

ORIGINAL RESEARCH

Predictors of Use and Outcomes of Mechanical Valve Replacement in the United States (2008–2017)

Mohamad Alkhouli , MD; Fahad Alqahtani, MD; Trevor Simard, MD; Sorin Pislaru, MD, PhD; Hartzell V. Schaff, MD; Rich A. Nishimura , MD

BACKGROUND: Contemporary nationwide data on the use, predictors, and outcomes of mechanical valve replacement in patients less than 70 years of age are limited.

METHODS AND RESULTS: We identified hospitalizations for aortic valve replacement (AVR) or mitral valve replacement (MVR) in the Nationwide Inpatient Sample between January 1, 2008, and December 31, 2017. The study's end points included predictors of mechanical valve replacement and risk-adjusted in-hospital mortality. Among 253 100 hospitalizations for AVR, the use rate of mechanical prosthesis decreased from 45.3% in 2008 to 17.0% in 2017. Among 284 962 hospitalizations for MVR, mechanical prosthesis use decreased from 59.5% in 2008 to 29.2% in 2017 (P for trend < 0.001). In multilogistic regression analyses, female sex, prior sternotomy, prior defibrillator, and South/West geographic location were predictive of mechanical valve use. The presence of bicuspid valve was a negative predictor of mechanical AVR (odds ratio [OR], 0.68; 95% CI, 0.66–0.69; $P < 0.001$), whereas mitral stenosis was associated with higher mechanical MVR (OR, 1.28; 95% CI, 1.22–1.33; $P < 0.001$). Unadjusted in-hospital mortality decreased over time with AVR but not with MVR, regardless of prosthesis choice. Using years 2008 and 2009 as a reference, risk-adjusted mortality also decreased over time with AVR but did not decrease after MVR.

CONCLUSIONS: There is a substantial decline in the use of mechanical valve replacement among patients aged ≤ 70 years in the United States. Long-term durability data on bioprosthetic valve replacement are needed to better define the future role of mechanical valves in this age group.

Key Words: aortic valve replacement ■ bioprosthetic valve ■ mechanical valve ■ mitral valve replacement

Valvular heart disease (VHD) affects 2.5% of the US population, with aortic and mitral valve disease being the most common forms of VHD.¹ The management of VHD has evolved considerably over the past 2 decades, but several issues remain open.^{2,3} Among those unresolved questions is the question of optimal prosthesis choice in patients aged ≤ 70 years.⁴ Despite their near lifelong durability, mechanical prostheses require strict compliance with vitamin K antagonists and are associated with considerable bleeding risks. On the contrary, bioprosthetic valves typically do not require life-long

oral anticoagulation (OAC), but issues related to structural valve deterioration and valve thrombosis have not been resolved.⁵ Isaacs et al documented a nationwide trend in prosthesis choice favoring bioprosthetic over mechanical valves between 1998 and 2011.⁶ The unprecedented advances in transcatheter VHD interventions in the past decade afforded less invasive options for patients with failing surgical bioprostheses, which may have attenuated the main advantage of mechanical valves (namely, the lower need for reoperation).^{7,8} However, contemporary data on mechanical valve replacement remain limited. We

Correspondence to: Mohamad Alkhouli, MD, Department of Medicine, Mayo Clinic School of Medicine, 200 First St SW, Rochester, MN 55905. E-mail: Alkhouli.Mohamad@mayo.edu

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CLINICAL PERSPECTIVE

What Is New?

- Mechanical valve use continued to decline in the United States between 2008 and 2017, although considerable geographic variations exist.
- Certain patient risk factors were independently associated with valve type choice.
- Mortality declined after aortic valve replacement but not after mitral valve replacement regardless of valve choice.

What Are the Clinical Implications?

- The role of mechanical valve replacement is diminishing even among younger patients, highlighting the need for innovations in novel valve therapies that are durable and have minimal anticoagulation requirements.

Nonstandard Abbreviations and Acronyms

AVR	aortic valve replacement
MVR	mitral valve replacement
NIS	national inpatient sample
OAC	oral anticoagulation
VHD	valvular heart disease
VinV	valve in valve

recently documented the continuous decline in the use of mechanical valves.⁹ In this study, we sought to identify independent predictors of mechanical valve use, and the outcomes of bioprosthetic versus mechanical valve replacement in the United States using a national representative database.

METHODS

Data Sharing Statement

Data obtained from the National Inpatient Sample (NIS) could not be shared directly by the authors, but requests to access the National Readmission Database (NRD) data set from qualified researchers trained in subject confidentiality protocols may be sent to the Healthcare Cost and Utilization Project.

Study Data

The NIS was used to derive patient relevant information between January 1, 2008, and December 31, 2017. The NIS, part of the Healthcare Cost and Utilization Project, contains hospital inpatient stays derived from billing data

submitted by hospitals to statewide data organizations across the United States. These data include clinical and resource use information typically available from discharge abstracts. The NIS sampling frame includes data from 47 statewide data organization, covering >97% of the US population. The annual sample encompasses ~8 million discharges, which represents 20% of inpatient hospitalizations across different hospital types and geographic regions. The national estimates of the entire US hospitalized population are calculated using a standardized sampling and weighting method provided by the Agency for Healthcare Research and Quality. This self-weighting design of the new NIS reduces the margin of error for estimates and delivers more stable and precise estimates than previous versions of the NIS. The NIS has been used extensively to assess national trends in the use, disparities, and outcomes of VHD interventions.^{3,10,11} This study was exempted by institutional review board because it used publicly available deidentified data.

Study Population

Patients aged 50 to 70 years who underwent surgical aortic valve replacement (AVR) or mitral valve replacement (MVR) were identified in the NIS using *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)*, and *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)*, codes (Table S1). Patients who had concomitant coronary artery bypass grafting, surgical ablation of atrial fibrillation (AF) (MAZE procedure), or left atrial appendage exclusion were included. In addition, patients with multiple valve surgeries and those with infective endocarditis were excluded.

Study Outcomes

We assessed the predictors of mechanical valve use and the temporal trends in in-hospital mortality of bioprosthetic and mechanical AVR and MVR.

Statistical Analysis

Weighted data were used for all statistical analyses. For trend analysis, we used Cochran-Armitage test for categorical variables and linear regression for continuous variables. Descriptive statistics were presented as frequencies, with percentages for categorical variables. Predictors of mechanical valve use were assessed in univariate logistic regression analysis. Those with a *P* value of <0.1 were then further assessed in a multivariate logistic regression analysis. Because we could not differentiate between preexisting and postoperative AF in this database, the multivariate logistic regression analysis was repeated again without including AF as a sensitivity analysis.

Table 1. Baseline Characteristics of the Study Cohort

Baseline Characteristics	Aortic Valve Replacement			Mitral Valve Replacement		
	Bioprosthetic (N=163 049)	Mechanical (N=90 051)	P Value	Bioprosthetic (N=253 145)	Mechanical (N=31 817)	P Value
Demographics						
Age, mean±SD, y	63±5	60±6	<0.001	62±5	60±5	<0.001
50–55, y %	11.9	23.1		13.7	25.4	
56–60, y %	19.6	25.0		20.3	27.7	
61–65, y %	31.7	27.9		31.5	27.4	
66–70, y %	36.8	24.0		34.5	19.4	
Female sex, %	30.8	32.1		53.2	54.8	
Race/ethnicity, %			<0.001			<0.001
White	83.3	80.5		71.9	71.3	
Black	5.6	6.9		13.0	12.5	
Hispanic	6.1	7.5		7.2	8.3	
Primary payer, %			<0.001			<0.001
Medicare/Medicaid	49.5	40.0		56.5	45.5	
Private insurance	45.3	52.7		37.4	46.6	
Self-pay/no charge	5.2	7.3		6.0	7.9	
Lowest 25th percentile income, %	22.0	26.0	<0.001	27.0	29.8	
Hospital region, %			<0.001			<0.001
Northeast	23.2	16.3		20.8	17.3	
Midwest	25.5	25.6		25.5	24.2	
South	31.9	39.0		34.4	37.5	
West	19.3	19.1		19.3	21.0	
Rural location, %	2.4	3.1	<0.001	2.3	2.8	<0.001
Teaching hospital, %	76.4	69.9	<0.001	76.1	71.3	<0.001
Clinical comorbidities, %						
Hypertension	73.3	70.7	<0.001	65.2	60.8	<0.001
Diabetes mellitus	35.8	31.5	<0.001	31.4	26.6	<0.001
Coronary artery disease	51.5	47.4	<0.001	50.6	42.4	<0.001
Congestive heart failure	10.8	5.3	<0.001	21.4	11.4	<0.001
Peripheral vascular disease	18.1	19.8	<0.001	10.1	7.1	<0.001
Carotid artery disease	3.8	2.9	<0.001	2.7	1.9	<0.001
Chronic kidney disease	12.1	11.1	<0.001	19.0	14.3	<0.001
Chronic lung disease	20.3	20.8	0.003	27.7	25.6	<0.001
Anemia	16.7	17.4	<0.001	21.0	20.4	0.063
Liver disease	1.0	0.9	<0.001	1.6	1.2	<0.001
Atrial fibrillation	39.2	35.6	<0.001	60.3	60.5	0.628
Conduction disorders	4.8	4.3	<0.001	4.0	3.5	<0.001
Prior defibrillator	0.5	0.8	<0.001	1.5	1.9	<0.001
Prior sternotomy	4.1	5.7	<0.001	7.1	7.7	0.004
Prior stroke	5.3	4.8	<0.001	6.6	7.2	<0.001
Nonelective admission	25.8	27.8	<0.001	37.1	34.0	<0.001
Concomitant CABG	32.1	30.7	<0.001	29.2	24.8	<0.001
Concomitant appendage exclusion	6.3	4.4	<0.001	23.3	18.8	<0.001
Concomitant MAZE procedure	3.3	3.7	<0.001	13.7	15.5	<0.001

CABG indicates coronary artery bypass grafting.

To assess whether in-hospital mortality improved over time, multivariable regression models using generalized estimation equations with exchangeable

working correlation matrix were constructed. This was done to account for clustering of outcomes within hospitals. Variables included in the regression model were

age, sex, race, primary expected payer, rural location, median household income, and other clinically relevant comorbidities (diabetes mellitus, hypertension, coronary artery disease, chronic kidney disease, peripheral vascular disease, chronic lung disease, AF/atrial flutter, conduction disorders, anemia, and prior sternotomy). Risk-adjusted mortality values of each intervention (AVR and MVR) were presented per 2-year periods using the years 2008 and 2009 as a reference. $P < 0.05$ was considered statistically significant. All statistical analyses were performed with SPSS version 24 (IBM Corporation, Armonk, NY).

RESULTS

Trends and Predictors in Mechanical AVR

A total of 253 100 hospitalizations for isolated AVR in patients aged 50 to 70 years were included. Among those, the use rate of mechanical prosthesis decreased from 45.3% in 2008 to 17.0% in 2017 (Figure). The temporal trends in mechanical AVR per year, stratified by age subgroups, are shown in Table S2. Patients who received a mechanical prosthesis were younger (60 ± 6 versus 63 ± 5 years; $P < 0.001$), more likely to be women (32.1% versus 30.8%; $P < 0.001$), and more likely to be Black individuals (6.9% versus 5.6%) or Hispanics (7.5% versus 6.1%) ($P < 0.001$) than those who received a bioprosthetic valve. Most key comorbidities were more common in the bioprosthetic valve group (Table 1). The univariate logistic regression analysis is presented in Table S3. In the multivariate logistic regression analysis, age of 66 to 70 years (versus 50–55 years), female sex, Black or Hispanic race/ethnicity, peripheral vascular disease, prior sternotomy, prior defibrillator, nonelective admissions, geographic region other than Northeast, and rural location were independent predictors of receiving a mechanical prosthesis (Table 2). The presence of bicuspid aortic valve was a negative predictor of mechanical AVR (odds ratio [OR], 0.68; 95% CI, 0.66–0.69; $P < 0.001$). Removing AF from the multivariate analysis does not significantly change the results (Table S4).

Trends and Predictors in Mechanical MVR

A total of 284 962 hospitalizations for isolated MVR in patients aged 50 to 70 years were included. Among those, the use rate of mechanical prosthesis decreased from 59.5% in 2008 to 29.2% in 2017 (P for trend < 0.001) (Figure). The temporal trends in mechanical MVR per year, stratified by age subgroups, are shown in Table S2. Patients who received a mechanical valve had a distinctive risk profile that included a higher proportion of women, racial minorities, and treatment at nonteaching hospitals. Those patients also had a

Table 2. Predictors of Utilization of Mechanical Prostheses among Patients Undergoing Aortic Valve Replacement (Multivariable Logistic Regression)

Variables	Odd Ratio	95% CI		P value
		Lower	Upper	
Age				
50–55	Reference	Reference	Reference	Reference
56–60	0.64	0.62	0.66	<0.001
61–65	0.43	0.42	0.44	<0.001
66–70	0.31	0.30	0.32	<0.001
Race				
White	Reference	Reference	Reference	Reference
Black	1.08	1.05	1.12	<0.001
Hispanic	1.19	1.15	1.23	<0.001
Female sex	1.10	1.08	1.12	<0.001
Co-Morbidities				
Diabetes	0.88	0.87	0.90	<0.001
Hypertension	0.96	0.94	0.97	<0.001
Congestive heart failure	0.46	0.45	0.48	<0.001
Peripheral vascular disease	1.13	1.11	1.16	<0.001
Carotid artery disease	0.80	0.76	0.84	<0.001
Chronic kidney disease	0.98	0.96	1.01	0.26
Chronic lung disease	1.00	0.98	1.02	0.86
Anemia	1.01	0.99	1.03	0.40
Liver disease	0.79	0.72	0.86	<0.001
Atrial fibrillation	0.99	0.97	1.01	0.23
Conduction disorders	0.98	0.94	1.02	0.37
Prior defibrillator	1.27	1.14	1.41	<0.001
Prior sternotomy	1.52	1.46	1.58	<0.001
Prior stroke	0.92	0.89	0.96	<0.001
Surgery characteristics				
Non-elective	1.06	1.04	1.08	<0.001
Coronary bypass grafting	1.01	1.00	1.03	0.16
Bicuspid aortic valve	0.68	0.66	0.69	<0.001
Median household income				
0–25th percentile	Reference	Reference	Reference	Reference
26th–50th percentile	0.95	0.93	0.98	<0.001
51st–75th percentile	0.92	0.90	0.95	<0.001
76th–100th percentile	0.82	0.80	0.84	<0.001
Hospital characteristics				
Geographic location				
Northeast	Reference	Reference	Reference	Reference
Midwest	1.36	1.33	1.40	<0.001
South	1.61	1.57	1.65	<0.001
West	1.29	1.25	1.33	<0.001
Rural location	1.09	1.03	1.15	0.002
Teaching hospital	0.77	0.76	0.79	<0.001

AVR indicates aortic valve replacement.

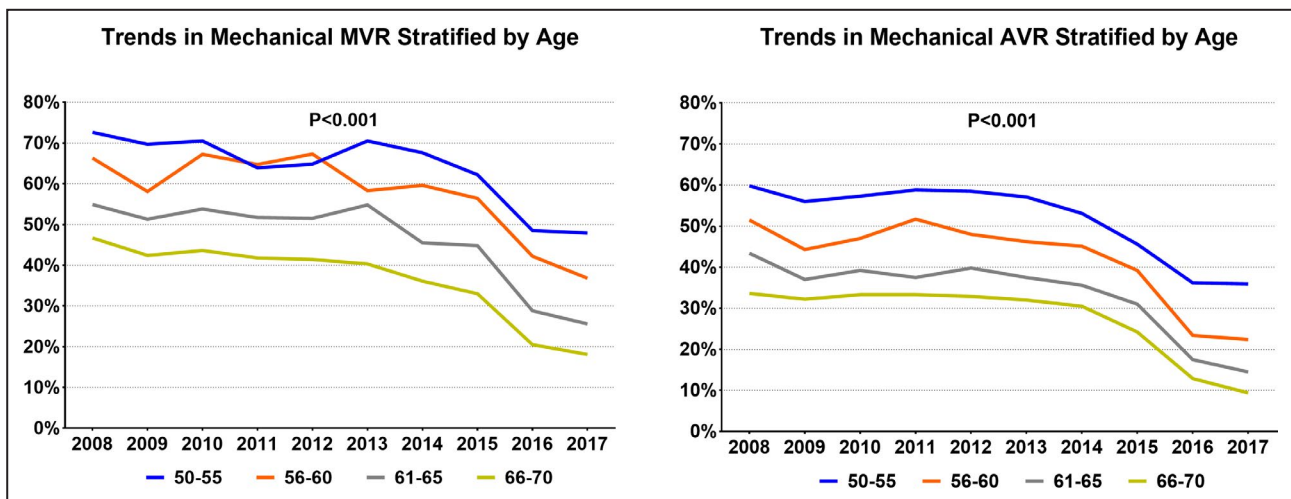


Figure. Trends in the use of mechanical and bioprosthetic valves among patients aged 50 to 70 years between 2008 and 2017. AVR indicates aortic valve replacement; and MVR, mitral valve replacement.

higher prevalence of diabetes mellitus, coronary artery disease, heart failure, renal insufficiency, AF, and prior stroke, but a lower prevalence of prior sternotomy (Table 1). The univariate logistic regression analysis is presented in Table S5. In the multivariate logistic regression analysis, factors that independently predicted mechanical MVR included female sex, AF, prior sternotomy, prior defibrillator, prior stroke, and geographic location in the South or the West (Table 3). The presence of mitral stenosis was independently associated with mechanical prosthesis in the MVR group (OR, 1.28; 95% CI, 1.22–1.33; $P < 0.001$). Removing AF from the multivariate analysis does not significantly change the results (Table S6).

Outcomes of Bioprosthetic and Mechanical Valve Replacement

In the AVR cohort, unadjusted in-hospital mortality decreased from 3.0% to 2.1% for bioprosthetic AVR and from 3.3% to 2.7% for mechanical AVR. In the MVR group, unadjusted in-hospital mortality decreased from 7.0% to 6.5% for bioprosthetic MVR and from 3.8% to 2.8% for mechanical AVR (Table 4). We observed a statistically significant decrease in risk-adjusted mortality after bioprosthetic or mechanical AVR but not with MVR over time (Table 5).

DISCUSSION

The current investigation identifies several independent predictors of mechanical valve use, and documents a continuous temporal improvement in the short-term outcomes of AVR but not MVR in this age group.

The choice of a mechanical prosthesis in younger patients referred for surgery is usually inspired by the substantially lower rates of reoperation, and in some reports by the improved survival compared with patients who received bioprostheses.^{4,12–17} However, the need for strict compliance with OAC, the risk of bleeding, and the lifestyle limitations associated with their use have been implicated in the significant decrease in the use rates of mechanical valves in the 2000s.^{6,12,18,19} Our study revealed a marked further decline in the use of mechanical valve replacement between 2008 and 2017. Reasons for these continuously declining trends are multifactorial, and deserve more discussion.

First, the issues surrounding the need for life-long OAC with mechanical prostheses have not been resolved: (1) Long-term management of OAC continues to be a key reason to avoid mechanical valve replacement, despite the low rates of valve-related complications among OAC-adhering patients,²⁰ and the documented success of various novel strategies (eg, self-management and telemedicine) in maintaining optimal intensity of anticoagulation after valve replacement.^{21–24} (2) The management of bridging anticoagulation before and after invasive procedures in patients with mechanical valves remains variable and a source of controversy and potential excess complications, despite the ample guidelines.^{5,25} (3) Attempts to broaden OAC options in patients with mechanical valves have not been successful. Although preclinical and observational clinical studies showed a promise for direct oral anticoagulant in patients with mechanical prostheses, randomized data were contradictory.^{26,27} The RE-ALIGN (Evaluate the Safety and Pharmacokinetics of Oral Dabigatran Etxilate in Patients After Heart Valve Replacement)

Table 3. Predictors of Utilization of Mechanical Prostheses among Patients Undergoing Mitral Valve Replacement (Multivariable Logistic Regression)

Variables	Odds Ratio	95% CI		P value
		Lower	Upper	
Age				
50-55	Reference	Reference	Reference	Reference
56-60	0.75	0.72	0.79	<0.001
61-65	0.47	0.45	0.49	<0.001
66-70	0.31	0.29	0.32	<0.001
Race				
White	Reference	Reference	Reference	Reference
Black	0.87	0.83	0.92	<0.001
Hispanic	1.04	0.97	1.10	0.26
Female	1.04	1.00	1.07	0.05
Co-Morbidities				
Diabetes	0.92	0.89	0.95	<0.001
Hypertension	0.94	0.91	0.97	<0.001
Congestive heart failure	0.49	0.47	0.52	<0.001
Peripheral vascular disease	0.77	0.73	0.82	<0.001
Carotid artery disease	0.87	0.77	0.97	0.01
Chronic kidney disease	0.87	0.84	0.92	<0.001
Chronic lung disease	0.88	0.84	0.91	<0.001
Anemia	0.99	0.95	1.03	0.47
Liver disease	0.80	0.70	0.92	0.002
Atrial fibrillation	1.14	1.11	1.19	<0.001
Conduction disorders	1.01	0.93	1.10	0.83
Prior defibrillator	1.13	1.00	1.28	0.05
Prior sternotomy	1.24	1.16	1.32	<0.001
Prior stroke	1.11	1.04	1.18	0.002
Surgery characteristics				
Non-elective	0.94	0.91	0.97	<0.001
Coronary bypass grafting	0.95	0.92	0.99	0.015
Surgical MAZE/LAA	0.89	0.86	0.92	<0.001
Mitral stenosis	1.28	1.22	1.33	<0.001
Median household income				
0-25th percentile	Reference	Reference	Reference	Reference
26th-50th percentile	0.95	0.91	0.99	0.02
51st-75th percentile	0.94	0.90	0.99	0.01
76th-100th percentile	0.75	0.72	0.79	<0.001
Hospital characteristics				
Geographic location				
Northeast	Reference	Reference	Reference	Reference
Midwest	1.04	0.99	1.10	0.11
South	1.25	1.19	1.31	<0.001
West	1.22	1.16	1.29	<0.001
Rural location	0.98	0.88	1.09	0.69
Teaching hospital	0.82	0.79	0.85	<0.001

LAA indicates left atrial appendage; and MVR, mitral valve replacement.

trial was stopped early because of the excess thromboembolic and bleeding events in the dabigatran arm.²⁸ Notably, the emergence of newer-generation pyrolytic carbon aortic heart valves (On-X; CryoLife, Kennesaw, GA), which are approved for a reduced target of international normalized ratio, does not seem to mitigate the declining rates of mechanical valve use.²⁹ (4) The argument that a large proportion of patients require OAC after valve surgery because of incident AF may be weakened in the contemporary era because of the growing adoption of percutaneous left atrial appendage exclusion techniques.^{4,30}

Second, the demonstrated feasibility of transcatheter valve-in-valve (VinV) implantation is hoped to offer a future solution for patients concerned about the risk of structural valve deterioration and need for reoperation with bioprosthetic valves. Although speculative, this might have contributed further to the declining rates of mechanical valve use.^{7,8,31} However, data to confirm this notion are lacking, and the rate of mechanical valve use had been declining even before VinV therapies became available. Nonetheless, caution remains advised when considering future VinV as a default strategy for failing bioprostheses in light of the concerns about the patient-prosthesis mismatch in patients with small aortic prostheses, the risk of coronary or left ventricular outflow obstruction with aortic and mitral VinV, respectively, and the increased risk of valve thrombosis in patients treated with VinV.^{8,32,33} Although novel techniques have been pioneered to mitigate some of these risks (eg, BASILICA [Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction trial]), long-term outcomes of these techniques remain unknown.³⁴

Third, the risk of bioprosthetic thrombosis must also be considered. Indeed, bioprosthetic thrombosis after transcatheter AVR has been demonstrated in up to 20% of patients who were not treated with OAC after implantation.³⁵ Whether this phenomenon is more common in transcatheter than surgical valves remains controversial, with most recent studies yielding conflicting results.^{36,37} Furthermore, patients who are successfully treated with OAC for clinically manifest bioprosthetic valve thrombosis have a high risk of recurrence and progress more rapidly to bioprosthetic failure.³⁸

Our study discerned patients and hospital characteristics that are associated with mechanical valve use. Plausibly, age was the strongest determinant of valve choice within the 50 to 70 years age group. However, other intriguing factors were also identified. (1) There were regional variations in the use of mechanical valves, with the highest use rates in the South and the lowest in the Northeast. The magnitude of these differences was more pronounced with AVR than with

Table 4. Trends in Unadjusted In-Hospital Mortality for Patients Aged 50 to 70 Years Who Underwent AVR and MVR Between 2008 and 2017

Operation	Valve Type	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
AVR	Bioprosthetic	3.0	2.4	2.5	1.8	1.7	2.2	1.7	2.1	2.2	2.1
	Mechanical	3.3	3.2	3.1	3.2	3.1	2.6	2.2	2.7	2.8	2.7
MVR	Bioprosthetic	7.0	3.8	4.9	3.8	3.9	6.4	4.9	4.1	3.8	6.5
	Mechanical	3.8	3.0	3.2	4.7	4.4	3.2	4.8	3.6	5.2	2.8

Data are given as percentage of patients.

AVR indicates aortic valve replacement; and MVR, mitral valve replacement.

MVR. There were also statistically significant but modest differences in the likelihood of mechanical valve use across different races. (2) The presence of certain comorbidities (diabetes mellitus, heart failure, and liver disease) was associated with lower odds of using a mechanical valve. Although speculative, this could have been related to the higher bleeding tendencies among these patients. (3) The presence of anemia or AF was not independently associated with lower or higher odds of mechanical valve use, although this has to be interpreted with caution given that we are unable to differentiate baseline versus postoperative AF in this database.

Our analysis also illustrated a continuous improvement in risk-adjusted mortality after AVR but not after MVR. This might be partially explained by the increasing selection bias among patients receiving MVR in the contemporary era, considering the substantial increase in mitral valve repair nationwide. In other words, the MVR cohorts over time increasingly constitute patients who may not be candidates for repair because of anatomical reasons (eg, calcified valve) or those who do not have access to mitral valve repair centers. The opposite is true for AVR, in which patients who are high risk for AVR are increasingly referred for transcatheter valve replacement. Although our trends analysis is risk adjusted, adequate

adjustment for anatomical and other variables (availability of valve repair or transcatheter interventions) is not feasible because of the administrative nature of the database used. A direct comparison between mechanical and bioprosthetic valve replacement was not performed in this study as its primary purpose was to assess the trends and predictors of mechanical valve use and not to compare the 2 valve types. In addition, several prior studies have addressed this question,^{4,5,39} and performing a contemporary comparative study requires clinical data sets with more granular data (eg, Society of Thoracic Surgery [STS] registry) to reduce the marked selection bias.

LIMITATIONS

(1) The NIS collects data for billing purposes, and therefore it is subject to errors and miscoding of diagnoses and clinical events. However, coding for major procedures is the main method for obtaining reimbursement, and hence this limitation is unlikely to significantly hamper our study results and conclusions. (2.) Preoperative risk scores routinely used in daily practice (eg, STS predicted risk of mortality [PROM] and Euro Score II) cannot be calculated in the NIS because of the lack of laboratory and echocardiographic data. Hence, the temporal trend in

Table 5. Trends in Adjusted In-Hospital Mortality for Patients Aged 50 to 70 Years Who Underwent AVR and MVR Between 2008 and 2017

Year	OR	95% CI		P Value	OR	95% CI		P Value
		Lower	Upper			Lower	Upper	
2008–2009	Reference	Bioprosthetic AVR			Mechanical AVR			
2010–2011	0.80	0.71	0.91	0.001	1.01	0.89	1.14	0.87
2012–2013	0.80	0.71	0.91	<0.001	0.90	0.79	1.02	0.10
2014–2015	0.77	0.68	0.87	<0.001	0.79	0.69	0.90	0.001
2016–2017	0.86	0.76	0.97	0.014	0.82	0.68	0.98	0.03
2008–2009	Reference	Bioprosthetic MVR			Mechanical MVR			
2010–2011	0.88	0.73	1.08	0.21	1.23	1.02	1.49	0.03
2012–2013	1.20	0.99	1.45	0.06	1.03	0.85	1.25	0.75
2014–2015	1.05	0.88	1.27	0.57	1.26	1.04	1.53	0.02
2016–2017	1.30	1.07	1.58	0.01	1.31	1.01	1.70	0.04

AVR indicates aortic valve replacement; MVR, mitral valve replacement; and OR, odds ratio.

predicted risk of mortality could not be thoroughly assessed.³ Diagnoses codes for AF do not report baseline versus postoperative AF. However, removing AF from the multivariate analyses did not result in a change of the significant predictors of mechanical valve use.⁵ Variation in practice, according to the operator's preference, valve size, and disease complexity, could not be measured in this data set. Similarly, although the outcomes analyses included rigorous risk adjustments, the potential effect of residual confounders cannot be completely eliminated because of the observational design of the study and the nature of the database used. (4) Because the NIS is unable to delineate the severity of valve and coronary artery disease in patients undergoing combined coronary bypass and valve surgery, we limited our study to isolated valve replacement. Hence, trends of mechanical valve use among patients undergoing combined bypass/valve surgery are not recorded. (5) Long-term data beyond hospital discharge are not available in NIS. Despite these limitations, the NIS affords a unique opportunity to comprehensively assess the use rates and outcomes of mechanical valve replacement in a contemporary US cohort.

CONCLUSIONS

This study suggests a diminishing role for mechanical valve replacement in contemporary US practice, and documents certain patient and hospital characteristics that are associated with the choice of bioprosthetic or mechanical valve.

ARTICLE INFORMATION

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Affiliations

From the Department of Cardiovascular Diseases, Mayo Clinic School of Medicine, Rochester, MN (M.A., T.S., S.P., R.A.N.); Division of Cardiology, West Virginia University, Morgantown, WV (F.A.); and Department of Cardiovascular Diseases, Mayo Clinic School of Medicine, Rochester, MN (H.V.S.).

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None.

Supplementary Material

Tables S1–S6

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SUPPLEMENTAL MATERIAL

Table S1. List of the International Classification of Diseases Codes Used in the Study.

<p>Mitral Valve Replacement</p>	<p>* Tissue valve replacement: 35.23 Open and other replacement of mitral valve with tissue graft 02RG07Z Replacement of Mitral Valve with Autologous Tissue Substitute, Open Approach 02RG08Z Replacement of Mitral Valve with Zooplastic Tissue, Open Approach 02RG0KZ Replacement of Mitral Valve with Nonautologous Tissue Substitute, Open Approach * Mechanical valve replacement: 35.24 Open and other replacement of mitral valve 02RG0JZ Replacement of Mitral Valve with Synthetic Substitute, Open Approach</p>
<p>Aortic Valve Replacement</p>	<p>* Tissue valve replacement: 35.21 Replacement of aortic valve with tissue graft 02RF07Z Replacement of Aortic Valve with Autologous Tissue Substitute, Open Approach 02RF08Z Replacement of Aortic Valve with Zooplastic Tissue, Open Approach 02RF0KZ Replacement of Aortic Valve with Nonautologous Tissue Substitute, Open Approach * Mechanical valve replacement: 35.22 Other replacement of aortic valve 02RF0JZ Replacement of Aortic Valve with Synthetic Substitute, Open Approach</p>
<p>Surgical Left Atrial Appendage Exclusion</p>	<p>ICD-9-CM 37.36 ICD-10-CM 02570ZK Destruction of Left Atrial Appendage, Open Approach 02B70ZK Excision of Left Atrial Appendage, Open Approach 02L70ZK Occlusion of Left Atrial Appendage, Open Approach 02L70CK Occlusion of left atrial appendage with extraluminal device, open</p>
<p>Surgical MAZE</p>	<p>ICD-9-CM 37.33 ICD-10-CM 02570ZZ Destruction of Left Atrium, Open Approach 02B70ZZ Excision of Left Atrium, Open Approach 02574ZZ Destruction of Left Atrium, Percutaneous Endoscopic 02B74ZZ Excision of Left Atrium, Percutaneous Endoscopic Approach</p>
<p>Coronary Artery Bypass Grafting</p>	<p>ICD-9-CM: 3610, 3611, 3612, 3613, 3614, 3615, 3616, 3617, 3619 ICD-10-CM: 02130KW, 02130Z3, 02130Z8, 02130Z9, 02130ZC, 02130ZF, 02130K8, 02130K9, 02130KC, 02130KF, 02130A9, 02130AC, 02130AF, 02130AW 02130J3, 02130J8 02130J9, 02130JC 02130JF, 02130JW 02130K3, 02120Z8, 02120Z9, 02120ZC, 02120ZF, 0213093, 0213098, 0213099, 021309C, 021309F, 021309W, 02130A3, 02130A8, 02120AW, 02120J3, 02120J8, 02120J9, 02120JC, 02120JF, 02120JW, 02120K3, 02120K8 02120K9, 02120KC 02120KF, 02120KW, 02120Z3, 02110Z9, 02110ZC, 02110ZF 0212093, 0212098, 0212099, 021209C, 021209F, 021209W, 02120A3, 02120A8, 02120A9, 02120AC 02120AF, 02110J3, 02110J8, 02110J9, 02110JC, 02110JF, 02110JW, 02110K3, 02110K8, 02110K9, 02110KC, 02110KF, 02110KW, 02110Z3, 02110Z8, 02100ZC 02100ZF 0211093 0211098, 0211099, 021109C, 021109F, 021109W, 02110A3, 02110A8, 02110A9, 02110AC, 02110AF, 02110AW, 02100J3, 02100K9, 02100KC, 02100KF, 02100KW, 02100Z3, 02100Z8, 02100Z9, 0210093, 0210099, 021009C, 021009F, 021009W, 02100A3, 02100A8, 02100A9, 02100AC, 02100AF, 02100AW</p>

Table S2. Utilization of Mechanical Prostheses Among Patients ≤ 70 years of age Undergoing Aortic or Mitral Valve Replacement Stratified by Age Group.

Age Group	Valve	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
50-55	Aortic	59.8%	56.0%	57.3%	58.8%	58.5%	57.1%	53.1%	45.6%	36.2%	35.9%
	Mitral	72.6%	69.7%	70.5%	63.9%	64.8%	70.5%	67.6%	62.2%	48.5%	47.9%
56-60	Aortic	51.5%	44.3%	47.0%	51.7%	48.0%	46.2%	45.1%	39.2%	23.4%	22.4%
	Mitral	66.3%	58.1%	67.2%	64.7%	67.3%	58.3%	59.6%	56.4%	42.2%	36.8%
61-65	Aortic	43.4%	37.0%	39.2%	37.5%	39.8%	37.5%	35.6%	31.0%	17.5%	14.5%
	Mitral	54.9%	51.3%	53.8%	51.7%	51.5%	54.8%	45.5%	44.8%	28.8%	25.6%
66-70	Aortic	33.6%	32.2%	33.3%	33.3%	32.9%	32.0%	30.5%	24.2%	12.9%	9.4%
	Mitral	46.7%	42.4%	43.6%	41.8%	41.4%	40.3%	36.1%	33.0%	20.5%	18.1%

Table S3. Predictors of Utilization of Mechanical Prostheses Among Patients Undergoing Aortic Valve Replacement (Univariate Logistical Regression).

Variables	Odd Ratio	95% CI		P-value
		Lower	Upper	
Age				
50-55	Reference	Reference	Reference	Reference
56-60	0.65	0.64	0.67	<0.001
61-65	0.45	0.44	0.46	<0.001
66-70	0.33	0.33	0.34	<0.001
Female	1.06	1.04	1.08	<0.001
Race				
White	Reference	Reference	Reference	Reference
Black	1.29	1.25	1.33	<0.001
Hispanic	1.29	1.25	1.33	<0.001
Diabetes	0.82	0.81	0.84	<0.001
Hypertension	0.88	0.86	0.89	<0.001
Congestive Heart Failure	0.47	0.45	0.48	<0.001
Peripheral Vascular Disease	1.12	1.10	1.14	<0.001
Carotid Artery Disease	0.75	0.71	0.78	<0.001
Chronic Kidney Disease	1.11	1.08	1.14	<0.001
Chronic Lung Disease	1.03	1.01	1.05	0.003
Anemia	1.05	1.02	1.07	<0.001
Liver Disease	0.84	0.78	0.92	<0.001
Atrial Fibrillation	0.86	0.84	0.87	<0.001
Conduction Disorders	0.89	0.86	0.93	<0.001
Prior Defibrillator	1.40	1.27	1.55	<0.001
Prior Sternotomy	1.42	1.37	1.47	<0.001
Prior Stroke	0.91	0.87	0.94	<0.001
Non-Elective	1.10	1.08	1.12	<0.001
Teaching Hospital	0.72	0.70	0.73	<0.001
Median Household Income				
0-25 th percentile	Reference	Reference	Reference	Reference
26 th -50 th percentile	0.89	0.87	0.91	<0.001
51 st -75 th percentile	0.83	0.81	0.85	<0.001
76 th -100 th percentile	0.70	0.68	0.71	<0.001
Hospital Region				
Northeast	Reference	Reference	Reference	Reference
Midwest	1.43	1.39	1.46	<0.001
South	1.73	1.69	1.77	<0.001
West	1.40	1.36	1.44	<0.001
Rural location	1.34	1.27	1.41	<0.001
Coronary Bypass Grafting	0.93	0.92	0.95	<0.001
Bicuspid Aortic Valve	0.78	0.76	0.79	<0.001

Table S4. Predictors of Utilization of Mechanical Prostheses Among Patients Undergoing Aortic Valve Replacement (Multivariable Logistic Regression) After Removing Atrial Fibrillation from the Model.

Variables	Odd Ratio	95% CI		P-value
		Lower	Upper	
Age				
50-55	Reference	Reference	Reference	Reference
56-60	0.64	0.62	0.66	<0.001
61-65	0.43	0.42	0.44	<0.001
66-70	0.31	0.30	0.32	<0.001
Female	1.10	1.08	1.12	<0.001
Race				
White	Reference	Reference	Reference	Reference
Black	1.09	1.05	1.13	<0.001
Hispanic	1.19	1.15	1.23	<0.001
Diabetes	0.88	0.87	0.90	<0.001
Hypertension	0.96	0.94	0.97	<0.001
Congestive Heart Failure	0.46	0.45	0.48	<0.001
Peripheral Vascular Disease	1.13	1.11	1.16	<0.001
Carotid Artery Disease	0.80	0.76	0.84	<0.001
Chronic Kidney Disease	0.98	0.96	1.01	0.25
Chronic Lung Disease	1.00	0.98	1.02	0.87
Anemia	1.01	0.99	1.03	0.42
Liver Disease	0.79	0.72	0.86	<0.001
Conduction Disorders	0.98	0.94	1.02	0.35
Prior Defibrillator	1.27	1.14	1.40	<0.001
Prior Sternotomy	1.52	1.46	1.58	<0.001
Prior Stroke	0.92	0.89	0.96	<0.001
Non-Elective	1.06	1.04	1.08	<0.001
Teaching Hospital	0.77	0.76	0.79	<0.001
Median Household Income				
0-25 th percentile	Reference	Reference	Reference	Reference
26 th -50 th percentile	0.95	0.93	0.98	<0.001
51 st -75 th percentile	0.92	0.90	0.95	<0.001
76 th -100 th percentile	0.82	0.80	0.84	<0.001
Hospital Region				
Northeast	Reference	Reference	Reference	Reference
Midwest	1.36	1.33	1.40	<0.001
South	1.61	1.57	1.65	<0.001
West	1.29	1.25	1.33	<0.001
Rural location	1.09	1.03	1.15	<0.001
Coronary Bypass Grafting	1.01	1.00	1.03	0.15
Bicuspid Aortic Valve	0.68	0.66	0.69	<0.001

Table S5. Predictors of Utilization of Mechanical Prostheses Among Patients Undergoing Mitral Valve Replacement (Univariate Logistical Regression).

Variables	Odd Ratio	95% CI		P-value
		Lower	Upper	
Age				
50-55	Reference	Reference	Reference	Reference
56-60	0.74	0.70	0.78	<0.001
61-65	0.47	0.45	0.49	<0.001
66-70	0.30	0.29	0.32	<0.001
Female	1.07	1.04	1.10	0.046
Race				
White	Reference	Reference	Reference	Reference
Black	0.97	0.93	1.02	<0.001
Hispanic	1.16	1.09	1.23	0.21
Diabetes	0.79	0.76	0.82	<0.001
Hypertension	0.83	0.80	0.85	<0.001
Congestive Heart Failure	0.47	0.45	0.49	<0.001
Peripheral Vascular Disease	0.69	0.65	0.72	<0.001
Carotid Artery Disease	0.68	0.61	0.76	<0.001
Chronic Kidney Disease	0.72	0.69	0.75	<0.001
Chronic Lung Disease	0.90	0.87	0.93	<0.001
Anemia	1.04	1.00	1.08	0.06
Liver Disease	0.77	0.68	0.88	<0.001
Atrial Fibrillation	1.15	1.12	1.20	<0.001
Conduction Disorders	0.87	0.80	0.94	0.001
Prior Defibrillator	1.26	1.12	1.42	<0.001
Prior Sternotomy	1.09	1.03	1.16	0.004
Prior Stroke	1.09	1.03	1.16	0.004
Non-Elective	0.87	0.84	0.90	<0.001
Teaching Hospital	0.78	0.75	0.81	<0.001
Median Household Income				
0-25 th percentile	Reference	Reference	Reference	Reference
26 th -50 th percentile	0.94	0.91	0.98	0.006
51 st -75 th percentile	0.93	0.89	0.97	<0.001
76 th -100 th percentile	0.73	0.70	0.76	<0.001
Hospital Region				
Northeast	Reference	Reference	Reference	Reference
Midwest	1.14	1.09	1.20	<0.001
South	1.32	1.26	1.38	<0.001
West	1.31	1.25	1.38	<0.001
Rural location	1.19	1.08	1.31	<0.001
Coronary Bypass Grafting	0.80	0.78	0.83	<0.001
Bicuspid Aortic Valve	0.93	0.90	0.97	<0.001

Table S6. Predictors of Utilization of Mechanical Prostheses Among Patients Undergoing Mitral Valve Replacement (Multivariable Logistic Regression) After Removing Atrial Fibrillation from the Model.

Variables	Odd Ratio	95% CI		P-value
		Lower	Upper	
Age				
50-55	Reference	Reference	Reference	Reference
56-60	0.76	0.72	0.80	<0.001
61-65	0.48	0.46	0.50	<0.001
66-70	0.31	0.30	0.33	<0.001
Female	1.03	1.00	1.07	0.07
Race				
White	Reference	Reference	Reference	Reference
Black	0.87	0.83	0.91	<0.001
Hispanic	1.04	0.98	1.11	0.23
Diabetes	0.92	0.89	0.95	<0.001
Hypertension	0.94	0.91	0.97	<0.001
Congestive Heart Failure	0.50	0.47	0.52	<0.001
Peripheral Vascular Disease	0.77	0.73	0.82	<0.001
Carotid Artery Disease	0.86	0.77	0.96	0.01
Chronic Kidney Disease	0.87	0.83	0.91	<0.001
Chronic Lung Disease	0.88	0.85	0.91	<0.001
Anemia	0.99	0.95	1.03	0.58
Liver Disease	0.80	0.70	0.92	<0.001
Conduction Disorders	1.02	0.93	1.11	0.73
Prior Defibrillator	1.13	1.00	1.28	0.06
Prior Sternotomy	1.24	1.16	1.32	<0.001
Prior Stroke	1.12	1.05	1.19	<0.001
Non-Elective	0.94	0.91	0.97	<0.001
Teaching Hospital	0.82	0.79	0.86	<0.001
Median Household Income				
0-25 th percentile	Reference	Reference	Reference	Reference
26 th -50 th percentile	0.95	0.91	0.99	0.02
51 st -75 th percentile	0.94	0.90	0.99	0.01
76 th -100 th percentile	0.76	0.72	0.79	<0.001
Hospital Region				
Northeast	Reference	Reference	Reference	Reference
Midwest	1.04	0.99	1.09	0.13
South	1.25	1.19	1.31	<0.001
West	1.22	1.16	1.29	<0.001
Rural location	0.98	0.88	1.09	0.73
Coronary Bypass Grafting	0.94	0.91	0.98	<0.001
Surgical MAZE/LAA	0.93	0.89	0.96	<0.001
Mitral Stenosis	1.30	1.24	1.36	<0.001