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Late Graft Failure is Rare After Endovascular Aneurysm Repair Using the Zenith Stent-Graft in a Cohort of High-Risk Patients

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Abstract

Objective: Device-specific data on the long-term efficacy of endovascular aortic aneurysm repair (EVAR) is limited by the constant evolution of stent-graft design. While some modifications, such as barb-mediated fixation probably enhance durability, others, such as thin-walled fabric, are of less certain benefit. The purpose of this study is to examine fifteen-years of a single center experience of EVAR using the Zenith stent-graft.

Methods: Retrospective analysis of 325 high-risk patients who underwent elective EVAR with Zenith stent-grafts between October 1998 and December 2005 under a physician-sponsored investigational device exemption. Patient charts and death registries were reviewed to identify late stent-graft failures and causes of death. Late stent-graft failures were defined as type I/type III endoleaks; enlarging aneurysm sac requiring revision; limb kinking/occlusion, stent-graft infection, renal artery occlusion, or aneurysm rupture occurring >30 days after the index procedure.

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Results: The mean age at treatment was 75.9 ± 7.4 years and 300/325 (92%) were men. The mean aneurysm diameter was 60 ± 9 mm and the median main body stent-graft diameter was 28 mm (range: 22–32 mm). Over a median follow-up time of 5.6 years (interquartile range: 2.6 – 8.7 years), there were 6 (2%) aneurysm-related deaths caused by the following: one stent-graft infection, one infection of a femoral-femoral bypass graft placed after limb occlusion, one infection of a stent-graft placed to treat a type IB endoleak, and three aneurysm ruptures. There were 19 (6%) late stent-graft failures occurring at a median time of 4.0 years (range: 39 days to 14.6 years) post-procedure. Patients with late stent-graft failure were more likely to have had impaired renal function (creatinine ≥ 2 mg/dL) (21% vs 6%, $P = .03$) and less likely to have had cardiac disease (42% vs 67%, $P = .04$) at the time of the index procedure. There was no significant association between late stent-graft failure and: age, sex, aneurysm size, stent-graft diameter, diabetes, smoking, or lung disease. Kaplan-Meier estimated overall survival was 60% at 5 years, 29% at 10 years, and 12% at 15 years. Kaplan-Meier estimated freedom from aneurysm-related mortality was 98% at 5 years, 97% at 10 years, and 97% at 15 years. **Conclusion:** Late-occurring stent-graft failures and aneurysm-related death are rare after EVAR using the Zenith stent-graft, especially in high-risk patients whose comorbidities diminish life expectancy.

Table of Contents Summary

This retrospective study examines a fifteen-year experience of 325 high-risk patients that underwent elective endovascular abdominal aortic aneurysm repair (EVAR) with the Zenith stent-graft. Late stent-graft failure (n=19) and aneurysm-related death (n=6) was rare, especially in high-risk patients whose comorbidities diminish life expectancy.

Keywords

Abdominal aortic aneurysm; EVAR; Zenith stent-graft; late graft failure

INTRODUCTION

Endovascular aneurysm repair (EVAR) is now the most common treatment method for both intact and ruptured abdominal aortic aneurysms (AAA)[1]. The short-term advantages of EVAR over open surgical repair have been supported by several randomized controlled trials including the USA OVER (USA Open Versus Endovascular Repair)[2], DREAM (Dutch Randomized Endovascular Aneurysm Management)[3], UK EVAR 1 and 2 (United Kingdom Endovascular Aneurysm Repair 1 and 2)[4, 5], and French ACE (Anevrysme de l'aorta abdominale, Chirurgie versus Endoprothese)[6] trials. These benefits include improved perioperative and 30-day mortality and shorter hospital stays and operative time. However, several of these trials have called into question the long-term stability and benefits of EVAR[7–10]. Specifically, concerns have been raised regarding higher re-intervention rates in patients undergoing EVAR compared to open surgical repair[7].

Additionally, most of the early stent-grafts studied are now obsolete, having been modified or replaced[11] in an effort to eliminate observed failure modes. As beneficial as these changes may be, the continual evolution of device design has resulted in a paucity of device-specific data on the long-term performance of current devices. The Zenith bifurcated stent-graft

(Cook Inc., Bloomington, IN) is different in this regard, having undergone few major changes in either the stent-graft or its means of delivery since its introduction in 1998[12].

Although the Zenith stent-graft did not become widely available in the United States until it received approval from the Food and Drug Administration (FDA) in 2003, we gained access to the device in 1998 for use in high-risk patients under a physician-sponsored investigational device exemption (IDE). We have previously reported shortand mid-term outcomes of this study[13, 14] and the purpose of the current study is to examine fifteen-years of a single center experience of EVAR using the Zenith stent-graft.

METHODS

Three hundred and twenty-five high-risk patients underwent elective endovascular AAA repair using the Zenith stent-graft between October 1998 and December 2005 at the University of California, San Francisco (UCSF) Medical Center under an IDE approved by the FDA. Institutional review board (IRB) approval was granted for this study by the Committee on Human Research at the University of California, San Francisco and all participants gave informed written consent.

Candidates for enrollment were considered to be high-risk (for conventional repair) based on the following criteria: presence of a hostile abdomen, age ≥ 75 years old, creatinine ≥ 2 mg/dL or requiring hemodialysis, disabling chronic obstructive pulmonary disease (home oxygen therapy or forced expiratory volume in one second < one liter), heart failure with an ejection fraction of < 25%, or myocardial infarction within the past 6 months. Patient demographic information, medical comorbidities (diabetes mellitus, chronic obstructive pulmonary disease [COPD], renal function, smoking, and cardiac disease), medication use (statin, aspirin, clopidogrel), and aneurysm characteristics were collected at the time of the index operation. Cardiac disease included but was not limited to the presence of coronary artery disease, atrial fibrillation, congestive heart failure, history of myocardial infarction, or intervention for cardiac disease of any origin. Additional inclusion criteria have been previously reported[14] but include the presence of a proximal aneurysm neck of >15 mm in length, ≤28 mm in diameter, with an angulation ≤80 degrees between the infrarenal neck and aneurysm.

Follow-up included computed tomographic angiography (CTA), multi-view abdominal radiographs, and clinical examination at 1, 6, and 12 months, and yearly thereafter. In 2007, the protocol was revised. If the CTA at the 1 month follow-up did not demonstrate a type I or III endoleak, a non-contrast CT scan was performed at 6 and 12 months, and yearly thereafter.

All data on complications, re-intervention, stent-graft failure, and mortality were collected prospectively until 2006. Subsequent follow-up data were collected retrospectively by in-depth review of hospital records, death certificates, and the National Death Registry. Late stent-graft failures were defined as type I/type III endoleaks; enlarging aneurysm sac requiring revision; limb kinking/occlusion, stent-graft infection, renal artery occlusion, or aneurysm rupture occurring >30 days after the index procedure. Interventions for type II

endoleaks were only reported if associated with late graft failure because our treatment strategy for type II endoleaks evolved over the study period. In the beginning of the study, all type II endoleaks from the inferior mesenteric artery were treated with coil embolization. Type II endoleaks associated with lumbar arteries were treated only if the endoleak persisted past 1 month follow-up. In 2003, our management of type II endoleaks changed and these endoleaks were only embolized if there was radiographic evidence of aneurysm sac enlargement.

Statistical Analysis

All statistical analysis was performed using STATA version 15.0 (StataCorp, College Station, Texas). Summary statistics were reported using mean and standard deviation for continuous variables and frequency and percentage for categorical variables. Differences between groups were calculated using a two-tailed Student's *t* test for continuous variables and Fisher's exact test for categorical variables. Kaplan-Meier survival analyses were used to estimate freedom from all-cause mortality, freedom from aneurysm-related mortality, and freedom from late stent-graft failure. The log-rank test was used to compare survival between groups. Statistical significance was set at $P \leq .05$.

RESULTS

The mean age at operation was 75.9 ± 7.4 years and 300/325 (92%) were men. The mean aneurysm diameter was 60 ± 9 mm and the median main body stent-graft diameter was 28 mm (range: 22–32 mm) (Table I). Twenty-one (7%) patients in the cohort had a baseline creatinine ≥ 2 mg/dL and the majority of patients had cardiac disease (n = 213, 66%) and a history of smoking (n=210, 65%). There were no perioperative deaths, no failed insertions, and no conversions to open repair during the index procedure. The median follow-up time was 5.6 years (interquartile range: 2.6 – 8.7 years) and ranged from one month to 16.3 years. Two hundred and twenty-seven (70%) patients were deceased at the time of this study and 33 (10%) had been lost to follow-up (defined as evidence that a patient was alive but without a vascular surgery follow-up within a year). Among the known causes of death, a cardiac cause was the most common (16%) followed by cancer (14%). The causes of deaths in this cohort were unknown in 46% of the deaths.

Kaplan-Meier estimated overall survival was 60% at 5 years, 29% at 10 years, and 12% at 15 years (Figure 1). During the follow-up period, there were 6 (2%) aneurysm-related deaths caused by the following: one primary stent-graft infection, one infection of a femoral-femoral bypass graft placed after limb occlusion, one infection of a stent-graft placed to treat a type IB endoleak, and three aneurysm ruptures. Kaplan-Meier estimated freedom from late-occurring aneurysm-related mortality was 98% at 5 years, 97% at 10 years, and 97% at 15 years (Figure 2).

There were 19 (6%) primary late-occurring stent-graft failures at a median time of 4.0 years (range: 39 days to 14.6 years) post-procedure (Table II). Type III endoleaks were the most common form of late-occurring stent-graft failure (n=5) presenting at a median time of 2.4 years (range: 1 month to 14.6 years) post-procedure. Four of the five type III endoleaks resulted from separation of a limb graft from the main body. These were treated with iliac

limb extensions, which resulted in complete resolution of the endoleak. There was one case of type III endoleak occurring at the bifurcation of the main body graft. This was treated with placement of a Zenith Renu graft, iliac plug to the contralateral limb, and a femoral-femoral artery bypass. There were three cases of aneurysm rupture presenting at a median time of 6.1 years (range: 6.8 months to 6.6 years) post-procedure. Two of these patients were undergoing regular vascular surgery surveillance and one had declined further surveillance. The first patient experienced loss of proximal fixation with a rapidly enlarging sac and presented with rupture soon after. The second patient had a persistent type II endoleak followed by aneurysm rupture, which was treated with IMA and lumbar artery ligation, but the patient passed away from a myocardial infarction soon after. The third patient had a type II endoleak that was associated with sac enlargement who underwent unsuccessful embolization. The patient declined all further treatment and management until presenting to the emergency room one year later with likely aneurysm rupture.

Other causes of late-occurring stent-graft failure included: type I endoleak (n = 3), enlarging aneurysm sac of unknown origin requiring graft revision (n = 3), renal artery occlusion (n = 1), distal stent-graft migration causing limb kink without occlusion (n = 1), infected stent-graft (n = 1), and limb occlusion (n = 2). Two of the three type I endoleaks were distal endoleaks treated with limb extensions. There was no identifiable form of endoleak in the three patients with enlarging aneurysm sacs of unknown origin. The first patient underwent repeat EVAR (re-lining of the graft) with resolution of sac expansion. The other two patients underwent placement of a Zenith Renu graft, occlusion of the contralateral limb, and cross-femoral artery bypass graft, which resulted in resolution of sac expansion. None of these patients underwent explant of the device. There were no cases of proximal stent-graft migration. Kaplan-Meier estimated freedom from late-occurring stent-graft failure was 96% at 5 years, 91% at 10 years, and 77% at 15 years (Figure 3).

Patients with late-occurring stent-graft failure were more likely to have had impaired renal function (creatinine ≥ 2 mg/dL) (21% vs 6%, $P = .03$) and less likely to have had cardiac disease (42% vs 67%, $P = .04$) at the time of the index procedure (Table III). However, patients with cardiac disease had a shorter survival time when compared to patients without, which would make them less likely to live long enough to develop a late stent-graft failure (log-rank test, $P = .02$) (Figure 4). There was no statistically significant difference in age, sex, aneurysm size, stent-graft diameter, diabetes mellitus, smoking, or COPD between patients with and without late stent-graft failure.

DISCUSSION

These long-term outcomes of EVAR using the Zenith stent-graft are notable for low rates of aneurysm-related death, direct endoleak (types I and III), and limb occlusion, and this is similar to other long-term Zenith cohorts that have been studied[15, 16]. These data on the long-term performance of the Zenith stent-graft circa 1999 are important in as much as they predict the long-term behavior of the current device, which shares the same basic features.

The apparent stability of the Zenith-based repair can be attributed to the characteristic features of the original stent-graft such as: the supra-renal stent, caudally-oriented barbs,

densely woven fabric, tight attachment between stents and fabric, and a long trunk, all of which are present in the current device. However, in addition, patient selection may have played a role in the apparent stability of the repair. During the period of this study, the widest available stent-graft measured only 32 mm in diameter: wide necks – a known risk factor for proximal migration, neck dilatation, type I endoleak and death[17–19] –were excluded.

Patient selection also impacted the overall survival. All the patients in this early study were considered too sick to undergo open repair, which, at the time of this study, was still the gold standard. Their general ill health is reflected in shortened life-expectancy. As shown in the survival plots, the at-risk population declined rapidly for reasons unrelated to the aneurysm or the repair.

Late-occurring stent-graft failure was more common in the presence of renal impairment and less common in the presence of cardiac disease. Although renal disease is a well-known risk factor for poor outcome after any form of aneurysm repair[20], it is difficult to understand exactly how poor renal function would have affected stent-graft performance. We do not believe that cardiac disease had any true protective effect on late-occurring stent-graft failure, other than the expected reduction in the at-risk population through premature death.

The most common mode of late-occurring stent-graft failure was type III endoleak, which occurred five times and up to 14.6 years post-procedure. Other studies have reported similar findings. Turney *et al.* reported a single case of a type III endoleak requiring explant > 10 years after index operation[21]. A recent retrospective analysis of two European centers reported cases of type III endoleaks up to 10.8 years after EVAR with the Zenith stent-graft[22]. Verzini *et al.* reported 11 cases of type III endoleak over a mean follow-up time of 99.2 ± 2.9 months in their cohort of 610 patients treated with the Zenith stent-graft[15]. Although late type III endoleaks are rare, this would suggest either an unstable stent-graft structure or position. Increasing the degree of inter-component overlap could help mitigate against this late-occurring complication, but it also argues for lifelong surveillance in patients, even if the stent-graft has appeared stable for many years.

Although the basic features of the Zenith stent-graft are all present in the current version of this device, there have been changes. In 1999, a long stent just above the bifurcation was found to be fracture-prone and replaced with two shorter stents. In 2002, the sutured connection between the uncovered proximal stent and the proximal margin of the graft was doubled after several top stents became disconnected from the remainder of the stent-graft, which, deprived of its anchor, migrated downstream. In 2004, stents were distributed more widely down the main body of the stent-graft to enhance the flexibility of the stent-graft and help it accommodate severe neck angulation. Since patients in this study underwent EVAR between 1998–2005, we used these modified devices as each became available. None of the changes had any noticeable effect on the steps in stent-graft deployment, or in the short-term results, that would have led us to track any changes in real-time.

In 2006, a 36 mm-wide main body was made available to permit treatment of wider necks. In an effort to reduce iliac limb occlusions, the Spiral-Z stent iliac limb grafts were

introduced in 2011. The Spiral-Z iliac limb grafts incorporate a continuous nitinol spiral stent to enhance flexibility and kink resistance. All of these changes were made in the expectation that they would enhance, not degrade, device performance, but one cannot always assume that the long-term behavior of the original version predicts the long-term behavior of the current version. This is particularly true of reductions in stent-graft bulk and delivery system profile. Recently introduced low-profile stent-grafts currently lack long-term data on outcomes and cannot yet be relied upon to demonstrate stable long-term performance[23]. The Cook Zenith Low Profile AAA device is no exception, given that it has different stents, delivery system, and fabric compared to the original device. Thus, these devices may not be the best choice for a young otherwise healthy patient.

Limitations

There are several limitations to this study. This was a single center study of medically high risk patients, so the results may not be generalizable to a younger cohort of average risk patients. The majority of patients in this cohort died over the follow-up period, and in 46% of these cases, the cause of death was unknown. We recognize that this could result in an under-representation of the number of aneurysm related deaths. Since the modality for identifying type II endoleaks (CTA) and management of type II endoleaks changed throughout the study period, data on type II endoleaks were not included in this study unless associated with late stent-graft failure. Finally, several potentially important risk factors for late graft failure (aneurysm neck length, thrombus, or calcification, and iliac stenosis/tortuosity) were not examined in this study.

CONCLUSION

Late-occurring stent-graft failure and aneurysm-related death were rare after EVAR using the Zenith stent-graft, particularly in high-risk patients whose comorbidities diminished life expectancy. However, a steady trickle of life-threatening failure modes warrants lifelong follow-up of some kind.

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Key Findings:

In a cohort of 325 high-risk patients, late stent-graft failure (n=19, 6%) and aneurysm-related death (n=6) was rare after EVAR using the Zenith stent-graft. However, Type I (n=3) and III endoleaks (n=5) continued to occur several years after the index procedure.

Take home Message:

Proper patient selection and use of the Zenith stent-graft offers acceptable long-term outcomes, however late stent-graft failure may still occur and lifetime surveillance is indicated.

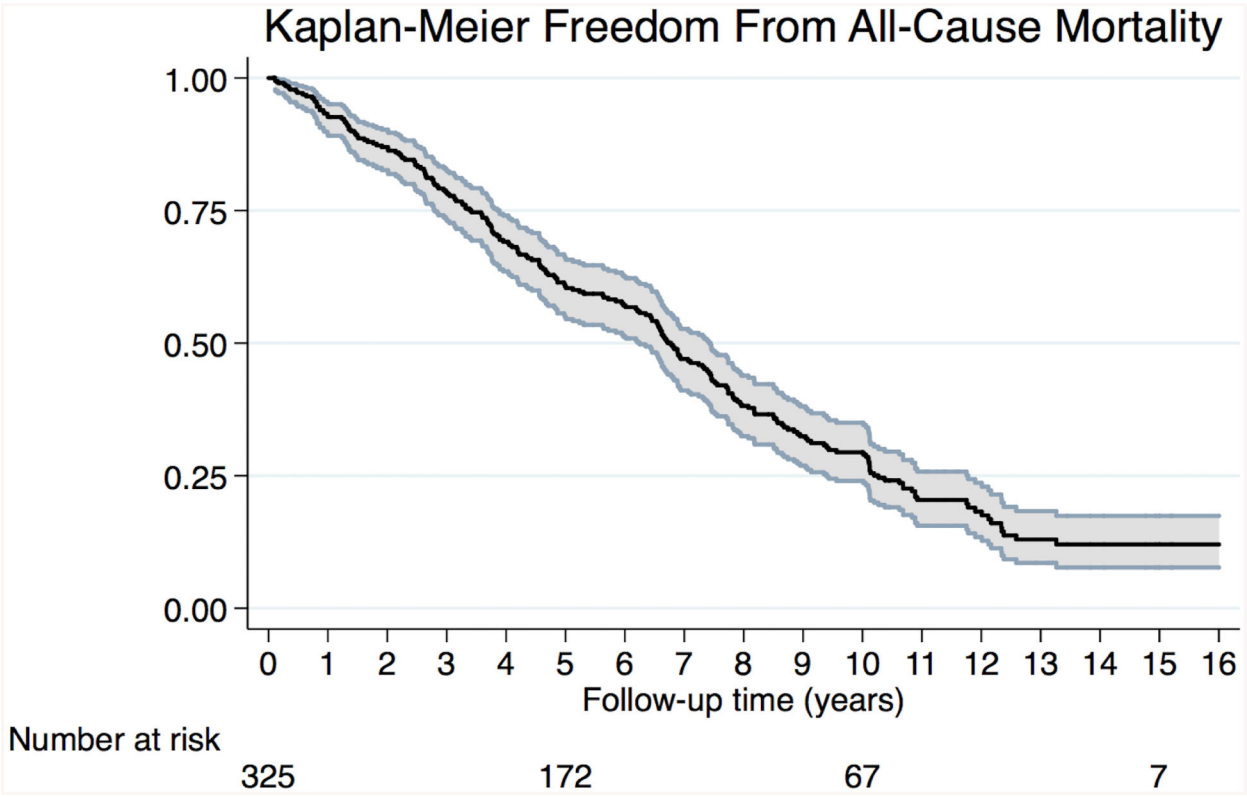

Figure 1.
Kaplan-Meier analysis of all-cause mortality.

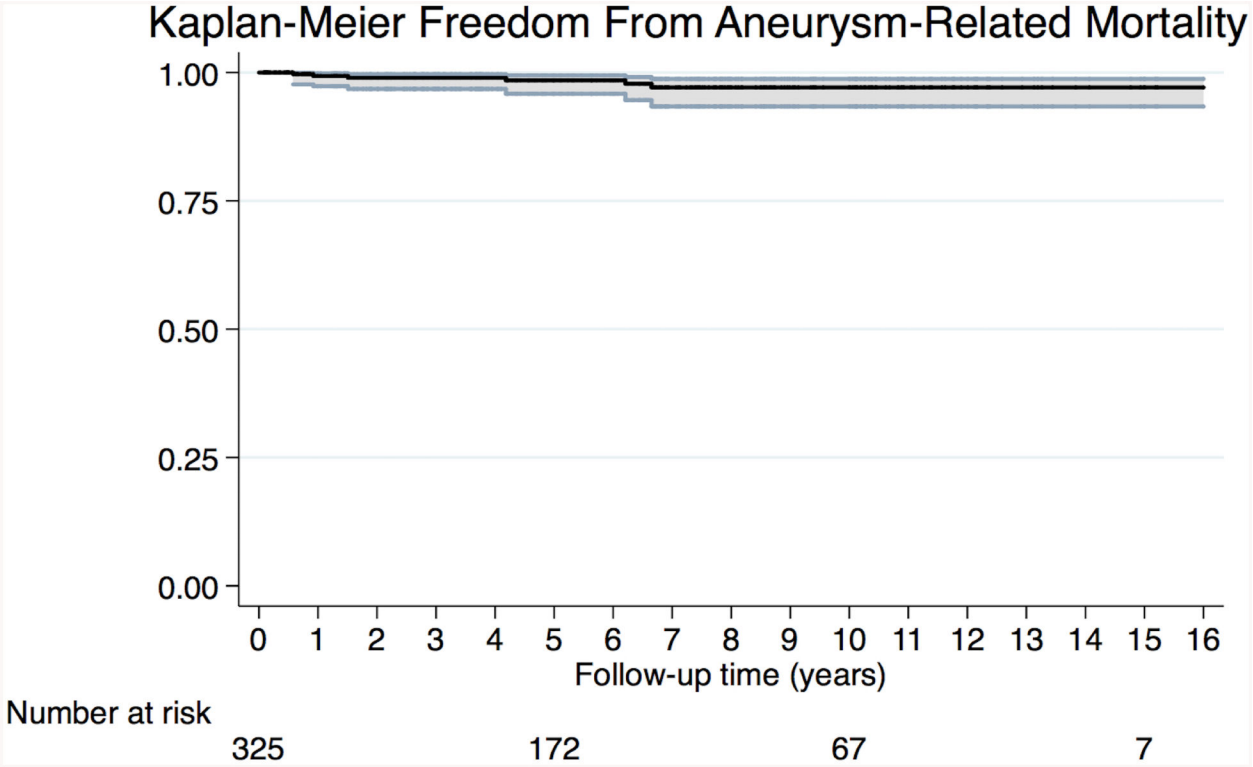

Figure 2.
Kaplan-Meier analysis of aneurysm-related mortality.

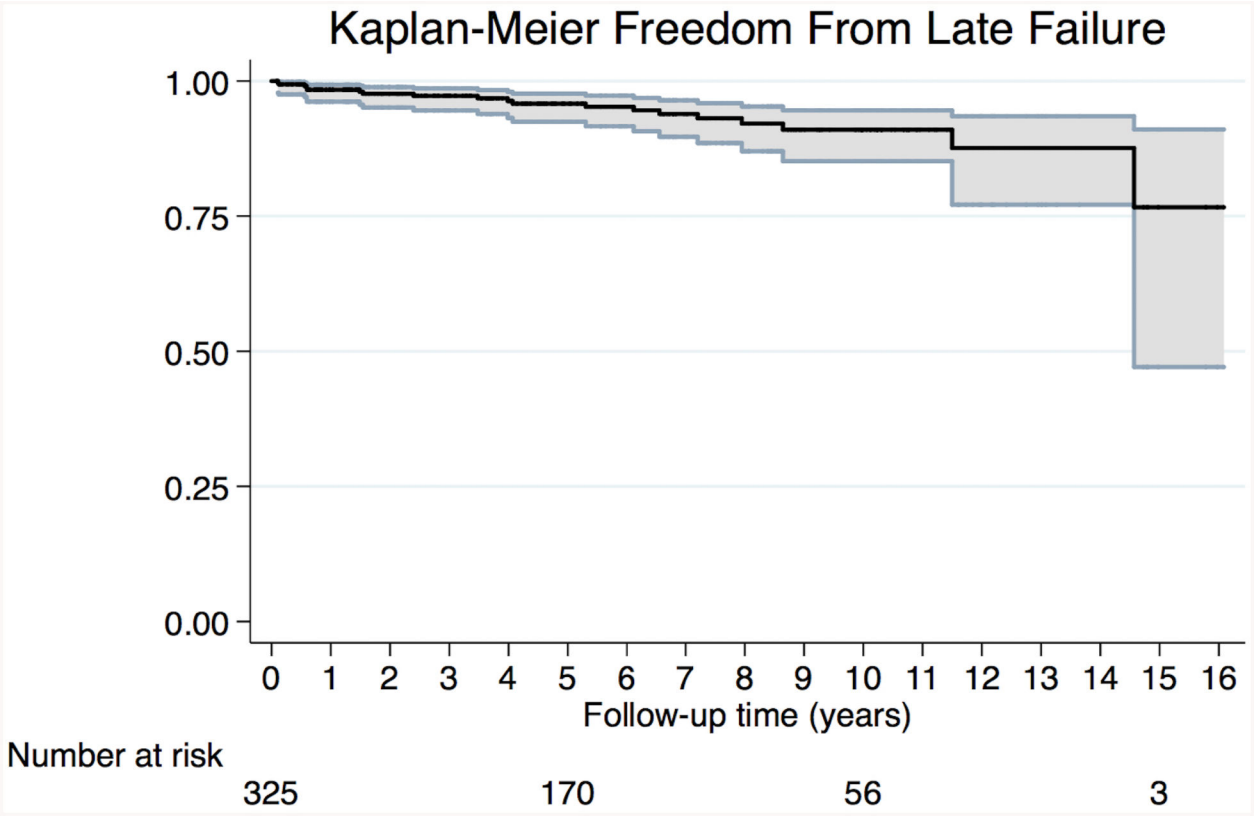

Figure 3.
Kaplan-Meier analysis of freedom from late stent-graft failure.

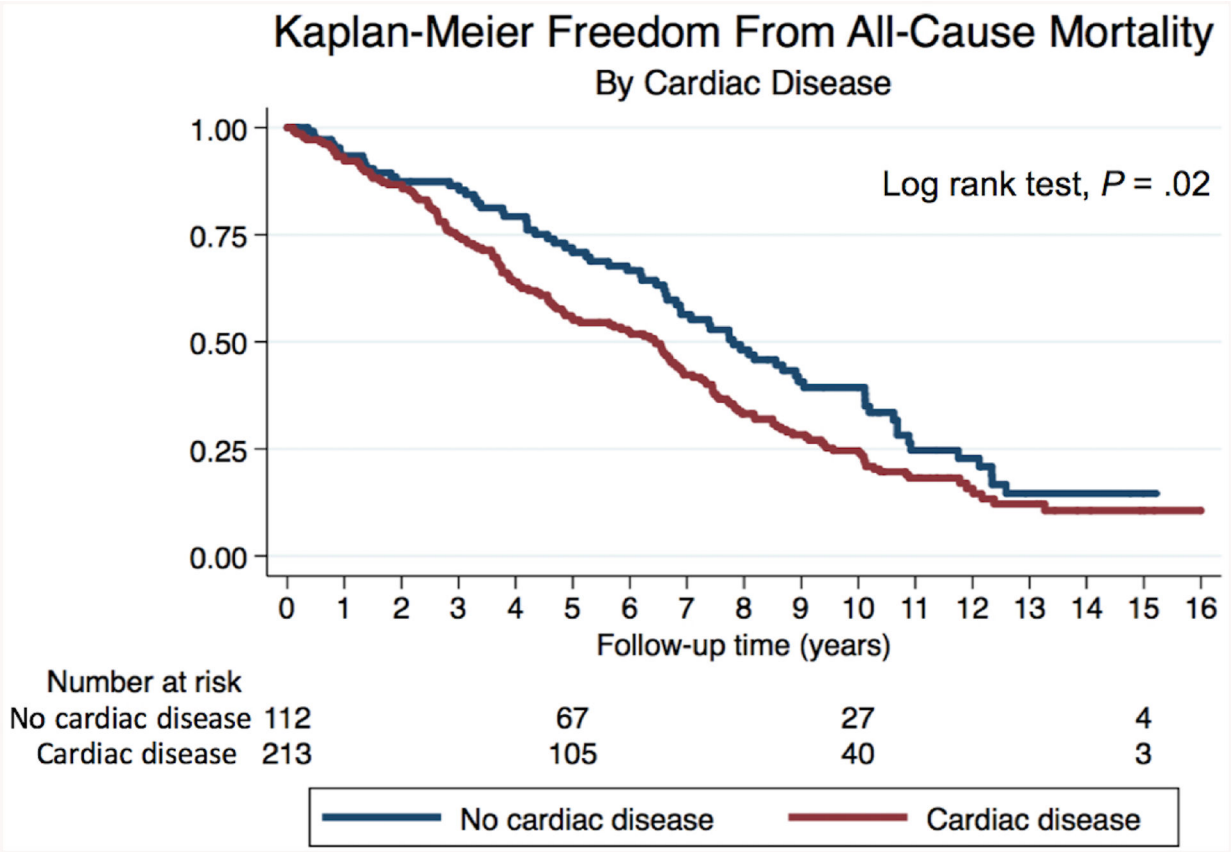

Figure 4.
Kaplan-Meier analysis of all-cause mortality by cardiac disease (log rank test, $P = .02$).

Table I.

Characteristics of Participants at Time of Index Operation

Variable	Data (n=325)
Age at operation (years)	
Mean ± SD	75.9 ± 7.4
Range	56.4–95.3
Sex	
Male	300 (92%)
Female	25 (8%)
Follow-up (years)	
Median (Interquartile Range)	5.6 (2.6–8.7)
Range	0.1–16.3
Medical comorbidities	
Diabetes mellitus	51 (16%)
Smoker	49 (15%)
Past smoker	210 (65%)
Cardiac disease	213 (66%)
COPD	102 (31%)
Preoperative creatinine > 2 mg/dL	21 (7%)
Medication use	
Aspirin	169 (52%)
Statin	167 (51%)
Clopidogrel	18 (6%)
Aneurysm size (mm)	
Mean ± SD	59.5 ± 9.4
Range	32–100
Stent-graft diameter (mm)	
Median	28
Range	22–32

COPD = chronic obstructive pulmonary disease

Table II.

Primary Causes of Stent-Graft Failure After 30 Days

Stent-Graft Failure	N=19	Time Since Operation (years)
Type III endoleak	5	0.1, 1.5, 2.4, 8.6, 14.6
Type I endoleak	3	3.5, 7.9, 11.5
Enlarging aneurysm sac requiring graft revision	3	4.1, 5.3, 7.2
Aneurysm rupture	3	0.6, 6.1, 6.6
Limb occlusion	2	0.1, 0.6
Limb kink without occlusion	1	4.0
Infected stent-graft	1	1.5
Renal artery occlusion	1	0.6

Table III.

Characteristics of Participants With and Without Late Stent-Graft Failure

Variable	Late Failure (n=19)	No Late Failure (n=306)	*P* value[a]
Age at operation (years)			.85
Mean ± SD	75.6 ± 7.3	75.9 ± 7.5	
Range	58.7–90.8	56.3–95.3	
Sex			.65
Male	17 (90%)	283 (93%)	
Female	2 (11%)	23 (8%)	
Follow-up (years)			.83
Median (Interquartile Range)	4.7 (2.8–7.8)	5.7 (2.6–8.7)	
Range	0.5–16.3	0.1–16.3	
Medical comorbidities			
Diabetes mellitus	5 (26%)	46 (15%)	.20
Smoker	4 (21%)	45 (15%)	.51
Cardiac disease	8 (42%)	205 (67%)	**.04**
COPD	6 (32%)	96 (31%)	.99
Preoperative creatinine ≥ 2 mg/dL	4 (21%)	17 (6%)	**.03**
Medication use			
Aspirin	7 (37%)	162 (53%)	.24
Statin	7 (37%)	160 (52%)	.24
Clopidogrel	1 (5%)	17 (6%)	.99
Aneurysm size (mm)			.20
Mean ± SD	62.2 ± 10.6	59.3 ± 9.3	
Range	43–84	32–100	
Stent-graft diameter (mm)			
Median	28	28	.59
Range	22–32	22–32	

Boldface *P* values were below the .05 level required for statistical significance. COPD = chronic obstructive pulmonary disease

[a] *P* values were calculated using a two-tailed Student's *t*-test for continuous variables and a Fisher's exact for categorical variables.