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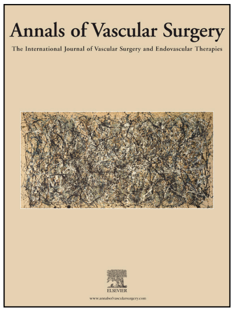

LONG-TERM OUTCOMES AND RISK FACTORS ANALYSIS FOR PATIENTS UNDERGOING THORACIC ENDOVASCULAR AORTA REPAIR (TEVAR), ACCORDING TO THE AORTIC PATHOLOGIES

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LONG-TERM OUTCOMES AND RISK FACTORS ANALYSIS FOR PATIENTS UNDERGOING THORACIC ENDOVASCULAR AORTA REPAIR (TEVAR), ACCORDING TO THE AORTIC PATHOLOGIES

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KEYWORDS: Thoracic endovascular aorta repair; Endoprosthesis; Aortic pathology; Aortic dissection.

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ABSTRACT

Objective: Thoracic endovascular aortic repair (TEVAR) has become a standard treatment for acute and chronic thoracic aorta diseases. We analysed long-term outcomes and risk factors of TEVAR procedures according to the aortic pathology.

Methods: Demographics, indications, technical details, and outcomes of patients undergoing TEVAR procedures in our institutions were prospectively collected and retrospectively analyzed. Overall survival was determined using Kaplan-Meier methods while Log-rank tests were used to compare the survival between groups. Cox regression analysis was used to identify risk factors.

Results: Between June 2002 and April 2020, 116 patients underwent TEVAR for different thoracic aorta diseases. Among them, 47 patients (41%) underwent TEVAR for aneurysmatic aortic disease, 26 (22%) for type-B aortic dissection, 23 (20%) for penetrating aortic ulcer, 11 (9%) after previous type-A dissection treatment and 9 (8%) for traumatic aortic injury. Patients with post-traumatic aortic injury were younger ($p<0.01$), with less hypertension ($p<0.01$), diabetes ($p<0.01$) and prior cardiac surgery ($p<0.01$). Survival was different based on indication for TEVAR (log rank 0.024). Patients after previous type-A dissection treatment had the worst survival rate (50% at 5 years) while survival for aneurysmatic aortic disease was 55% at 5 years. No late death occurred in the traumatic group. Cox-regression model identified independent predictors for mortality: age (HR 1.05, 95% CI 1.01-1.09, p= 0.006), male gender (HR 3.2, 95% CI 1.1-9.2, p=0.028), moderate COPD (HR 2.1, 95% CI 1.02-4.55, p=0.043), previous cardiac surgery (HR 2.1, 95% CI 1.008-4.5, p=0.048), and treatment indication for aneurysm (HR 2.6, 95% CI 1.2-5.2, p=0.008).

Conclusions: TEVAR is a safe and effective procedure with excellent long-term results in case of traumatic aortic injury. The overall long-term survival is affected by aortic pathology, associated comorbidities, gender and previous cardiac surgery.

INTRODUCTION

Thoracic endovascular aortic repair (TEVAR) represents an alternative technique to conventional surgery for patients suffering from thoracic aorta diseases. The continuous evolution of TEVAR techniques increases its use to a wider spectrum of complex aortic pathologies including acute syndromes and traumatic injuries. Endovascular results are encouraging and characterized by lower mortality and shorter hospital stay when compared to the open treatment (1-3). However, the descending thoracic aorta can be affected by a variety of different pathologies, and therefore it is important to determine how a specific disease can affect the outcome after TEVAR. Furthermore, it is important to study the different outcomes following TEVAR in order to be able to deal with possible complications or need for re-intervention, which could be related to specific disorders varying from individual anatomical features to different aetiologies (4). Therefore, a comparison between subgroups-related outcomes can help in determining whether the results after TEVAR are procedure-related or aetiology-linked, and what is the real benefit of these procedures (5). Moreover, TEVAR is successful in patients at high-risk for surgery but it is questionable if results are related to the underlying pathology. This could allow the recognition of subgroups of patient with aortic disorders that can benefit the most from such treatment. The purpose of this study was to evaluate the long-term outcomes and to identify the risk factors of patients undergoing TEVAR for different aortic pathologies.

METHODS

1.0 Study design

This is a single centre retrospective observational study. The institutional cardiac surgery database developed for quality control purposes was queried to identify patients undergoing

TEVAR between June 2002 and April 2020. Patients were divided into 5 subgroups according to the presenting pathology: thoracic aorta aneurysm, type-B dissection, penetrating aortic ulcer (PAU), previous type-A dissection treatment and traumatic aortic injury. Other less frequent pathologies such as transections, mycotic aneurysms, and septic aneurisms were not available in our experience. Data about preoperative (age, gender, smoking, hypertension, diabetes, hypercholesterolemia, COPD, BMI, BSA, creatinine, LVEF, atrial fibrillation, peripheral vascular disease, prior PCI/stent, prior cardiac surgery), intraoperative(procedure type, concomitant procedures, endoleak), and postoperative characteristics (reoperation) were prospectively collected and retrospectively analysed. All 116 patients were followed at our dedicated aortic office during the study time. To what may concern the follow-up, in our clinic all patients with aortic disease are followed-up by clinical examinations and serial Computed-Tomography (CT) scans, at 1 month, 6 months, and yearly thereafter. This study was conducted using an anonymized database and, given the retrospective nature of the work and quality control purposes, the ethical committee approval was waived. Outcome criteria were defined according to the Reporting Standards for Thoracic Endovascular Aortic Repair (6). All patients signed the informed consent for the endovascular procedure and for the use of anonymized clinical data for research and quality control purposes. All methods were conducted in accordance with the relevant guidelines and regulations (Declaration of Helsinki).

2.0 Operative technique

All operations were performed in a hybrid operating room, under general anaesthesia and without routine pre-operative placement of a cerebrospinal fluid (CSF) drain. The femoral artery was surgically exposed and used as first choice vascular access via direct arteriotomy or prosthetic conduit. The second choice for the vascular access was the iliac artery or the axillary artery. A pigtail catheter was routinely inserted in the contralateral groin in order to perform angiographies during the procedure. Before TEVAR deployment, a bolus of 5000 IU of heparin was administrated in order to achieve an activated clotting time above 200 seconds. Left subclavian artery revascularization by left carotid-subclavian bypass or by in-situ laser fenestration using a radial or a brachial access was only performed if the vessel's origin was covered by the endoprothesis. Cardiac rapid pacing by mean of a temporary wire in the jugular vein was used during the stent-graft deployment in the arch. Protamine was administrated at the end of the procedure. Additional vascular procedures were performed according to the patients' medical history. Patients were extubated in the hybrid room to evaluate the neurologic status. Spinal drain insertion was considered at this time point if neurologic symptoms occurred.

3.0 Statistical analysis

Continuous variables are presented as mean ± standard deviation, while categorical or ordinal variables are presented as number and percentage. Statistical analysis comparing the groups was performed using the ANOVA test for continuous variables, and the chi-square test for categorical variables. Long-term survival was obtained with Kaplan-Meier analysis and statistical significance between groups was calculated using the log-rank test. Cox-regression model was used to identify independent risk factors associated with long-term mortality. Odds ratios (OR) and 95% confidence intervals (CI) were derived from the model. Covariates were determined by investigators and were either known to be competing causes of the outcome of interest or were significantly different among baseline characteristics. All statistical analyses were performed using SPSS 21.0 (SPSS, Inc, Chicago, IL, USA) at 95% confidence interval level ($p<0.05$).**RESULTS**

Demographics

In total, 116 patients were included in this analysis. The pathology type and demographics details are shown in Table 1. A total of 47 (41%) patients underwent TEVAR for chronic aneurismatic aortic disease, 26 (22%) for complicated type-B aortic dissection, 23 (20%) for penetrating aortic ulcer, 11 (9%) after previous type-A dissection treatment and 9 (8%) for traumatic aortic injury. Compared to the other groups, patient with post-traumatic aortic injury were younger ($p<0.01$), with less systemic hypertension ($p<0.01$), less diabetes ($p<0.01$) and less history of previous cardiac surgery ($p<0.01$). No differences between groups were observed for gender ($p=0.66$), smoke habit ($p=0.28$), hypercholesterolemia ($p=0.19$), moderate chronic obstructive pulmonary disease (COPD) ($p=0.077$), BMI ($p=0.61$), BSA ($p=0.23$), serum creatinine level ($p=0.23$), left ventricular ejection fraction ($p=0.178$), atrial fibrillation ($p=0.56$), peripheral vascular disease ($p=0.05$), and prior coronary angioplasty and stenting ($p=0.077$).

Intraoperative characteristics and adverse events

In the aneurism group 39/47 (82%) patients had an isolated endoprosthesis, 4/47 (8.5%) underwent TEVAR associated with a carotid-subclavian bypass, 2/47 (4.2%) had a TEVAR with subclavian fenestration, and 2/47 (4.2%) had a double-branched TEVAR. In the type-B dissection group, 22/26 (84%) patients were treated with isolated endoprosthesis, 2/26 (7.6%) with TEVAR associated with a carotid-subclavian bypass, and 2/26 (7.6%) patients had a TEVAR associated with a subclavian fenestration. In the PAU group, 18/23 (78%) patients underwent isolated endoprosthesis, 3/23 (13%) were treated with a TEVAR associated with a carotid-subclavian bypass, and 2/23 (9%) patients had a TEVAR with concomitant subclavian fenestration. In the group of patients treated after previous type-A dissection, all patients (11/11) had an isolated endoprosthesis in the descending aorta. In the post-traumatic group, 8/9 (88%) patients had an isolated endoprosthesis and 1/9 (11%) underwent TEVAR with left carotid-subclavian bypass. Urgent cases were significantly higher in this group (p=0.032). No difference between groups was observed for the operation type (p=0.849).

Different TEVAR devices were implanted during study time: 74 (63.7%) patients received Medtronic Valiant Captivia. 7 (6%) patients received Medtronic Talent, 25 (21%) patients received Bolton Relay, 1 (0.8%) patient received Optimed Sinus XL, 2 (1.7%) patients received Bolton double branched. 6 (5%) patients received Medtronic Valiant Navios and 1 (0.8%) patient received Bolton custom made prosthesis.

Concerning the hospital mortality, no difference was detected between groups (p=0.372) but a higher mortality rate was reported in the aneurysmatic group (3/47, 6.3%). In this group, causes of death were bowel infarction (n=1), stroke (n=1), and paraplegia (n=1) complicated by mechanical ventilation and septic shock. In the other groups, bowel infarction, stroke and paraplegia were not reported. There was no difference in the overall number of concomitant procedures (p=0.307) nor in the rate of endoleak (p=0.061).

Long-term mortality and risk-factor analysis for survival

During the follow-up (median time: 116 months), 24/116 (20%) patients required a reintervention: 15/116 (12%) for endoleak, 5 (4.3%) for aneurism progression on abdominal aorta, 1/116 (0.8%) for iliac stenting, 1/116 (0.8%) for aortic fenestration, 1/116 (0.8%) for an aorto-oesophageal fistula and 1/116 (0.8%) for aortic rupture. No difference in reintervention rate was observed between different aortic pathologies (p=0.061) (Table 3).

At 1, 3, and 5 years, the estimated survival rates were 87%, 68% and 55%, respectively, for the aneurysm group; 92%, 92%, and 83%, respectively, for the type-B dissection group; 96%, 83%, and 83%, respectively, for the PAU group; 98%, 50%, and 50%, respectively, for the type-A aortic dissection group. No late death occurred in the post-traumatic group. Kaplan-Meier estimates curves of survival are shown in Figure 1. The log-rank test showed a significant difference between estimated survivals (p=0.024). The Cox-regression model identified some independent predictors for mortality: age at time of surgery (HR 1.05, 95% CI 1.01-1.09, p= 0.006), male gender (HR 3.2, 95% CI 1.1-9.2, p=0.028), moderate COPD (HR 2.1, 95% CI 1.02-4.55, p=0.043), previous cardiac surgery (HR 2.1, 95% CI 1.008-4.5, p=0.048), and treatment indication for aneurysm (HR 2.6, 95% CI 1.2-5.2, p=0.008) (Table 4).

DISCUSSION

TEVAR is a less invasive alternative to open surgery for the repair of several thoracic aortic pathologies resulting in lower complication rate, shorter recovery time, shorter hospital stay, and, potentially, improved survival [1-3]. This single-centre retrospective study analysed early and midterm outcomes after TEVAR, as well as the predictors for midterm mortality. In our cohort, the indications for TEVAR included aneurysmatic disease, complicated type-B dissection, penetrating aortic ulcer, type-A dissection and traumatic injury. Patients with post-traumatic aortic injury presented less risk factors and less previously performed cardiac surgery procedures compared to the others groups.

The analysis of the early outcomes showed no significant difference in mortality between the different aortic pathologies with a higher mortality rate in the aneurism group (3/47, 6.3%) due to bowel infarction, stroke and septic shock. Patients with an aneurysmatic aortic disease were older and presented with significant comorbidities, which can cause a higher non–aortic-related mortality rate after TEVAR (7). The early mortality rate for the aneurysmatic aortic disease group reported in the present study (3/47, 6.3%) was similar to data described in published large series (6.5%-9.8%) (8, 9). Similarly, no difference in postoperative endoleak rate was observed between different aortic pathology groups (p=0.061) and 12% of patients (15/116) required reintervention for endoleak (predominantly for type-1 endoleaks).

In our studied population, risk factors for long-term mortality after TEVAR at Cox regression modelling were age, male gender, moderate COPD, previous cardiac surgery and treatment indication for aneurysm. Khoynezhad et al, prospectively collected data from 153 patients and the independent risk factors for late mortality after TEVAR were COPD, postoperative myocardial infarction, and acute kidney failure (9). Chung et al, identify as independent risk factors to predict late mortality the preoperative leukocytosis, the aneurysm diameter, and concurrent debranching (10). Different studies reported different risk factors, so it can be hypothesized that risk-factors reflect the different studied populations.

In our long-term results, patients with thoracic aortic aneurysm, had a survival rates at 1, 3, and 5 years respectively of, 87%; 68% and 55%. Our result reflects the midterm survival on larger population after thoracic endovascular aortic repair in more than 10,000 Medicare patients. Schaffer et al, reported that isolated thoracic aortic aneurysm was associated with the lowest early incidence of death, but were affected by a comparatively higher incidence of late death [11]. Conversely Dufour et al showed that aortic aneurysms were the most complicated and were affected by highest mortality rates probably due to the evolution of the atherosclerotic disease [12]. In the Regis-TEVAR Study, the survival at 4 year for aneurysm pathology treated with TEVAR was 65±5% [13].

In our study, the estimated survival rates for the type-A dissection were 98%, 50%, and 50% at 1, 3, and 5 years, respectively. Recently, the use of a stent-assisted balloon-induced intimal disruption and relamination of aortic dissection technique treated for a residual dissection of the descending thoracic aorta after type-A dissection has shown an immediate remodelling of the thoraco-abdominal aorta, which should improve their long-term outcomes in terms of aortic-related events [14].

The survival for the type-B dissection group was 92%, 92%, and 83%, while for the PAU group it was 96%, 83%, and 83%, respectively. Moreover, TEVAR for acute complicated type-B aortic dissection has proved to be safe and promoted the remodeling of the stented thoracic aorta [15]. Jàanosi et al reported a series of 63 PAU treated with TEVAR. The in-hospital mortality was 7.9% and a multivariate analysis model indicated that a PAU depth >15mm was an independent predictor of mortality (hazard ratio 6.92, p=0.03) [16].

Patients treated with TEVAR for blunt thoracic trauma have a 100% short and long-term survival in our cohort of patients. This group also represents the youngest group with less comorbidities. Dufour et al, similarly show that patients with traumatic aortic injuries had the best long-term outcomes [12]. The present study has some limitations. This is a retrospective study with limited follow-up time. Moreover, this study includes 116 patients only, with small subgroup populations. This small group size makes difficulties in generalizing our findings, particularly when dissections, aortic ulcers and pseudo-aneurysm groups are concerned.

In conclusion, TEVAR is a safe and effective procedure with excellent long-term results for the treatment of the traumatic aortic injuries. However, when other aortic diseases treated by TEVAR are concerned, the overall long-term survival seems to be affected by aortic pathology, associated comorbidities, gender and previous cardiac surgery.

AUTHOR CONTRIBUTIONS

Michele Gallo: data curation, writing, analysis

Jos C. van den Berg: reviewing, supervision

Tiziano Torre: data curation, writing, editing

Manuela Riggi: data collection, writing

Stefanos Demertzis: study design, supervision

Enrico Ferrari: Writing, Reviewing and Study Design, supervision

CONFLICTING INTEREST

The authors declare no conflict of interest related to this article.

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DATA AVAILABILITY STATEMENT

The dataset generated and analysed during the current study is available from the corresponding author upon reasonable request.

FIGURE

Figure 1. Long-term survival after TEVAR stratified by aortic pathology**.**

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Table 1. Demographic characteristics after TEVAR stratified by aortic pathology.

	Aneurysm (n=47)	**Type-B (n=26)**	**Ulcer (n=23)**	**Type-A (n=11)**	**Traumatic (n=9)**	**p-value**
Age, mean ± SD, y	74.4±7.8	68±11	75.1±6.8	65.5±8.6	51.2±18	**<0.01**
Female, n (%)	9 (19%)	7 (27%)	8 (34%)	2 (18%)	2 (22%)	0.663
Smoking, n (%)	28 (59%)	10 (38%)	13 (56%)	7 (63%)	3 (33%)	0.281
Hypertension, n (%)	41 (87%)	25 (96%)	23 (100%)	11 (100%)	3 (33%)	**<0.01**
Diabetes, n (%)	10 (21%)	3 (11%)	12 (52%)	1 (9%)	1 (11%)	**0.005**
Hypercholesterolemia, n (%)	37 (78%)	16 (61%)	20 (86%)	5 (45%)	4 (44%)	0.190
Lung disease ≥ moderate, n (%)	9 (19%)	2 (7%)	8 (34%)	3 (27%)	0	0.077
BMI kg/m2, mean ± SD	25.2±4	26.5±5	25.6±4	26±4	28.9±9	0.616
BSA m2, mean ± SD	1.80±0.22	1.89±0.20	1.84±0.23	1.94±0.22	1.99±0.28	0.232
Serum creatinine, mean ± SD	122.53±88	125.32±143	80.17±22	92.8±25	93.67±20.4	0.231
LVEF, %, mean ± SD	53.6±10	58.2±8.9	54.4±14	49.8±9.8	61.4±6.3	0.300
Atrial fibrillation, n (%)	3 (6%)	1 (3%)	3 (13%)	1 (9%)	-	0.567
Peripheral vascular disease, n (%)	11 (23%)	14 (53%)	5 (21%)	4 (36%)	4 (44%)	0.053
Prior PCI-stent, n (%)	6 (12%)	4 (15%)	9 (39%)	-	-	0.077
Previous cardiac surgery, n (%)	12 (25%)	2 (7%)	5 (21%)	11 (100%)	-	**<0.01**

Table 2. Intraoperative characteristics and adverse events after TEVAR stratified by aortic pathology.

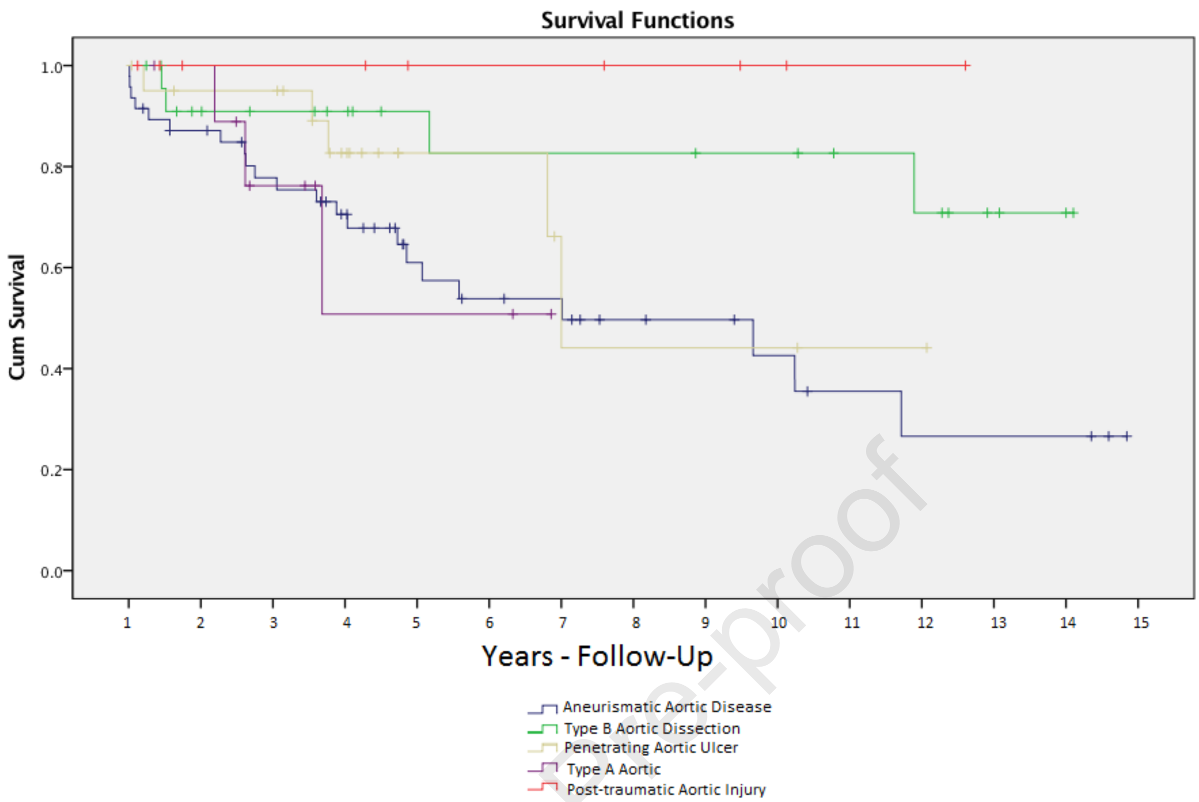
	Aneurysm (n=47)	Type-B (n=26)	Ulcer (n=23)	Type-A (n=11)	Traumatic (n=9)	p-value
Procedures						
Isolated endoprothesis	39 (82%)	22 (84%)	18 (78%)	11 (100%)	8 (88%)	0.849
TEVAR + Carotid-subclavian bypass	4 (8.5%)	2 (7.6%)	3 (13%)	0	1 (11%)	
TEVAR + Subclavian fenestration	2 (4.2%)	2 (7.6%)	2 (9%)	0	0	
Double branched TEVAR	2 (4.2%)	0	0	0	0	
Urgent case	2 (4.2%)	5 (19%)	1 (4.3%)	0	6 (66%)	0.032
30 days Mortality	3 (6.3%)	0	0	0	0	0.372
Concomitant Procedures						
Visceral artery stenting	0	1 (3.8%)	0	1 (9%)	0	0.307
Coronary PCI/Stenting	1 (2.1%)	0	0	0	0	
Iliac-femoral bypass	0	2 (7.6%)	0	0	0	
Aortic celiac bypass	1 (2.1%)	1 (3.8%)	0	0	0	
Endoleak						
I-A	2 (4.2%)	1 (3.8%)	0	1 (9%)	0	0.065
I-B	3 (6.3%)	2 (7.6%)	0	2 (18%)	1 (11%)	
I-A + I-B	0	1 (3.8%)	1 (4.3%)	0	0	
III	0	0	0	1 (9%)	0	

Table 3. Indication for reoperation after TEVAR during the follow-up.

	Aneurysm (n=47)	**Type-B (n=26)**	**Ulcer (n=23)**	**Type-A (n=11)**	**Traumatic (n=9)**	**p-value**
Endoleak	5	4	1	4	1	0.061
Abdominal aortic aneurism	2	3	0	0	0	
Iliac stenting	1	0	0	0	0	
Aortic fenestration	0	0	0	1	0	
Aorto-oesophageal fistula	1	0	0	0	0	
Aortic rupture	1	0	0	0	0	

Table 4. Independent predictors for long-term mortality after TEVAR

	Hazard Ratio (95% CI)	**p-value**
Age	1.05 (1.01-1.09)	0.006
Male gender	3.2 (1.1-9.2)	0.028
Smoking	1.9 (0.9-4.1)	0.061
Hypertension	1.2 (0.3-4.1)	0.699
Dyslipidaemia	1.7 (0.78-3.8)	0.173
Diabetes	1.3 (0.58-3.15)	0.471
COPD moderate	2.1 (1.02-4.55)	0.043
Chronic kidney failure	1.9 (0.9-4.1)	0.075
Peripheral vascular disease	0.47 (0.15-1.4)	0.200
Previous cardiac surgery	2.1 (1.008-4.5)	0.048
Preoperative ejection fraction	0.9 (0.94-1.004)	0.086
Endoleak	1.31 (0.5-3.1)	0.549
Indication for traumatic	0.043(0-7.9)	0.230
Indications for Type-A dissection	1.6 (0.4-5.3)	0.430
Indications for Type-B dissection	0.34 (0.12-1.006)	0.051
Indications for PAU	0.83 (0.31-2.1)	0.700
Indications for aneurysm	2.6 (1.2-5.2)	0.008


Survival Functions
Cum Survival
1.0
0.8
0.6
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11
12
13
14
15
Years - Follow-Up
Aneurismatic Aortic Disease
Type B Aortic Dissection
Penetrating Aortic Ulcer
Type A Aortic
Post-traumatic Aortic Injury