Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in Patients With Rheumatoid Arthritis (from the Nationwide Inpatient Database)

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Little is known on the outcomes of surgical aortic valve replacement (SAVR) versus transcatheter aortic valve implantation (TAVI) in patients with rheumatoid arthritis (RA). We queried the Nationwide Inpatient Sample Database (2012 to 2016). We performed a propensity-score-matched analysis based on 25 clinical and hospital variables to compare patients with RA who underwent SAVR versus TAVI. Our primary outcome was in-hospital mortality. Our final analysis included 5,640 hospitalizations with RA who underwent isolated AVR; of whom, 2,465 (43.7%) underwent TAVI. There was an increasing trend in TAVI procedures during the study years (p_{trend}= 0.001). There was a trend toward reduced in-hospital mortality among TAVI compared with SAVR but did not reach statistical significance (0.8% vs 1.6%, odds ratio = 0.50; 95% confidence interval 0.23 to 1.06, p = 0.097). TAVI was associated with lower rates of postoperative bleeding (28.7% vs 43.9%, p <0.001), blood transfusion (12.3% vs 40.2%, p <0.001), acute kidney injury (9.8% vs 16.0%, p <0.001), cardiac tamponade (0.0% vs 1.6%, p <0.001), and discharges to skilled nursing facility (SNF) (20.1% vs 42.2%, p <0.001). However, TAVI was associated with a higher rate of complete heart block (14.3% vs 6.1%, p <0.001) and pacemaker implantations (14.8% vs 5.7%, p <0.001). There were no differences between both groups in cardiogenic shock, acute stroke, acute myocardial infarction, and vascular complications. In conclusion, real-word data showed no significant difference in in-hospital mortality between TAVI and SAVR in patients with RA. TAVI was associated with lower rates of acute kidney injury and bleeding complications at the expense of higher incidence of pacemaker implantations. **(Am J Cardiol 2019;124:1099−1105)**

Rheumatoid arthritis (RA) is an autoimmune disease that affects around 1% of the population.[1,2] RA can involve the heart in different ways as part of its extra-articular manifestations.[2−4] Abnormalities of cardiac valves are more prevalent in RA patients compared with normal population,[2,3] mainly involving the aortic and mitral valves.[3] Studies have reported various rates of aortic valve disease with RA, ranging from 9% to 33% of all patients with RA.[1] RA can involve the aortic valves through different mechanisms.[3] It can result in valve fibrosis that is usually a complication of chronic or recurrent acute valvulitis.[5,6] RA can also result in variable degrees of valvular calcification.[5,6] Noninfectious endocarditis,[7] rheumatoid nodules, and granulomas are related to RA and can also result in valvular abnormalities.[3,4,8] All these valvular involvement mechanisms can result in stenosis, insufficiency, or both.[8,9] We conducted this current analysis to compare outcomes of transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) in patients with RA using a large national database.

Methods

This study was conducted using the National Inpatient Sample (NIS) database. The NIS is the largest all-payer inpatient database in the United States. The NIS contains more than 7 million hospital stays each year, which represent approximately 20% of discharge data nationally.[10] The NIS was developed as part of the Healthcare Cost and Utilization Project.[11] Data quality assessments are performed annually to guarantee internal validity of the NIS.[10,12] In addition, the NIS has been externally validated.[13,14] The NIS reports data using the International Classification of Diseases, Ninth

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Edition (ICD-9) up to September 2015, whereas data from October 2015 up to 2016 are reported using ICD-10 codes. Data from the NIS have been used previously to describe trends and outcomes of AVRs.[14–16] This study was exempt from institutional review board because the data from the NIS database are deidentified and are publicly available.

We queried the NIS database (2012 to 2016) to identify patient hospitalizations with ICD-9 or ICD-10 procedural codes for TAVI or SAVR. To identify hospitalizations for isolated AVR, we excluded records with a diagnosis of aortic insufficiency without a diagnosis of aortic stenosis, combined TAVI and SAVR, concomitant coronary artery bypass grafting (CABG), mitral valve surgery, pulmonary valve surgery, tricuspid valve surgery, ASD or VSD closure. We also excluded cases with missing data on baseline characteristics or study outcomes. We described temporal trends and baseline characteristics among RA patients who underwent TAVI versus SAVR during the study years. The primary outcome was all-cause in-hospital mortality. Other outcomes included cardiac arrest, cardiogenic shock, use of mechanical circulatory support devices, major bleeding, blood transfusion, acute kidney injury (AKI), acute myocardial infarction (MI), acute stroke, vascular complications, cardiac tamponade, ventricular arrhythmias, complete heart block, permanent pacemaker insertions, and length of hospital stay. Clinical characteristics and inpatient outcomes were abstracted and reported using ICD-9 and ICD-10 codes, Clinical Classifications Software codes, and Elixhauser co-morbidities (Supplementary Table 1).

We employed propensity score method to match hospitalizations with RA who underwent TAVI to those who underwent SAVR at 1:1 ratio. The matching was performed using MatchIt R package (R software).[17] Nearest neighbor technique was adopted to match each case to a control that is closest in terms of calculated propensity score. The propensity score was calculated from the following 25 matching

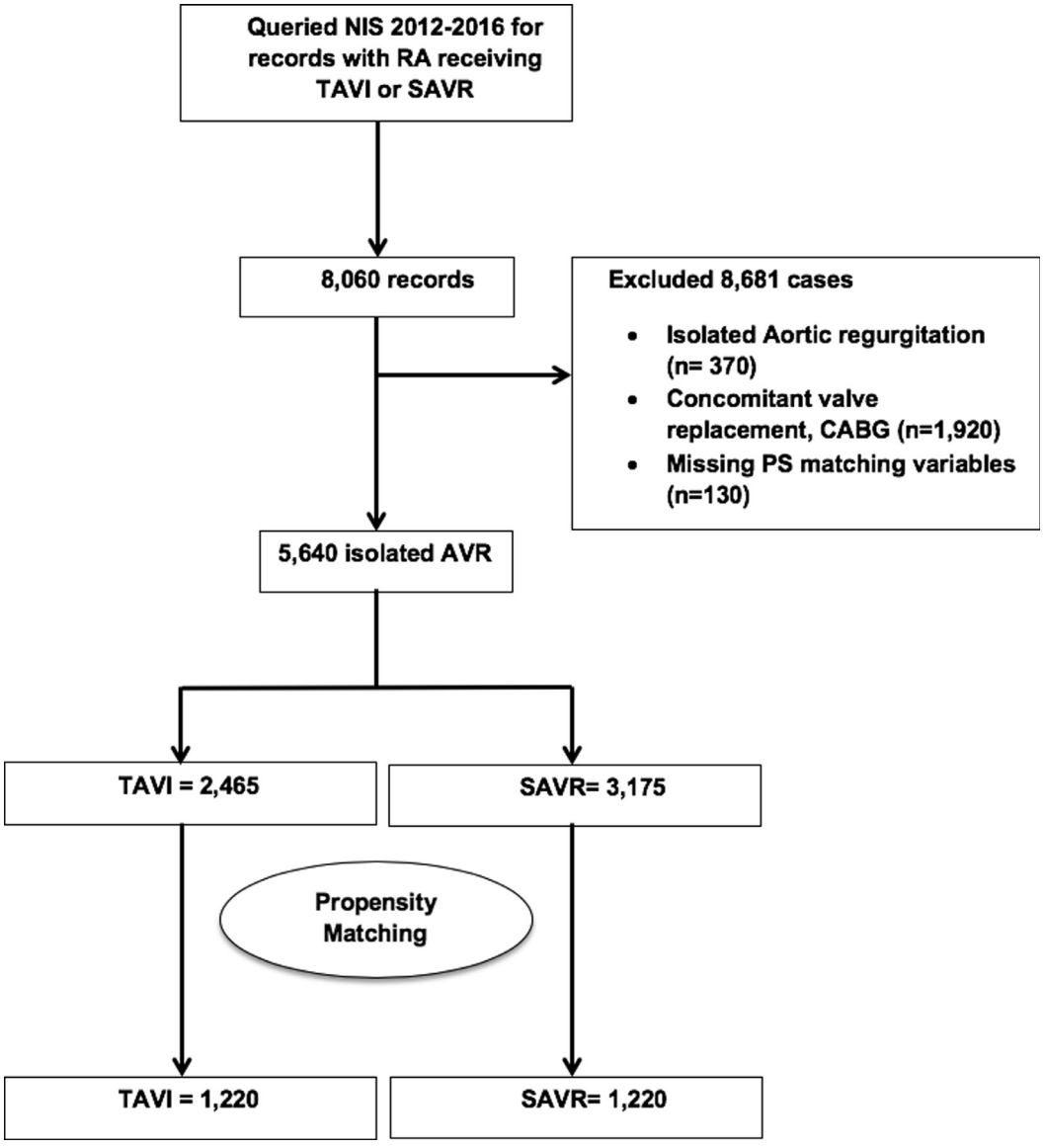

Figure 1. Study flow sheet.

variables: age, gender, race, diabetes mellitus, hypertension, history of smoking, carotid artery disease, chronic lung disease, hypothyroidism, chronic kidney disease, pulmonary circulation disorders, peripheral arterial disease, fluids/electrolytes disorders, obesity, history of heart failure, coagulopathy, chronic liver disease, history of implantable cardiac defibrillator, history of cardiac pacemaker, previous MI, previous percutaneous coronary intervention, previous coronary artery bypass grafting, hospital bed size, hospital region, and hospital location/ teaching status. A multivariable regression analysis was conducted to further explore the comparative outcomes of hospitalizations for TAVI versus SAVR. The model included the same 25 variables used in the propensity matching analysis.

All analyses were conducted using the weighting samples for national estimates in adjunct with Healthcare Cost and Utilization Project regulations for using NIS database.[18] We compared categorical values using chi-square test, and continuous variables using Student's *t* test. We reported categorical variables as numbers and percentages, whereas we reported continuous variable as mean ±standard deviation or median and interquartile range depending on the skewness of the results curve. Associations were considered significant if the p value was <0.05. We used the SPSS software (IBM SPSS Statistics for Windows, Version 24.0; Armonk, New York: IBM Corp Released 2016) and R software (R Foundation for Statistical Computing, Vienna, Austria) for all statistical analyses.[19]

Results

The study flow sheet is outlined in Figure 1. Our initial analysis resulted in 8,060 hospitalizations with RA who underwent TAVI or SAVR. After excluding cases with isolated aortic regurgitation, concomitant other valvular replacement, coronary artery bypass grafting, or cases with missing variables on mortality or baseline characteristics, our analysis yielded 5,640 hospitalizations with RA who underwent isolated AVR; of whom, 2,465 (43.7%) underwent TAVI. There was a significant increase in the proportion of TAVI procedures during the study years (17.7% in 2012 vs 63.4% in 2016, $p_{trend} = 0.001$), and a corresponding reduced proportion of SAVR procedures (82.3% in 2012 vs 36.6% in 2016, $p_{trend} = 0.001$) among patients with RA who underwent isolated AVR (Figure 2). After propensity matching, our analysis yielded 1,220 cases in each of the TAVI and SAVR groups. Baseline characteristics of the study cohort are presented in Table 1. Before matching, patients who underwent TAVI were older, more likely to have female gender, white race, history of heart failure, diabetes, hypertension, peripheral arterial disease, pulmonary circulation disorders, chronic lung disease, and chronic kidney disease. Also, TAVI was more commonly performed in larger hospitals, urban teaching hospitals. After matching, standardized mean differences for all baseline characteristics were less than 10% between both groups, suggesting minimal differences (Supplementary Figure 1).

In the matched cohort, there was a trend toward reduced in-hospital mortality among TAVI compared with SAVR but did not reach statistical significance (0.8% vs 1.6%, odds ratio = 0.50; 95% confidence interval 0.23 to 1.06, p = 0.097). Similar results were obtained on multivariable analysis, with no significant difference in in-hospital mortality between TAVI and SAVR (odds ratio = 0.78; 95% confidence interval 0.39 to 1.56, p = 0.47).

After propensity matching, there were no significant differences between TAVI and SAVR groups with regards to cardiac arrest (2.0% vs 1.2%, p = 0.150), cardiogenic shock (1.6% vs 2.5%, p = 0.198), use of mechanical circulatory support devices (1.2% vs 0.8%, p = 0.422), acute stroke (2.0% vs 1.6%, p = 0.548), acute MI (1.6% vs 1.2%, p = 0.496), vascular complications (0.8% vs 0.8%, p > 0.999), respiratory complications (2.5% vs 2.9%, p = 0.615), hemodialysis (0% vs 0.4%, p = 0.062), and ventricular arrhythmias (3.3% vs

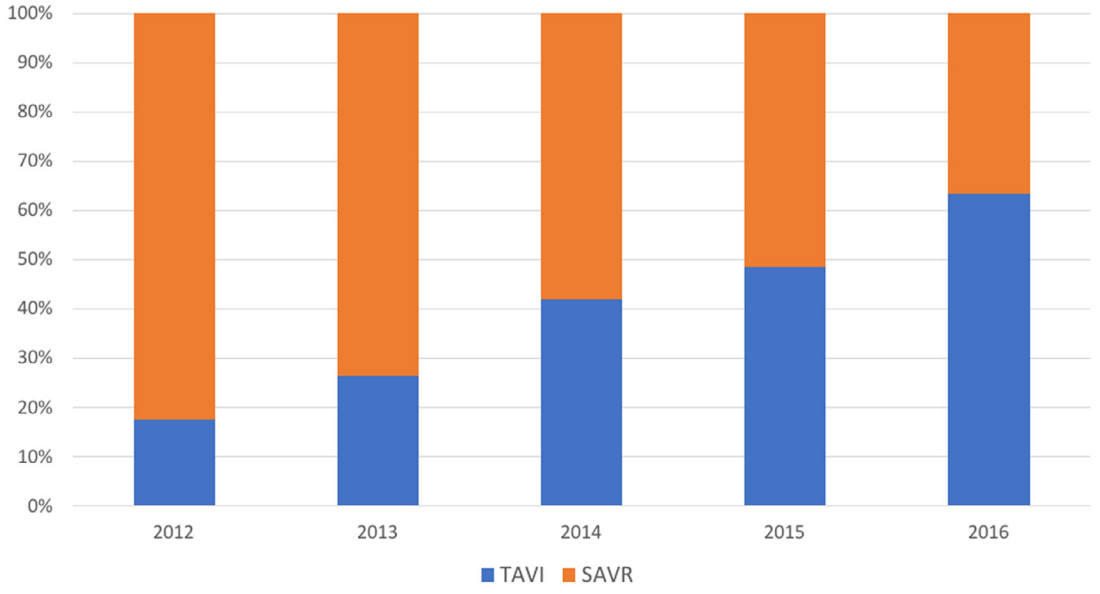

Figure 2. Temporal trends in TAVI and SAVR procedures in patients with RA.

Table 1
Baseline characteristics among the unmatched and matched cohorts of TAVI versus SAVR in RA

Characteristic	Unmatched cohort					Matched cohort*			
	TAVI (n = 2,465)		SAVR (n = 3,175)		p Value	TAVI (n = 1,220)		SAVR (n = 1,220)	
Age (years)	79.96 ± 7.45		69.85 ± 9.84		<0.001	76.12 ± 6.65		77.02 ± 7.75	
Women	1655	(67.5%)	2035	(64.1%)	.007	890	(73.0%)	850	(69.7%)
Race									
White	2035	(82.6%)	2540	(80.0%)	.015	1000	(82.0%)	1005	(82.4%)
Black	130	(5.3%)	160	(5.0%)	.715	65	(5.3%)	75	(6.1%)
Hispanic	100	(4.1%)	165	(5.2%)	.049	55	(4.5%)	55	(4.5%)
Asian/pacific islander	25	(1.0%)	15	(0.5%)	.024	15	(1.2%)	15	(1.2%)
Native American	NR	NR	20	(0.6%)	.024	NR	NR	NR	NR
Other race	50	(2.0%)	70	(2.2%)	.710	20	(1.6%)	15	(1.2%)
Heart failure	125	(5.1%)	15	(0.5%)	.000	NR	NR	NR	NR
Diabetes mellitus	780	(31.6%)	760	(23.9%)	.000	345	(28.3%)	355	(29.1%)
Anemia	625	(25.4%)	650	(20.5%)	.000	300	(24.6%)	270	(22.1%)
Healed myocardial infarct	230	(9.3%)	185	(5.8%)	.000	100	(8.2%)	95	(7.8%)
Smoking	460	(18.7%)	405	(12.8%)	.000	190	(15.6%)	175	(14.3%)
Carotid artery disease	50	(2.0%)	80	(2.5%)	.245	35	(2.9%)	45	(3.7%)
Pulmonary circulation disorders	45	(1.8%)	NR	NR	.000	NR	NR	NR	NR
Peripheral arterial disease	645	(26.2%)	595	(18.7%)	.000	240	(19.7%)	225	(18.4%)
Chronic lung disease	835	(33.9%)	885	(27.9%)	.000	380	(31.1%)	420	(34.4%)
Hypothyroidism	575	(23.3%)	740	(23.3%)	1.00	315	(25.8%)	300	(24.6%)
Chronic kidney disease	635	(25.8%)	415	(13.1%)	.000	260	(21.3%)	230	(18.9%)
Chronic liver disease	45	(1.8%)	75	(2.4%)	.193	20	(1.6%)	20	(1.6%)
Coagulopathy	410	(16.6%)	1010	(31.8%)	.000	260	(21.3%)	315	(25.8%)
Obesity	370	(15.0%)	760	(23.9%)	.000	240	(19.7%)	270	(22.1%)
Fluid and electrolyte disorder	435	(17.6%)	1010	(31.8%)	.000	265	(21.7%)	255	(20.9%)
Hypertension	1950	(79.1%)	2380	(75.0%)	.000	960	(78.7%)	875	(71.7%)
Prior implantable defibrillator	40	(1.6%)	NR	NR	.000	15	(1.2%)	NR	NR
Prior cardiac pacemaker	245	(9.9%)	105	(3.3%)	.000	80	(6.6%)	60	(4.9%)
Prior PCI	435	(17.6%)	175	(5.5%)	.000	130	(10.7%)	120	(9.8%)
Prior coronary bypass	310	(12.6%)	85	(2.7%)	.000	80	(6.6%)	60	(4.9%)
Prior TIA/stroke	305	(12.4%)	285	(9.0%)	.000	105	(8.6%)	140	(11.5%)
Hospital bed size									
Bed size small	90	(3.7%)	270	(8.5%)	.000	55	(4.5%)	55	(4.5%)
Bed size medium	470	(19.1%)	660	(20.8%)	.000	210	(17.2%)	225	(18.4%)
Bed size large	1905	(77.3%)	2245	(70.7%)	.000	955	(78.3%)	940	(77.0%)
Hospital location/teaching status									
Rural hospital	40	(1.6%)	140	(4.4%)	.000	25	(2.0%)	40	(3.3%)
Urban-nonteaching	185	(7.5%)	640	(20.2%)	.000	125	(10.2%)	155	(12.7%)
Urban-teaching	2240	(90.9%)	2395	(75.4%)	.000	1070	(87.7%)	1025	(84.0%)
Hospital region									
Northeast	640	(26.0%)	695	(21.9%)	.059	350	(28.7%)	305	(25.0%)
Midwest	580	(23.5%)	845	(26.6%)	.059	275	(22.5%)	285	(23.4%)
South	800	(32.5%)	1055	(33.2%)	.059	360	(29.5%)	420	(34.4%)
West	445	(18.1%)	580	(18.3%)	.059	235	(19.3%)	210	(17.2%)

NR = not reportable. Per Healthcare Cost and Utilization Project regulations, frequencies fewer than 11 should not be reported.
PCI = percutaneous coronary intervention.
* Standardized mean differences less than 10) in all baseline variables among the matched cohort.

2.0%, p = 0.078). TAVI was associated with lower rates of postoperative bleeding (28.7% vs 43.9%, p <0.001), requirement of blood transfusion (12.3% vs 40.2%, p <0.001), AKI (9.8% vs 16.0%, p <0.001), cardiac tamponade (0.0% vs 1.6%, p <0.001), and discharges to skilled nursing facility (20.1% vs 42.2%, p <0.001). TAVI associated with higher rate of complete heart block (14.3% vs 6.1%, p <0.001) and pacemaker implantations (14.8 vs 5.7%, p <0.001; Figure 3, Table 2). The temporal changes in in-hospital complications after TAVI are outlined in Supplementary Table 2. No significant trend change was found in all complications, except for an increase in acute stroke during the years (p_{trend}= 0.014).

Discussion

In this observational analysis including 5,640 patients with RA, we sought to evaluate the comparative outcomes of TAVI versus SAVR. There was a significant uptrend in the proportion of patients with RA who underwent TAVI during the study years. In-hospital mortality was not statistically different between TAVI and SAVR, although there was a trend toward lower mortality among the TAVI group. TAVI was associated with a lower incidence of AKI, major bleeding, blood transfusions, cardiac tamponade, and with a higher incidence of complete heart block and pacemaker implantations.

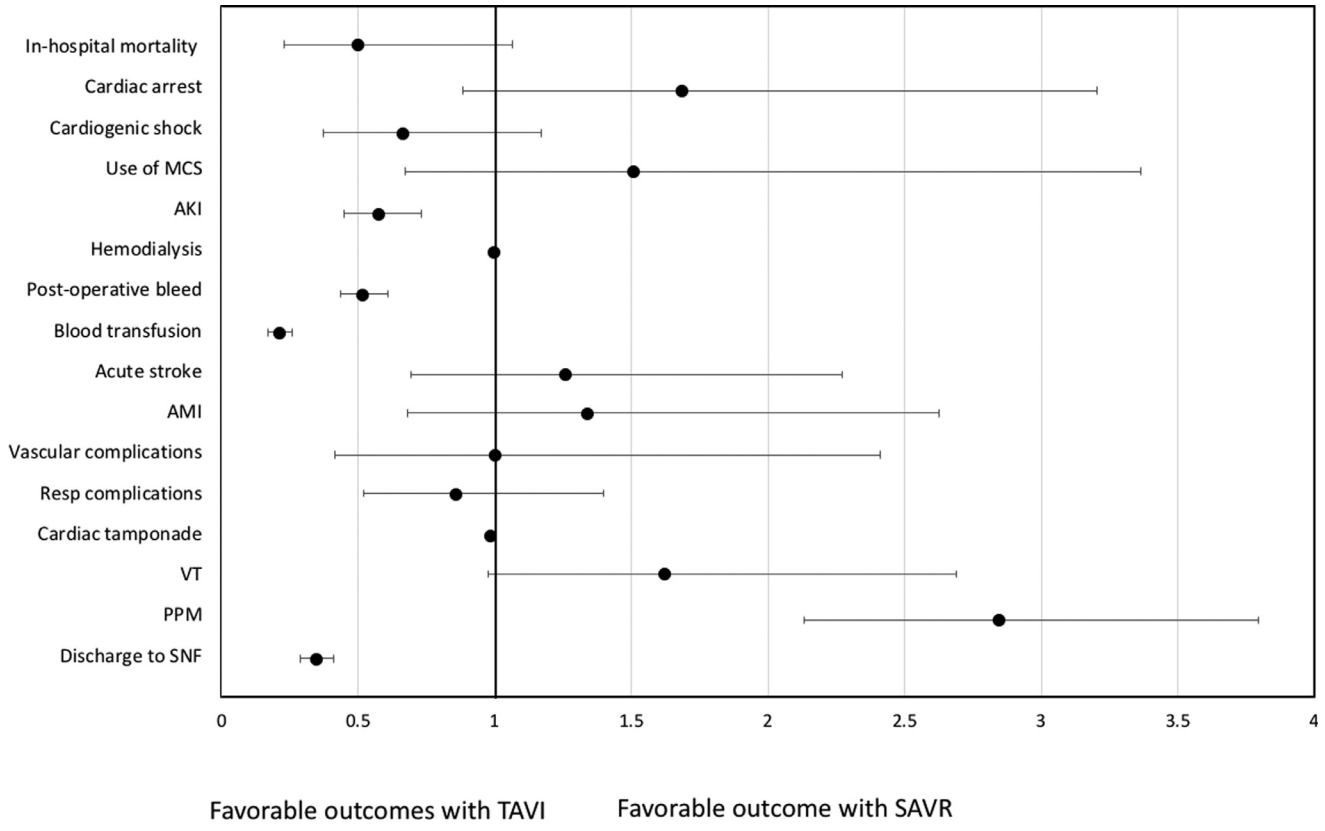

Figure 3. Forest plot for comparative outcomes of TAVI and SAVR in patients with RA.

Studies comparing TAVI versus SAVR in all comers showed comparable in-hospital mortality between TAVI and SAVR.[20] In this analysis, which was focused only on patients with RA, there was a signal toward better safety profile with TAVI compared with SAVR, evidenced by lower AKI, post-operative bleeding and cardiac tamponade events, as well as a trend toward lower in-hospital mortality.

Renal disease is common in patients with RA, either as part of the disease pathology or complication of some of the immune-targeted therapies for RA. Hence, renal complications come to consideration when selecting the type of valve replacement procedure. We found a significantly lower incidence of AKI as well as trend toward lower rate of hemodialysis among patients who underwent TAVI

Table 2
Comparison of in-hospital outcomes between TAVI and SAVR in the matched cohort

Outcome	TAVI (n = 1,220)		SAVR (n = 1,220)		OR	95% CI	p Value
In-hospital mortality	NR	NR	20	(1.6%)	.496	.231−1.064	.097
Cardiac arrest	25	(2.0%)	15	(1.2%)	1.681	.882−3.204	.150
Cardiogenic shock	20	(1.6%)	30	(2.5%)	.661	.373−1.171	.198
Use of MCS	15	(1.2%)	NR	NR	1.506	.674−3.366	.422
Acute kidney injury	120	(9.8%)	195	(16.0%)	.573	.450−.731	<0.001
Hemodialysis	NR	NR	NR	NR	.996	.992−.999	.062
Post-operative bleed	350	(28.7%)	535	(43.9%)	.515	.435−.609	<0.001
Blood transfusion	150	(12.3%)	490	(40.2%)	.209	.170−.257	<0.001
Acute stroke	25	(2.0%)	20	(1.6%)	1.255	.693−2.272	.548
Acute myocardial infarction	20	(1.6%)	15	(1.2%)	1.339	.682−2.628	.496
Vascular complications	NR	NR	NR	NR	1.000	.415−2.411	1
Respiratory complications	30	(2.5%)	35	(2.9%)	.854	.521−1.399	.615
Hemopericardium	NR	NR	NR	NR	1.004	1.001−1.008	.062
Cardiac tamponade	NR	NR	20	(1.6%)	.984	.977−.991	<0.001
Ventricular arrhythmias	40	(3.3%)	25	(2.0%)	1.620	.977−2.688	.078
Complete heart block	175	(14.3%)	75	(6.1%)	2.557	1.926−3.394	<0.001
Permanent pacemaker insertion	180	(14.8%)	70	(5.7%)	2.843	2.131−3.794	<0.001
Discharge to SNF	245	(20.1%)	515	(42.2%)	.344	.287−.412	<0.001
Length of stay, days (mean ± SD)	5.68 ± 5.22		8.83 ± 7.49				<0.001

NR = not reportable. Per Healthcare Cost and Utilization Project regulations, frequencies fewer than 11 should not be reported.

compared with SAVR. It is plausible that cardiopulmonary bypass carries a higher risk for AKI in patients with RA who are already prone for renal disease. Patients with RA commonly have associated autoimmune platelet and coagulation disorders; in addition, immune-targeted therapies might potentially contribute to worsening of those disorders. As a result, patients with RA are more prone to bleeding complications compared with the general population, which might have translated to the observed higher postoperative bleeding and transfusion with SAVR in our analysis. Similar to studies on all-comers, we found no difference in acute cerebrovascular events after TAVI compared with SAVR.[21] Reports have raised concerns on higher stroke risk associating earlier generations of TAVI valves, but more recent reports on newer generation valves showed comparable stroke risk to SAVR.[22]

Notably, the present study cohort showed significant female predominance; a finding that is likely related to the prevalence of RA in the general population.[4] This comes in discordance with clinical trials evaluating TAVI as well as other cardiovascular diseases, which usually have higher male representation. In our analysis, the rates of mortality in the TAVI group among patients with RA were similar to that observed in clinical trials for TAVI in low surgical risk patients.[23] Although RA does not contribute to the Society of Thoracic Surgery risk score, It is plausible that in some cases, performance of TAVI was selected on the basis of having RA and presumed increased complications with SAVR. To the best of our knowledge, this is the first study comparing TAVI and SAVR in patients with RA. Real-world data from a national database demonstrated an increasing trend in the number of TAVI procedures in patients with RA. There was no significant difference in mortality among patients with RA who underwent TAVI compared with SAVR. TAVI was associated with a lower incidence of AKI, postoperative bleeding, and cardiac tamponade, whereas TAVI was associated with a higher incidence of pacemaker implantations. Future studies are still warranted to evaluate the long-term outcomes for TAVI versus SAVR in patients with RA.

This current analysis has certain limitations. Being an administrative database, the NIS is liable to documentation errors. Also, it is time-discrete with limited information to hospitalization outcomes. Many important information were unfortunately irretrievable from this dataset. This includes data on imaging tests (e.g., left ventricular size and function and aortic root dimensions), medications (e.g., use of steroids and immunosuppressants), as well laboratory results. Also, procedural information for TAVI such as valve size, paravalvular leak, and procedural success would have been valuable. We have included ICD codes for any bleeding events, which might explain the relevantly higher number of events compared with randomized trials which mainly reported major bleeding events.[23] In absence of laboratory and clinical data, we believed it would be inaccurate to discern major bleeding events through this dataset. However, even with these limitations, our study addressed a current knowledge gap in the literature about the comparative outcomes of TAVI and SAVR in the specific population of patients with RA.

Disclosures

The authors have no conflicts of interest to disclose.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2019.07.009.

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