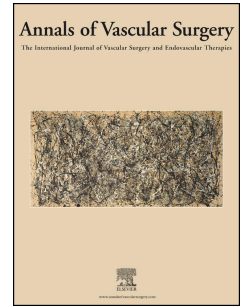


Journal Pre-proof

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

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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>.

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

2

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23 **Word count:** 3108

24 **Keywords:** EVAR, late open conversion, Endoleaks, rupture

25 **Running title:** Late open conversion after EVAR.

26

27 **Abstract**

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

34 **Methods:** This retrospective single-center study reviewed all patients who underwent EVAR from
35 2004 to 2020. Open surgical conversions > 1 month post EVAR were identified. Conversions for
36 graft infection were excluded. Indications for conversion and operative technique were analyzed.
37 Primary endpoint of the study was 30-day mortality. Secondary endpoints were re-interventions
38 and follow up mortality.

39 **Results:** During 2004 and 2020, 443 consecutive EVARs were performed, and 28 patients
40 required open surgical conversion, with an additional 3 referred from other hospitals (N=31). The
41 median age was 75 (range 58-93); 94% were male. Conversion was performed after a median
42 time of 55 months (range 16 - 209). Twenty patients underwent elective and 11 emergency
43 conversion. Indications for open conversion were graft migration respectively disease progression
44 with endoleak type Ia and/ or Ib in 52 % (16/31) and sac expansion due to endoleak type II in 26 %
45 (8/31). Of the 31 patients, 17 (55%) had at least one previous endovascular re-intervention. All
46 patients met the device-specific instructions for use for each implanted endograft.

47 In-hospital intervention rate was 16 % (5/31). 30-day mortality rate was 3% (1/31) with one patient
48 died due to multi-organ failure after rupture with complete endograft replacement. Five patients
49 (16%) died during follow-up. Mid-term follow-up was 47.5 months (range 24 -203) with estimated
50 cumulative survival rates of 97%, 89%, and 84%, at 1, 3, and 5 years, respectively.

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

55 Introduction

56

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

65 The occurrence of endoleak, potentially leading to AAA rupture, is still the main complication after
66 EVAR if not treated by re-intervention [6]. Long-term incidence of endoleak in the OVER trial was
67 30.5%, with one third of these patients needing at least one re-intervention [7]. Still, in daily
68 practice, EVAR is increasingly used in patients with difficult anatomy who fail to meet the criteria
69 defined by the device-specific instructions for use (IFU) [8]. This may lead to even more
70 endoleaks, but also other complications such as graft kinking and graft occlusion. Although most of
71 these complications can be treated by endovascular re-interventions [7-10], open conversion is
72 sometimes the last treatment option with an estimated incidence of 0-9% [11]. The mortality rates
73 of these conversions have been reported to be remarkably high, ranging from 20-40%, especially
74 in urgent cases [11-15].

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

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83 Methods

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

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

99 Adherence to device-specific IFU

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

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110 Late open conversion

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

117

118 Data analysis and statistics

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

125

126 **Results**

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

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

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

139

140 Re-interventions before conversion

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

146

147 Reasons and operative technical details of late open conversion

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

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

153 Conversion was required for multiple indication, including endoleak, migration, sac enlargement,
154 rupture, limb thrombosis and claudication (Table 4). In 80 % of patients, there was more than one
155 indication for conversion. Four patients had more than one type of endoleak. Three patients had
156 limb thrombosis as the indication for conversion, two of whom presented with repetitive uni-lateral
157 thrombosis as indication for repair. Acute rupture was the reason for conversion in nine patients
158 (29%). All patients presenting with a rupture had endoleak type I with disease progression or graft
159 migration or endoleak type III with stentgraft disconnection. Only one rupture occurred due to sac
160 enlargement due to endoleak type II.

161 In 24 cases (77%), open surgical conversion was performed via midline laparotomy and in seven
162 (23%) via left-sided lumbotomy. Median duration of surgery was 260 minutes (range 80 - 480) with
163 median intraoperative blood loss of 2550 ml (range 300 - 10000).

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

171 30-day morbidity and mortality

172 30-day mortality rate was 3% (1/31). The patient who died, on the fourth day after surgery,
173 required emergency conversion due to rupture and underwent complete EVAR explantation with
174 in-situ replacement using a bifurcated graft. Postoperatively, the patient developed abdominal
175 compartment syndrome and required re-laparotomy for decompression and open abdominal
176 treatment. The patient ultimately succumbed to multi-organ failure. Overall 30-day morbidity rate
177 was 26% (8/31). Among them, five patients required in-hospital re-intervention (15%). Two of the
178 elective conversion patients experienced acute limb ischemia due to graft occlusion, requiring
179 surgical revascularization. One urgent conversion patient developed acute limb ischemia due to
180 peripheral embolism and received endovascular revascularization. The remaining two urgent
181 conversion patients required additional interventions, one for abdominal compartment syndrome
182 through decompression laparotomy and the other for evacuation of a retroperitoneal hematoma.
183 One patient experienced non-transmural colon ischemia without intervention, and one patient had
184 a stroke but recovered completely. Pneumonia treated with antibiotics occurred in one patient. All
185 postoperative complications were observed in the group of urgent conversions, despite two
186 surgical revisions for graft occlusion. Patients who underwent elective and/or partial explantation or
187 graft-preserving interventions did not experience significant postoperative complications. Notably,

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

191 Follow up mortality

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

196

197 **Discussion**

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

202 In our cohort, the rate of late open surgical conversion was 7%. This is slightly higher compared to
203 a meta-analysis conducted by Goudekettig et al. in 2019, which reported a conversion rate of
204 5.3% (95% CI, 3.1%-7.4%) based on data from 27 studies encompassing a total of 791 patients
205 (617 elective and 174 urgent cases) [17]. A more recent multicenter study conducted by Perini et
206 al. even reported a rate of late open conversion of 2.22 % (232/10472 patients) [11]. The higher
207 rate in our cohort might be based on the comparable lower number of endovascular repair in
208 abdominal aortic aneurysm in the reported years and the tendency to prefer open conversion
209 towards endovascular solutions in treatment of endoleaks.

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

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

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

226 Despite a high frequency of suprarenal clamping, we did not observe any significant deterioration
227 in kidney function or the onset of new transient or permanent dialysis. One possible explanation for
228 this is the relatively short duration of suprarenal clamping, with a median time of 33 minutes (range
229 28 - 46).

230 The literature also supports that postoperative mortality rates are higher in patients who undergo
231 emergency conversions, with rates reported between 29.2% and 43.2% [20-21]. This finding is
232 consistent with other studies highlighting multi-morbidity and emergency conversions as factors
233 associated with increased mortality [3,9,10,14,17,22]. We observed a low 30-day mortality rate of
234 3%, with the single patient who died having undergone emergency conversion due to rupture. In
235 16% of our patients (5/31) a partial conversion was performed and in 19% (6/31) the complete
236 graft could be preserved. This highlights the lower mortality rate compared to cases requiring
237 complete graft removing, a finding consistent with previous studies [23,24].

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

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

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

256
257 Various surgical techniques for late open surgical conversion after EVAR have been described,
258 which primarily differ in terms of the approach (transperitoneal vs. retroperitoneal), proximal cross-
259 clamping site (suprarenal, infrarenal, or supraceliac), and extent of graft removal (complete vs.
260 partial). These choices are typically guided by clinical factors, such as suprarenal fixation and the
261 reason for graft removal, as well as the surgeon's preference.

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

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

283 **Limitation**

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

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

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

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

299 **Conclusion**

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

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

310

311

312 **ACKNOWLEDGEMENTS:**

313 None

314 **DISCLOSURES AND CONFLICTS OF INTEREST:**

315 None

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431 **Figure legend:**

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

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

434 Figure 3: Partial EVAR explantation with remaining iliac limbs

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436 **Table legend:**

437 Table 1: Device-specific instruction for use

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

439 Table 3: Details of initial EVAR procedures

440 Table 4: Indication for late open conversion

441 Table 5: Technical aspects of open conversion

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451 **Table legend:**

452 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

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465 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)

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

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473 Table 3: Details of initial EVAR procedures

Variables	N=31 (%)	474
Preoperative aneurysm diameter, cm, median, range	6,2 (4,9 -10)	475
Implanted endografts		476
Medtronic Endurant	17 (45)	
Medtronic Talent	4 (23)	477
Boston Scientific Vanguard	4 (10)	
Guidant Ancure	3 (10)	478
Vascutek Terumo Anaconda	1 (3)	
Lombard Medical Aorfix	1 (3)	479
Gore Excluder	1 (3)	
Configuration		480
Bifurcation	30 (97)	481
Tube	1 (3)	482
	N=7	
Device adjuncts		483
Embolization	5	484
Palmaz stent	1	485
Cuff extension	1	486
Intraoperative endoleaks		487
Type Ia	2	488
Type II	6	

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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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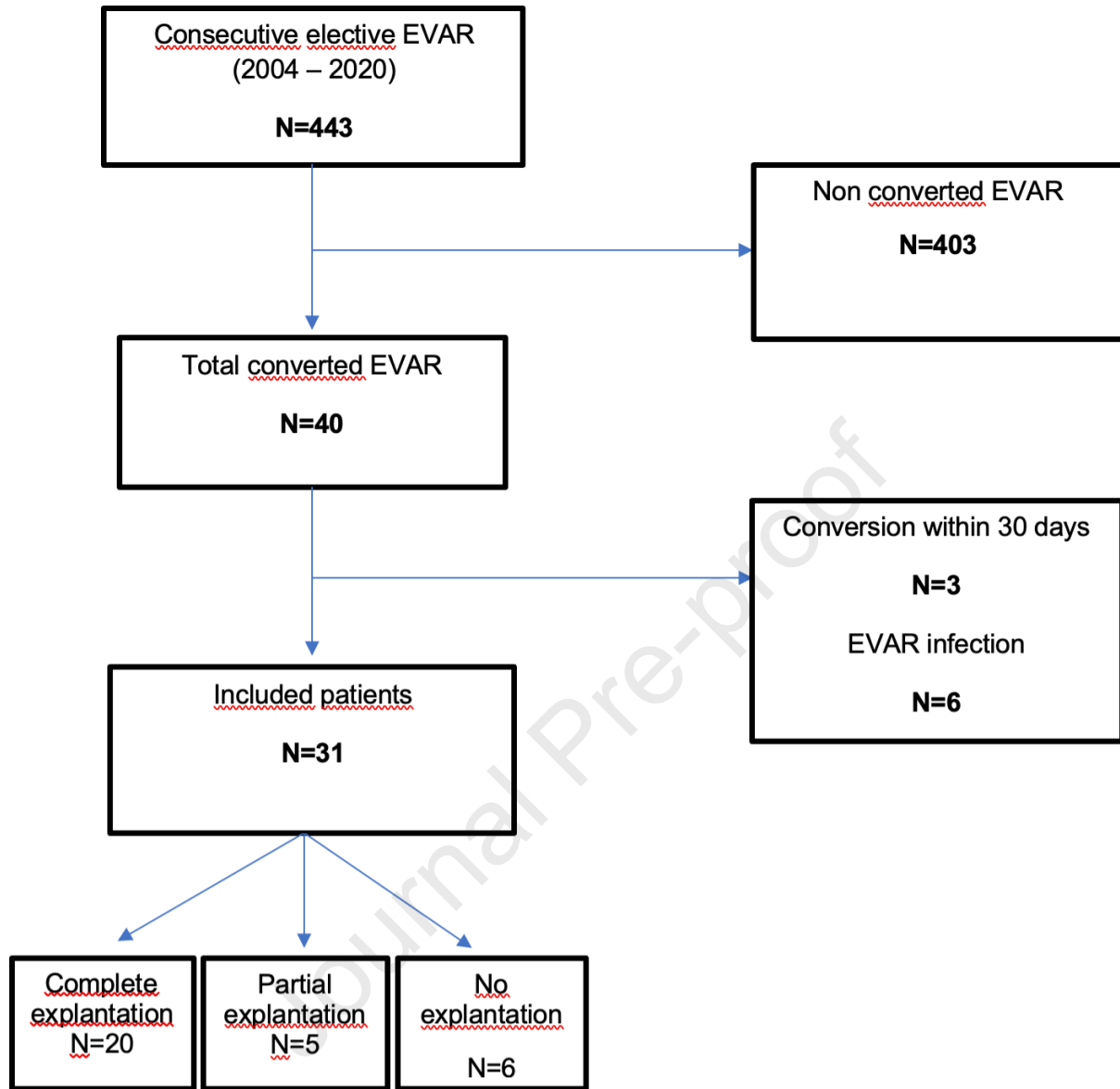


Fig. 1: Flowchart of patient selection according to in- and exclusion criteria

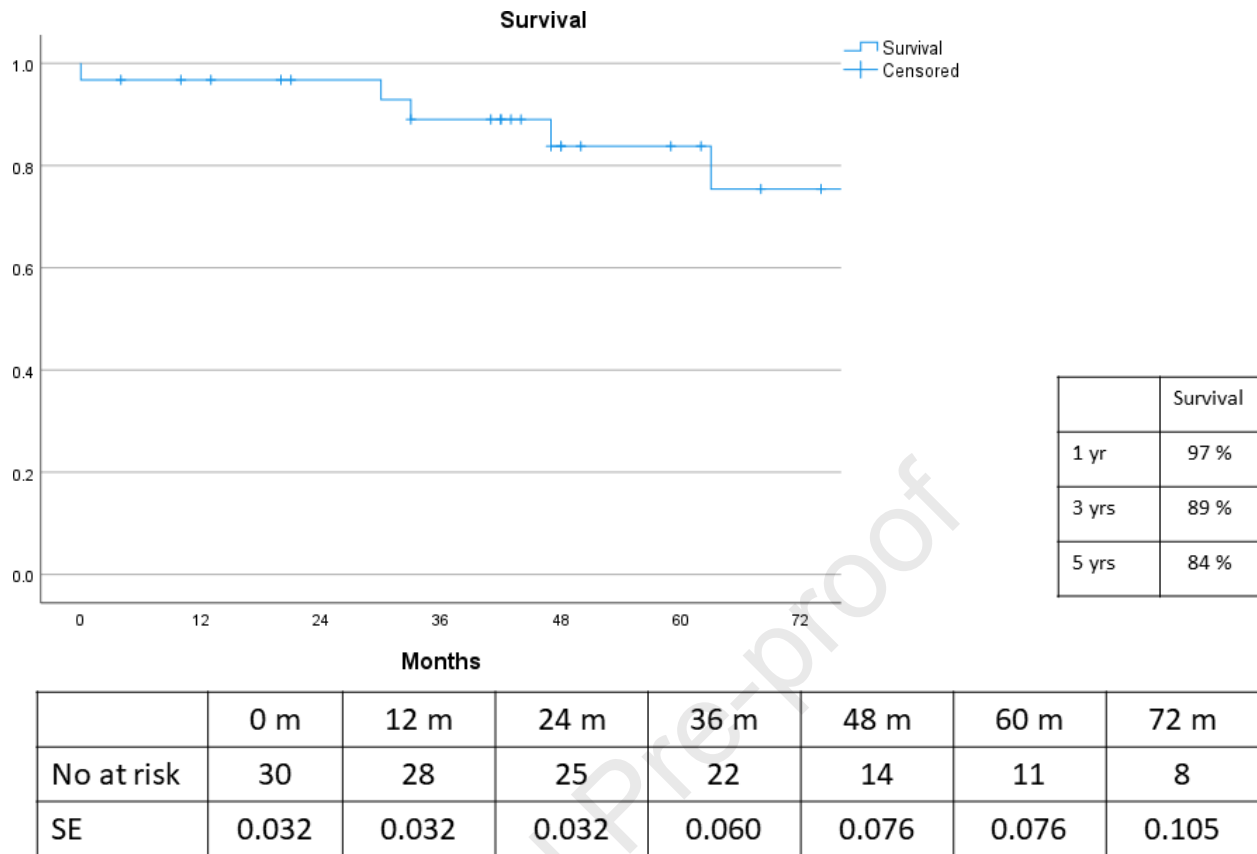
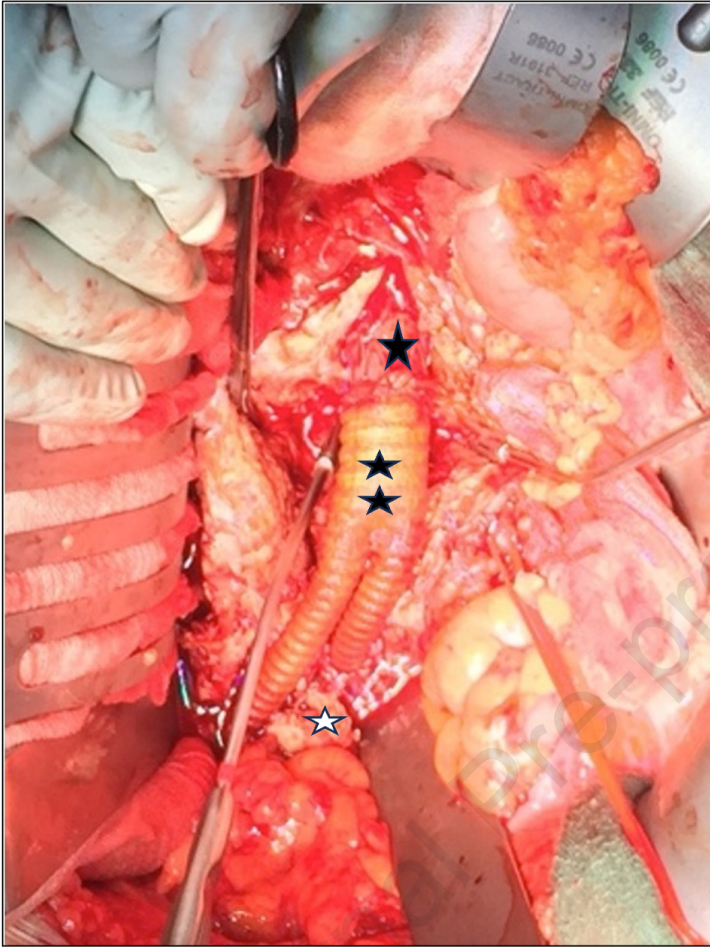


Fig. 2: Cumulative survival of patients with late open conversion after EVAR



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

Figure 3: Partial EVAR explantation with remaining iliac limbs