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

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(Article begins on next page)

Clinical Investigation

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ABSTRACT

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

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

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

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

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

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

TEXT

Introduction

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

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

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

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

Materials &Methods

Study design and preoperative evaluation

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

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

All patients underwent pre-operative computed tomography angiography (CTA) to define aortic diameter, identify the origin of visceral vessels from the TL or FL and proximal and distal landing zones and evaluate integrity of the vascular accesses.
Patients have been consented for personal data collection and data use for scientific purposes at the time of surgery. This present study was designed as a retrospective analysis of those prospectively collected information, therefore ethical committee approval was waived.

Endovascular procedures

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

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

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

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

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

Post-operative and Follow-up

During the hospital stay, patients were evaluated with clinical and laboratory examinations. Doppler ultrasound (DUS) control of the vascular accesses and the visceral vessels was performed along with a CTA before discharge within 30 days from surgery, which represented the first follow-up time-point.

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

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

Statistical analysis

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

Results

A total of 21 patients (16 male, mean age 63±10 years) with pD-TAAA were enrolled in the study. Mean aortic diameter at time of indication for F/B-TEVAR was 61±6.2mm. Patients demographics are shown in Table 1. TBAD was the initial presenting disease in 11 (52.3%) cases, the rest presented originally with a type A aortic dissection and had underwent successful proximal aortic surgery. Two patients (9.5%) were affected by connective tissue disorders. Five patients (24%) presented a Crawford type I TAAA, 15 (71.3%) a Crawford type II and one patient (4.7%) Crawford type III TAAA. Endovascular treatment was needed after a mean of 47 months (3 – 120) from the disease onset. Previous TEVAR was already in place in 3 (14%) cases, while two patients (9.5%) presented FET with Thoraflex (Terumo Aortic, Sunrise). A staged approach was used in 12 cases (57%) with mean interval between the first and second procedure of 58 days.

Procedure details and technical success

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

Overall 84 visceral vessels were successfully targeted (20 coeliac trunks, 21 superior mesenteric arteries, 42 renal arteries, 1 accessory renal artery; one coeliac trunk was chronically occluded). Seventy-two (85.7%) vessels were targeted with fenestrations and 12 (14.3%) with downward branches. Seven target vessels (8%) originated from the FL: in 5 cases an endovascular fenestration was necessary to reach the target vessel, while in the remaining 2 cases a branch configuration close to a large tear of the lamella was used for the revascularization. Previous renal artery stent and celiac artery stent were present in three and two cases respectively (6% of target vessels; Fig. 1). Misalignment between fenestration and target vessel impeding visceral stent grafting did not occur. Data from each procedure are shown in Table 2.

Technical success was achieved in 18 patients (86%), with two cases of type Ic EL and one case of type IIIc EL left untreated [23]. One patient underwent early reintervention due to access complication (brachial pseudo-aneurysm). Two patients (9.5%) experienced post-procedural spinal cord ischemia, both resolved within one-month follow-up. At 30 days no type Ia or Ib EL were reported, but there were six type II EL (28.5%), two type Ic EL (9.5%) and one type IIIc EL (4.7%). Type Ic and IIIc EL were treated with visceral vessel stent-graft relining; a successful treatment was achieved in two patients, while a minimal residual type IIIc EL following the procedure was left untreated. Estimated freedom from reintervention at 12 and 24 months was 85.9 ± 7% (Fig. 2).

Follow-up and clinical success

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

Discussion

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

The encouraging results obtained with the use of endovascular repairs for TAAAs, have led to the evaluation of the feasibility of such treatment in pD-TAAAs, at least for high risk patients [7-8]. The presence of re-entry tear in the abdominal aorta reduces the possibilities of a complete FL thrombosis with simple TEVAR. For this reason, different techniques have been used to increase technical success: F/B-TEVAR, FL embolization with coils and plugs, the knickerbocker technique, the Petticoat technique and the STABILISE technique [30-33].

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

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

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

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

In the cases observed reintervention was required exclusively for visceral stents endoleak complications, while no occlusions were reported. This observation may be due to the fact that the visceral vessels were rarely atherosclerotic and the stent graft used were usually rather short due to the narrow gap between the aortic endograft and the target vessel.

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

The only residual type IIIc EL despite relining, occurred in our experience with the case of physician-modified endograft. Considering the lack of aneurysm sac growth and patient’s frailty it was decided to postpone eventual further treatment. The fenestrations have been designed too large to reduce the risk of misalignment and failure to cannulate, but insufficient flaring of the mating stent graft was then not able to cope with the gap between the aortic and the visceral components. The procedure was however successful in promote thrombosis of the FL in the thoracic portion of the fissured TAAA with survival of the patient.

False lumen thrombosis occurred in 86% of the present experience, a rate similar to others reported in literature, with aneurysm sac shrinkage in 62% of cases and no aortic-related deaths [10, 34-36]. This suggests that, although burdened by a higher risk of reintervention, F/B-TEVARmay obtain a stable seal of the aortic wall and the false lumen, representing a potentially valid solution for pD-TAAA. Relative motion of the visceral stent-grafts and the aortic component may be less pronounced in pD-TAAA if compared to atherosclerotic TAAA, perhaps reducing the long-term risks of secondary ELs. However a situation of particular risk may be the use of longer stents to reach vessels taking off from aneurysmal FL, unless the presence of a rigid lamella may sustain the stent in position.

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

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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FIGURES

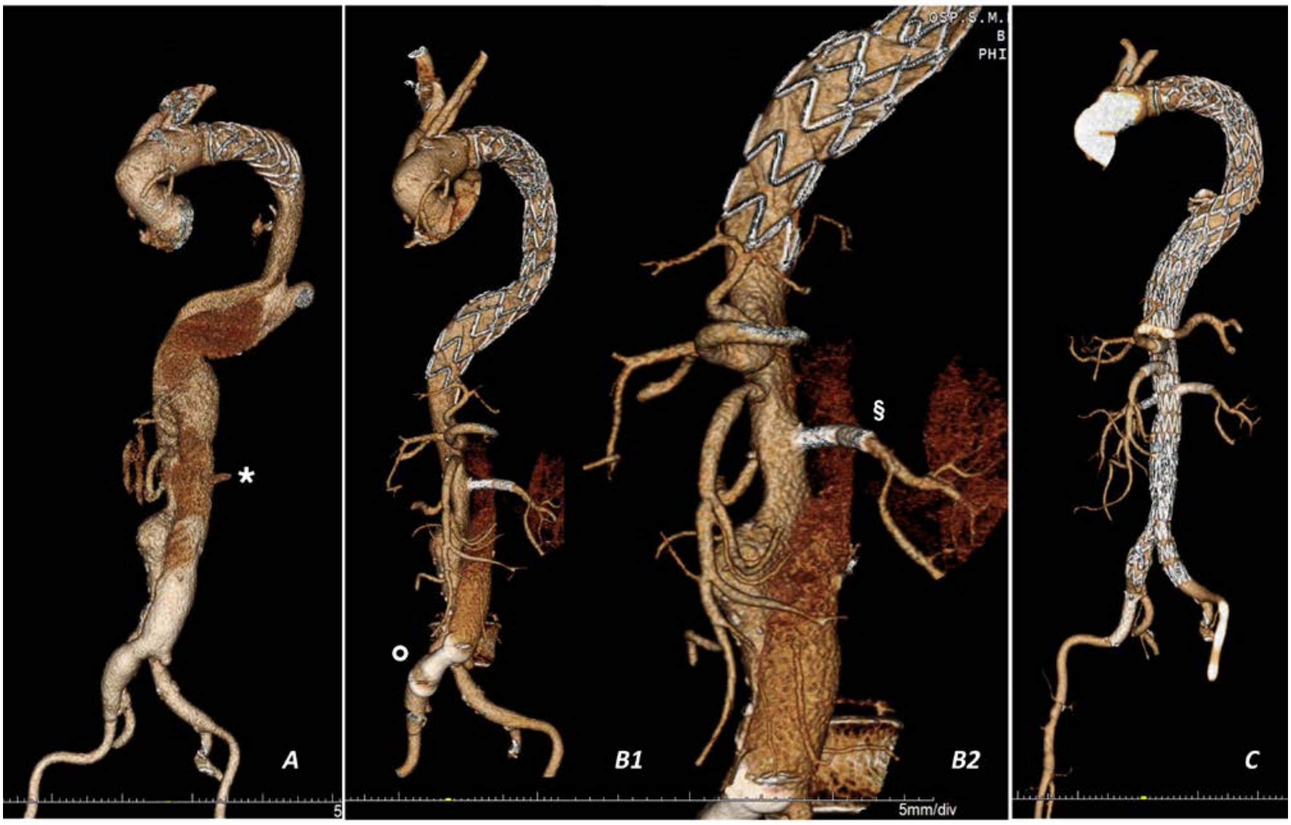

Fig. 1 Patient 17. Fig. 1.A: 3D-CT 3 years after Ascending + arch replacement with Frozen elephant trunk showing pD-TAAA with left renal artery originating from FL (*). Fig. 1.B: 3D-CT after first stage with TEVAR + Amplatzer plug in the false lumen of the right common iliac artery (°) + left renal stent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

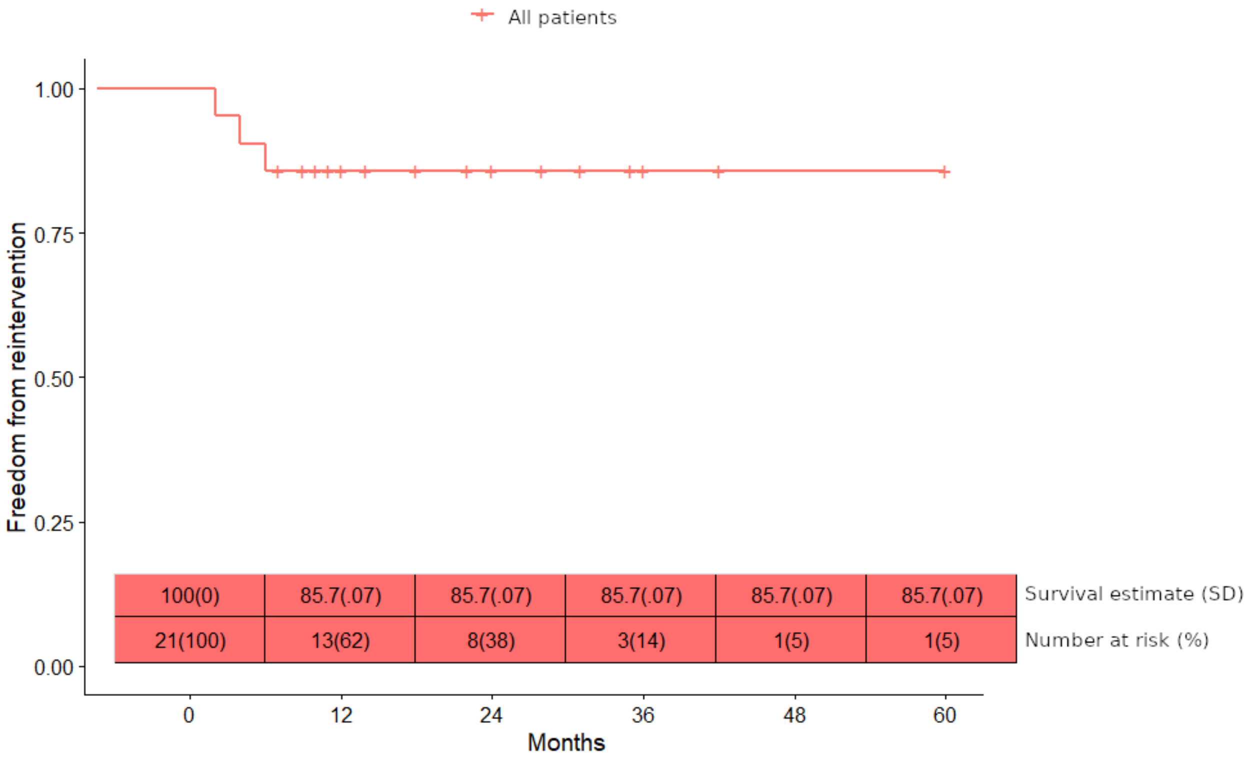

Fig. 2 Kaplan Meier freedom from reintervention curve

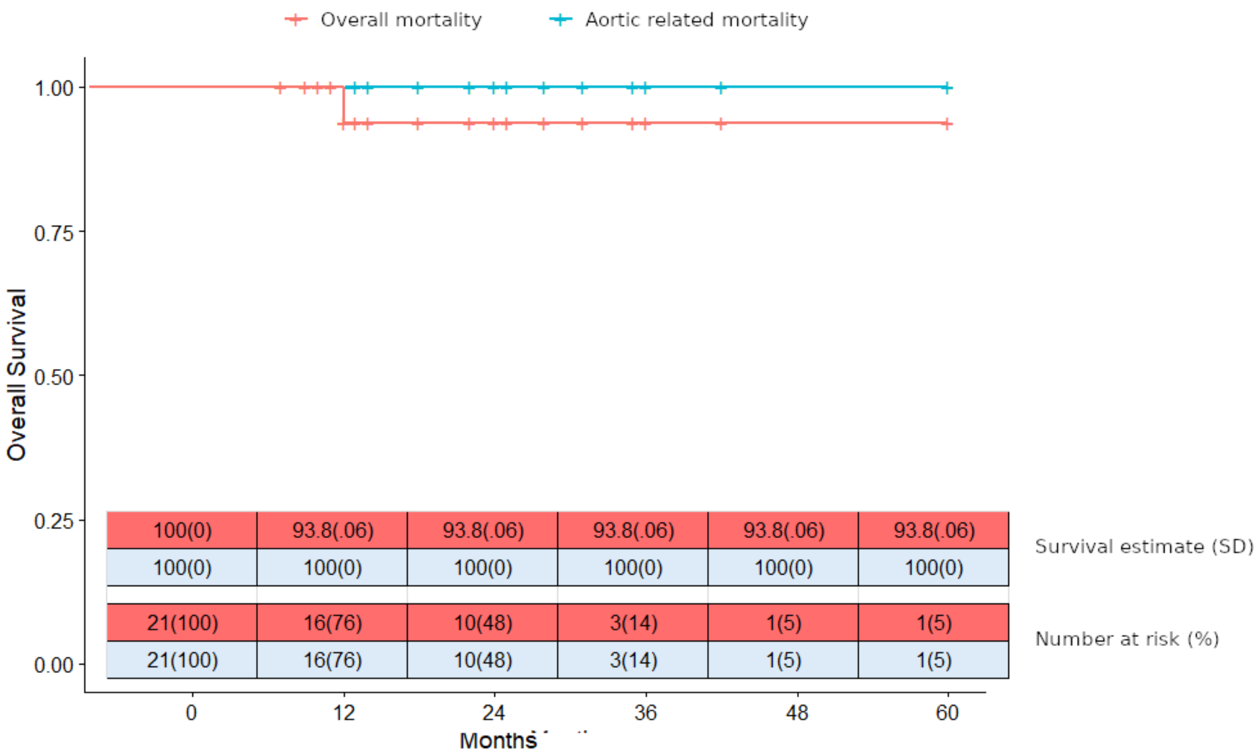

Fig 3 Kaplan Meier survival curves (blue line: aortic-related survival; red line: overall survival)

TABLES

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 connettive tissue disorders	2 (9.5%)
Original Type B aortic dissection	11 (52.3%)

*severe obesity evaluated as Body Mass Index >35

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

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.