Original Article

Mechanical versus bioprosthetic valves in patients on dialysis

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Background: The aim of this study is to evaluate the outcomes of bioprosthetic versus mechanical valves in patients on dialysis.

Methods: All patients who underwent aortic (AVR) or mitral valve replacement (MVR) at a single institution from 2011–2017 were reviewed. Primary stratification was bioprosthetic versus mechanical valves. The primary outcome was all-cause mortality. Secondary outcomes included hospital readmission, valve reoperation rates and bleeding events. Kaplan-Meier curves were generated and Cox proportional hazards regression models were used for risk-adjustment.

Results: During the study period, 3,969 patients underwent AVR or MVR, of which 97 (2.4%) were on dialysis. In dialysis patients, unadjusted 30-day mortality was comparable between bioprosthetic (12.7%) versus mechanical (5.9%) valves (P=0.31). However, the bioprosthetic group had higher rates of 1-year (40.3% versus 15.2%; P=0.03) and 5-year mortality (67.9% versus 60.7%; P=0.02). Most patients were readmitted within 5 years with no differences between the groups (bioprosthetic 80.3% versus mechanical 100%; P=0.57). There were no valve reoperations in either group at 5 years. The 5-year readmission rate was higher in the mechanical cohort (10.5% versus 53.8%; P=0.05). Risk-adjusted analysis confirmed these findings, where mechanical valves were independently associated with reduced mortality at 1-year and 5-years.

Conclusions: Despite the limited life expectancy of patients on dialysis, mechanical valves have an intermediate term mortality benefit compared to bioprosthetic valves. This comes at the expense of a higher rate of readmission for bleeding. Although valve choice should consider multiple factors, these data suggest that mechanical valve usage in dialysis patients is reasonable.

Keywords: Dialysis; valve replacement; aortic valve; mitral valve; survival

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Introduction

End-stage renal disease (ESRD) continues to be a major healthcare burden. According to the annual report from the United States Renal Data System, approximately 30 million American adults have chronic kidney disease. In 2015, 124,111 new cases of ESRD were reported, with 690,899 cumulative cases (1). The management of valvular heart disease in ESRD can be challenging. Foremost, in-hospital and long-term morbidity and mortality is extremely high for patients undergoing heart surgery who have ESRD (2,3). Furthermore, there continues to be debate on the choice of prosthetic valve. Mechanical valves offer durability but require anticoagulation, while bioprosthetic valves do not require anticoagulation but have more limited durability. Implantation of mechanical valves has been questioned due to the decreased life expectancy and platelet dysfunction in ESRD patients (4,5). However, historically, there are concerns over early calcification and failure of bioprosthetic valves in these patients as well (6,7). To date, there are few

studies that have compared valve types in patients with ESRD with varying results (3,8-12). This study evaluated the impact of mechanical versus bioprosthetic valves on early and mid-term outcomes in patients with ESRD.

Methods

Study population

Adult patients aged 18 years or older undergoing either aortic valve replacement (AVR) or mitral valve replacement (MVR) at a single institution between 2011 and 2017 were included. The Society of Thoracic Surgeons Database was also used to obtain patient characteristics, risk algorithms, and mortality data. Urgent or emergent cases and endocarditis involving concomitant (other) valve surgery or coronary bypass grafting were included. This study was approved by the institutional review board (IRB approval # PRO16020002).

Baseline characteristics

Primary stratification of the study population was mechanical versus bioprosthetic valve replacement. Baseline preoperative and intraoperative characteristics were then compared between these cohorts. Preoperative variables included demographics such as age and sex, and comorbidities which included diabetes mellitus, hypertension, chronic lung disease, intravenous drug abuse, infective endocarditis, peripheral arterial disease, cerebrovascular disease, coronary artery disease, heart failure and preoperative use of an intra-aortic balloon pump. Operative variables that were compared included type of valve (AVR or MVR), approach (sternotomy versus right mini-thoracotomy), concomitant operations, cardiopulmonary bypass time, and aortic cross-clamp time.

Outcomes

The primary outcome was all-cause mortality, measured at 30 days, 1-year, and 5-years after valve surgery. Secondary outcomes included valve reoperation, hospital readmission and readmission for bleeding. Other secondary outcomes included postoperative complications such as blood product transfusion, sepsis, stroke, prolonged intubation, pneumonia, limb ischemia, pacemaker placement, gastrointestinal bleed and atrial fibrillation.

Kaplan-Meier curves were generated to evaluate unadjusted 30-day, 1 and 5-year mortality for mechanical versus bioprosthetic replacements. Kaplan-Meier curves were also generated for the secondary outcomes of valve reoperation, hospital readmission and readmission for bleeding. Cox proportional hazards regression models were developed for risk adjustment. All candidate variables were evaluated in univariate Cox regression analysis, and those variables that were associated with the outcome in univariate analysis were then incorporated in the multivariable Cox proportional hazards regression models.

All continuous data in this study are presented as mean ± standard deviation and all categorical data as number (percentage). Data analyses were performed with SAS statistical software version 9.4 (SAS Institute Inc., Cary, NC, USA). Continuous variables were compared using the unpaired student's *t*-test and categorical variables were compared using chi-square. In all analyses, a two-tailed P value of less than 0.05 was considered significant.

Results

Comparison of baseline variables

During the study period, 3,969 patients underwent AVR (n=3,118) or MVR (n=851), of which 97 (2.4%) were on dialysis. In total, there were 72 AVRs and 42 MVRs in the dialysis cohort. All patients who had concomitant AVR and MVR had the same valve type (bioprosthetic or mechanical) implanted in both positions. Demographics and comorbidities were similar except patients who received mechanical valves were significantly younger compared to patients who received bioprosthetic valves (*Table 1*). There was also a higher percentage of patients on immunosuppressive medications and lower percentage patients with peripheral vascular disease who received a mechanical valve. Patients who had recent or history of intravenous drug use were more likely to receive a mechanical valve (*Table 1*). Intraoperative data, including operative approach, concomitant procedures, cardiopulmonary bypass and aortic cross-clamp times were similar between valve choices (*Table 2*).

Operative outcomes

Post-operative complications for bioprosthetic versus mechanical valves were similar (*Table 3*). Unadjusted 30-day mortality was also comparable for bioprosthetic and mechanical valves (12.7% and 5.9%, respectively, P=0.31) (*Figure 1*). In addition, 30-day hospital readmission

Table 1 Baseline characteristics

Characteristics	Total	Bio prosthesis	Mechanical	P value
# Patients	97	63	34	
Mitral	42 (43.3%)	26 (41.3%)	16 (47.1%)	
Aortic	72 (74.2%)	50 (79.4%)	22 (64.7%)	
Patient characteristics				
Age	60.8±12.8	63.9±12.9	55.1±10.3	0.001
Sex				
Male	65 (67.0%)	44 (69.8%)	21 (61.8%)	0.420
Female	32 (33.0%)	19 (30.2%)	13 (38.2%)	
Race				
White	81 (83.5%)	58 (92.1%)	23 (67.6%)	0.002
Black	16 (16.5%)	5 (7.9%)	11 (32.4%)	
BMI	30.4±8.15	31.3±8.99	28.7±6.11	0.145
BSA	2.02±0.30	2.04±0.32	1.99±0.26	0.421
History and risk factors				
Diabetes	53 (54.6%)	36 (57.1%)	17 (50.0%)	0.570
Hypertension	84 (86.6%)	52 (82.5%)	32 (94.1%)	0.110
Chronic lung disease	40 (41.2%)	25 (39.7%)	15 (44.1)	0.894
IV drug abuse				
Yes	7 (7.2%)	2 (3.2%)	5 (14.7%)	0.001
Recent	7 (7.2%)	2 (3.2%)	5 (14.7%)	
Remote	9 (9.3%)	3 (4.8%)	6 (17.6%)	
Infective endocarditis				
None	59 (60.8%)	38 (60.3%)	21 (61.8%)	0.569
Treated	8 (8.2%)	4 (6.3%)	4 (11.8%)	
Active	30 (30.9%)	21 (33.3%)	9 (26.5%)	
Immunosuppressive medication therapy	21 (21.6%)	7 (11.1%)	14 (41.2%)	0.001
History of mediastinum radiation therapy	2 (2.1%)	1 (1.6%)	1 (2.9%)	0.654
History of peripheral arterial disease	26 (26.8%)	23 (36.5%)	3 (8.8%)	0.003
History of CVD	25 (25.8%)	14 (22.2%)	11 (32.4%)	0.276
History of heart failure	42 (43.3%)	26 (41.3%)	16 (47.1%)	0.583
Any arrhythmia	50 (51.5%)	35 (55.6%)	15 (44.1%)	0.282
Cardiogenic shock				
No	94 (96.9%)	60 (95.2%)	34 (100%)	0.644
Yes	1 (1.0%)	1 (1.6%)	0 (0.0%)	
Yes: at time of procedure	1 (1.0%)	1 (1.6%)	0 (0.0%)	
Yes: not at procedure, but within 24 hrs	1 (1.0%)	1 (1.6%)	0 (0.0%)	

Table 1 *(continued)*

Table 1 *(continued)*

Characteristics	Total	Bio prosthesis	Mechanical	P value
Creatinine	5.12±2.91	4.74±2.70	5.82±3.19	0.083
Total albumin	3.18±0.68	3.07±0.76	3.37±0.47	0.045
Total bilirubin	0.80±0.45	0.80±0.46	0.79±0.43	0.888
Preoperative hemodynamics				
Ejection fraction (%)	54.5±12.2	53.7±12.1	55.9±12.6	0.402
Aortic stenosis	61 (62.9%)	42 (66.7%)	19 (55.9%)	0.294
Mitral stenosis	24 (24.7%)	14 (22.2%)	10 (29.4%)	0.434
STS risk algorithms				
Mortality	14.6±12.2	16.5±14.1	11.3±6.64	0.128

Table 2 Operative variables

Variables	Total	Bio prosthesis	Mechanical	P value
# Patients	97	63	34	
Operation approach				
Full sternotomy	89 (91.8%)	58 (92.1%)	31 (91.2%)	0.852
Partial sternotomy	5 (5.2%)	3 (4.8%)	2 (5.9%)	
Right thoracotomy	1 (1.0%)	1 (1.6%)	0 (0.0%)	
Right mini-thoracotomy	2 (2.1%)	1 (1.6%)	1 (2.9%)	
Incidence				
First CV surgery	84 (86.6%)	57 (90.5%)	27 (79.4%)	0.103
First re-Op CV surgery	11 (11.3%)	6 (9.5%)	5 (14.7%)	
Second re-Op CV surgery	2 (2.1%)	0 (0.0%)	2 (5.9%)	
Status				
Elective	22 (22.7%)	17 (27.0%)	5 (14.7%)	0.097
Urgent	71 (73.2%)	42 (66.7%)	29 (85.3%)	
Emergent	4 (4.1%)	4 (6.3%)	0 (0.0%)	
Perfusion time (min)	160±65.3	158±70.7	163±55.0	0.723
Cross clamp time (min)	123±52.5	124±57.4	122±42.8	0.828
Pre-op IABP	1 (1.0%)	1 (1.6%)	0 (0.0%)	0.233
Concomitant procedures				
CABG	38 (39.2%)	23 (36.5%)	15 (44.1%)	0.464
Tricuspid	19 (19.6%)	11 (17.5%)	8 (23.5%)	0.472

Table 3 Postoperative outcomes

Variables	Total	Bio prosthesis	Mechanical	P value
# Patients	97	63	34	
Blood product transfused	75 (77.3%)	49 (77.8%)	26 (76.5%)	0.883
Sepsis	6 (6.2%)	3 (4.8%)	3 (8.8%)	0.428
Stroke				
No	96 (99.0%)	62 (98.4%)	34 (100%)	0.460
Yes, embolic or ischemic	1 (1.0%)	1 (1.6%)	0 (0.0%)	
Pulmonary ventilation >24 hrs	26 (26.8%)	18 (28.6%)	8 (23.5%)	0.593
Pneumonia	7 (7.2%)	4 (6.3%)	3 (8.8%)	0.653
Limb ischemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.99
Pacemaker	6 (6.2%)	5 (7.9%)	1 (2.9%)	0.426
GI event	9 (9.3%)	6 (9.5%)	3 (8.8%)	0.910
New onset atrial fibrillation	46 (47.4%)	25 (39.7%)	21 (61.8%)	0.038

Mortality	Bioprosthetic	Mechanical	P value
30-day	8 (12.7%)	2 (5.9%)	0.31
1-year	25 (40.3%)	5 (15.2%)	0.03
5-year	40 (67.9%)	11 (60.7%)	0.02

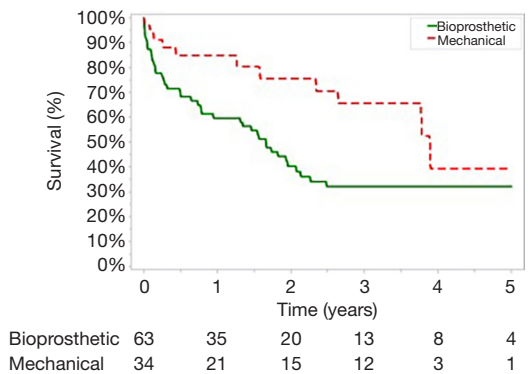

Figure 1 Freedom from mortality.

Inpatient readmission	Bioprosthetic	Mechanical	P value
30-day	19 (35.2%)	11 (36.4%)	0.99
1-year	34 (64.8%)	21 (69.6%)	0.71
5-year	40 (80.3%)	24 (100%)	0.57

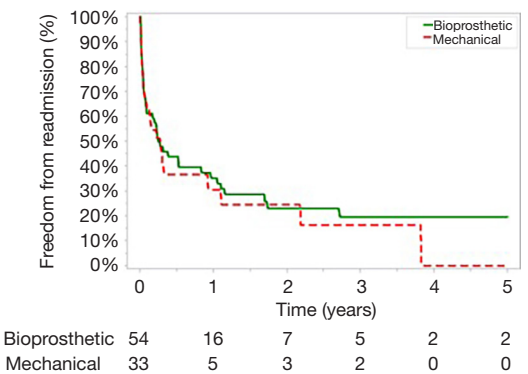

Figure 2 Freedom from inpatient readmission.

(bioprosthetic 35.2% *vs.* mechanical 36.4%, P=0.99) and readmission for bleeding (bioprosthetic 3.7% *vs.* mechanical 3.2%, P=0.89) were not significantly different between the groups (*Figures 1* and *2*).

Long-term outcomes

The mean follow-up was similar between patients who received a bioprosthetic (1.77±1.80 years) versus mechanical valve (2.01±1.63 years) (P=0.51). No patients had valve reoperations at 5 years in either group. The 1-year and 5-year unadjusted mortality rates were higher in the bioprosthetic group (1-year: bioprosthetic 40.3% versus mechanical 15.2%, P=0.03 and 5-year: bioprosthetic 67.9% versus mechanical 60.7%, P=0.021) (*Figure 1*). Although 1- and 5-year hospital readmission rates were comparable, the mechanical cohort did have a higher rate of 5-year readmission for bleeding (P=0.05) (*Figures 2* and *3*).

Inpatient readmission	Bioprosthetic	Mechanical	P value
30-day	2 (3.7%)	1 (3.2%)	0.89
1-year	5 (10.5%)	5 (16.7%)	0.37
5-year	5 (10.5%)	8 (53.8%)	0.05

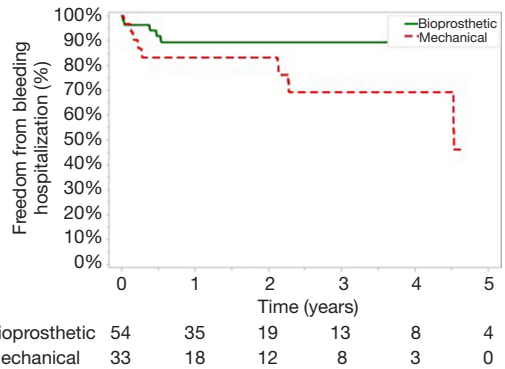

Figure 3 Freedom from re-hospitalization for bleeding.

After risk adjustment, the use of a mechanical prosthesis had a significant survival benefit at both 1-year (HR, 0.27, 95% CI: 0.10–0.74, P=0.010) and 5-year (HR, 0.43, 95% CI: 0.21–0.86, P=0.017) (*Tables 4* and *5*). Chronic lung disease as well as double valve replacement or MVR (as compared to AVR) were also shown to be strong predictors of 1- and/or 5-year mortality (*Tables 4* and *5*). Other variables that may have been expected to have an independent impact on mortality, such as age, gender, endocarditis, urgency of operation, heart failure and other concomitant procedures such as CABG or tricuspid valve procedures, did not have a significant impact on 1- or 5-year mortality (*Tables 4* and *5*).

Discussion

There is a growing population of patients with ESRD.

Table 4 Association between variables and 1-year mortality [30 total deaths (25 bio-prosthesis, 5 mechanical)]

Variables	Univariate models			Multivariate model*		
	Hazard ratio	95% CI	P value	Hazard ratio	95% CI	P value
Mechanical *vs.* bio-prosthesis	0.34	0.13–0.90	0.029	0.27	0.10–0.74	0.010
Age	1.02	0.99–1.05	0.242			
Female *vs.* male	1.50	0.72–3.11	0.279			
Chronic lung disease (*vs.* none)	2.82	1.19–6.70	0.019	4.94	1.91–12.79	0.001
Infective endocarditis (*vs.* none)						
Treated	1.33	0.39–4.55	0.645			
Active	1.28	0.58–2.79	0.540			
History of peripheral arterial disease	1.62	0.77–3.41	0.201			
Heart failure within 2 weeks	0.97	0.44–2.12	0.938			
Concomitant CABG	0.71	0.33–1.52	0.378			
Concomitant tricuspid	1.39	0.60–3.24	0.448			
Prior CT surgery (incidence)	1.42	0.54–3.72	0.478			
Status (*vs.* elective)						
Urgent	1.25	0.51–3.09	0.625			
Emergent	2.27	0.46–11.27	0.316			
Procedure type (*vs.* AVR)						
MVR	2.55	1.11–5.90	0.028	4.91	1.88–12.84	0.001
AVR and MVR	2.71	1.09–6.74	0.032	3.16	1.18–8.49	0.023

*, included any variables from the univariate models with P<0.200 in the multivariate model. AVR, aortic valve replacement; MVR, mitral valve replacement.

Table 5 Association between variables and 5-year mortality [51 total deaths (40 bio-prosthesis, 11 mechanical)]

Variables	Univariate models			Multivariate model*		
	Hazard ratio	95% CI	P value	Hazard ratio	95% CI	P value
Mechanical *vs.* bio-prosthesis	0.46	0.23–0.89	0.021	0.43	0.21–0.86	0.017
Age	1.01	0.99–1.03	0.318			
Female *vs.* male	1.14	0.64–2.04	0.657			
Chronic lung disease (*vs.* none)	2.63	1.35–5.12	0.005	3.85	1.85–8.03	<0.001
Infective endocarditis (*vs.* none)						
Treated	0.90	0.32–2.54	0.841			
Active	1.16	0.63–2.15	0.635			
History of peripheral arterial disease	1.37	0.76–2.48	0.294			
Heart failure within 2 weeks	0.62	0.35–1.11	0.107	0.60	0.32–1.12	0.107
Concomitant CABG	0.77	0.43–1.37	0.374			
Concomitant tricuspid	1.48	0.75–2.89	0.257			
Prior CT surgery (incidence)	1.41	0.63–3.16	0.402			
Status (*vs.* elective)						
Urgent	1.45	0.72–2.91	0.301			
Emergent	2.10	0.58–7.64	0.260			
Procedure type (*vs.* AVR)						
MVR	1.48	0.74–2.96	0.262	2.58	1.17–5.71	0.019
AVR and MVR	1.71	0.86–3.37	0.123	2.02	0.96–4.25	0.064

*, included any variables from the univariate models with P<0.200 in the multivariate model. AVR, aortic valve replacement; MVR, mitral valve replacement.

Though survival has improved from the 1970's to 2000's, once a person is diagnosed with ESRD requiring dialysis, there is still a significant loss of life years. It is estimated that a 50 year old with ESRD has an average life-years lost of almost 25 years (13). Cardiovascular diseases account for approximately 50% of mortalities in patients with ESRD (1).

Cardiac surgery in patients with preoperative ESRD has been shown to be associated with increased morbidity and mortality (14-17). The overall long-term prognosis and quality of life of these patients are quite poor ((15). There continues to be a debate on the most appropriate valve choice for a patient on ESRD. First, historically, there were concerns of early calcification of bioprosthetic valves and subsequent failure in small series from the 1970's (6,7). In addition to this, Ribeiro and colleagues showed that there is increased prevalence of cardiac valve calcification in patients on hemodialysis (18). Such studies suggest that the physiologic dysregulation of calcium in patients on hemodialysis makes them more prone to the development of calcium. These concerns manifested itself in the 1998 AHA/ACC guidelines for valve choice in dialysis patients which suggested that mechanical valves should be implanted (19).

The benefits of mechanical valves in patients with ESRD have also been questioned. These valves require anticoagulation to prevent thrombosis. The risk of major bleeding is significantly increased when patients on dialysis are placed on aspirin and warfarin (20). Furthermore, adjusted survival of these patients has been improving over the years, but is still quite dismal. The 5-year adjusted survival for a patient on hemodialysis was 34.5% in 2000 and 40.2% in 2008 (1). Due to the dismal survival rates, it is argued that patients on hemodialysis likely would not benefit from the durability of a mechanical valve. This was a conclusion of Williams and colleagues (8). In their study, they

discovered minimal differences in survival of ESRD patients who receive a mechanical versus a bioprosthetic valve, even in patients who were younger than 65 years, suggesting that there is actually minimal impact of valve choice. Similar findings were discovered in the largest series utilizing the United States Renal Data System database done by Herzog and colleagues. Over a two-decade period, they identified 5,858 ESRD patients who had undergone heart valve surgery. Their study demonstrated no significant survival differences related to the choice of valve implanted (2). Their study was instrumental in changing guidelines resulting in the more liberal use of mechanical valves. Unlike guidelines from 1998, the most recent guidelines do not explicitly give suggestions on valve type for ESRD (21).

Our data showed that indeed there was a survival benefit at 1 and 5 years for patients receiving a mechanical versus a bioprosthetic valve. In addition, 1 and 5-year mortality was negatively impacted when the patient required an MVR or an AVR/MVR, or had chronic lung disease. There were no significant differences in hospital readmissions although readmissions for bleeding were higher at 5 years in the mechanical group. The mechanical cohort did have a younger patient population, and this may be because of bias on part of the surgeons to recommend a mechanical prosthesis in younger patients because of life expectancy. However, there was no difference in STS PROM between the two groups. Patients with mechanical valves were less likely to have peripheral arterial disease and this may be a surrogate for age and status at the time of surgery.

These data reaffirms the reduced survival of ESRD patients who require cardiac valve operations. However, the overall 5-year survival in this study was 35.6%, which is similar to patients on dialysis who do not require cardiac valve surgery. This supports valve surgery in patients with ESRD with acceptable longer-term mortality, particularly when the patient survives to discharge from their index hospitalization. The data also suggests that it is not unreasonable to implant a mechanical valve in patients who have ESRD requiring dialysis. However, the increased risk of bleeding while on anticoagulation must be recognized. Our study did show increased readmission rates due to bleeding in patients with mechanical valves at 5-years. The reasons for the survival benefit are unclear and quite possibly may be a result of selection bias by giving healthier ESRD patients a mechanical valve, although similarities in our demographics and preoperative comorbidities do not suggest this. Historical studies have suggested that early calcification could be a potential cause of early prosthetic failure (6,7,22). Although our study did not have any valve reoperations, it is unknown whether these patients deteriorated clinically from valve failure and were deemed to be nonoperative candidates due to incrementally higher surgical risk. Similarly, although the absolute hospital readmission rates were similar between the cohorts, the scope and severity of the clinical issues leading to readmission were not measured.

Study limitations

The principal limitation of our study is the relatively small sample size, which is a reflection of the rarity of operating on patients on dialysis who need valve surgery, particularly in the era of less invasive transcatheter therapies (23,24) and in an effort to minimize hospital mortality in this critical population (25). This may affect the ability to detect significant differences between the groups and subject the analyses to type II error. This study was also retrospective and not randomized, allowing for selection bias. The decision on who to operate on and choice of valve were individualized and made by the primary surgeon. Therefore, potentially, an ESRD patient who is expected to live longer as assessed by the surgeon, may have a higher propensity to receive a mechanical valve.

Conclusions

This study demonstrates that mechanical valves provide an intermediate term mortality benefit as compared to bioprosthetic valves in patients undergoing AVR and/or MVR. This benefit in survival must be balanced with the burden of anticoagulation and the increased risk of readmission for bleeding. Although valve choice should be individualized, these data suggest that mechanical valve usage is reasonable in patients on dialysis.

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Footnote

Conflicts of Interest: TG Gleason—Medical Advisory Board, Abbott; A Kilic—Medical Advisory Board, Medtronic, Inc.

The other authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by the institutional review board (IRB approval # PRO16020002).

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