the last two decades. Endograft technology and treatment of complications like endoleaks, graft migration or graft occlusion developed over time. However, sometimes open surgical conversion maybe required. Our aim was to analyze the indications, the technical aspects and outcomes in patients who underwent open conversion after EVAR with different types and generations of endografts.

Methods: This retrospective single-center study reviewed all patients who underwent EVAR from 2004 to 2020. Open surgical conversions > 1 month post EVAR were identified. Conversions for graft infection were excluded. Indications for conversion and operative technique were analyzed. Primary endpoint of the study was 30-day mortality. Secondary endpoints were re-interventions and follow up mortality.

Results: During 2004 and 2020, 443 consecutive EVARs were performed, and 28 patients required open surgical conversion, with an additional 3 referred from other hospitals (N=31). The median age was 75 (range 58-93); 94% were male. Conversion was performed after a median time of 55 months (range 16 - 209). Twenty patients underwent elective and 11 emergency conversion. Indications for open conversion were graft migration respectively disease progression with endoleak type Ia and/ or Ib in 52 % (16/31) and sac expansion due to endoleak type II in 26 % (8/31). Of the 31 patients, 17 (55%) had at least one previous endovascular re-intervention. All patients met the device-specific instructions for use for each implanted endograft.

In-hospital intervention rate was 16 % (5/31). 30-day mortality rate was 3% (1/31) with one patient died due to multi-organ failure after rupture with complete endograft replacement. Five patients (16%) died during follow-up. Mid-term follow-up was 47.5 months (range 24 -203) with estimated cumulative survival rates of 97%, 89%, and 84%, at 1, 3, and 5 years, respectively.

Conclusion: Late open conversion remains a valuable treatment option and can be performed safely in elective and emergency setting with a low early mortality. Lifelong surveillance, and prompt intervention when necessary are essential in ensuring optimal outcomes after EVAR and preventing the need for emergent conversions.

Introduction

Endovascular aneurysm repair (EVAR) has become the preferred treatment for abdominal aortic aneurysm (AAA) with suitable anatomy [1-4]. This minimally invasive technique has now replaced open aneurysm repair as the preferred treatment modality for most patients with suitable anatomy. Although many reports demonstrated lower morbidity and short-term mortality for EVAR compared with open surgical repair [1-4], randomized controlled trials have not shown a long-term survival benefit [1,3]. The EVAR-1 trial clearly demonstrated higher survival rate for open repair after 15-year follow-up [5]. Simultaneously, the re-intervention rate was much higher in the EVAR group, above all because of persistent endoleaks and sac growth [5].

The occurrence of endoleak, potentially leading to AAA rupture, is still the main complication after EVAR if not treated by re-intervention [6]. Long-term incidence of endoleak in the OVER trial was 30.5%, with one third of these patients needing at least one re-intervention [7]. Still, in daily practice, EVAR is increasingly used in patients with difficult anatomy who fail to meet the criteria defined by the device-specific instructions for use (IFU) [8]. This may lead to even more endoleaks, but also other complications such as graft kinking and graft occlusion. Although most of these complications can be treated by endovascular re-interventions [7-10], open conversion is sometimes the last treatment option with an estimated incidence of 0-9% [11] . The mortality rates of these conversions have been reported to be remarkably high, ranging from 20-40%, especially in urgent cases [11-15].

The present study aimed to review indications of open conversion, procedural details and outcome over a retrospective observational period of 17 years, including different generations of stent-grafts in a tertiary aortic center with a high open surgical experience.

Methods

All consecutive EVARs performed between January 2004 and December 2020 in our institution were reviewed. All patients who required late open surgical conversion > 30 days after initial EVAR procedure were identified, including those who underwent open conversion after EVAR implantation at an outside institution. Inclusion criteria involved patients who underwent complete or partial removal of the endograft or open surgical modifications, such as aortic neck banding or lumbar vessel suture/clipping, to address type II endoleaks after failed endovascular attempt. Patients who underwent conversion within 30 days after initial EVAR or due to an infected endograft were excluded from the study (Fig. 1).

Data were collected from hospital charts and included patient demographics, comorbidities, indication for EVAR (elective vs. ruptured), aneurysm diameter at EVAR and conversion, time from EVAR implantation to conversion, used EVAR device, presence of intraoperative endoleak (including type), reason for open surgical conversion, operative technique and details. Primary endpoint of the study was 30-day mortality. Secondary endpoints were re-interventions and follow up mortality. Patients were followed up until the date of death or December 31, 2022, meaning that even the last included patients in the analysis had at least two years follow-up.

Adherence to device-specific IFU

DB and MR reviewed the computed tomography angiographies (CTA prior EVAR of all patients and evaluated aneurysm anatomy according to IFU criteria of each stent-graft (Table 1).

Late open conversion

The indications for late open conversion were discussed within the endoleak board consisting of vascular surgeon, interventional angiologist and interventional radiologist. An open conversion included complete or partial explantation of the endograft via median laparotomy or lumbotomy, as well as open surgical modifications such as banding of the aortic neck around the endograft main body, or ligation/clipping of lumbar arteries. The final decision was left at discretion of the treating surgeon.

Data analysis and statistics

Continuous variables are presented as median values and interquartile range and categorical variables as absolute numbers and percentages. Statistical analysis was performed with SPSS version 29 (SPSS, Armonk, NY: IBM Corp). We calculated the frequency of various operative factors, including stent graft details, interval to open surgical conversion, indications for conversion, open surgical approach, and techniques used. Time-dependent outcomes were analyzed using the Kaplan-Meier method.

Results

During the 17-year period from 2004 and 2020, a total of 443 EVARs were performed at our institution. We identified 31 patients, who required open surgical conversion. Of these, three patients (9.7 %) were referred who had initial EVAR procedure in another hospital. Patients had an average age of 75 years (range 58-93) and 94% were male. Demographic data are summarized in Table 2.

Initial EVAR was performed electively in 30 patients and as an emergency in one patient due to a ruptured AAA. All patients met the device-specific instruction for use for each endograft. In ten patients (32%) a severely kinked iliac axis was found. In all but one patient, a bifurcated device was used. Adjunct procedures were performed in 7 patients (23%): one Palmaz stent and one aortic cuff were successfully placed to address an intraoperatively detected type Ia endoleak; two

patients underwent prophylactic embolization of the inferior mesenteric artery (IMA), and three patients underwent embolization of lumbar arteries to prevent type IIa or IIb endoleaks (Table 3).

Re-interventions before conversion

Before the conversion was performed, seventeen patients (55%) underwent a mean of 1.5 ± 1.0 endovascular interventions. The majority of re-interventions were due to type II endoleaks with sac expansion (n=9, 53%), which were treated by coil embolization or laparoscopic clipping. In six patients (35 %) proximal and/or distal extension/endoanchors were performed due to endoleak type Ia and / or Ib. In two patients (12 %) limb occlusion occured which was endovascular treated.

Reasons and operative technical details of late open conversion

Open conversion was performed after a median of 55 months (range 16 - 209) from the time of initial EVAR.

Explanted grafts included 17 Medtronic Endurant II (55 %), 4 Medtronic Talent (13%), 4 Boston Scientific Vanguard (13%), 3 Guidant Ancure (10%), 1 Terumo Anaconda (3%), 1 Lombard Medical Aorfix (3%) and 1 Gore Excluder (3 %).

Conversion was required for multiple indication, including endoleak, migration, sac enlargement, rupture, limb thrombosis and claudication (Table 4). In 80 % of patients, there was more than one indication for conversion. Four patients had more than one type of endoleak. Three patients had limb thrombosis as the indication for conversion, two of whom presented with repetitive uni-lateral thrombosis as indication for repair. Acute rupture was the reason for conversion in nine patients (29%). All patients presenting with a rupture had endoleak type I with disease progression or graft migration or endoleak type III with stentgraft dissconnection. Only one rupture occured due to sac enlargement due to endoleak type II.

In 24 cases (77%), open surgical conversion was performed via midline laparotomy and in seven (23%) via left-sided lumbotomy. Median duration of surgery was 260 minutes (range 80 - 480) with median intraoperative blood loss of 2550 ml (range 300 - 10000).

Complete explantation of stent-grafts was performed in 20 patients (65%) followed by aorto-iliac reconstruction with a bifurcated polyester graft. Five patients (16%) underwent partial graft explantation (Fig. 3) and in six patients (19%) stent-grafts were left untouched, with lumbar artery ligation and proximal neck banding in one case. Twenty-one patients (68%) required suprarenal clamping during median time of 33 minutes (range 28 - 46) and four (13%) infrarenal. In case we explanted stent-grafts with suprarenal fixation, struts were cut-off and not explanted to avoid aortic wall damage and more extensive preparation. Details can be found in Table 5.

30-day morbidity and mortality

30-day mortality rate was 3% (1/31). The patient who died, on the fourth day after surgery, required emergency conversion due to rupture and underwent complete EVAR explantation with in-situ replacement using a bifurcated graft. Postoperatively, the patient developed abdominal compartment syndrome and required re-laparotomy for decompression and open abdominal treatment. The patient ultimately succumbed to multi-organ failure. Overall 30-day morbidity rate was 26% (8/31). Among them, five patients required in-hospital re-intervention (15%). Two of the elective conversion patients experienced acute limb ischemia due to graft occlusion, requiring surgical revascularization. One urgent conversion patient developed acute limb ischemia due to peripheral embolism and received endovascular revascularization. The remaining two urgent conversion patients required additional interventions, one for abdominal compartment syndrome through decompression laparotomy and the other for evacuation of a retroperitoneal hematoma. One patient experienced non-transmural colon ischemia without intervention, and one patient had a stroke but recovered completely. Pneumonia treated with antibiotics occurred in one patient. All postoperative complications were observed in the group of urgent conversions, despite two surgical revisions for graft occlusion. Patients who underwent elective and/or partial explantation or graft-preserving interventions did not experience significant postoperative complications. Notably,

despite frequent suprarenal clamping (21/31), there were no significant incidents of kidney function deterioration or the need for dialysis. No cardiac complications were detected. Median length of hospital stay was 10 days (range 7 - 30).

Follow up mortality

Five patients (16%) died during median follow-up of 47 months (range 24 -191). Kaplan-Meier estimated survival rate was 97%, 89%, and 84% at 1, 3, and 5 years, respectively (Standard error exceeds 10 % at 6 years follow up) (Fig. 2). Follow-up information until death or the end of follow-up (December 2022) was available for all patients, resulting in a follow-up index of 1.0.

Discussion

Late open surgical conversion continues to be an important treatment option following failed EVAR, despite advancements in endograft design and surgeon experience. Although many late complications of EVAR can be managed using endovascular techniques, there are instances where late open conversion becomes necessary [15-16].

In our cohort, the rate of late open surgical conversion was 7%. This is slightly higher compared to a meta-analysis conducted by Goudeketting et al. in 2019, which reported a conversion rate of 5.3% (95% CI, 3.1%-7.4%) based on data from 27 studies encompassing a total of 791 patients (617 elective and 174 urgent cases) [17]. A more recent multicenter study conducted by Perini et al. even reported a rate of late open conversion of 2.22 % (232/10472 patients) [11]. The higher rate in our cohort might be based on the comparable lower number of endovascular repair in abdominal aortic aneurysm in the reported years and the tendency to prefer open conversion towards endovascular solutions in treatment of endoleaks.

For a controlled conversion, main aim is to perform in an elective setting. High peri- and postoperative experience in an aortic center could facilitate this complex procedure and diminsh

peri- and postoperative operative mortality risk. This might explain why no death occured after elective conversion. However, some patients might require an urgent/emergency conversion. The average rate of urgent conversion varies around 22% (7.8% - 38.7%) [17-18]. In our study, urgent conversion had to be performed in 35% (11/31) of patients mainly due to rupture. Perini et al. also observed a similar trend and proposed that non-compliance with post-EVAR surveillance protocols may contribute to this phenomenon [19].

Urgent late open conversions are associated with significantly higher rates of intra- and postoperative morbidity and mortality [20]. Current literature reports a high morbidity rate of 67.6% within 30 days after conversion, especially in emergency cases [19]. Our study confirmed these findings as well, as 12 patients required emergency conversions. In these patients, we observed a similarly high postoperative complication rate of 66%, including one case of graft occlusion with acute limb ischemia, one case of abdominal compartment syndrome, one case of retroperitoneal hematoma, one case of conservatively managed non-transmural colon ischemia, one stroke, and one pneumonia.

Despite a high frequency of suprarenal clamping, we did not observe any significant deterioration in kidney function or the onset of new transient or permanent dialysis. One possible explanation for this is the relatively short duration of suprarenal clamping, with a median time of 33 minutes (range 28 - 46).

The literature also supports that postoperative mortality rates are higher in patients who undergo emergency conversions, with rates reported between 29.2% and 43.2% [20-21]. This finding is consistent with other studies highlighting multi-morbidity and emergency conversions as factors associated with increased mortality [3,9,10,14,17,22]. We observed a low 30-day mortality rate of 3%, with the single patient who died having undergone emergency conversion due to rupture. In 16% of our patients (5/31) a partial conversion was performed and in 19% (6/31) the complete graft could be preserved. This highligths the lower mortality rate compared to cases requiring complete graft removing, a finding consistent with previous studies [23,24].

In our study we excluded conversions for graft infection, which typically exhibit higher morbidity and mortality rates compared to cases without graft infection [19]. The low 30-day mortality rate observed in our cohort suggests that late EVAR conversions may have comparable mortality rates to primary elective open repair, which range from 2% to 3% according to other reports [1,3,15,25]. In our patient cohort, the follow-up mortality rate was 16% (5/30). Three patients died from causes unrelated to the aorta, while the cause of death remained unclear in two patients. The estimated 5-year survival rate was 84%, which is comparable to the survival rates seen after elective repair of AAA with EVAR according to previous studies [3-4].

A significant proportion of patients (52%) underwent secondary interventions before surgical conversion, which is also reported in the literature, [3-4]. The most common indications for open surgical conversion in our study was aneurysm sac enlargement due to type II endoleaks and migration respectively disease progression leading to endoleak type I a and/or Ib, similar to the experience reported by other centers [8,9,11-13,26].

It is important to consider that our study included patients over a long retrospective time period. As a result, different endografts were used, and the indications for conversion varied. Furthermore, advancements in endovascular treatment options such as EndoAnchors, fenestrated and branched EVAR, chimney EVAR, and coil and Onyx embolization prior to LOC should also be taken into account when assessing the outcomes and indications for surgical conversion [27].

Various surgical techniques for late open surgical conversion after EVAR have been described, which primarily differ in terms of the approach (transperitoneal vs. retroperitoneal), proximal cross-clamping site (suprarenal, infrarenal, or supraceliac), and extent of graft removal (complete vs. partial). These choices are typically guided by clinical factors, such as suprarenal fixation and the reason for graft removal, as well as the surgeon's preference.

In our series, the most common approach was transperitoneal access through laparotomy (84%), which is consistent with the literature. However, some surgeons prefer the retroperitoneal approach [20]. Within our patient cohort, three different techniques were performed: complete replacement of endograft with an in-situ prosthetic graft, partial replacement of the endograft, and preservation with cerclage technique or ligation of lumbar arteries. Whenever possible, the decision should be made to offer the least invasive conversion option to the patient. Therefore, partial endograft removal or even preservation of the endograft can be considered, if the procedure is expected to be durable. Similar to other series, patients in our cohort presented with enlarging aneurysms, active endoleaks, and periaortic inflammation, which can contribute to difficulties in stent removal [17].

The adherence to the instructions for use (IFU) as a predictor of outcomes after EVAR remains a topic of ongoing debate. Some authors downplay the impact of IFU criteria and suggest that EVAR can be safely performed outside of the recommended guidelines [28-30]. However, large studies have demonstrated an increased incidence of type I endoleaks, sac expansion, and the need for early re-interventions in patients who undergo EVAR outside of the IFU criteria [5, 28]. In our cohort all patients met the device-specific instruction for use of each graft. Nevertheless in ten out of 31 patients a severly kinked iliac axis was found, which is not inlcuded in instruction for use but is generally accepted as a risk factor for EVAR failure. However, the majority of late conversions in our study were due to endoleak type Ia/Ib due to graft migration and or disease progression and endoleak type II with sac expansion. Therefore, close follow-up in these patients remains crucial to detect and manage these complications

Limitation

This study has several limitations that should be acknowledged. Firstly, it is a single-center study with a retrospective analysis, which may introduce biases and limit the generalizability of the findings to other settings. Additionally, the small number of patients included in the study may impact the statistical power and precision of the results.

The reported low early mortality has to be carefully interpreted due to the fact that complete and partial replacement and graft preservation was included in the analysis.

Another limitation is the long retrospective observation period, which spans from January 2004 to December 2020. During this time, there have been advancements in endograft techniques and treatment options for endoleaks, which could have influenced the outcomes and management strategies. The evolving nature of the field should be taken into consideration when interpreting the results.

Despite these limitations, it is important to highlight that this study provides data on a rare pathology from a tertiary hospital with expertise in open surgical procedures. The findings contribute to the existing literature and provide insights into the outcomes and management of late open surgical conversions after EVAR.

Conclusion

Open surgical conversion after EVAR is a well-established treatment and can serve as a rescue modality for patients. It is recommended to perform the conversion in an elective setting at a high-volume aortic center. In our center, the most common indication for conversion were endoleak type Ia respectively Ib due to graft migration or disease progression and endoleak type II endoleak with sac enlargement. This highlights the critical importance of lifelong surveillance to detect potentially problematic developments and prevent the need for emergency conversions.

Overall, open surgical conversion remains a valuable treatment option for patients who have undergone EVAR. Lifelong surveillance, adherence to suitability parameters, and prompt intervention when necessary are essential in ensuring optimal outcomes and preventing the need for emergent conversions.

ACKNOWLEDGEMENTS:

None

DISCLOSURES AND CONFLICTS OF INTEREST:

None

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Figure legend:

Figure 1: Flowchart of patient selection according in – and exclusion criteria

Figure 2: Cumulative survival of patients with late open conversion after EVAR

Figure 3: Partial EVAR explantation with remaining iliac limbs

Table legend:

Table 1: Device-specfic instruction for use

Table 2: Demographic data of patients undergoing late open conversion (LOC)

Table 3: Details of initial EVAR procedures

Table 4: Indication for late open conversion

Table 5: Technical aspects of open conversion

Table legend:

Table 1: Device-specific instruction for use

	Medtronic Endurant	Medtronic Talent	Guidant Ancure	Vascutek Terumo Anaconda	Lombard Medical Aorfix	Gore Excluder
Proximal neck:						
- length	> 10 mm	> 10 mm	> 15 mm	> 15 mm	>10 mm	>15 mm
-diameter		18 – 32 mm	< 26 mm	17.5 – 31 mm	19 – 29 mm	16 – 32 mm
-angulation	<60°	<60°	<60°	< 90°	<90°	<60°
Distal neck:						
- length	>15 mm	> 15 mm	> 20 mm	> 20 mm	>10 mm	>10 mm
- diameter	8 – 25 mm	8 – 22 mm	< 13 mm	8.5 – 21 mm	9 – 19 mm	8 – 25 mm

Table 2: Demographic data of patients undergoing late open conversion (LOC)

Variables	N=31 (%)
Age at initial EVAR, years	73 (54-88)
Age at LOC, years	75 (58-93)
LOC interval[a], months, median (range)	55 (16-209)
Male sex	29 (93)
Risk factors	
Obesity	5 (16)
Chronic kidney disease	10 (32)
CAD	9 (29)
Hypertension	30 (96)
Smoking (ongoing)	8 (26
Diabetes	7 (23)
Dyslipidemia	17 (55)
ASA score	
3	20 (71)
4	11 (35)

(Abbreviations: ASA=Association of Society of Anesthesiology, CAD=Coronary artery disease, EVAR=Endovascular aortic repair, LOC=Late open conversion)

Table 3: Details of initial EVAR procedures

Variables	N=31 (%)
Preoperative aneurysm diameter, cm, median, range	6,2 (4,9 -10)
Implanted endografts	
Medtronic Endurant	17 (45)
Medtronic Talent	4 (23)
Boston Scientific Vanguard	4 (10)
Guidant Ancure	3 (10)
Vascutek Terumo Anaconda	1 (3)
Lombard Medical Aorfix	1 (3)
Gore Excluder	1 (3)
Configuration	
Bifurcation	30 (97)
Tube	1 (3)
	N=7
Device adjuncts	
Embolization	5
Palmaz stent	1
Cuff extension	1
Intraoperative endoleaks	
Type Ia	2
Type II	6

492 Table 4: Indication for late open conversion.

Variables	N=31(%)
Endoleak	28 (90)
Type I	19
Type II	8
Type III	2
Type V	2
Sac enlargement	25 (81)
With endoleak	23
Without endoleak	2
Migration	8
Disease progression	8
Rupture	9
Limb thrombosis	3

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501 Table 5: Technical aspects of open conversion

Variables	**N=31 (%)**
Access	
- **Laparotomy**	26 (84)
- **Left-sided lumbotomy**	5 (16)
Complete explantation	20 (65)
Partial explantation	5 (16)
- **Replacement of mainbody**	2
- **Replacement of both iliac limbs**	3
Additional procedures without explantation	6 (19)
- **Ligation of lumbar arteries and sac wrapping**	5
- **Neck banding, ligation of lumbar arteries and sac wrapping**	1

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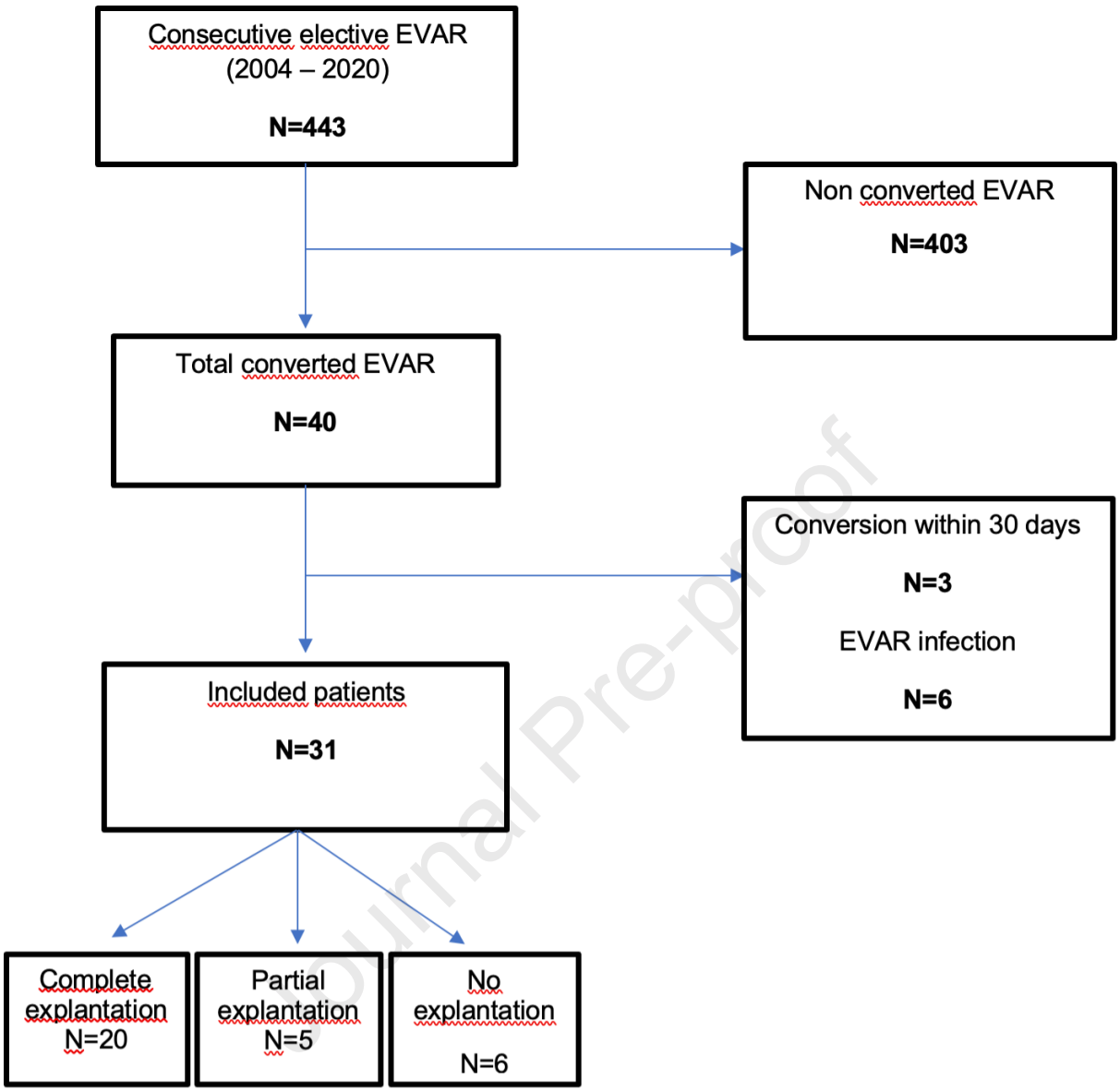
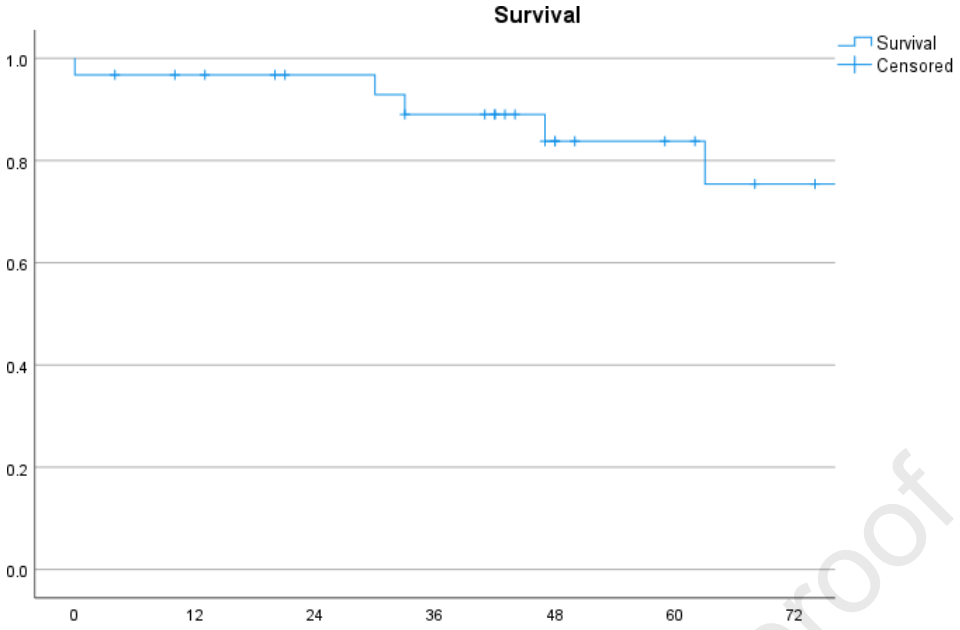


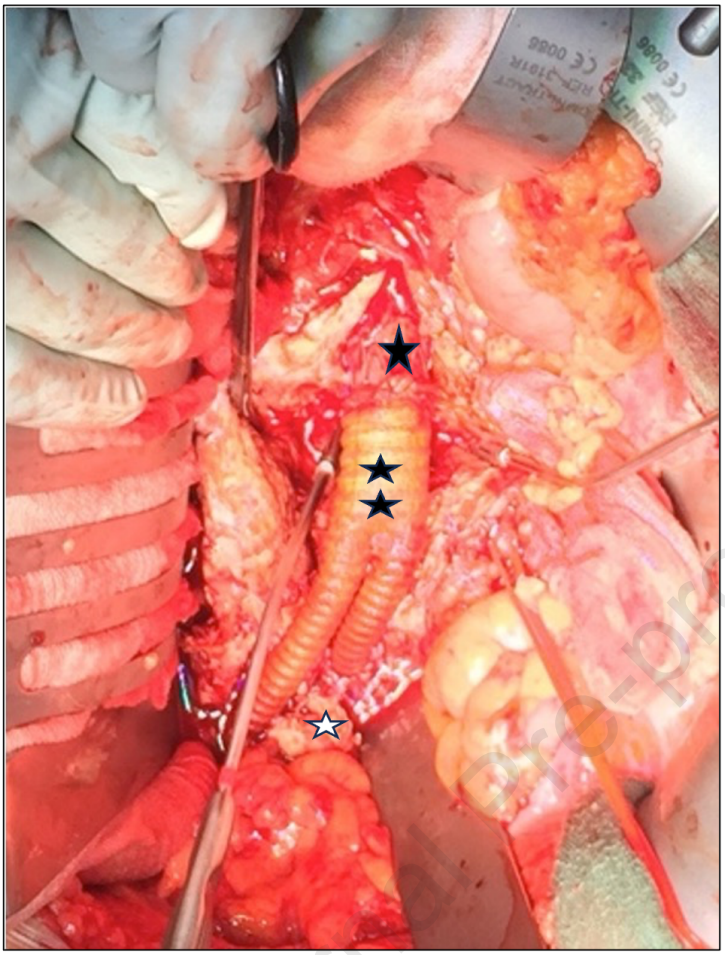
Fig. 1: Flowchart of patient selection according in- and exclusion criteria



	Survival
1 yr	97 %
3 yrs	89 %
5 yrs	84 %

	0 m	12 m	24 m	36 m	48 m	60 m	72 m
No at risk	30	28	25	22	14	11	8
SE	0.032	0.032	0.032	0.060	0.076	0.076	0.105

Fig. 2: Cumulative survival of patients with late open conversion after EVAR



(★Proximal anastomosis ,★★ replacement of mainbody with Dacron y-prosthesis,☆remaining iliac limbs)

Figure 3: Partial EVAR explantation with remaining iliac limbs