Technical eligibility for endovascular treatment of the aortic arch after open type A aortic dissection repair

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Glossary of Abbreviations

AAD: Stanford type A aortic dissection

AI: Aortic insufficiency

AIBS: Arch inner-branched stent

BMI: Body mass index

CABG: Coronary artery bypass graft

CI: Confidence interval

COPD: Chronic obstructive pulmonary disease

CT: Computed tomography

CTD: Connective tissue disease

IA: Innominate artery

IMH: Intramural hematoma

LCC: Left common carotid

LSA: Left subclavian artery

RCC: Right common carotid

TEVAR: Thoracic endovascular aortic repair

Central Picture/Graphical Abstract

Legend: Majority of post aortic dissections are eligible for endovascular arch repair.

Central Message

The majority of post type A aortic dissection patients are technically eligible for an endovascular arch-branched stent graft.

Perspective Statement

Optimal surgery of type A aortic dissections must consider immediate survival, extent of repair, and the risk for future reoperation. A substantial proportion of patients surviving the initial repair require reintervention. Given the increased risks of a reoperation, greater awareness of the criteria and potential eligibility for endovascular treatment of post-dissection aneurysm is needed.

Abstract

Objective: To report on the technical eligibility of patients previously treated for Stanford type A aorta dissection (AAD) for endovascular aortic arch repair based on contemporary anatomical criteria for an arch inner-branched stentgraft (AIBS).

Methods: All patients treated for AAD from 2004-2015 at a single aortic centre were identified. Extent of repair and use of circulatory arrest were reported. Survival and reoperation were assessed using Kaplan Meier and competing risk models. Anatomic assessment was performed using 3-dimensional CT-imaging software. Primary outcome was survival ≥ 1 year and fulfilment of the AIBS anatomical criteria.

Results: A total of 198 patients were included (158 Debakey I, 32 Debakey II, and 8 Intramural hematoma). Mortality was 30-days: 16.2%, 1-year: 19.2%, 10-years: 45.0%. There were 129 patients with imaging beyond 1 year (mean, 47.8 months), while 89 (69.0%) were AIBS eligible. During follow-up, 19 (14.7%) patients met the threshold criteria for aortic arch treatment, of which 14 (73.7%) would be considered eligible for AIBS. Patients who underwent AAD repair with circulatory arrest and no distal clamp were more often eligible for endovascular repair (88.8%) than those operated with a distal clamp (72.5%), p=0.021. Among patients who did not meet the AIBS anatomical criteria, the primary reasons were mechanical valve (40%) and insufficient proximal seal (30%).

Conclusion: More than two thirds of post AAD patients repair are technically eligible for endovascular AIBS repair. Development of devices that can accommodate a mechanical aortic valve and a greater awareness of sufficient graft length would significantly increase availability.

Introduction

Open surgical repair is the gold standard in the treatment of type A aortic dissections. For those patients successfully treated, approximately 10-15% will require reintervention within the next five years, including repair of the arch and descending thoracic aorta due to aneurysmal degeneration of the chronically dissected aorta.[1–4] There is still some debate regarding the optimal initial surgical technique, balancing more extensive aortic arch surgery with its inherent risks against a potential reduction of distal dilatation and need for reoperation.[5,6]

Endovascular treatment of complex aortic arch and descending aortic pathologies has rapidly evolved, however, and the landscape of how post-proximal aortic surgery reoperations can be treated has changed. Verscheure et al recently reported a technical success of 94.3% for the total endovascular treatment of chronic arch dissections among 70 patients from 13 international centres of expertise.[7] For endovascular arch repair to be possible, the anatomy of the ascending aorta and the arch must be technically suitable for an endovascular approach, and Milne et al have reported that 71.2% of these types of patients were eligible for a subsequent arch inner-branched stent graft (AIBS) after a median follow-up of 6 months.[8] Notably, however, more than 90% of their patient cohort did not meet the conventional treatment threshold diameter of 55 mm.

The objective of the present analysis is to update the current data of eligibility for an endovascular AIBS with a larger patient cohort and longer follow-up, as well as to identify factors that play a role in this process.

Materials and methods

Patients

Prospectively registered data from all patients admitted and operated acutely for either a Stanford type A aortic dissection or ascending aortic intramural hematoma (IMH) from October 1, 2004 to January 1, 2015 from Uppsala University Hospital were collected. Data included age, sex, height, weight, smoking status, medical comorbidities, and post-operative living status of all patients. Known connective disease was also reported, as was the presence or absence of a bovine aortic arch or bicuspid aortic valve.

Procedures

The initial open surgical procedure and results for aortic dissection and IMH are previously described.[9–11] The data reported here include: the Debakey aortic dissection classification, the diameter of the implanted aortic graft, the use of a clamp for the distal ascending aortic anastomosis, whether concomitant coronary artery bypass grafting or reimplantation was carried out, whether or not the aortic valve was preserved or replaced (mechanical, biological, or composite graft), and whether any bypass to one of the supraaortic vessels or immediate aortic arch repair was carried out at the primary operation.

Endovascular Arch Inner-Branched Stentgraft

The endovascular aortic arch inner-branched stentgraft is designed and manufactured by Cook Medical (Bloomington, IN, USA). It is available with either one or two proximal sealing stents with options for up to three internal branches to the supraaortic vessels. To date, reports have focused on the stentgraft with two branches, thus often necessitating a left common carotid (LCC)-left subclavian artery (LSA) bypass.

The required anatomy includes: a uniform ascending aorta with a length ≥ 40 mm and diameter ≤ 38 mm, an innominate artery (IA) ≤ 18 mm. Kinking of a previous implanted aortic graft, albeit

subjective, is also a contraindication. In questionable cases, i.e., sealing lengths close to 40 mm or considerable angulation, minimum outer and inner curve lengths of 45 mm and 24 mm, respectively, are required by the stentgraft manufacturers. Furthermore, the presence of a mechanical aortic valve is a contraindication. See Table 1 for the detailed criteria.

Imaging evaluation and measurements

The most recent post-operative computed tomography (CT) images were assessed for each patient. For those patients who underwent subsequent aortic arch repair, either open, hybrid, or total endovascular reintervention, the most recent CT imaging prior to this procedure was used. All CT images were analyzed using the post-processing software 3mensio Vascular (3mensio Medical Imaging Bilthoven, The Netherlands), in which adequate centre-, outer-, and inner-line measurements were obtained. Measurements included the maximum diameter and length of the ascending aorta, from the IA to either the most proximal edge of prosthetic material or the most distal coronary artery to avoid coverage. Maximum diameters of the aortic arch and proximal descending aorta were also recorded. The IA, LCC and LSA were measured for their length and diameter, noting the presence of disease in these vessels. If either the IA or LCC were burdened with dissection, calcification, or tortuosity, more distal measurements were obtained for potential adjunct procedures, which were defined as either interposition-graft placement to ensure appropriate landing zone or supraaortic deviation, i.e., carotid-subclavian bypass, with endovascular bridging stentgraft extension. In the presence of a bovine aortic arch variant, diameters and angulation of the two vessels were obtained for this common origin of the LCC and IA in order to assess accommodation of two bridging stentgrafts for these particular vessels.

Outcomes

The primary outcome was fulfillment of the above-detailed technical criteria for endovascular inner branched aortic arch stentgraft for patients with ≥ one-year survival. The authors agreed in advance on the applied criteria, as given above. One experienced surgeon (JBL) then reviewed all imaging regarding anatomic suitability. In case of borderline conditions or uncertainties, two other surgeons (AW and KM) also evaluated the image material and consensus was reached on how to classify it. Rejection was then noted for one or more of the following issues: ascending aorta diameter, ascending aorta length, ascending aorta kinking, supraaortic landing zone suitability, presence of a mechanical valve, or severe aortic valve insufficiency and/or root dilatation, indicating a need for valve/root surgery.

Statistics

Data were assessed for normality with quantile-quantile plots. Continuous data are presented with mean values and 95% confidence intervals, and compared using t-tests. Categorical variables are reported as absolute numbers (%) and compared using the Chi-squared test. Data on survival were analyzed using Kaplan-Meier curve estimates, truncated at 10 years. A competing risks model, with subdistribution dependent only on the specific cause, was used to calculate the cumulative incidence of aortic reoperation with death as the competing risk.[12] A p-value less than 0.05 was considered statistically significant.

All data analysis was carried out using Stata, version 14.2 (StatCorp. 2015. Stata Statistical Software: Release 14. College Station, TX, USA: StataCorp LP.)

Ethical Considerations

The study complies with the Declaration of Helsinki. The regional ethical review board waived the need for individual informed patient consent.

Results

A total of 198 patients were identified, 124 (62.6%) men and 74 (37.4%) women. The mean age at the time of operation was 61.4 years (95% CI, 59.8-62.9). Six patients (3.0%) were identified with connective tissue disease, all of which were Marfan syndrome. Thirty-day mortality was 16.2% (n = 32), all of which were in-hospital, while mortality at one year was 19.2% (n=38). The maximum follow-up was 14.3 years, while Kaplan-Meier analysis revealed an estimated 10-year survival of 55.0% (95% CI, 45.6% - 63.5%), Figure 2a.

A total of 129 patients were available with follow-up CT imaging after one year (See Flowchart, Figure 1, for exclusion process). The mean duration to the most recent scanning was 47.8 months (95% CI, 40.3-55.3 months). There were 108 (83.7%) patients who fulfilled anatomical criteria for AIBS in terms of adequate ascending aortic sealing zone without kink, and adequate branch vessels sealing zone, Table 3. Of these patients, 16 had mechanical aortic valves precluding AIBS repair with the current standard device, and an additional three patients had severe aortic insufficiency with aortic root dilatation which cannot be treated with endovascular technique, rendering 89 (69.0%) patients as eligible candidates for endovascular arch repair as an alternative to open surgery, if indicated. No patients were ineligible due to supraaortic vessel pathology, although 18 (20.2%) of the 89 patients would require an adjunct procedure, six of which were bilateral and 12 unilateral. Thus, the most common cause of ineligibility was the presence of a mechanical valve (40.0%), followed by inadequate seal length (30.0%) and a combination thereof (17.5%), e.g., mechanical valve plus

inadequate seal length. It should be noted that 11 of the 12 patients who underwent coronary artery bypass grafting (CABG) or reimplantation also received a mechanical valve, thus entailing ineligibility. Of these 12 patients, only three had insufficient sealing length (Fig. 3).

For the evaluated cohort of 129 patients, those ineligible for AIBS were younger, had shorter ascending aortic seal length, and more often underwent primary ascending repair with a distal aortic clamp in place, Table 3. Circulatory arrest with no clamping of the distal ascending aorta was employed in 108 (83.7%) patients. The difference in the use of this technique among patients deemed technical candidates (88.8%) against those who were not (72.5%) was statistically significant (p=0.021). The mean length of the ascending graft sealing zone was 46.3 mm (95% CI, 44.2-48.3) in patients who underwent ascending repair with total circulatory arrest, versus 39.5 mm (95% CI, 33.6-45.3), p=.0.01, in patients with distal clamp during repair.

In the follow-up period, 19 (14.7%) patients developed aortic arch dilatation to >55 mm, thus meeting the threshold criteria for aortic arch repair, of which 14 (73.7%) would be considered eligible for an endovascular inner branch graft. A total of 13 arch repairs (68.4%) were carried out, of which two, in the most recent time period, used an endovascular AIBS. In addition to the 13 aortic arch repairs, there were 11 patients who underwent open aortic repair for indications other than aortic arch or descending aorta dilatation (5 aortic insufficiency, 4 endocarditis, 2 pseudoaneurysm), rendering a total reoperation rate of 18.6% at a mean duration of 7.1 years (95% CI, 6.6 - 7.7). Accounting for the competing risk of death in Figure 2b, the total risk for aortic reoperation at 10 years was 14.3% (95% CI, 9.1-20.5). The risk of reoperation was 20.0% (95%CI, 12.4-29.0) for patients younger than the mean age of 61.4 and 5.1% (95% CI, 1.7-11.6) for the older patients.

Discussion

It is evident that patients treated for an aortic dissection sustain a considerable risk of need for future aortic reintervention.[1,2,13] The present study reiterates this risk, with almost 20% of the surviving patients undergoing some form of aortic reoperation. Moreover, it confirms that a substantial number of patients (14.7%) ultimately meet the conventional threshold diameter for aortic arch repair of 55 mm.[14] Considering the progressive nature of the disease, the proportion of patients developing critical arch dilatation is expected to increase with longer follow-up in this patient cohort with a mean age of 61 years at the time of primary type A aortic pathology.

Conventional treatment has consisted of a second sternotomy and open arch repair, which inherently limits patient selection due to greater technical complexity, in addition to the increased morbidity of the patients. Hybrid options, with supraaortic vessel debranching and thoracic endovascular aortic repair (TEVAR) stent placement, are available alternatives for some patients.[15,16] More recently, a total endovascular approach for treating the aortic arch has also been advocated, in large part due to its less invasive nature. Moreover, previously implanted prosthetic material in the ascending aorta offers a profitable proximal landing zone for a stentgraft. Spear et al reported on their experience of 43 post-dissection endovascular procedures, 19 of which were performed in the aortic arch with three technical failures.[17] The largest report to date, by Verscheure et al, noted a technical success of 94.3% and a low combined mortality and stroke rate of 4.3% in the treatment of chronic arch dissections among 70 patients, suggesting that this treatment has "come of age".[7]

Of course, much of the success and improvement of a total endovascular treatment will be predicated on patient selection. Milne et al identified approximately 70% of their post-dissection patients as technical candidates for endovascular arch repair, although the majority (90%) did not meet the threshold aortic arch diameter of 55 mm during a median follow-up of six months.[8] It is therefore unknown how longer follow-up would impact the potential proportion of patients who could be offered this treatment.

Although the almost 70% technical eligibility reported in the present study appears unchanged, there are several key differences. First, the above data represent a larger cohort with longer follow-up, with a mean follow-up to re-imaging of almost four years. On the surface, this may suggest that patients rarely alter their anatomical suitability over time. Second, patients with mechanical valves were excluded in the present analysis. The reason a mechanical aortic valve is regarded as a contraindication for AIBS is related to the fact that the top cap of the stent graft delivery system needs to go through the aortic valve during deployment of the stent graft. This would result in malfunctioning of the mechanical valve, thus making mechanical valve a contraindication to the current AIBS technique. A modified delivery system could potentially allow for stent graft implantation without need to cross the aortic valve. Based on a single case with a modified short bullet nose, Spear et al have suggested that mechanical valves are no longer an absolute contraindication.[18] However, the modified bullet nose delivery system requires an additional 3 cm of sealing zone to allow for stent graft implantation. Additionally, although custom made bullet nose delivery systems have at times been produced by Cook, it is not readily available, and regulatory constraints may limit their availability in the future. It was in this light, and as per advice from the manufacturer, that the more conservative exclusion criterion was applied.

Another important finding is the difference in eligibility between those patients in whom a clamp for the distal anastomosis was used. Notwithstanding other important consequences of surgical techniques, such as operative time and neurological complications, it could be argued that an open anastomosis with circulatory arrest may lead to a longer and therefore technically suitable landing zone for future endovascular options .[19,20] Although Table 3 suggests that coronary artery revascularization may hamper eligibility, these results were confounded by the concomitant placement of a mechanical aortic valve.

Having noted this, provided a satisfactory remedy for mechanical valves together with a greater awareness of the anatomical requirements of ensuring a graft of sufficient length and without kinking, the technical eligibility for a total endovascular solution could potentially reach more than 90%. Increasing trends in the use of bioprosthetic valves, coupled with the potential for future transcatheter valve-in-valve procedures, may also impact future eligibility.[21–24]

Finally, it is interesting to note the significant difference in age between the technically eligible and ineligible groups. A type I error might be at play, but one could speculate whether more complex dissections, or at least more complex surgery, among younger patients has impacted their technical suitability. At any rate, older patients do not appear to be less suitable for AIBS candidacy, although the often-accompanying comorbidities of age are not taken into account in this study regarding candidacy. This is somewhat underscored in Figure 2, where the competing risk of death is substantial. While the less invasiveness of an endovascular approach maintains its appeal, these procedures are extremely complex, and clinical evaluation of potential candidates is compulsory. The reported eligibility of 70% is promising, and future long-term studies and focus on patient selection are anticipated.

Limitations

By its nature, a retrospective analysis has its limitations, particularly regarding the bias of patient selection. The patients included were only those who underwent surgery for their primary dissection. The external and internal validity of the Swedish patient data registries are otherwise robust, and unique personal identity numbers for all Swedish patients allow for complete follow-up on survival data. Follow-up imaging, however, was lacking for 26 patients. The reasons for no imaging were often because of poor patient clinical status. Although data from these images would have been useful, this again reflects common clinical practice. Even for those patients who underwent follow-up imaging, as indicated above, only 68.4% of those meeting the threshold for repair were indeed treated.

The definition of technical eligibility presents itself as somewhat of a moving target. Improved devices should be anticipated, but this vouches for the current analysis, in that the conservative criteria yields an already high proportion of patients who are currently technically eligible for a potential endovascular reoperation. The majority of the patients included in this study underwent repair at the era prior to the availability of the total endovascular arch repair technique. With increasing knowledge among cardiac surgeons performing type A dissection repair regarding the anatomical requirements for future endovascular arch repair, specifically the need for a long and straight ascending aortic graft as a landing zone, the proportion of eligible patients may increase over time.

Conclusion

This large patient cohort with long follow-up confirms that a substantial number of patients require further aortic repair following acute AAD or IMH open surgery. The majority of these patients, including those who meet the threshold indication for treatment, are technically eligible for the contemporary endovascular arch inner-branched stentgraft. Accommodation of a mechanical aortic valve would significantly increase this availability. Increasing age is not associated with a loss of eligibility, in contrast to the use of a clamp for the distal ascending aorta anastomosis at the primary surgery. These findings should help guide clinicians in their considerations of surgical approach and post-operative surveillance.

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Tables

Table 1: Technical anatomic criteria for the custom made Cook aortic arch branched stent graft. *

- Ascending aorta diameter ≤ 38 mm.
- Uniform ascending aorta with no significant angulation/kinking.
- Sealing zone in the ascending aorta with true, centre-line length ≥ 40 mm and/or outer-curve length ≥ 49 mm, inner-curve length ≥ 24 mm.
- Suitable innominate and left common carotid artery landing zone with diameters ≤ 18 mm.
- Iliac artery access accommodating a minimum 22 French sheath.
- Native or biological aortic valve, i.e., mechanical aortic valve contraindicated.

*Written correspondence with Cook Medical (Bloomington, IN, USA) custom aortic stentgraft representatives.

Table 2: Baseline patient characteristics for the 198 patients followed after open surgical repair of an acute Stanford Type-A aortic dissection or ascending aorta intramural hematoma.

Variable[a]	Total (n=198)
Age, years	61.4 (59.8-62.9)
Male Sex	124 (62.6%)
BMI, kg/m^2	26.6 (26.1-27.1)
Smoking, No.	
Never	110 (55.6%)
Previous	32 (16.2%)
Active	56 (28.3%)
Hypertension	133 (67.2%)
Diabetes Mellitus	8 (4.0%)
Ischemic Heart Disease	12 (6.1%)
COPD	13 (6.6%)
Connective Tissue Disease	6 (3.0%)
Aortic Bovine Trunk	15 (7.6%)
Bicuspid aortic valve	8 (4.0%)
Ascending aortic IMH	8 (4.0%)
Aortic dissection	
Debakey Type I	158 (79.8%)
Debakey Type II	32 (16.2%)

BMI, Body mass index
COPD, Chronic Obstructive Pulmonary Disease
IMH, Intramural Hematoma
[a]Continuous data are shown as the mean (95% Confidence Intervals) and categoric data as number (%).

Table 3: Comparison of patient characteristics, pathology, and technical aspects for the 129 patients evaluated for AIBS eligibility, as well reasons for ineligibility.

	Eligible AIBS candidates (n=89)	Ineligible AIBS candidates (n=40)	p
Mean Age	60.2 (58.0-62.4)	55.7 (52.0-59.3)	.027[a]
Patient Sex Male (%) /Female (%)	56 (62.9) / 33 (37.1)	26 (65.0) / 14 (35.0)	.820[a]
Pathology			
Type I AAD	68 (76.4%)	36 (90.0%)	.071
Type II AAD	18 (20.2%)	3 (7.5%)	.070
IMH	3 (3.4%)	1 (2.5%)	.792
Bovine Trunk	7 (7.9%)	6 (15.0%)	.213
CTD	5 (5.6%)	3 (7.5%)	.682
Ascending aortic seal length, mm	48.3 (46.4-50.1)	38.2 (34.0-42.3)	<.001[a]
Ascending aortic diameter, mm	32.2 (31.5-32.9)	32.7 (31.6-33.8)	.410 [a]
Circulatory Arrest, no distal clamp (%)	79 (88.8)	29 (72.5)	.021
CABG or coronary reimplantation (%)	2 (2.2)	13 (32.5)	<.001
Mechanical valve (%)	0	20 (50.0)	<.001
Biological valve (%)	8 (9.0)	3 (7.5)	.779
Reason for ineligibility			
Mechanical Valve only (%)		16 (40.0)	
Inadequate seal only (%)		12 (30.0)	
AI/Root dilatation (%)		2 (5.0)	

Diameter (%)	2 (5.0)
Kink (%)	1 (2.5)
Combination (%)	7 (17.5)

AAD, Stanford Type A aortic dissection
AI, aortic insufficiency
AIBS, arch inner-branched stent
CABG, coronary artery bypass graft
CTD, connective tissue disease
IMH, intramural hematoma
[a]Compared using t-tests; all other tests were performed using Chi-squared tests.

Figures and Figure Legends

Figure 1:

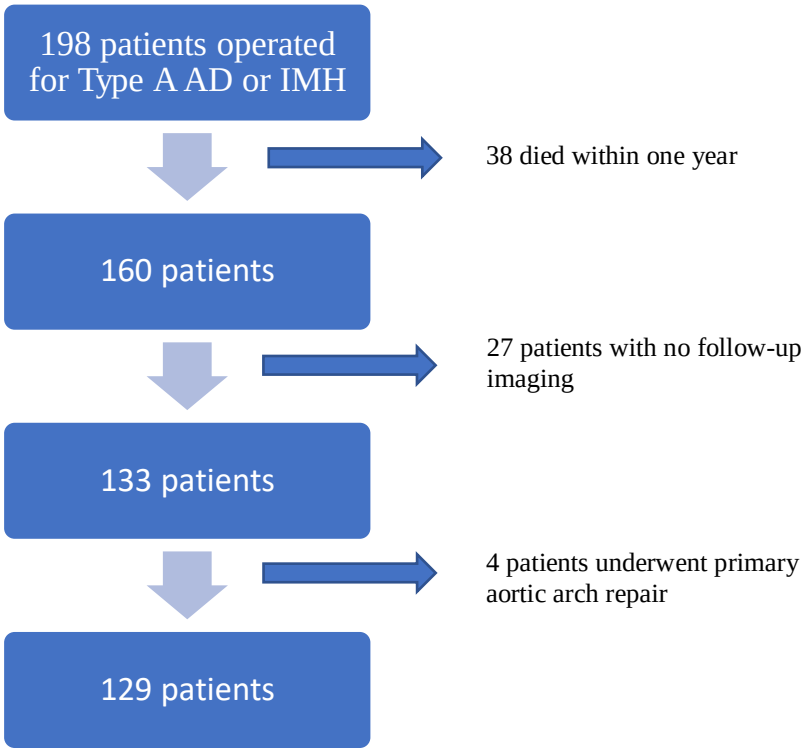


Figure 1: Flowchart for the exclusion and selection of 129 patients evaluated for technical eligibility for an arch inner-branched stentgraft from an initial cohort of 198 patients.

Figure 2a:

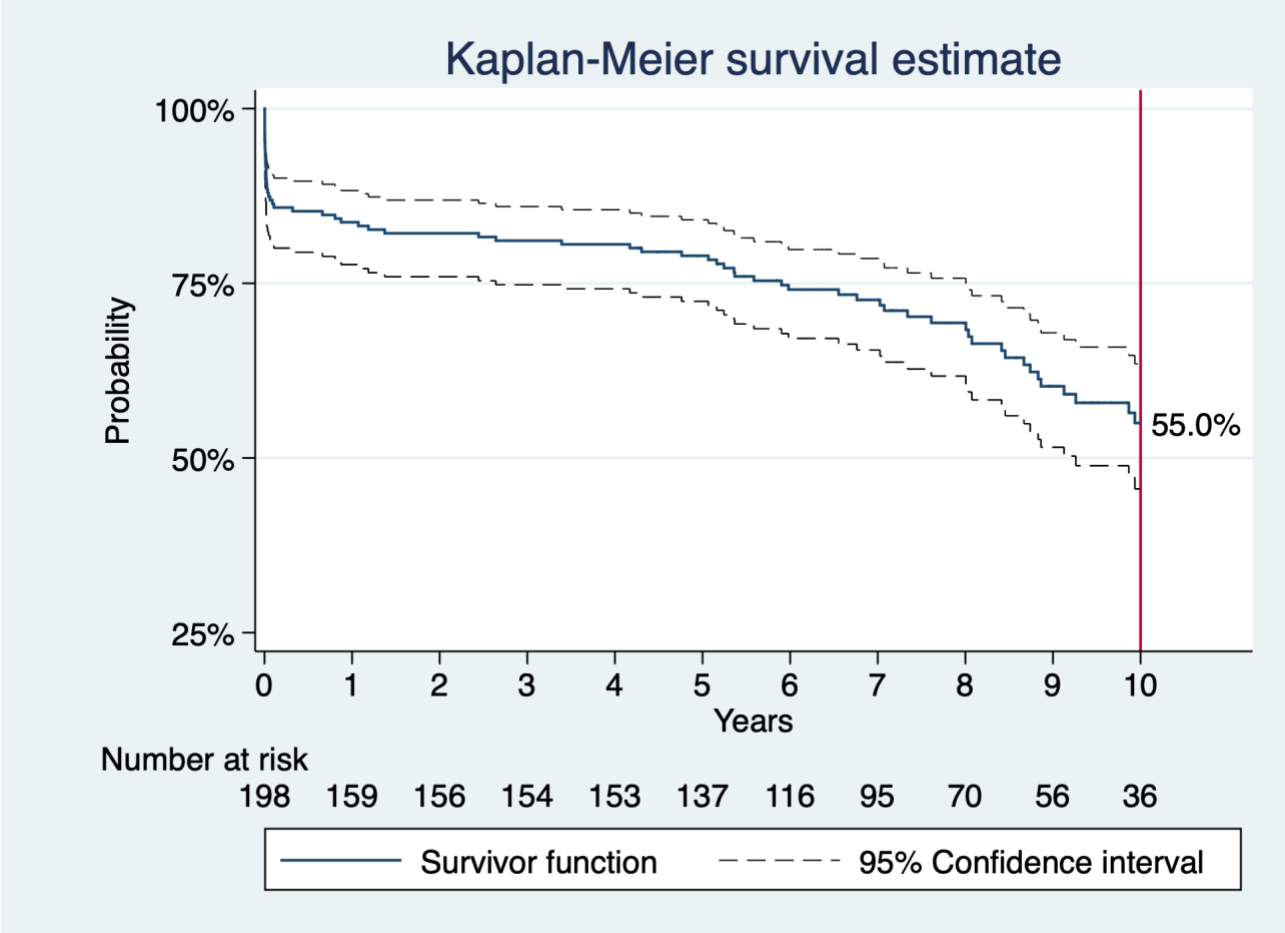
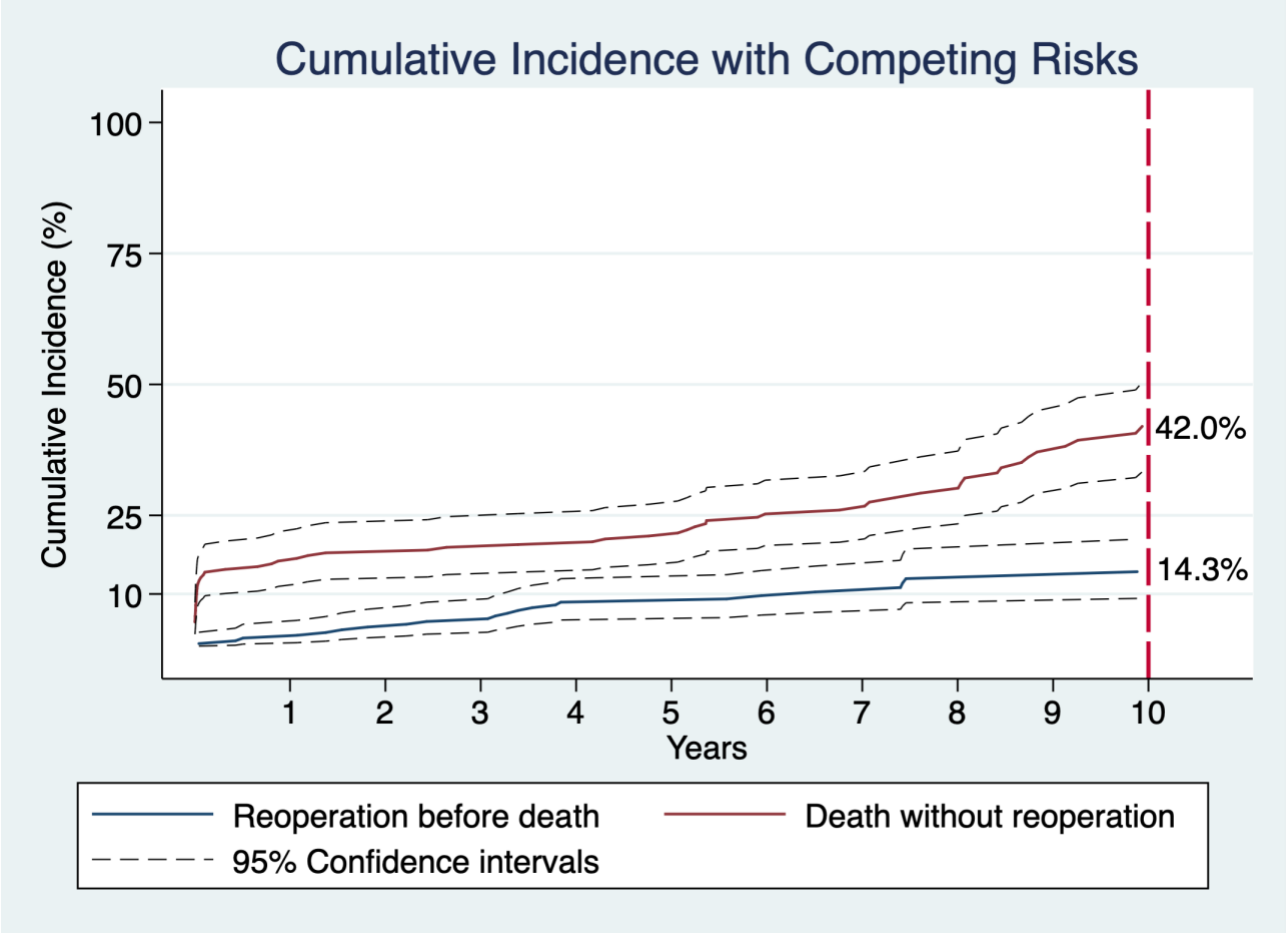

Kaplan-Meier survival estimate
100%
75%
50%
25%
Probability
55.0%
0
1
2
3
4
5
6
7
8
9
10
Years
Number at risk
198
159
156
154
153
137
116
95
70
56
36
Survivor function
95% Confidence interval

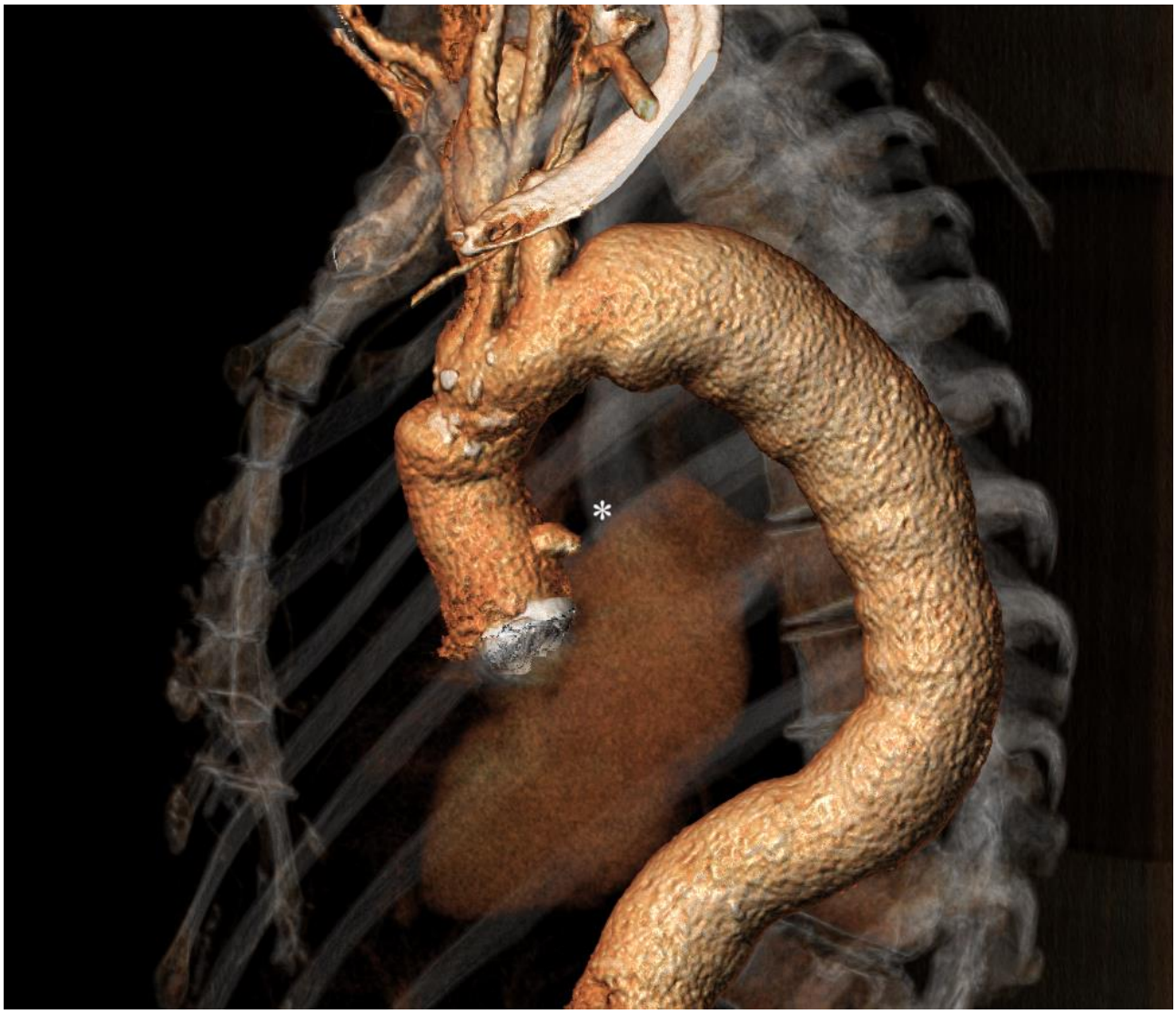
Figure 2b:



Figures 2a and b: Survival analysis using Kaplan-Meier estimates in 2a, whereas estimates of the cumulative incidence of aortic reoperation in 2b are demonstrated using a competing-risks subdistribution model with death as the competing risk. Estimates at are presented with 95% confidence intervals and truncated at ten years.

492 Figure 3:

493



494

495 Figure 3: Three-dimensional reconstructed computed tomographic image of a post-aortic dissection
496 repair. Reimplantation of the coronary arteries (asterisk) shortens the landing zone of a potential
497 endovascular arch inner-branched stentgraft. Note, the maximum diameter of the aortic arch was
498 approximately 5 cm.