Original Article

Title: A 20-year multicenter analysis of dialysis-dependent patients who had aortic or mitral valve replacement: Implications for valve selection

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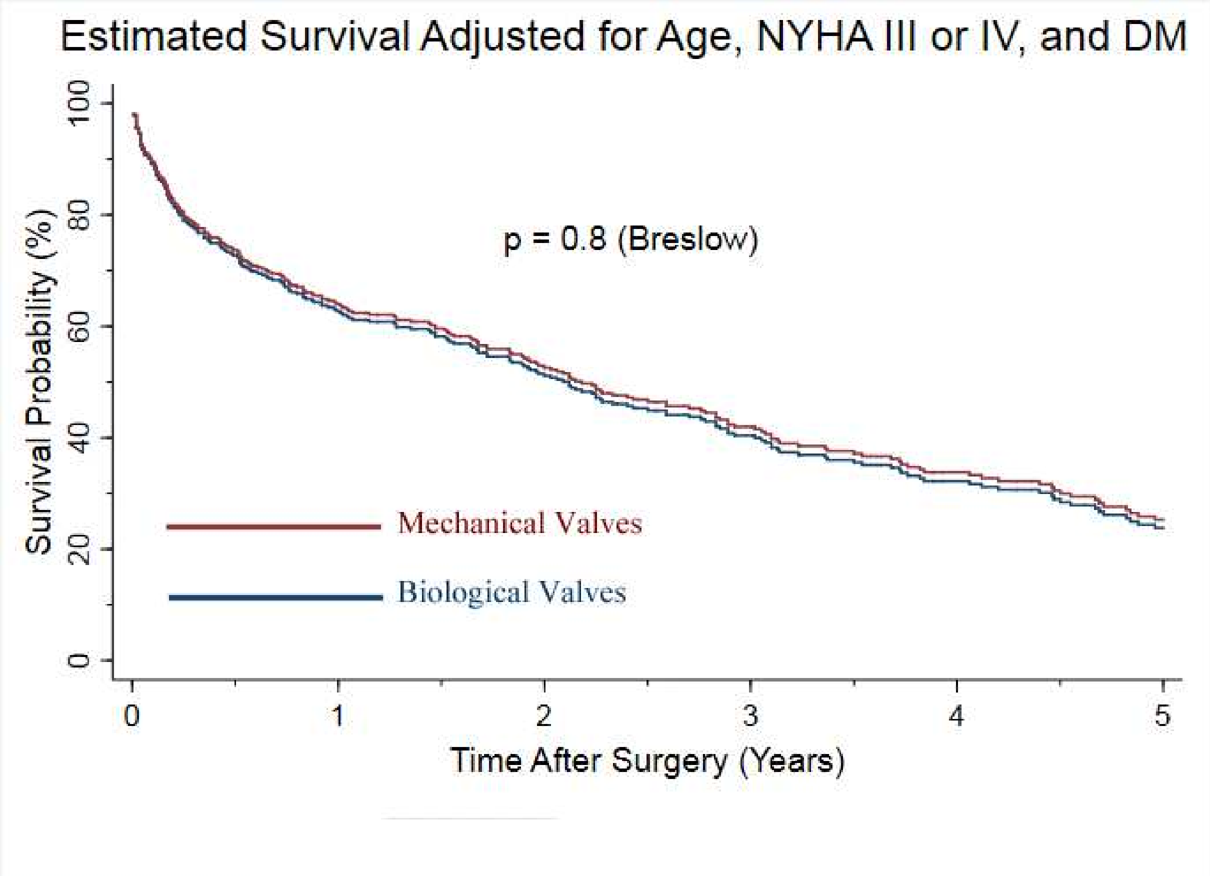
Glossary of Abbreviations

AVR- Aortic valve replacement
MVR-Mitral valve replacement
TAVR-Transcatheter Aortic Valve Replacement
NYHA-New York Heart Association
ESRD- End stage renal disease
LOS- Length of stay
DM- Diabetes mellitus
HR- Hazard Ratio

Central Picture



Central Message

The majority of dialysis-dependent patients undergoing valve replacement have poor survival. Given that survival is short, biological valves may be the more appropriate choice in most patients.

Perspective Statement

There is little data to guide valve type selection in dialysis-dependent patients. Our findings show that long-term survival is poor in patients undergoing valve replacement surgery. Due to the short survival time, a biological valve is likely sufficient for most patients; however, young patients without diabetes or heart failure may survive long enough to justify placement of a mechanical valve.

Structured Abstract

Objective: Valve selection in dialysis-dependent patients can be difficult because long-term survival is diminished and bleeding risks while on anticoagulation are greater in patients with renal failure. This study analyzed long-term outcomes of dialysis-dependent patients undergoing valve replacement to help guide optimal prosthetic valve type selection

Methods: Dialysis-dependent patients undergoing aortic and/or mitral valve replacement at 3 institutions over 20 years were examined. The primary outcome was long term survival. A Cox regression model was used to estimate survival by five ages, presence of diabetes, and/or heart failure symptoms.

Results: 423 available patients were analyzed. 341 patients had biological and 82 had mechanical valves. Overall complication and 30-day mortality rates were similar between the groups. Thirty day readmission rates for biological and mechanical groups were 15% (50/341) and 28% (23/82, p=0.005). Five year survival was 23% and 33% for the biological and mechanical groups, respectively. After adjusting for age, NYHA class, and diabetes using a multivariable Cox regression model, survival was similar between groups (HR 0.93, CI 0.66-1.29, p=0.8). A Cox regression model based on age, diabetes, and heart failure, estimated that patients only 30 or 40 years old, with NYHA class I-II failure without diabetes had a >50% estimated 5-year survival(p=<0.001).

Conclusion: Patients who were on dialysis and underwent valve replacement surgery had poor long-term survival. Young patients without diabetes or NYHA III or IV symptoms may survive long enough to justify placement of a mechanical valve; however, a biological valve is suitable for most patients.

Abstract: 249/250 words

Introduction

There are 120,000 cases of new end stage renal disease (ESRD) diagnosed every year and this number continues to rise. Approximately 90% of these patients are started on hemodialysis. Mortality rates among dialysis patients remain high. Overall 5 year survival for patients with ESRD on dialysis is about 40% (1). Cardiovascular diseases comprise the leading cause of death in this patient population, as a result cardiac surgeons perform an increasing number of high risk operations, including valve replacement surgery (1).

There is debate about the optimal choice of prosthesis for valve replacement in dialysis-dependent patients. Early AHA/ACC guidelines (1998) recommended placement of mechanical valves in all dialysis-dependent patients undergoing valve replacement surgery (2). However, based on small reports that showed equivalent outcomes in patients who received both types of valves, in 2006, the guidelines were revised and ceased to have explicit criteria for valve selection; the most current guidelines also do not give specific guidance. The most current recommendation is that valve selection should be individualized to the patient (3). Unfortunately, there is a paucity of reports which aid in this selection process, as most studies have small samples sizes, are single center, and/or are retrospective in nature.

Compared to mechanical valves, biological valves have poor longevity which has been attributed to advanced calcification and degeneration (4). These processes are thought to be exacerbated by hematological changes in patients with ESRD; however studies comparing mechanical vs biological valves in hemodialysis dependent patients have not shown a definitive survival advantage of one valve type (5-7). A prevailing challenge with mechanical valve replacement in the dialysis population is that these patients require frequent AV fistulae access and are more prone to major bleeding events(8). Given the poor long-term survival of dialysis-dependent patients it is reasonable to believe that those receiving bioprosthetic valves may die before valve failure.

The purpose of this study was to compare postoperative outcomes and long-term survival of patients who required pre-operative hemodialysis and underwent valve replacement surgery with either biological or mechanical valves. We hypothesized that the majority of patients would not live long enough postoperatively to justify placement of a mechanical valve.

Methods

All patients who were on pre-operative hemodialysis who underwent mitral valve replacement (MVR) or aortic valve replacement (AVR) between January 1998 and August 2017 were identified retrospectively at 3 institutions located in the Midwest. Two institutions were major academic hospitals and one was a community hospital. The requirement for individual consent for this study was waived by the institutional review boards at each institution. Inclusion criteria included patients who underwent aortic and/or mitral valve replacement and required preoperative hemodialysis for≥30 days. Those who underwent transcatheter valve replacement (TAVR) or aortic root replacement were excluded. EuroScore II was calculated based on age, gender, renal impairment, extracardiac arteriopathy, poor mobility, previous cardiac surgery, chronic lung disease, active endocarditis, critical preoperative state, diabetes on insulin, NYHA class, left ventricular function, recent MI, pulmonary hypertension, urgency of operation, weight of intervention, and surgery on thoracic aorta. If the data was not available the variable was omitted from the EuroScore II calculation. Preoperative diabetes does not distinguish between those patients who were on insulin.

The primary outcome measure was long-term survival. Secondary outcomes included estimated survival by a Cox-regression model for 5 ages (30, 40, 50, 60, and 70 years old) and presence or absence of diabetes mellitus and/or heart failure, 30-day mortality, hospital length of stay (LOS), ventilator hours, need for reoperation, and 30-day readmission rates. Survival data were obtained for all patients through interrogation of institutional medical records databases, obituaries, and the Social Security Death Index. Operative mortality was defined as death that occurred during the index hospitalization or within 30 days of the operation. Long-term survival data included death from all causes. The follow-up closing date was October 7th, 2017.

The Shapiro-Wilk test was used to assess the distribution of the study population. To address missing data, multiple imputation was employed. The expected maximization method was used for continuous variables and regression was used for categorical variables. Continuous data were reported as mean ± SD, or median [Interquartile range] as appropriate, and were compared between groups using the Students t-test and Mann-Whitney U test, respectively. Categorical variables were compared using chi-squared analysis. Survival estimates were generated using the Kaplan-Meier method and subsequently compared using the log rank test. Predictors of mortality were identified by univariable analysis using a p-value cutoff of 0.1 and then entered into a multivariable analysis. A multivariable Cox regression model was used to estimate survival based on those factors found to be significant for survival: age and the presence or absence of diabetes and/or NYHA III or IV symptoms. Propensity score matching using a caliper of 0.1 was performed using variables from Table 1.A logistic model with nearest neighbor algorithm, greedy method, and a 1:1 match was used. Variables selected included age, diabetes, EuroScore II, redo operation, valvulopathy, coronary artery disease, gender, endocarditis, hypertension, peripheral vascular disease, cerebrovascular disease, previous valve procedure, preoperative ejection fraction, and preoperative NYHA III or IV heart failure symptoms. Statistics were done using STATA Version 15.0 (STATA Corp, College Station, Texas). A P-value of ≤0.05 was considered statistically significant.

Results

Four hundred and ninety-two patients underwent valve replacement over the 20 year period and 423 were included in the analysis. Sixty-nine patients were excluded because they underwent aortic root replacement or TAVR. Three-hundred and forty-one patients underwent replacement with a biological valve and 82 underwent replacement with a mechanical valve. There were no patients who had undergone preoperative kidney transplantation. One-hundred and forty nine (35%) were from Indiana University, 196 (46%) were from Barnes-Jewish Hospital, and 80 (18%) were from Christian Northeast Hospital. Median follow up was 1.28 [IQR: 0.2, 3.1] years and survival data were available for 81% of patients. Baseline preoperative characteristics are summarized in Table 1. The average age for patients who had biological valves was 60 ±13.5 and 51±12.8 years for patients who had mechanical valves placed (p=<0.001). The average EuroScore II was 12.3%±7.8 and 8.9%±6.7 for the biological valve and mechanical valve groups, respectively (p=0.002). Eighty-one (23%) and 14 (17%) of the biological and mechanical valve groups were reoperations, respectively. More specifically, 54 (15%) of the biological valve group had a previous valve operation and 11 (13%) of the mechanical valve group had a previous valve operation. There were no significant differences between evaluated intra-operative variables (Table 1). Overall complication and 30-day mortality rates were similar between groups (Table 2). However, 23/82 (28%) of patients in the mechanical valve group were readmitted within 30 days compared to 50/341 (15%) in the biological valve group (p=0.005). Regarding 30 day mortality, cause of mortality was available for 40/55 patients. Of these patients, 20 died from a cardiac related cause, 5 were pulmonary related, 5 were neurologic, 1 was vascular, and 10 were sepsis related.

Presence of diabetes mellitus, age, and NYHA III or IV symptoms were all significant predictors of mortality (Table 3). Having two or more valves replaced was not a predictor of poor outcomes (HR: 0.873, (95% CI: 0.625-1.220, p=0.43) as demonstrated by the univariable Cox analysis. Based on Kaplan Meier analysis, five year survival was 23% for the biological valve group and 33% for the mechanical valve group. Ten-year survival was 5% and 20% with a median survival of 2.06 [1.56, 2.36] and 3.02 [1.69, 4.34] years for the biological and mechanical groups, respectively (p=0.017, Figure 1). No patients in either group survived longer than 13 years. When adjusted for age, NYHA class, and diabetes using a multivariable Cox regression model, survival was similar between groups (HR 0.93, 95% CI 0.66-1.29, p=0.86, Figure 2). Propensity score matching yielded 75 patients in the biological valve group and 75 patients in the mechanical valve group (Supplemental Figures 1-4). Survival was similar in each group (Supplemental Figure 4). Patients who received a biological valve spent significantly more hours on the ventilator (Supplemental Table 1).

A Kaplan Meier analysis comparing patients with and without endocarditis showed a 5 year survival of 25% and 25%, respectively (p=0.591). Cox regression using variables found to be significant for long-term survival was employed to estimate 5-year survival based on five ages (30, 40, 50, 60, and 70 years old), diabetes, and NYHA class ≥3 (p=<0.001, Figure 4, Table 4). Only patients who were 30 or 40 years old and in NYHA class I-II failure without diabetes had a >50% estimated 5-year survival (Harrell's C coefficient 0.61, Table 4).

Discussion

The vast majority of hemodialysis patients who underwent valve replacement surgery had poor long-term survival. At five years postoperatively, only 23% and 33% of patients were alive in the biological and mechanical groups, respectively. These findings are similar to previous smaller studies. Brinkman *et al.* showed that overall survival of patients undergoing dialysis at 6 years was 15.9% in a cohort of 72 patients (9), and Zhibing and colleagues showed an estimated 5 year patient survival rate with bioprosthetic valves of 53% versus 56.8% with mechanical valves in 73 dialysis-dependent patients who had undergone surgery (4).

Cardiovascular disease remains the most common cause of death in patients requiring dialysis. This patient population represents an ongoing challenge to physicians as they are high risk surgical candidates (1). Valve selection in dialysis patients presents a dilemma to cardiac surgeons as they must assess the risk for accelerated bioprosthetic valve deterioration due to calcification against the morbidity and mortality associated with anticoagulation (4,10,11). Anticoagulation in this patient population can be problematic, especially in those who require vascular access several times per week. Furthermore, they must assess these risks and benefits in the face of known poor long-term survival. Previous guidelines established in 1998 from the American College of Cardiology and American Heart Association recommended placement of mechanical heart valve prostheses for patients with ESRD requiring dialysis (2). These recommendations were based on concern for accelerated calcification of bioprosthetic valves. However, several studies subsequently have shown that there was no difference in survival between patients who received mechanical versus biological prostheses (4,9,12-15). The most notable study done by Herzog *et al.* retrospectively identified 5858 dialysis patients who underwent heart valve replacement surgery from the US Renal Data System database. It showed that survival with tissue prosthetic valves at 5 years was 13.8% vs 14.9% in patients who received mechanical valves (5). The guidelines were subsequently updated in 2006 and 2014, and they no longer have specific recommendations for valve selection in this patient population. It is recommended to individualize prosthesis selection. However, choice of valve type remains difficult as there is limited data defining long-term survival in this population (3,12).

Our findings of very poor long-term survival (13% overall at 10 years) mirrors the US renal data system estimation of survival as well as other studies (16, 17). After adjusting for age, NYHA class, and diabetes there was no difference in survival between those who had biological valves, or those who had mechanical valves placed in this current stud. Furthermore, propensity score matching corroborated our multivariable analysis.

To delineate who might live long enough to warrant a mechanical valve, a Cox-Regression analysis was performed to estimate survival based on 5 different ages (30, 40, 50, 60, or 70 years old), and the presence of diabetes and/or heart failure. Only patients aged 30 or 40 years old in NYHA class I-II failure without diabetes had a >50% estimated 5-year survival (Figure 4, Table 4). In our study, this represented only 24 patients, or 7% of the total group of 423. In our model, a physician can evaluate a patient based on age, and presence of diabetes or heart failure and gain insight regarding survival following valve replacement. This model may help guide valve selection in this complicated group of patients. Larger prospective studies are needed to corroborate our findings.

In our study 15% of patients with biological valves were readmitted versus 28% of patients with mechanical valves within 30 days of discharge. Of those who had a known reason for readmission, 10/70 (14%) in the mechanical valve group were readmitted for bleeding complications versus 6/70 (8.5%) in the biological valve group. The majority of bleeding complications occurred within the first few months of initiation of anticoagulation. Because anticoagulation carries an increased risk of morbidity and inconveniences these patients, mechanical valves should be reserved for only those with an estimated long term survival that is longer than the time a biological valve might deteriorate. This study suggests that only very young people (e.g.30-40 years old) without diabetes or NYHA III or IV symptoms have a high enough estimated survival to warrant consideration of a mechanical valve and anticoagulation.

The limitations of this study include that it was retrospective in nature and thus subject to the threats inherent to this design. Furthermore, as no standardized protocols were used for the selection of valve type, surgeon bias likely influenced the data. We had limited echocardiographic data to confirm the longevity of valves. Due to limitation of databases and data accrual from a multi-institutional study, follow up of patients was not 100% complete, which limits the accuracy of results. However, estimated survival rates were highly statistically significant, which indicates sufficient numbers were available for estimation of long-term mortality. A larger prospective randomized study would be needed to corroborate our results.

In conclusion, patients who require dialysis and undergo valve replacement surgery have poor long-term survival. Valve type must ultimately be tailored to each patient. Since most patients have very poor short term (<5 year) survival, biological valves should be strongly considered. In our model, only young patients (age 30 or 40), without diabetes or NYHA III or IV symptoms had an estimated 5-year survival >50%; Therefore, only in this small segment of the overall population may it be justifiable to place a mechanical valve.

Table 1: Preoperative characteristics of hemodialysis-dependent patients who underwent valve replacement with biologic or mechanical valves

Preoperative Variable	**Biologic(n=341)**	**Mechanical (n=82)**	**p value**
Age	60.1 ± 13.5	50.9 ±12.8	**<0.001**
Gender (Female)	123 (36)	30 (37)	0.898
BMI	29.2 ±7.8	29.9 ±8.2	0.581
Race (white)	222 (65)	50 (62)	0.605
Euro Score II	9.43±7.86	6.79±6.71	**0.002**
NYHA Class III or IV	234 (68)	54 (66)	0.872
Ejection Fraction	50.8 ±14.9	53.5 ±14.9	0.170
Smoker	141 (42)	38 (47)	0.885
HTN	304 (89)	73 (90)	0.845
Cerebrovascular disease	93 (27%)	15 (18%)	0.062
Dyslipidemia	201 (59%)	40 (48%)	0.112
Diabetes	159 (46)	32 (40)	0.267
PVD	103 (30)	16 (20)	0.074
Chronic Lung Disease	107 (31)	19 (23)	0.070
Previous Sternotomy	81 (23)	14 (17)	0.239
Previous valve operation	54 (15)	11 (13)	0.731
Endocarditis	121 (35)	24 (30)	0.364
Intraoperative Variable			
AVR	211	42	N/A
MVR	89	28	
Two or more valves	41	12	
AVR + MVR	39	10	
AVR +MVR + TVR	1	0	
AVR + TVR	1	1	
MVR + TVR	0	1	
Cross clamp time (min)	118.8 ±57	127.0 ±64	0.301
CPB time (min)	169.4±76	185.38±90	0.148
Tricuspid valve procedure	28 (8%)	8 (10%)	0.36
Concomitant CABG	96 (28)	15 (18.2)	0.092

BMI, body mass index; NYHA, New York Heart Association Heart Failure Class. HTN, hypertension. PVD, peripheral vascular disease. AVR, aortic valve replacement. MVR, mitral valve replacement. TVR, tricuspid valve repair or replacement. CPB, cardiopulmonary bypass. CABG, coronary artery bypass

Table 2: Postoperative outcomes of dialysis dependent patients who underwent valve replacement with biological or mechanical valves.

Variable	Biologic (n=341)	Mechanical (n=82)	p value
Ventilator Hours	33[10,118]	19[10,117]	0.081
Reoperation for bleeding	16 (5)	5 (6)	0.572
Sepsis	42 (12)	5 (6)	0.167
Stroke	14 (4)	4 (5)	0.759
Atrial fibrillation	109 (32)	23 (28)	0.595
Length of Stay	13 [5, 21]	13 [8,22]	0.632
30 day Mortality	47 (14)	8 (10)	0.462
30 day readmission	50 (15)	23 (28)	**0.005**
Readmission for bleeding	6/70(8.5)	10/70(14)	0.084

Table 3: Univariable and multivariable predictors of mortality following valve replacement in patients with end stage renal disease who required hemodialysis.

	Univariable Analysis			Multivariable Analysis		
Variable	Hazard Ratio	95% CI	p-value	Hazard Ratio	95% CI	p value
Age	1.03	1.02-1.04	<0.001	1.09	1.011-1.11	<0.001
Gender	1.02	0.96-1.53	0.13			
Race	1.02	0.91-1.52	0.24			
BMI	1.00	0.99-1.03	0.42			
EuroScore II	1.01	1.00-1.05	0.14			
NYHA Class III or IV	1.39	1.03-1.89	0.033	1.36	1.01-1.82	0.048
Ejection Fraction	0.98	0.97-0.99	0.12			
Smoker	1.10	0.97-1.61	0.17			
HTN	0.91	0.62-1.33	0.64			
CVD	1.03	0.85-1.40	0.50			
Dyslipidemia	1.00	0.78-1.30	0.97			
PVD	0.76	0.61-0.99	0.14			
Chronic Lung Disease	0.91	0.72-1.16	0.91			
Previous Sternotomy	0.79	0.61-1.04	0.11			
Previous Valve	0.86	0.62-1.20	0.86			
Endocarditis	1.21	0.89-1.52	0.30			
Diabetes	1.41	1.25-1.63	0.001	1.54	1.21-2.01	0.001

HTN, Hypertension. NYHA, New York Heart Association. CVD, Cerebrovascular disease. PVD, Peripheral vascular disease

Figure 1: Unadjusted Kaplan Meier analysis for dialysis-dependent patients undergoing valve replacement with mechanical vs biological valves.

Figure 2: Overall survival of dialysis-dependent patients undergoing valve replacement surgery with biological and/or mechanical valves. Four hundred twenty three patients were included in the analysis.

Figure 3: Cox regression analysis for patients undergoing valve replacement. Estimation of 5 year survival was generated using a cox regression analysis. Variables included in this model were age, NYHA III or IV symptoms, and presence of diabetes which were all significant predictors of mortality.

Figure 4: Patient plots showing estimated survival for a 30 year old dialysis-dependent patient without diabetes and NYHA III or IV heart failure symptoms and a 70 year old dialysis-dependent patient with diabetes and NYHA III or IV symptoms following valve replacement using a cox regression analysis. ($p=<0.001$) DM-Diabetes mellitus, NYHA-New York Heart Association.

Supplementary Figure 1: Variables included in the propensity analysis and their before and after matching standardized differences. PVD-Peripheral vascular disease, CVD- cerebrovascular disease, NYHA-New York Heart Association, CAD- Coronary artery disease.

Supplementary Figure 2: Standard differences pre-propensity matching.

Supplementary Figure 3: Standard differences post-propensity matching.

Supplementary Figure 4: Survival analysis of propensity-matched groups using Kaplan Meier method.

Table 4: Estimated 5 year survival based on 5 ages (p<0.001, HR 1.09: 95% CI [1.01-1.11]), diabetes (p<0.001, HR 1.54: 95% CI [1.21-2.01]), and/or NYHA heart failure symptoms (p=0.048, HR 1.36: 95% CI [1.01-1.82]).

Age Group	**No Diabetes**		**+ Diabetes**	
	NYHA I-II	NYHA III-IV	NYHA I-II	NYHA III-IV
30 years	61%	50%	46%	35%
40 years	54%	43%	38%	27%
50 years	46%	34%	30%	19%
60 years	35%	27%	22%	13%
70 years	31%	19%	16%	8%

NYHA, New York Heart Association Heart Failure Class. HR, Hazard Ratio

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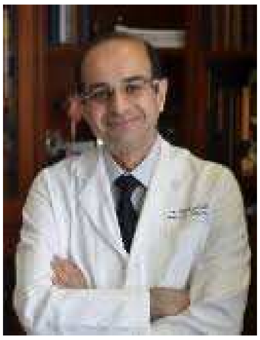

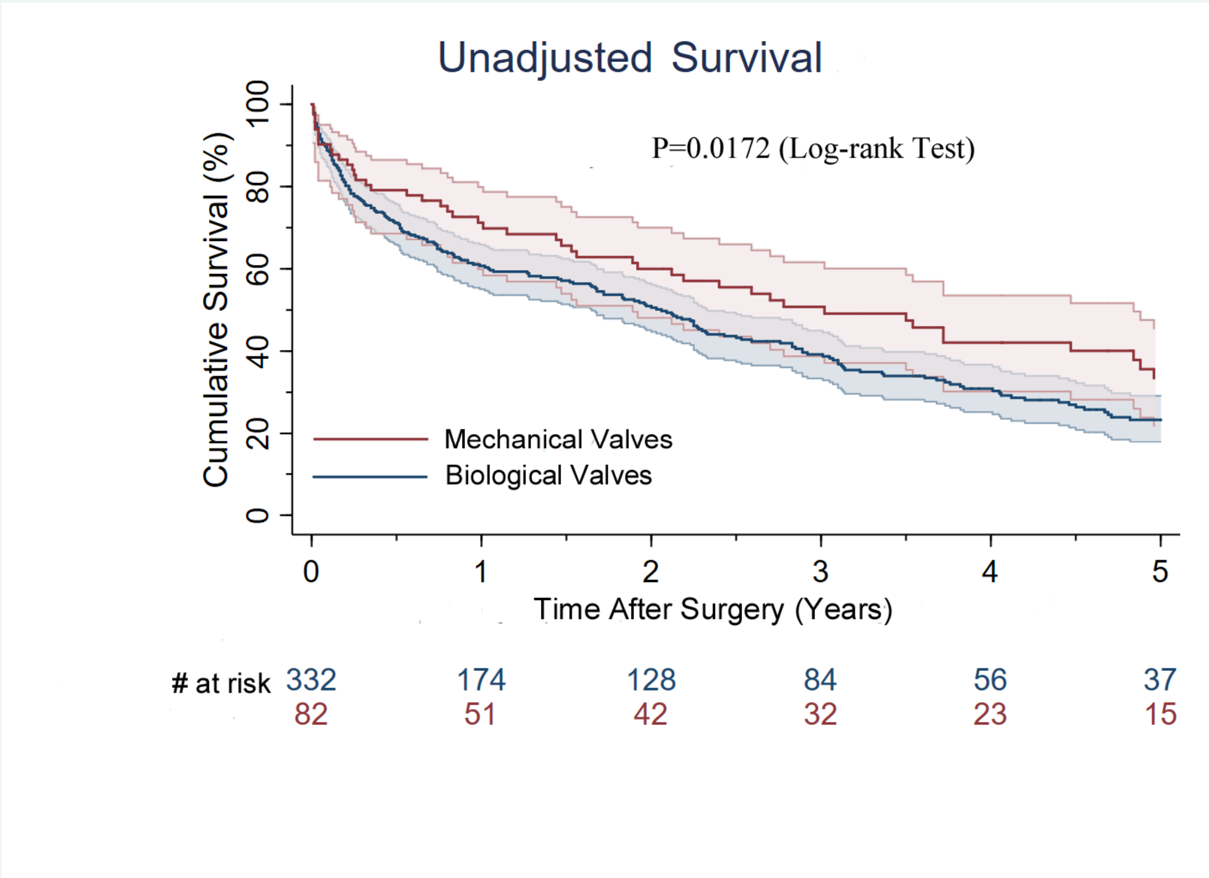
Unadjusted Survival
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Cumulative Survival (%)
0
20
40
60
80
100
Mechanical Valves
Biological Valves
0
1
2
3
4
5
Time After Surgery (Years)
at risk
332
174
128
84
56
37
82
51
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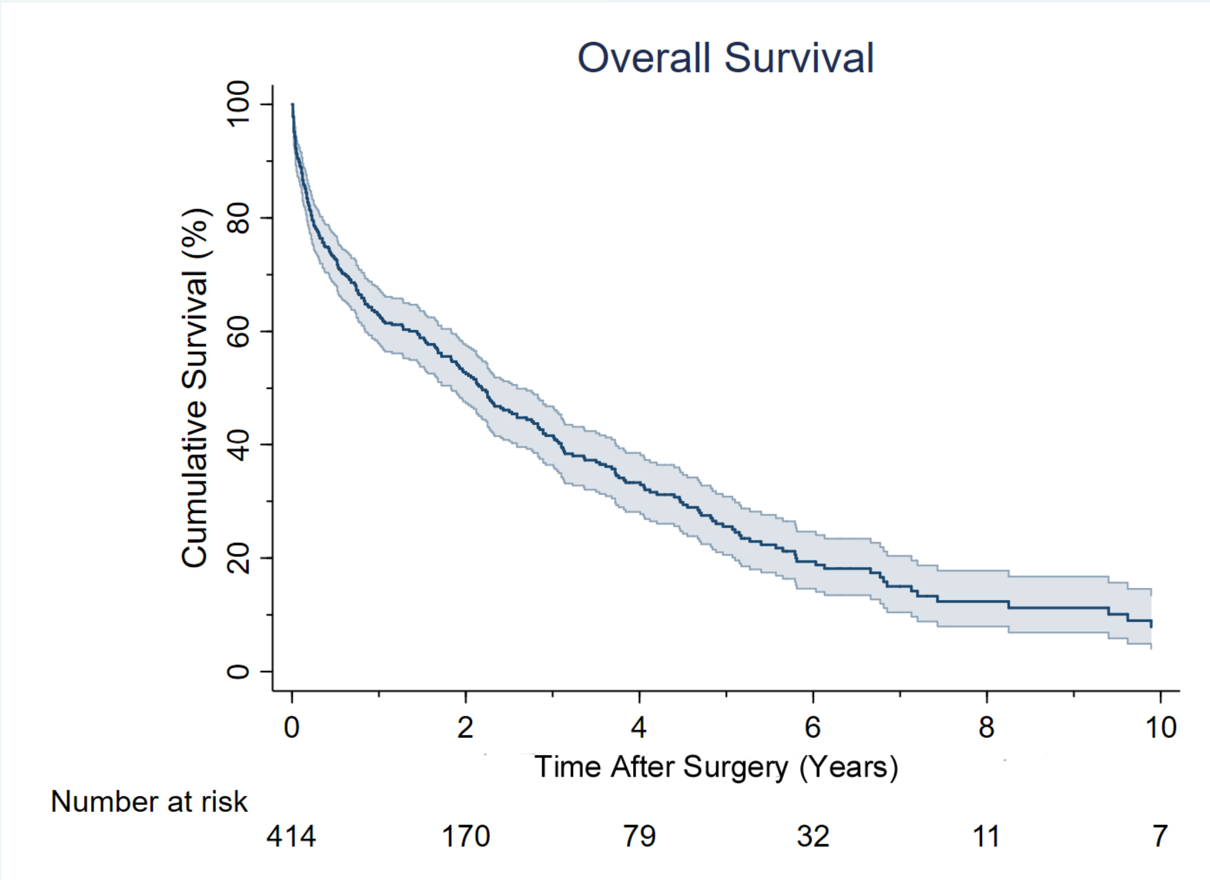
Overall Survival
Cumulative Survival (%)
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20
40
60
80
100
0
2
4
6
8
10
Time After Surgery (Years)
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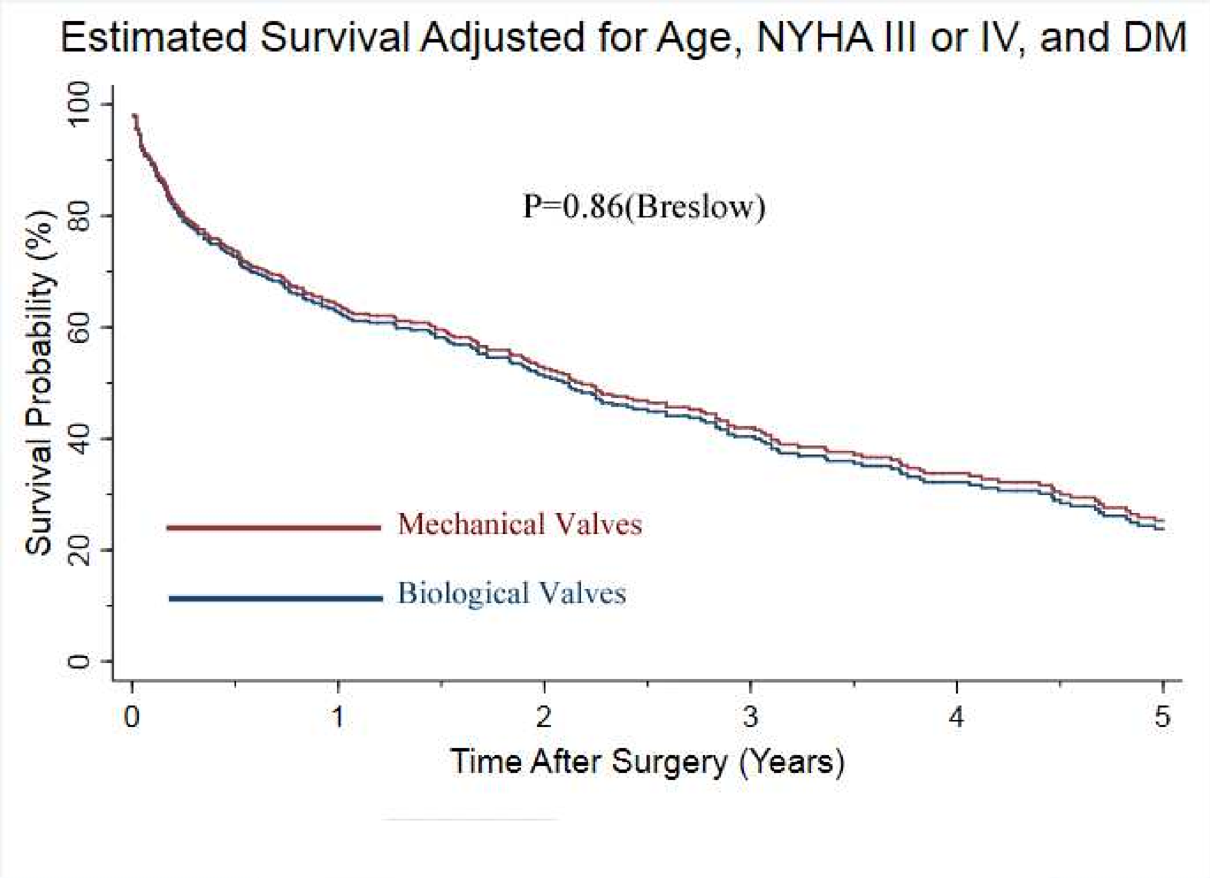
32
11
7


Estimated Survival Adjusted for Age, NYHA III or IV, and DM
Survival Probability (%)
0
20
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P=0.86(Breslow)
Mechanical Valves
Biological Valves
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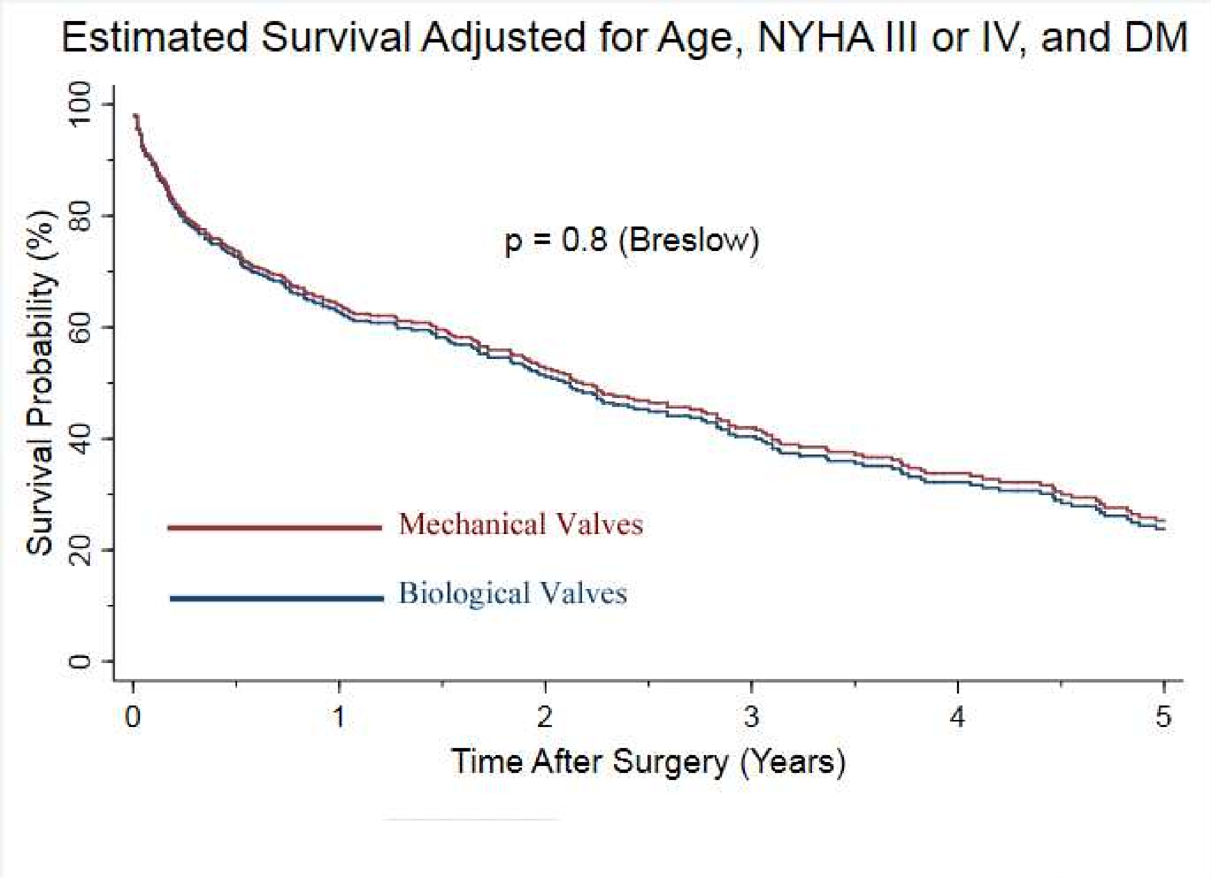
Time After Surgery (Years)


Estimated Survival Adjusted for Age, NYHA III or IV, and DM
Survival Probability (%)
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Mechanical Valves
Biological Valves
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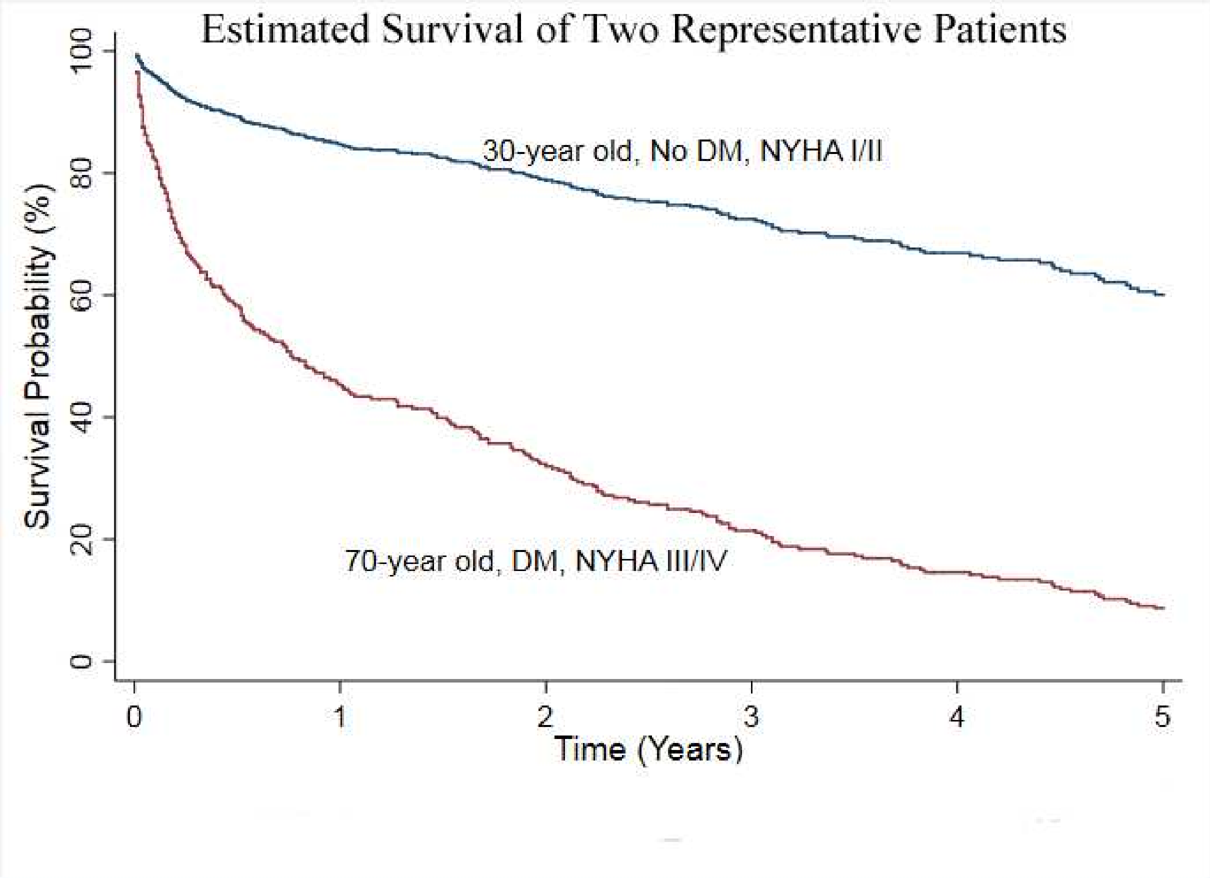
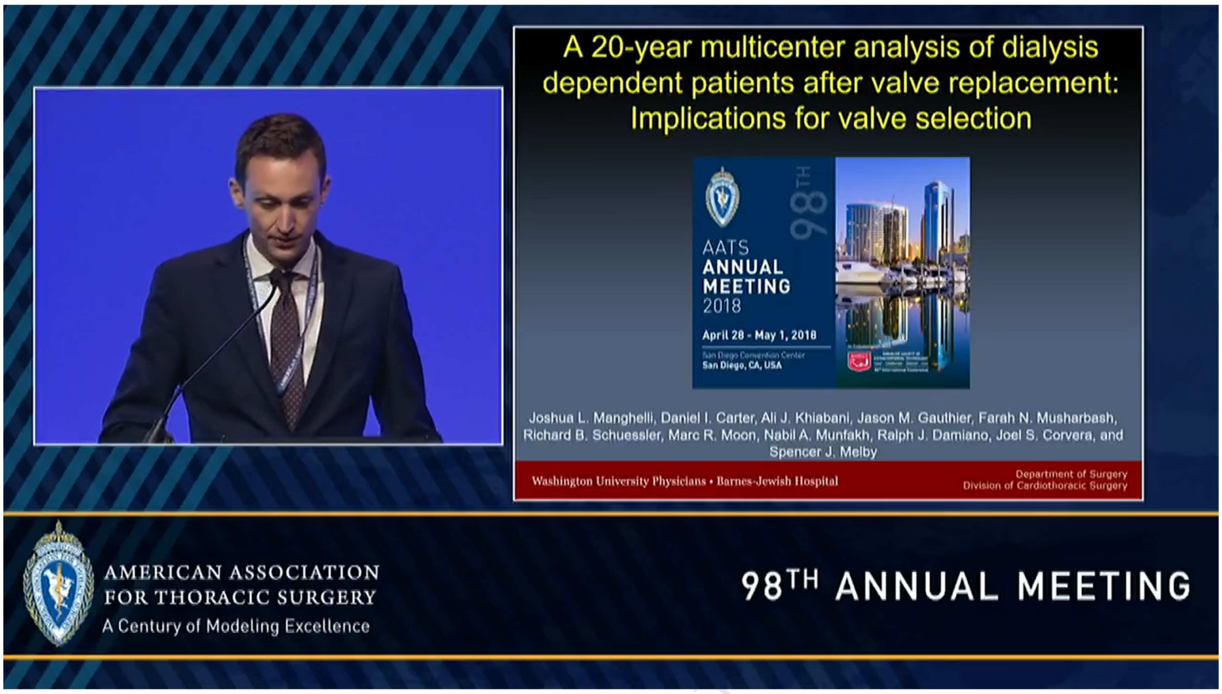
5
Time After Surgery (Years)


Estimated Survival of Two Representative Patients
30-year old, No DM, NYHA I/II
70-year old, DM, NYHA III/IV
Survival Probability (%)
0
20
40
60
80
100
0
1
2
3
4
5
Time (Years)


A 20-year multicenter analysis of dialysis dependent patients after valve replacement: Implications for valve selection
AATS
ANNUAL
MEETING
2018
98TH
April 28 - May 1, 2018
San Diego, CA, USA
Joshua L. Manghelli, Daniel I. Carter, Ali J. Khiabani, Jason M. Gauthier, Farah N. Musharbash, Richard B. Schuessler, Marc R. Moon, Nabil A. Munfakh, Ralph J. Damiano, Joel S. Corvera, and Spencer J. Melby
Washington University Physicians • Barnes-Jewish Hospital
Department of Surgery
Division of Cardiothoracic Surgery
AMERICAN ASSOCIATION
FOR THORACIC SURGERY
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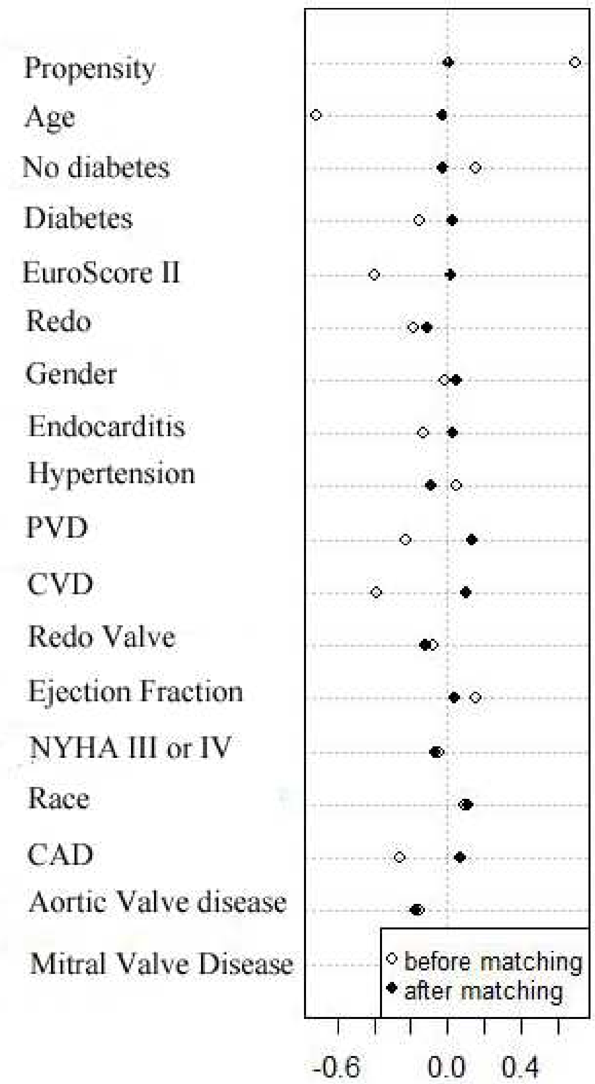
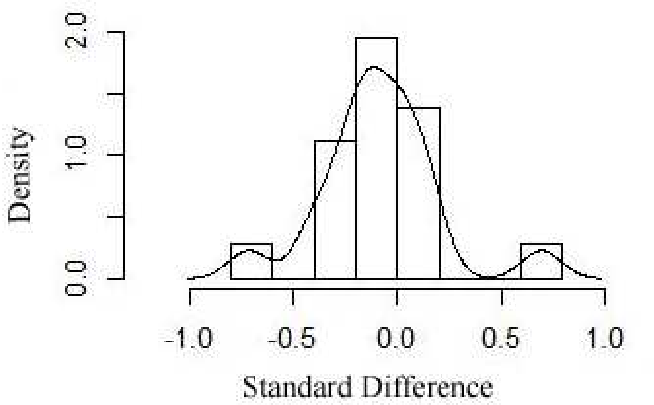
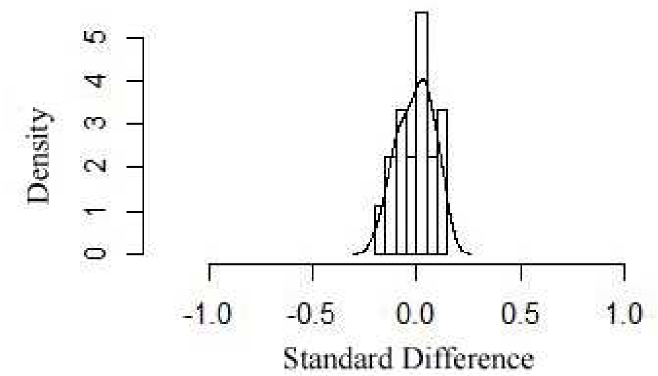
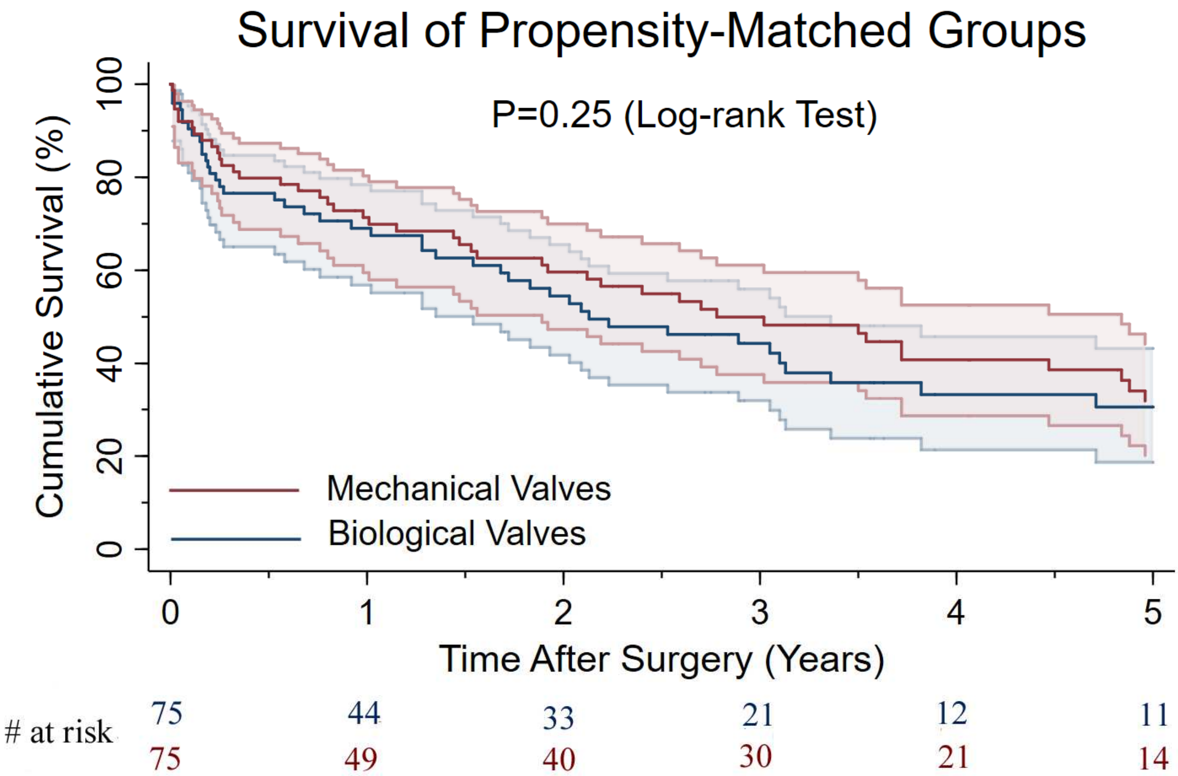
98TH ANNUAL MEETING


Propensity
Age
No diabetes
Diabetes
EuroScore II
Redo
Gender
Endocarditis
Hypertension
PVD
CVD
Redo Valve
Ejection Fraction
NYHA III or IV
Race
CAD
Aortic Valve disease
Mitral Valve Disease
before matching
after matching
-0.6
0.0
0.4


2.0
1.0
0.0
Density
-1.0
-0.5
0.0
0.5
1.0
Standard Difference


Density
0
1
2
3
4
5
-1.0
-0.5
0.0
0.5
1.0
Standard Difference


Survival of Propensity-Matched Groups
P=0.25 (Log-rank Test)
Cumulative Survival (%)
0
20
40
60
80
100
Mechanical Valves
Biological Valves
0
1
2
3
4
5
Time After Surgery (Years)
at risk
75 44 33 21 12 11
75 49 40 30 21 14