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

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Abstract

Purpose
To report early and mid-term results of post-aortic dissection thoracoabdominal aneurysms (pD-TAAA) treated by complex endografting in three tertiary referral hospitals.

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
In total, 21 patients (16 males, mean age 63 ± 10 years) with pD-TAAA underwent aortic repair by fenestrated or branched thoracoabdominal endografts for visceral vessels. Mean TAAA diameter was 61 ± 6.2 mm. Spinal cord drainage was performed in all patients. A staged approach was used in 12 (57%) cases. Technical success was achieved in 18 (86%) patients. No in-hospital deaths occurred. Two patients experienced transient post-procedural spinal cord ischemia. At 30 days, six type II endoleaks (29%), two type Ic endoleak (9.5%) and one type IIIc endoleak (5%) 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 ± 0.7%. In 13 cases, TAAA diameter decreased at least 5 mm, while increased > 5 mm in only one case. Complete false lumen thrombosis was achieved in 18 patients (86%).

Conclusion
Complex endografting for pD-TAAA showed favorable mid-term results. Staged and carefully planned endovascular procedures may represent a safe and effective therapeutic option in patients deemed at high risk of open repair.

Keywords: Chronic dissection, Thoracoabdominal, Aortic aneurysm, TEVAR, Complex endografting, Fenestrated Aortic dissection.

Introduction

Uncomplicated type B aortic dissection (TBAD) at the time of diagnosis requires strict blood pressure control and radiological monitoring [1, 2]. Different studies, however, reported a 30-day mortality of 6–10% even with best medical treatment [3, 4]. Long-term survival is negatively affected by the disease, with only 50–70% of patients alive at five years [5,6,7]. 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 for 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 [9,10,11]. 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 aortic TL and the possible involvement of the iliac arteries in the dissection.

With this multicenter 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 and 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 thoracoabdominal endovascular aortic repair (F/B-TEVAR) in three tertiary care Italian centers between 2012 and 2018 was conducted. Inclusion criteria were: pD-TAAA with maximum aortic diameter > 60 mm, rapidly growing aneurysms (> 5 mm in 6 months) or symptomatic/ruptured TAAA. Surgical indication was discussed in a multidisciplinary team involving vascular and cardiac surgeons, anesthesiologists, 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.

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 incomplete FL thrombosis [12,13,14]. Secondary outcomes were: FL thrombosis, freedom from reintervention and TAAA diameter decrease > 5 mm.

A computed tomography angiography (CTA) was performed in all patients to define aortic diameters, to identify the origin of visceral vessels from the TL or FL, proximal and distal landing zones, entries and re-entries from TL to FL, and to evaluate integrity of the vascular accesses.

All patients 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 preoperative planning included a coverage of more than 10 cm of thoracic aorta, a staged procedure was performed: the first step aimed to exclude all proximal thoracic entry tears by TEVAR, followed by a second stage with the F/B-TEVAR, with a minimum delay of one month for elective procedures. For the initial intervention, proximal landing zone was planned just distal to supra-aortic trunks takeoff, either in the native non-dissected thoracic aorta, or inside a surgical or endovascular graft if present. Standard oversizing was 15–20%; minimum neck length of at least 25 mm for the native aorta and 40 mm when landing into a graft was planned. If a coverage of a supra-aortic trunk was needed to obtain a suitable neck, extra-anatomic revascularization with surgical cervical debranching was planned during the same hospitalization, anticipating proximal TEVAR to decrease the risk of neurological complications.[2, 15,16,17].

Preservation of hypogastric artery direct flow was attempted in all feasible cases during the F/B-TEVAR stage, again to reduce the risk of spinal cord ischemia (SCI).

Fenestrated endografts were preferred in case of narrow true lumen and when antegrade access for the eventual B-TEVAR was unfavorable, 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 [18].

A Cook F/B-TEVAR (Cook Medical, Brisbane Australia) was used in all cases, except for one patient with pD-TAAA contained rupture, for which a four-fenestration physician-modified Medtronic Navion (Medtronic Vascular, Santa Rosa, CA) endograft was required [19]. Off-the-shelf Zenith t-Branch thoracoabdominal stent graft (Cook Medical, Birsbane, Australia) was preferred to reduce

construction waiting times in patients with suitable anatomy, with a true lumen diameter of at least 25 mm at the level of visceral level and favorable antegrade access.
Branched grafts had always straight outer downward 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 single case depending on the vessel anatomy. Usually balloon expandable stent grafts were used for fenestrations (Advanta V12, Getinge, Goteborg, Sweden; BeGraft, Bentley, InnoMed, GmbH, Hechingen, Germany) and self-expanding stents were used for branches (Fluency, Bard, Tempe, AZ) [20]. Target vessels were engaged from a femoral access in case of fenestrations, while a brachial approach was preferentially 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 preexisting tear or through a neo-fenestration. All procedures were performed in hybrid operating room under general anesthesia.
Cerebrospinal fluid (CSF) drainage was placed in all cases during the F/B-TEVAR intervention and maintained for 48/72 h, with a target spinal cord pressure < 12 mmHg [21]. Other peri-operative monitoring included: clinical control in intensive care unit (ICU) for at least 48 h, strict arterial pressure control with a mean arterial pressure target > 85 mmHg, hemotransfusion when hemoglobin < 10 g/dl [22, 23].
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 experienced endovascular operator with more than 5-year experience in complex endografting in all cases.

Postoperative 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 and 12 months and yearly thereafter, in the absence of complications. Parameters evaluated at follow-up included, between all other clinical information, 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 if normally distributed; otherwise, median and range are used. Categorical variables are presented as percentage. Kaplan–Meier survival estimates were calculated to assess overall mortality, aortic-related mortality and freedom from reintervention. Curves are displayed as a solid line up to a value of standard error (SE) < 0.10; dotted lines refer to estimates with a SE ≥ 0.10. Statistical significance was set at $p < 0.05$. 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 males, mean age 63 ± 10 years) with pD-TAAA were included in the study. Mean aortic diameter at time of indication for F/B-TEVAR was 61 ± 6.2 mm. Patients' demographics are shown in Table 1. TBAD was the initial presenting disease in 11 (52%) 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%) a Crawford type II and one patient (5%) Crawford type III TAAA. Endovascular treatment of the pD-TAAA was needed after a median of 48 months (range 3–120) from the disease onset. Previous proximal TEVAR was already in place in 3 (14%) cases at presentation, while two patients (9.5%) presented FET with thoraflex graft (Terumo Aortic, Sunrise). A staged approach to pD-TAAA was used in 12 cases (57%) with median interval between the first and second procedures of 58 days (range 5–170).

Procedure Details and 30-day Results

Custom-made fenestrated and branched devices were used for 18 patients (86%) patients; 2 cases (9.5%) were treated with off the shelf Zenith t-branch thoracoabdominal stent graft; in one case (5%), due to urgent setting characterized by contained thoracic rupture after the first stage of TEVAR in a symptomatic patient, a physician-modified endograft was used. Four patients (19%) underwent a carotid–carotid–subclavian bypass, while in three cases a carotid–subclavian bypass (14%) was performed prior to proximal TEVAR as a first stage. Common iliac arteries were used as bilateral distal sealing zones in 17 patients, while distal abdominal aorta was used as landing zone in 2 patients. In 1 case (5%), one iliac limb endograft sealed in the external iliac artery with hypogastric occlusion; in the last case (5%) one IBD was used together with a contralateral hypogastric occlusion. 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 and not revascularized. Seventy-two (85.5%) vessels were targeted with fenestrations and 12 (14.5%) with downward branches. Seven target vessels (8%) originated from the FL: in 5 cases, an endovascular fenestration was necessary to reach the target vessel (Fig. 1), while in the remaining 2 cases a branch configuration close to an existing large tear of the lamella was used for the revascularization. Two visceral vessels (2.5%) were already stented at original presentation: one left renal artery and one celiac artery. Misalignment between fenestration and target vessel, impeding visceral stent grafting, never occurred. Data from each procedure are shown in Table 2.
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. At 30 days, no type Ia or Ib EL was reported, but there were six type II EL (29%), two type Ic EL (9.5%) and one type IIIc EL (5%). Technical success was achieved in 18 patients (86%), with two cases of type Ic EL and one case of type IIIc EL left untreated. Clinical success at 30 days was 62%.

Follow-Up

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. 2. No cerebral ischemic complications or visceral vessel loss were reported. In 13 cases (62%) TAAA diameter decreased at least 5 mm, with only one (5%) TAAA diameter increase. Three patients underwent aortic related re-intervention during follow up: 2 type Ic and 1 type IIIc EL were treated with visceral vessel stent graft relining; successful treatment was achieved in two patients, while a minimal residual type IIIc EL was left untreated in the last case. Estimated freedom from reintervention at 12 and 24 months was 85.7% ± 0.7% (Fig. 3). Complete FL thrombosis was obtained in 18 patients, reaching a clinical success rate 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. However, during chronic phase, these patients present high risk of aortic aneurysmal degeneration and rupture [24]. The estimated aortic growth after TBAD ranges from 1 to 7.1 mm/year as reported by Blount et al. [25].

Open repair of pD-TAAA has always been considered the gold standard despite not negligible mortality and morbidity rates [26,27,28]. Analyses of volume-related outcomes over a wide range of hospitals reveal the "real-world" picture, with an overall mortality reaching 22.3% and postoperative complication rate exceeding 55% [29].

The encouraging results obtained with the use of complex endovascular repairs for TAAAs have led to extend the indications for such treatment in pD-TAAAs, at least for high-risk patients [7, 8]. The presence of multiple re-entry tears in the abdominal aorta and in the visceral and iliac arteries reduces the possibilities of a complete FL thrombosis with simple TEVAR [30]. For this reason, different techniques have been used to enhance FL thrombosis: F/B-TEVAR, FL embolization with coils and plugs, the knickerbocker technique, the Petticoat and the STABILISE techniques [31,32,33,34].

Compared with other approaches, F/B-TEVAR is burdened by an increased complexity in planning due to the extreme variability in the origin of the visceral vessels from the TL or FL, their eventual dissection, the narrowness of the TL and the possible involvement of the iliac arteries.

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 [9,10,11, 35,36,37]. Early and mid-term outcomes of our study are similar to those present in the published 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 [9,10,11, 35,36,37]. 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 for atherosclerotic aneurysms.

In the present study, two cases of transient SCI were reported (9.5%), which is in average with the data reported in the literature, with a range 0–15% [9, 10, 35,36,37]. This evidence seems to support the hypothesis of 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, 32].

In our cases, reintervention during follow up was required exclusively for visceral stent 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 was 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 stents in order to avoid a visceral dissection when dealing with the extremely fragile arterial 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 lesson learnt was that fenestrations had been designed too large with the aim of reducing 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 promoting thrombosis of the FL in the thoracic portion of the fissured TAAA with successful patient survival.

False lumen thrombosis occurred in 86% of patients in the present experience, a rate similar to others reported in the literature, with aneurysm sac shrinkage in 62% of cases and no aortic-related deaths [10, 35,36,37]. This suggests that, although burdened by a higher risk of reintervention, F/B-TEVAR may obtain a stable seal of the aortic 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 should be underlined: the experience suffers from a small number of treated patients, low event rates and short follow-up. The multi-center nature of the study may have introduced biases regarding different patients and material selection, although most of the operators shared common training in the same University Center of Perugia.

Conclusion

F/B-TEVAR for pD-TAAA is a feasible therapeutic solution with favorable mid-term results when performed in centers with experience in complex endografting. Staged procedures and careful planning of adjuvant techniques are crucial for success of these endovascular repairs in patients often deemed at high open surgical risk. Results of larger multi-center experiences with longer follow-up are eagerly awaited for definitive answers regarding the role of endovascular treatment compared to open surgery in post-dissection thoracoabdominal aneurysms.

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Table 1. Patients' demographics and risk factors

Comorbidities and risk factors	N (%)
Age	63 ± 10 years
Male gender	16 (76%)
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[a]	1 (5%)
Marfan or connective tissue disorders	2 (9.5%)
Original Type B aortic dissection	11 52%) 12

[a]Severe obesity evaluated as body mass index > 35

Table 2. Dissection characteristics, details of the procedures and outcomes

Patient	Sex	Age	Crawford TAAA 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

Patient	Sex	Age	Crawford TAAA 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
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 stent graft	Y	Y	N	N
6	M	72	II	55	N	Car-car-subcl TEVAR	CM 4 fen	R-IBD L-IIA occlusion	Y	Y	N	N
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 stent graft	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	t-branch	N	Y	N	Type Ic EL	N

Patient	Sex	Age	Crawford TAAA 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
						TEVAR					(6 months)	
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 Ic 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 stent graft; Iliac FL plug; EIA stent graft	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 + C	TEVAR	Physician-modifie	CA stent graft	Y	N	Type IIIc EL	N

Patient	Sex	Age	Crawford TAAA 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
					ABG LRA stent graft		d endograft				(4 months)	

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

Fig.1. Patient 17. **A** 3D-CT 3 years after ascending + arch replacement with frozen elephant trunk showing pD-TAAA with left renal artery originating from FL (*). **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 (§). **C** 3D-CT after custom-made four-fenestration thoracoabdominal endograft and external iliac artery stent graft with the resulting complete FL thrombosis

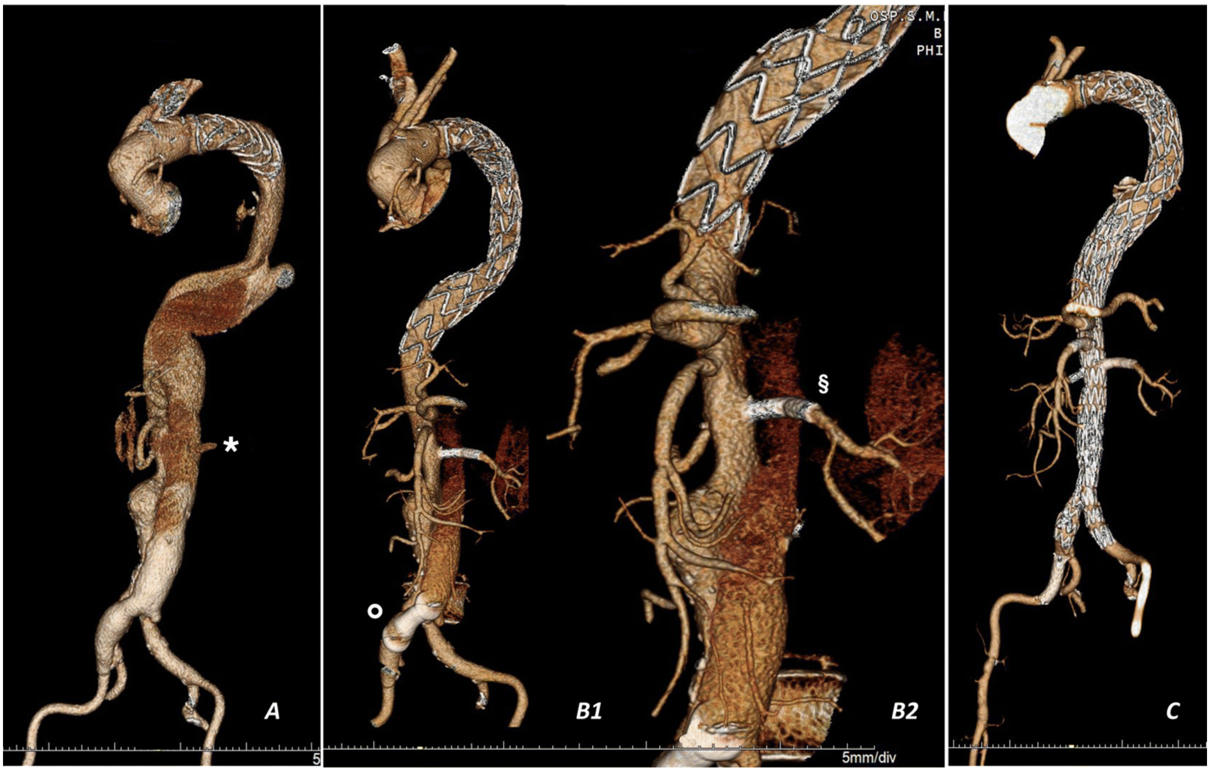

Fig.2. Kaplan–Meier survival curves (blue line: aortic-related survival; red line: overall survival)

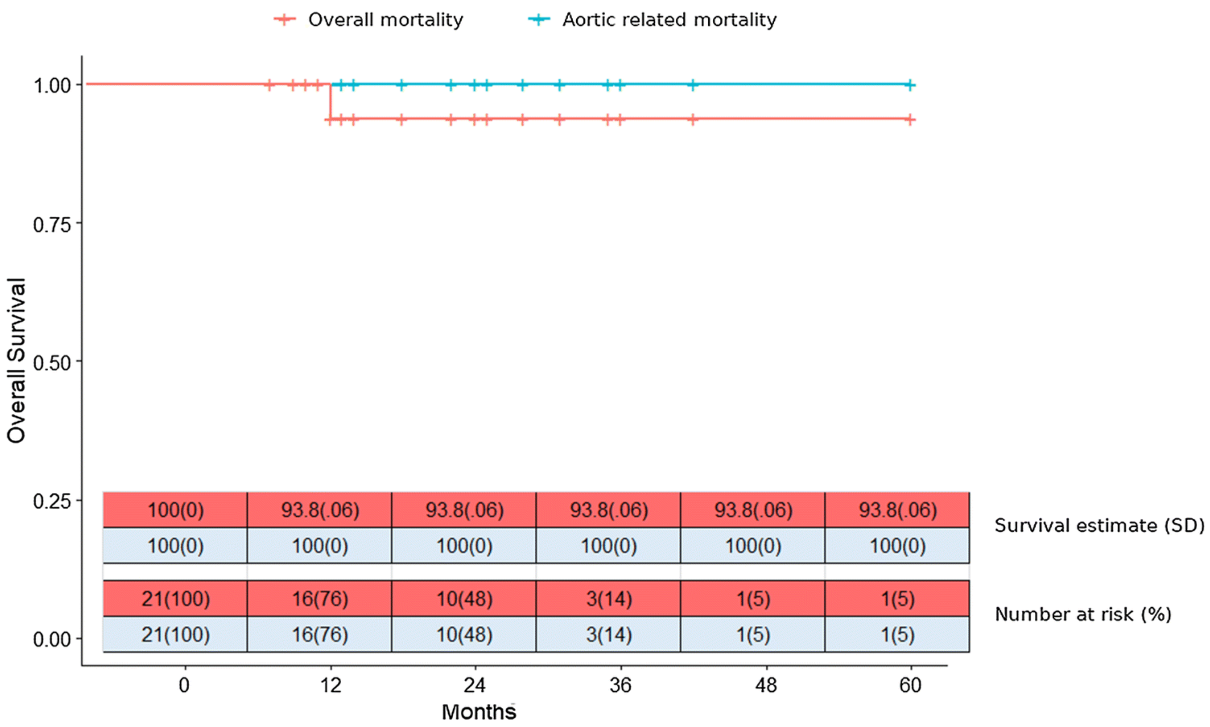

Fig.3. Kaplan–Meier freedom from reintervention curve