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Mid-Term Outcomes of Complex Endografting for Chronic Post-Dissection Thoracoabdominal Aortic Aneurysms

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3 **Mid-term outcomes of complex endografting for chronic post-dissection thoracoabdominal**
4 **aortic aneurysms.**

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6

7 **ABSTRACT**

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9 **Purpose:** to report early and mid-term results of post aortic dissection (AD) thoraco-abdominal
10 aneurysms (pD-TAAA) treated by complex endografting in three high-volume centres.

11

12 **Materials and methods:** a review of all patients with pD-TAAA unfit for open surgery treated with
13 complex endovascular repair from 2012 to 2018 was performed. Simple thoracic endografts
14 (TEVAR) were excluded. Staged procedures in case of extensive aortic coverage were always
15 planned.

16

17 **Results:** 21 patients (16 male, mean age 63 ± 10 years) with pD-TAAA underwent aortic repair by
18 fenestrated or branched thoraco-abdominal endografts for visceral vessels. Mean TAAA diameter
19 was 62 mm (range 55-83). Spinal cord drainage was performed in all patients. A staged approach
20 was used in 12 (57%) cases. Technical success was achieved in 18 patients. No in-hospital deaths
21 occurred. Two patients (9.5%) experienced transient post-procedural spinal cord ischemia. At 30
22 days, six type II endoleaks (28.5%), two type Ic endoleak (9.5%) and one type IIIc endoleak (4.7%)
23 were reported. At a mean follow-up of 23 ± 13 months, no late aortic-related deaths occurred. Three
24 patients underwent reintervention for type Ic and IIIc endoleaks. No visceral vessel occlusion was
25 observed. Estimated freedom from reintervention at 12 and 24 months was $85.7 \pm 7\%$. In 13 cases
26 TAAA diameter decreased at least 5 mm, while in only one case there was a volume increase.

27 Complete false lumen thrombosis was noted in 18 patients (86%).

28 **Conclusion:** complex endografting for pD-TAAA showed favourable results. Staged procedures
29 and careful planning allow to treat safely with excessive risk in case of open repair.

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34 **KEYWORDS:** chronic dissection; thoraco-abdominal; aortic aneurysm; F/B-TEVAR; complex
35 endografting

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40 **TEXT**

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42 **Introduction**

43 Uncomplicated type B aortic dissection (TBAD) at the time of the diagnosis requires a strict
44 blood pressure control combined with strict radiological follow-up [1-2]. Different studies,
45 however, reported a 30-day mortality of 6-10% even in presence of optimal blood pressure control
46 [3-4]. Long term survival is negatively affected by the disease, with only 50-70% of patients alive
47 at five years [5-7]. Approximately 30% of patients with uncomplicated TBAD will ultimately
48 present a post-dissection thoracoabdominal aortic aneurysm (pD-TAAA) [8]. Such evolution in the
49 descending aorta may also occur in patients successfully treated for a type A aortic dissection by
50 ascending aorta and/or aortic arch replacement.

51 In case of pD-TAAA open surgery is the treatment option of choice, even if it represents an
52 extremely demanding procedure both for the patient and the physician.

53 In the recent literature, few selected centers proposed total endovascular aortic repair of pD-TAAA
54 with fenestrated and branched endografts as a valuable alternative to open surgery [9-11].
55 Endovascular treatment of such a complex entity is extremely challenging due to the anatomic
56 variability between different patients, in terms of visceral vessels' origin from the true lumen (TL)
57 or false lumen (FL), the narrowness of the TL and the possible involvement of the iliac arteries in
58 the dissection.

59 With this multicentric study we aim to analyze early and mid-term outcomes of total endovascular
60 pD-TAAA repair in three centers with experience in complex endografting of atherosclerotic
61 aneurysms.

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63 **Materials &Methods**

64 *Study design and preoperative evaluation*

65 A retrospective analysis of all information regarding consecutive patients with pD-TAAA
66 deemed unfit for open surgery and treated with complex fenestrated/branched thoraco-abdominal
67 endovascular aortic repair (F/B-TEVAR) in three Italian centres between 2012 and 2018 was
68 conducted. Inclusion criteria were: pD-TAAA with maximum aortic diameter >60 mm, rapidly
69 growing aneurysms (> 10 mm in 12 months) with <60 mm diameter, or symptomatic/ruptured
70 TAAA. Surgical indication was discussed with a multidisciplinary team involving vascular and
71 cardiac surgeons, anaesthesiologists, cardiologists and radiologists. All patients with chronic aortic
72 dissections treated with simple TEVAR were not included in the present study. Primary outcomes
73 were: technical and clinical success of the procedure and overall survival rates. Secondary
74 outcomes were: FL thrombosis, freedom from reintervention and TAAA diameter decrease.

75 Technical success was defined as complete coverage of primary entry tear, target vessels patency
76 and absence of type I or III endoleaks (EL). Clinical success was defined as the absence of death,
77 type I or III EL, infection, significant aneurysm expansion (≥ 5 mm), rupture or complete FL
78 thrombosis [12-13].

79 All patients underwent pre-operative computed tomography angiography (CTA) to define aortic
80 diameter, identify the origin of visceral vessels from the TL or FL and proximal and distal landing
81 zones and evaluate integrity of the vascular accesses.

82 Patients have been consented for personal data collection and data use for scientific purposes at the
83 time of surgery. This present study was designed as a retrospective analysis of those prospectively
84 collected information, therefore ethical committee approval was waived.

85

86 *Endovascular procedures*

87 All endografts were designed to be deployed in the true lumen. When the pre-operative
88 planning included a coverage of more than 10 cm of thoracic aorta a stage procedure was
89 performed: the first step was an exclusion of the proximal thoracic entry tears, followed by a second
90 stage with the F/B-TEVAR, with an average delay of one month. The proximal landing zone was
91 planned to be either the native non-dissected aorta or a previous surgical graft or endograft with a
92 standard oversizing between 15-20% and a length of at least 25 mm for the native aorta and 40 mm
93 when landing in an endograft or frozen elephant trunk (FET). When landing in Ishimaru zones Z1
94 or Z2 a supra-aortic trunks revascularization was required, the surgery was always performed
95 within the 48 hours before the first endovascular stage to reduce the risks of neurologic
96 complications [2, 14-16]. Preservation of hypogastric artery direct flow was attempted in all
97 feasible cases during the F/B-TEVAR stage. Fenestrated endografts were preferred in case of
98 narrow true lumen and when antegrade access for the eventual B-TEVAR was unfavourable as in
99 most of the cases with previous arch replacement. A minimal graft lumen diameter of 18 mm was
100 designed in all cases with narrow aortic true lumen at the level of visceral arteries. In case of < 18
101 mm true lumen, a double diameter-reducing wire was planned for constraint before full deployment
102 [17].

103 A Cook F/B-TEVAR (Cook Medical, Brisbane Australia) was used in all cases, except for one
104 pD-TAAA contained rupture for which a four fenestrations physician-modified Medtronic Navion

105 (Medtronic Vascular, Santa Rosa, CA) endograft was required [18]. Off-the-shelf Zenith t-Branch
106 thoraco-abdominal stent graft (Cook Medical, Birsbane Australia) was used when anatomically
107 suitable.

108 Branched grafts had always straight outer directional branches. Visceral stent-grafts in different
109 configurations (balloon expandable or self-expanding stent-grafts, eventually re-enforced by bare
110 metal stents) were chosen in each dingle case depending on the vessel anatomy. Usually balloon
111 expandable stent-graft was used for fenestrations (Advanta V12, Getinge; BeGraft, Bentley
112 InnoMed) and self-expanding stent was used for branches (Fluency, Bard) [19]. Target vessels were
113 engaged from a femoral access in case of fenestrations, while a brachial approach was used for
114 branches. When endovascular fenestration of the lamella was required, this was performed with a
115 progressive non-compliant balloon dilatation over a guidewire displaced across the two lumens at
116 the level of a pre-existing tear or through a neo-fenestration. All procedures were performed in
117 hybrid operating room under general anaesthesia.

118 Cerebrospinal fluid (CSF) drainage was placed in all cases during the F/B-TEVAR intervention and
119 maintained for 48/72 hours, with a target spinal cord pressure < 12 mmHg [20]. Other peri-
120 operative monitoring included: clinical control in intensive care unit (ICU) for at least 48 hours,
121 strict arterial pressure control with a mean arterial pressure target > 85 mmHg, haemo-transfusion
122 when haemoglobin < 10 g/dl [21-22].

123 Due to the complexity of the treatment, all procedures were performed by a multidisciplinary team
124 consisting of Vascular and Endovascular Surgeons and Radiologists, with the presence of at least
125 one of the most experienced endovascular operators in all cases (FV, CF, GP).

126

127 *Post-operative and Follow-up*

128 During the hospital stay, patients were evaluated with clinical and laboratory examinations.
129 Doppler ultrasound (DUS) control of the vascular accesses and the visceral vessels was performed

130 along with a CTA before discharge within 30 days from surgery, which represented the first follow-
131 up time-point.

132 All patients received acetylsalicylic acid 100 mg/daily and prophylactic regimen low molecular
133 weight heparin (LMWH). Dual antiplatelet therapy was started after CSF drainage removal and
134 continued lifelong if well tolerated or at least for six months.

135 Follow-up consisted of clinical evaluation and CTA imaging at 6 months and yearly thereafter, in
136 absence of complications. Parameters evaluated at follow-up were aneurysm diameter, FL patency,
137 target vessel patency, presence and characterization of ELs, reinterventions, complications and
138 mortality.

139

140 *Statistical analysis*

141 Continuous variables are expressed as mean and standard deviation or range. Categorical
142 variables are presented as percentage. Kaplan-Meier survival estimates were calculated to assess
143 overall mortality, aortic-related mortality and freedom from re-intervention. Curves are displayed as
144 a solid line up to a value of standard error (SE) < .10; dotted lines refer to estimates with a SE ≥ .10.
145 Statistical significance was set at $p < .05$. All statistical analyses were conducted with R version
146 3.6.2. (R foundation for statistical computing, Wien, Austria)

147

148 **Results**

149 A total of 21 patients (16 male, mean age 63 ± 10 years) with pD-TAAA were enrolled in the
150 study. Mean aortic diameter at time of indication for F/B-TEVAR was 61 ± 6.2 mm. Patients
151 demographics are shown in Table 1. TBAD was the initial presenting disease in 11 (52.3%) cases,
152 the rest presented originally with a type A aortic dissection and had underwent successful proximal
153 aortic surgery. Two patients (9.5%) were affected by connective tissue disorders. Five patients
154 (24%) presented a Crawford type I TAAA, 15 (71.3%) a Crawford type II and one patient (4.7%)
155 Crawford type III TAAA. Endovascular treatment was needed after a mean of 47 months (3 – 120)

156 from the disease onset. Previous TEVAR was already in place in 3 (14%) cases, while two patients
157 (9.5%) presented FET with Thoraflex (Terumo Aortic, Sunrise). A staged approach was used in 12
158 cases (57%) with mean interval between the first and second procedure of 58 days.

159

160 *Procedure details and technical success*

161 Custom made fenestrated and branched devices were used for 18 patients (86%) patients; 2 cases
162 (9.4%) were treated with off the shelf Zenith t-branch thoraco-abdominal stent graft (Cook
163 Australia, Brisbane, Australia); in one case (4.7%), due to urgent setting characterised by contained
164 thoracic rupture after the first stage of TEVAR in a symptomatic patient, a physician-modified
165 endograft was used. Due to an inadequate proximal landing zone four patients (19%) underwent a
166 carotid-carotid-subclavian bypass, while in three cases a carotid-subclavian bypass (14%) was
167 performed . Common iliac arteries were generally used as distal landing zone with the exception of
168 2 cases (9%) of unilateral external iliac landing zone and hypogastric occlusion (patients 1 and 6),
169 one case (5%) of IBD (patient 6) and 2 cases (9%) where distal abdominal aorta was used as
170 landing zone (patients 5 and 21).

171 Overall 84 visceral vessels were successfully targeted (20 coeliac trunks, 21 superior mesenteric
172 arteries, 42 renal arteries, 1 accessory renal artery; one coeliac trunk was chronically occluded).

173 Seventy-two (85.7%) vessels were targeted with fenestrations and 12 (14.3%) with downward
174 branches. Seven target vessels (8%) originated from the FL: in 5 cases an endovascular fenestration
175 was necessary to reach the target vessel, while in the remaining 2 cases a branch configuration close
176 to a large tear of the lamella was used for the revascularization. Previous renal artery stent and
177 celiac artery stent were present in three and two cases respectively (6% of target vessels; Fig. 1).

178 Misalignment between fenestration and target vessel impeding visceral stent grafting did not occur.

179 Data from each procedure are shown in Table 2.

180 Technical success was achieved in 18 patients (86%), with two cases of type Ic EL and one case of
181 type IIIc EL left untreated [23]. One patient underwent early reintervention due to access

182 complication (brachial pseudo-aneurysm). Two patients (9.5%) experienced post-procedural spinal
183 cord ischemia, both resolved within one-month follow-up. At 30 days no type Ia or Ib EL were
184 reported, but there were six type II EL (28.5%), two type Ic EL (9.5%) and one type IIIc EL (4.7%).
185 Type Ic and IIIc EL were treated with visceral vessel stent-graft relining; a successful treatment was
186 achieved in two patients, while a minimal residual type IIIc EL following the procedure was left
187 untreated. Estimated freedom from reintervention at 12 and 24 months was $85.9 \pm 7\%$ (Fig. 2).

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189

190 *Follow-up and clinical success*

191 Mean follow-up was 23 ± 13 months, without any loss at follow-up. No late aortic-related deaths
192 occurred; one death at 21 months from the procedure due to acute cardiac failure after myocardial
193 infarction was reported. Overall survival curve is depicted in Fig. 3. No cerebral ischemic
194 complications or visceral vessel loss were reported. In 13 cases TAAA diameter decreased at least 5
195 mm, with only one TAAA diameter increase. Complete FL thrombosis was obtained in 18 patients,
196 reaching a clinical success of 86%. The reason for a residual FL perfusion was a type II EL in two
197 cases (left untreated due to the absence of aneurysm growth) and a type IIIc EL in one case.

198

199 **Discussion**

200 Patients with uncomplicated acute TBAD are typically managed medically with
201 antihypertensive drug therapy. However, during chronic phase, these patients are at higher risk for
202 aneurysmal dilatation and rupture of the affected aorta [24]. The estimated aortic growth after
203 TBAD ranges from 1 mm to 7.1mm/year as reported by Blount et al. [25]. Open repair of PD-
204 TAAA has always been considered the gold standard despite a not negligible mortality and
205 morbidity rates [26-28]. Analyses of volume-related outcomes over a wide range of hospitals reveal
206 the “real world” picture, with overall mortality reaching 22.3% and postoperative complication rate
207 exceeding 55% [29].

208

209 The encouraging results obtained with the use of endovascular repairs for TAAAs, have led to the
210 evaluation of the feasibility of such treatment in pD-TAAAs, at least for high risk patients [7-8].

211 The presence of re-entry tear in the abdominal aorta reduces the possibilities of a complete FL
212 thrombosis with simple TEVAR. For this reason, different techniques have been used to increase
213 technical success: F/B-TEVAR, FL embolization with coils and plugs, the knickerbocker technique,
214 the Petticoat technique and the STABILISE technique [30-33].

215 Compared with other techniques, F/B-TEVAR is burdened by an increased complexity in planning
216 due to the difficulties in sizing the TL (often compressed by the FL), the extreme variability in the
217 origin of the visceral vessels from the TL or FL, the narrowness of the TL and the possible
218 involvement of the iliac arteries in the dissection.

219 For these reasons, only high-volume centers with experience in complex endografting were the first
220 to use such approach for pD-TAAA with encouraging results at least in the short term. Early and
221 mid-term outcomes of our study are similar to those present in literature in terms of technical
222 success and early and mid-term mortality, with favorable outcomes considering the complexity of
223 the pathology and the high prevalence of comorbidities of the patients enrolled [9-11, 34-36].

224 Interestingly, results of the published literature came from very few, selected centers highly devoted
225 to complex endografting, while in the present experience, similar results have been obtained in
226 centers with low annual incidence of pD-TAAA, but well experienced in complex endografting.

227 In the present study two cases of transient SCI were reported (9.5%), which is in average with the
228 data reported in literature, with a range 0-15% [9-10, 34-36]. This evidence seems to support the
229 idea where there is a higher possibility of recovery after SCI in patients undergoing pD-TAAA
230 endovascular treatment rather than after open repair, however further comparative studies are
231 needed [9, 31].

232 In the cases observed reintervention was required exclusively for visceral stents endoleak
233 complications, while no occlusions were reported. This observation may be due to the fact that the

234 visceral vessels were rarely atherosclerotic and the stent graft used were usually rather short due to
235 the narrow gap between the aortic endograft and the target vessel.

236 The reason for a not negligible incidence of type Ic and IIIc ELs is not clear, but as suggested by
237 Oikonomu et al, it may be due to the excessive caution during sizing and deployment, along with
238 the insufficient flaring of the bridging in order to avoid a visceral dissection when dealing with the
239 extremely fragile aortic walls and narrow TL [10].

240 The only residual type IIIc EL despite relining, occurred in our experience with the case of
241 physician-modified endograft. Considering the lack of aneurysm sac growth and patient's frailty it
242 was decided to postpone eventual further treatment. The fenestrations have been designed too large
243 to reduce the risk of misalignment and failure to cannulate, but insufficient flaring of the mating
244 stent graft was then not able to cope with the gap between the aortic and the visceral components.

245 The procedure was however successful in promote thrombosis of the FL in the thoracic portion of
246 the fissured TAAA with survival of the patient.

247 False lumen thrombosis occurred in 86% of the present experience, a rate similar to others reported
248 in literature, with aneurysm sac shrinkage in 62% of cases and no aortic-related deaths [10, 34-36].

249 This suggests that, although burdened by a higher risk of reintervention, F/B-TEVAR may obtain a
250 stable seal of the aortic wall and the false lumen, representing a potentially valid solution for pD-
251 TAAA. Relative motion of the visceral stent-grafts and the aortic component may be less
252 pronounced in pD-TAAA if compared to atherosclerotic TAAA, perhaps reducing the long-term
253 risks of secondary ELs. However a situation of particular risk may be the use of longer stents to
254 reach vessels taking off from aneurysmal FL, unless the presence of a rigid lamella may sustain the
255 stent in position.

256 Study limitations are: the experience suffers from small number of treated patients, low event rates
257 and short follow-up. The multi-center nature of the study may introduce biases regarding different
258 patients and material selection, although most of the operators shared a common training in the
259 same University Center of Perugia.

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Conclusion

Complex endografting for pD-TAAA is a feasible therapeutic solution with favourable mid-term results when performed in highly experienced centres. Staged procedures and careful planning of adjuvant techniques are compulsory in order to perform endovascular repair in patients often evaluated with high surgical risk in case of open repair. Larger multi-center experiences with longer follow-up are suggested for definitive answers regarding the role of endovascular treatment compared to open surgery in post-dissection thoraco-abdominal aneurysms.

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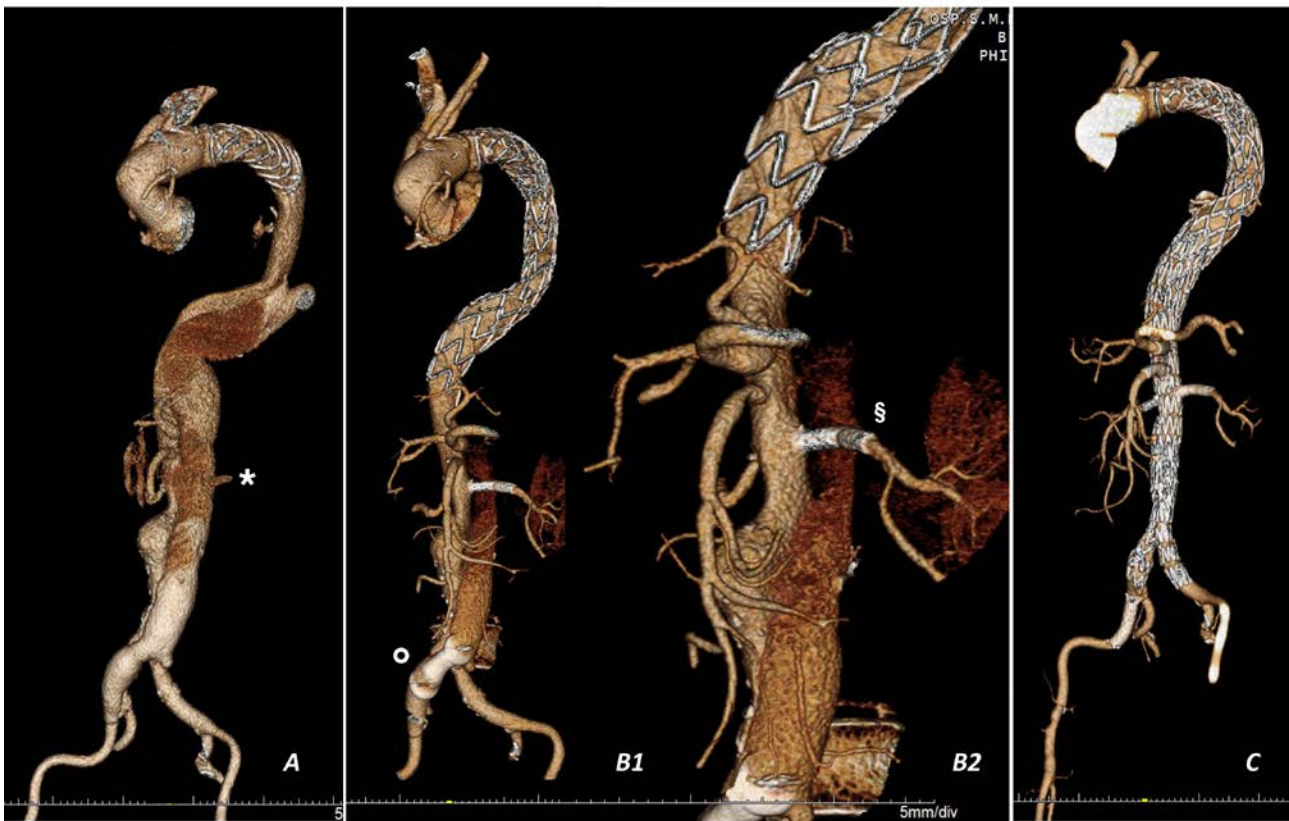
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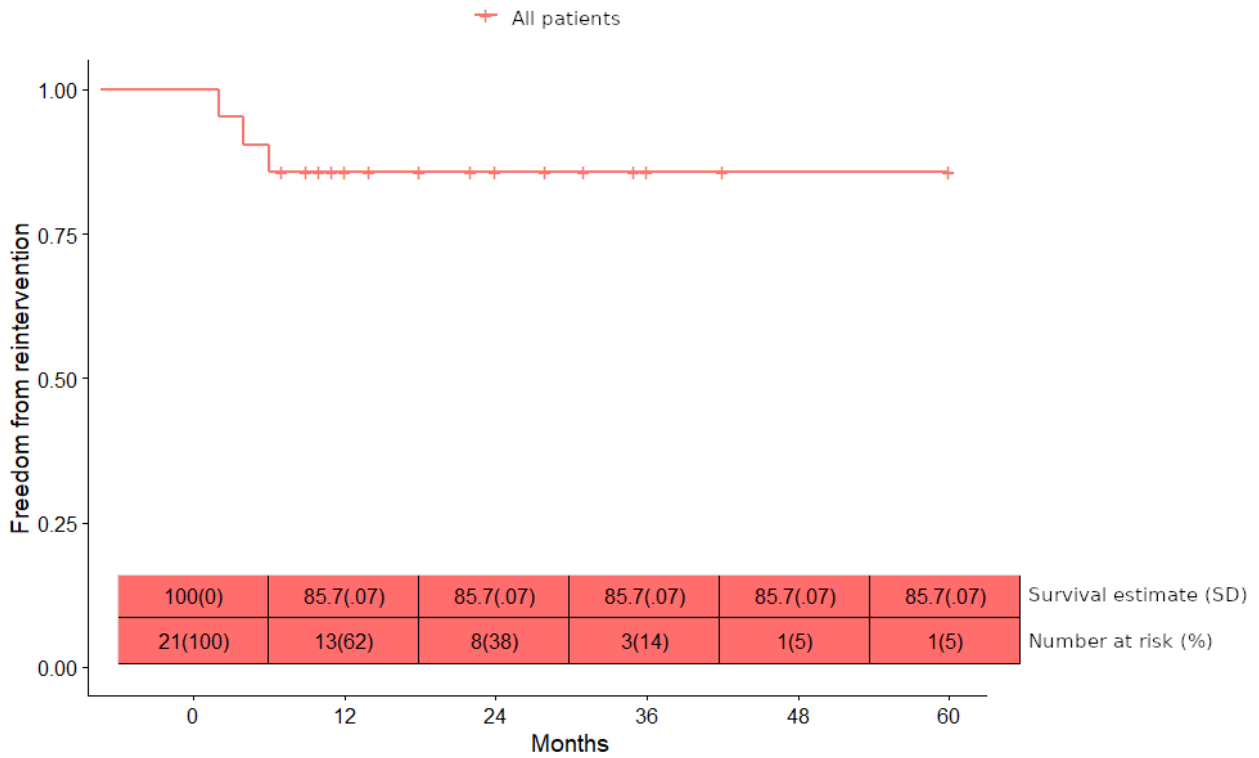
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394 **FIGURES**

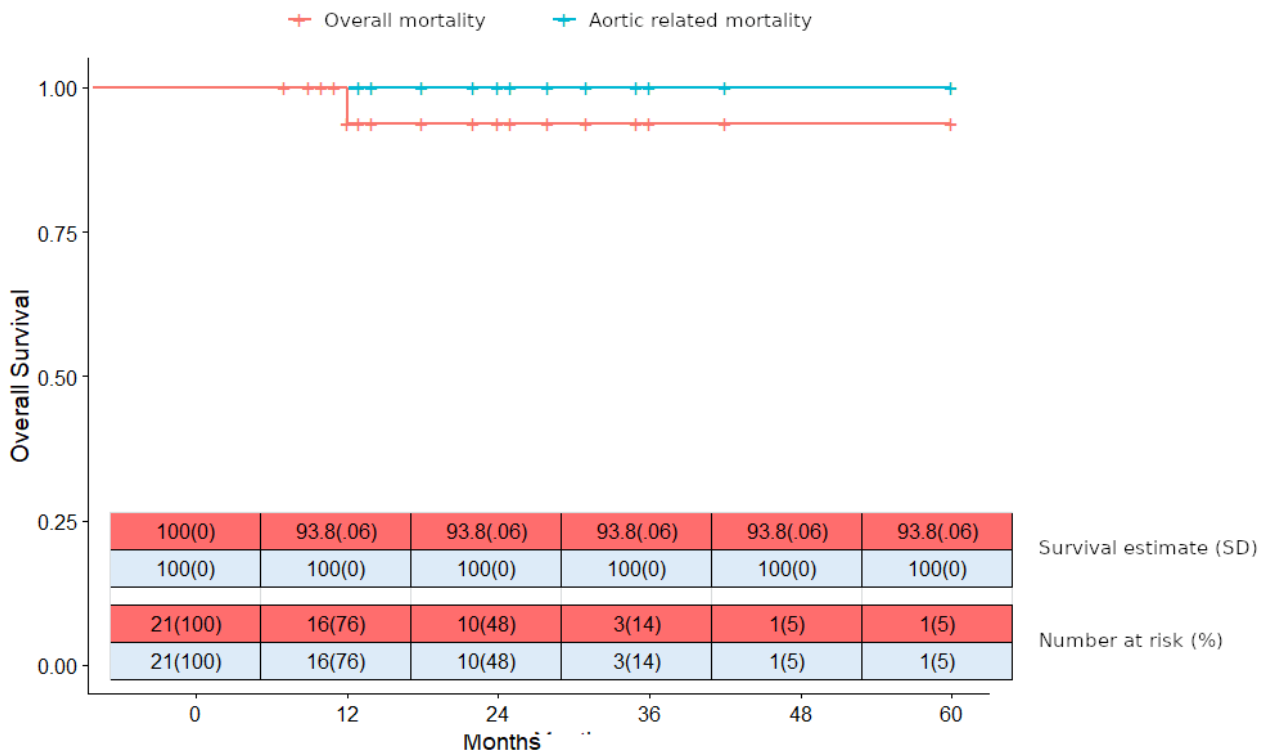


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396 **Fig. 1** Patient 17. Fig. 1.A: 3D-CT 3 years after Ascending + arch replacement with Frozen
397 elephant trunk showing pD-TAAA with left renal artery originating from FL (*). Fig. 1.B: 3D-CT
398 after first stage with TEVAR + Amplatzer plug in the false lumen of the right common iliac artery
399 (°) + left renal stent graft from the TL (§). Fig. 1.C: 3D-CT after custom-made 4-fenestrations
400 thoraco-abdominal endograft and external iliac artery covered stent graft with the complete false
401 lumen thrombosis.



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403 **Fig. 2** Kaplan Meier freedom from reintervention curve



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405 **Fig 3** Kaplan Meier survival curves (blue line: aortic-related survival; red line: overall survival)

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409 **TABLES**

410 **Table 1** Patients demographics and risk factors

Comorbidities and risk factors	N (%)
Age	63±10 years
Male gender	16 (71%)
Hypertension	20 (95%)
Diabetes	3 (14%)
Smoking	7 (33%)
Chronic obstructive pulmonary disease	4 (19%)
Chronic renal insufficiency	2 (9.5%)
Coronary artery disease	9 (43%)
Severe obesity*	1 (4.7%)
Marfan or connective tissue disorders	2 (9.5%)
Original Type B aortic dissection	11 (52.3%)

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412 *severe obesity evaluated as Body Mass Index >35

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414 **Table 2** Dissection characteristics, details of the procedures and outcomes

Patient	Sex	Age	Crawford TAA type	Aneurysm diameter (mm)	Previous aortic intervention(s)	Staged procedure	Endograft characteristics	Adjunctive procedure(s)	Spinal drain	Total False lumen thrombosis	Reintervention (months from primary procedure)	Long term mortality
1	M	55	II	65	Ascending repl	Car-car-subcl TEVAR	CM 5 fen	Right IIA occlusion	Y	N	N	N
2	F	47	II	60	Ascending repl	N	CM 4 fen	N	Y	Y	N	N
3	M	74	II	63	Ascending repl	N	CM 4 fen	N	Y	Y	N	N
4	M	60	II	58	N	N	CM 4 fen	N	Y	Y	N	N
5	F	59	III	56	Ascending repl TEVAR Double barrel R-iliac CA BMS	N	CM 3 fen	L-gastric artery microplug; CA stentgraft	Y	Y	N	N
6	M	72	II	55	N	Car-car-	CM 4 fen	R-IBD	Y	Y	N	N

						subcl		L-IIA				
						TEVAR		occlusion				
7	M	64	II	62	N	N	CM 4 fen	N	Y	Y	N	N
						Car-subcl						
8	M	70	II	60	N	TEVAR	CM 4 fen	LRA stentgraft	Y	Y	N	N
9	M	61	II	56	Arch repl	N	CM 4 fen	N	Y	Y	N	N
10	M	69	I	55	Ascending repl	N	CM 4 fen	N	Y	Y	N	N
11	F	68	II	55	N	N	CM 4 fen	N	Y	Y	N	N
						Car-car-						
12	M	46	I	60	Ascending repl	subcl	CM 4 fen	N	Y	Y	N	N
						TEVAR						
						Car-car-						
13	M	47	II	55	TEVAR	subcl	t-branch	N	Y	N	Type III EL (6 months)	N
						TEVAR						
												acute MI
14	F	83	II	69	TEVAR	TEVAR	CM 3 branch	N	Y	Y	N	(21 months)
												Brachial pseudoaneurysm
15	M	63	II	62	N	TEVAR	t-branch	N	Y	Y	(1 month) + Type III EL (2 months)	N
16	M	60	I	68	FET	TEVAR	CM 4 fen	N	Y	Y	N	N
						Ascending repl						
17	M	73	II	80	CABG	TEVAR	CM 4 fen	LRA stentgraft; Iliac FL plug; EIA stentgraft	Y	Y	N	N
					FET							
						Car-subcl						
18	M	59	I	68	N	TEVAR	CM 4 fen	N	Y	Y	N	N
						Car-subcl						
19	M	68	II	62	N	TEVAR	CM 4 fen	N	Y	Y	N	N
20	M	58	I	58	N	N	CM 4 fen	N	Y	Y	N	N
						Ascending repl+						
21	F	66	II	65	CABG	TEVAR	Physician modified endograft	CA stentgraft	Y	N	Type III EL (4 months)	N
					LRA stentgraft							

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Car-subcl: carotid-subclavian bypass; CA: celiac artery; CABG: coronary artery bypass graft; CM: custom made; EIA: external iliac artery; EL: endoleak; FET: Frozen Elephant Trunk; F: female; IBD: iliac branch device; IIA: internal iliac artery; L: left; LRA: left renal artery; M: male; MI: myocardial infarction; R: right; Y: yes; N: no.