Comparison of Outcomes of Transcatheter Versus Surgical Aortic Valve Replacement in Patients ≥80 Years of Age

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Transcatheter aortic valve implantation (TAVI) procedures have increased exponentially since FDA approval in 2011. Older patients who underwent aortic valve replacement, either TAVI or surgical aortic valve replacement (SAVR), have elevated risk. Using the National Readmission Database, we included patients ≥80 years who underwent either TAVI or SAVR from 2011 to 2015. In-hospital outcomes of TAVI versus SAVR were compared using propensity-matched analysis to reduce the confounding effect of between-group imbalances. We identified a total of 30,590 TAVI and 54,204 SAVR procedures performed during the study period. The propensity score-matching algorithm yielded 19,713 patients in each group. The in-hospital mortality rates were significantly lower in TAVI compared with SAVR (3.4% vs 6.8%, p <0.001). Similarly, the 30-day readmission rate (15.2% vs 18.1% p = 0.001), in-hospital complications, mean length of stay (7 vs 12 days, p <0.001), and hospital cost (US$ 60,534 vs US$ 67,426) were significantly lower for TAVI patients. There was a significant increase in the use of TAVI (26 cased per month in 2011 to 1,237/month in 2015) and a decrease in SAVR (1,409/month in 2011 to 859/month in 2015) during the study period. In-patient mortality significantly decreased for patients who underwent TAVI (4.4% in 2011 to 2.5% in 2015) and did not significantly change for patients who underwent SAVR (5.0% in 2011 to 4.7% in 2015). Overall, the number of SAVR procedures remained two thirds higher than TAVI. In conclusion, in octo- and nonagenarians, TAVI is an effective and safer alternative to SAVR as it is associated with lower in-hospital mortality, lower major in-hospital complications, lower 30-day readmission rate, and hospital costs. Despite this, SAVR remained the most common approach in octogenarians, although the trends in this data set, suggest a shift in practice patterns for this cohort. **(Am J Cardiol 2019;123:1853−1858)**

The number of transcatheter aortic valve implantation (TAVI) procedures has increased significantly over the past years.[1−3] This trend will continue as medical technology and newer generation TAVI devices become available,[4] operator techniques improve, and indications expand for broader anatomical and patient risk subsets. Current 2017 AHA/ACC Guidelines recommend that the choice for proceeding with TAVI versus Surgical Aortic Valve Replacement (SAVR) should be based on multiple factors including surgical risk, frailty, comorbid conditions, and patient preference. Compared with the previous 2014 guidelines, the 2017 update includes a class IIa recommendation for intermediate risk patients and class Ia for patients with symptomatic severe aortic stenosis with high or prohibitive risk for SAVR.[5] Additionally, 2 recent meta-analyses showed similar outcomes for low to intermediate risk patients underwent TAVI when compared with SAVR.[6,7] Furthermore, there are also ongoing randomized control clinical trials exploring outcomes in TAVI versus SAVR in low risk patients.[8] Importantly, frailty and medical comorbidities are more common in the older population potentially making them better candidates for a less invasive approach to aortic valve replacement.[9] However, previous studies suggest that older patients who undergo TAVI have similar outcomes to younger patients.[10,11]

Methods

The study cohort was derived from the National Readmission Database (NRD), a publicly available database of all-payer hospital inpatient stays developed by the Agency for Healthcare Research and Quality as part of the Healthcare Cost and Utilization Project. The study included the NRD databases from January 2011 to August 2015. The NRD was constructed from 22 States with reliable, verified patient linkage numbers in the State Inpatient Databases that could be used to track the patient across hospitals within a State, while adhering to strict privacy guidelines.

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The NRD database includes approximately 14 million patients and around 2,000 hospitals per year. National estimates are obtained using sampling weights provided. Patients have a unique identifier, which allows each patient to be tracked (the variable named “NRD_visitlink”). We determined the time between the first admission and the readmission using the variable “NRD_daystoevent” and calculating the difference between that variable and the length of stay (LOS). A detailed explanation of all the variables in the NRD is available online (https://www.hcup-us.ahrq.gov/db/nation/nrd/nrddde.jsp). This study was deemed exempt by the Institutional Review Board as the NRD is a publicly available database that contains de-identified patient information.

The study population was identified using the International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) procedure codes for TAVI (35.05 and 35.06) and SAVR (35.21 and 35.22). ICD-9 codes were queried. Exclusion criteria consisted of patients <80 years of age (n = 233,974), those admitted during the month of December (for the years 2011 to 2014, and September for 2015) (n = 37,370), same day admission transfers (n = 35,125), out of state patients (n = 39,533), and patients who did not have mortality data (n = 137) (Supplemental Figure 1).

Baseline patient characteristics such as age, gender, primary expected payer, median household income, and relevant comorbidities were collected. The severity of co-morbid conditions was defined using a validated Deyo modification of Charlson Co-morbidity Index (CCI).[8,12] Other characteristics such as teaching status of the hospital, median household income, insurance status, elective admission status, and discharge disposition were also included.

The primary outcome was in-hospital mortality. Secondary outcomes include 30-day mortality, 30-day all-cause readmission (both unplanned and planned readmissions were included), acute kidney injury, cardiogenic shock, stroke or transient ischemic attack (TIA), complete heart block, pacemaker placement, mechanical circulatory support use, transfusion, LOS, hospital costs (adjusted for inflation up to July 2018), cardiac complications, and vascular complications. ICD-9 codes were utilized to identify the primary diagnosis in the readmission. The ICD-9-CM codes used to identify and define these variables are listed in Tables 1 and 2 in the Supplement. Univariate differences in baseline characteristics between readmitted and nonreadmitted patients were evaluated using Pearson chi-square tests for categorical variables and Wilcoxon rank-sum tests for continuous variables. The propensity score was calculated by first using a logistic regression model for different variables that included patient demographics, co-morbidities, and hospital characteristics; then we matched all patients using a one-to-one scheme without replacement using the nearest number neighbor algorithm with a maximum caliber of 0.01 of the propensity score. Using the matched cohort, modified Poisson regression was used to analyze statistical significance between our outcomes in both groups, results are reported as risk ratios (RR) with 95% confidence intervals (CIs). Statistical analysis was performed with Stata 14. A p value less than 0.05 was considered significant for all the analyses.

Results

A total of 84,794 patients underwent aortic valve replacement (AVR) between 2011 and 2015, of which 30,590 (36.1%) underwent TAVI and 54,204 (63.9%) underwent SAVR. The mean age of the total population was 84.4 ± 3.2 years; with study population at 44.6% female gender. Patients who underwent TAVI had significantly higher prevalence of hypertension, diabetes mellitus, end stage renal disease, heart failure (HF), chronic lung disease, peripheral vascular disease, history of previous myocardial infarction, previous coronary artery bypass graft (CABG), previous stroke or TIA, anemia, liver disease and cancer. The baseline patient and hospital characteristics stratified by AVR method are shown in Table 1.

The most common causes for 30-day readmission in patients that underwent TAVI were HF (22.9%), sepsis (6.3%), gastrointestinal bleed (5.3%), and postoperative infection or complication (5.2%). Among patients that underwent SAVR, HF was the most common cause of 30-day readmission (21.4%), followed by atrial fibrillation or other arrhythmias (10.4%), postoperative infection or complication (8.1%), and pleural effusion (4.9%). Figure 3 shows the etiologies for 30-day readmission between both groups. In the unmatched cohort, there was an inverse relation in the use of SAVR and patient age (Figure 2). TAVI was performed in 17.7% of patients 80 years old and in 76% of patients 90 years old with a direct correlation between the CCI score, which increased with age, and the use of TAVI over SAVR as shown in Figure 2. Between 2011 and 2015, there was a significant increase in the use of TAVI (26 cases per month in 2011 to 1,237 cases per month in 2015) and a decrease in SAVR (1,409 cases per month in 2011 to 859 cases per month in 2015). Moreover, mortality significantly decreased for patients who underwent TAVI (4.4% in 2011 to 2.5% in 2015) and did not significantly change for patients who underwent SAVR (5.0% in 2011 to 4.7% in 2015).

The propensity score-matching algorithm yielded 19,713 well-matched patients in each group. The baseline characteristics are listed in Table 1 and the in-hospital clinical outcomes are shown in Figure 1. The in-hospital mortality rates were significantly lower in TAVI compared with SAVR (3.4% vs 6.8%; RR: 0.48, 95% CI: 0.40 to 0.57, p <0.001), as well as the 30-day mortality rate (3.9% vs 7.4%, p <0.001). The 30-day readmission rate was lower in TAVI (15.2% vs 18.1%; RR: 0.81; 95% CI: 0.73 to 0.90; p = 0.001). The TAVI group had significantly lower rates of postprocedural complications including cardiogenic shock (2.4% vs 6.2%; RR: 0.37; 95% CI: 0.30 to 0.45; p <0.001), mechanical circulatory support use (1.6% vs 4.4%, RR: 0.36, 95% CI: 0.29 to 0.45; p <0.001), acute kidney injury (15.9% vs 26.6%, RR: 0.52, 95% CI: 0.47 to 0.57; p <0.001), cardiac complications (9.4% vs 15.6%, RR: 0.56, 95% CI:0.50 to 0.63; p <0.001), vascular complications (35.5% vs 49.2%, RR: 0.57, 95% CI:0.50 to 0.65; p <0.001), stroke or TIA (2.5% vs 3.4%, RR: 0.73;95% CI: 0.59 to

Table 1
Baseline characteristics during index admission

Variables	Overall (N = 84,794)	TAVR (N = 30,590)	SAVR (N = 54,204)	p value	Propensity score-matched TAVR (N = 19,713)	Propensity score-matched SAVR (N = 19,713)	p value
Age (mean, years)	84.4	86.0	83.5	<0.001	85	85	0.903
Women	37,818 (44.6%)	15,191 (49.6%)	22,630 (41.7%)	<0.001	9,555 (48.4%)	9,354 (47.4%)	0.271
Hypertension	66,538 (78.4%)	24,591 (80.3%)	41,943 (77.3%)	<0.001	15,542 (78.8%)	15,514 (78.7%)	0.878
Diabetes mellitus	22,971 (27%)	8,963 (29.3%)	14,012 (25.8%)	<0.001	5,640 (28.6%)	5,707 (28.9%)	0.651
End stage renal disease	1,272 (1.5%)	600 (1.9%)	672 (1.2%)	<0.001	359 (1.8%)	375 (1.9%)	0.724
Congestive heart failure	44,330 (52.2%)	22,426 (73.3%)	21,909 (40.4%)	<0.001	12,575 (63.7%)	13,101 (66.4%)	0.053
Body mass index ≧ 30 kg/m^2	8,233 (9.7%)	3,050 (9.9%)	5,182 (9.5%)	0.347	2,070 (10.5%)	1,883 (9.5%)	0.096
Chronic pulmonary disease	18,621 (21.9%)	8,758 (28.6%)	9,865 (18.2%)	<0.001	5,047 (25.6%)	5,086 (25.8%)	0.856
Peripheral vascular disease	18,383 (21.6%)	8,666 (28.3%)	9,703 (17.9%)	<0.001	4,733 (24%)	4,633 (23.5%)	0.573
Smoker	21,877 (25.8%)	7,972 (26%)	13,903 (25.6%)	0.611	4,985 (25.2%)	5,001 (25.3%)	0.932
Prior myocardial infarction	7,971 (9.4%)	3,634 (11.8%)	4,033 (7.4%)	<0.001	2,007 (10.1%)	1,924 (9.7%)	0.524
Prior coronary artery bypass grafting	9,251 (10.9%)	5,959 (19.4%)	3,296 (6%)	<0.001	2,366 (12%)	2,322 (11.7%)	0.749
Prior stroke/transient ischemic attack	8,844 (10.4%)	4,032 (13.1%)	4,813 (8.8%)	<0.001	2,257 (11.4%)	2,342 (11.8%)	0.456
Known coronary artery disease	54,192 (63.9%)	20,841 (68.1%)	33,346 (61.5%)	<0.001	12,853 (65.2%)	12,794 (64.9%)	0.795
Carotid artery disease	5,579 (6.5%)	1,964 (6.4%)	3,610 (6.6%)	0.511	1,262 (6.4%)	1,340 (6.8%)	0.353
Atrial fibrillation	46,119 (54.3%)	14,304 (46.7%)	31,812 (58.6%)	<0.001	10,111 (51.2%)	10,132 (51.4%)	0.911
Prior implantable cardioverter-defibrillator	1,297 (1.5%)	805 (2.6%)	493 (0.9%)	<0.001	323 (1.6%)	327 (1.6%)	0.933
Anemia	18,095 (21.3%)	7,231 (23.6%)	10,868 (20%)	<0.001	4,406 (22.3%)	4,524 (22.9%)	0.507
Liver disease	695 (0.8%)	312 (1%)	385 (0.7%)	0.004	189 (0.9%)	193 (0.9%)	0.872
Cancer	2,442 (2.8%)	1,061 (3.4%)	1,382 (2.5%)	<0.001	690 (3.5%)	589 (2.9%)	0.090
Charlson comorbitiy index							
0	14,118 (16.6%)	2,053 (6.7%)	12,071 (22.2%)	<0.001	1,908 (9.6%)	1,788 (9%)	0.135
1	21,266 (25%)	6,485 (21.2%)	14,787 (27.2%)		4,729 (23.9%)	4,621 (23.4%)	
2	17,730 (20.9%)	6,555 (21.4%)	11,171 (20.6%)		4,284 (21.7%)	4,621 (23.4%)	
≥3	31,679 (37.3%)	15,497 (50.6%)	16,180 (29.8%)		8,790 (44.5%)	8,684 (44%)	
Other characteristics							
Hospital Bedsize							
Small	5,317 (6.2%)	1,468 (4.8%)	3,848 (7.1%)	0.041	997 (5%)	1,226 (6.2%)	0.255
Medium	13,542 (15.9%)	4,203 (13.7%)	9,339 (17.2%)		2,711 (13.7%)	3,052 (15.4%)	
Large	65,885 (77.7%)	24,919 (81.4%)	41,016 (75.6%)		16,005 (81.1%)	15,435 (78.3%)	
Median household income							
0−25th percentile	15,890 (18.7%)	5,580 (18.2%)	10,310 (19%)	0.264	3,582 (18.1%)	3,686 (18.7%)	0.631
26th−50th percentile	20,842 (24.5%)	7,406 (24.2%)	13,437 (24.7%)		4,916 (24.9%)	4,678 (23.7%)	
51st−75th percentile	22,886 (26.9%)	8,152 (26.6%)	14,738 (27.1%)		5,240 (26.5%)	5,244 (26.6%)	
76th−100th percentile	25,175 (29.6%)	9,452 (30.9%)	15,719 (29%)		5,975 (30.3%)	6,105 (30.9%)	
Primary payer							
Medicare/medicaid	80,910 (95.4%)	29,351 (95.9%)	51,548 (95.1%)	0.002	18,840 (95.5%)	18,810 (95.4%)	0.008
Private insurance	2,764 (3.2%)	765 (2.5%)	1,984 (3.6%)		530 (2.6%)	690 (3.5%)	
Self-pay/other	1,111 (1.3%)	459 (1.5%)	650 (1.2%)		335 (1.7%)	355 (1.8%)	
Discharge disposition							
Home	47,739 (56.3%)	21,107 (69%)	26,560 (49%)	<0.001	13,842 (70.2%)	8,575 (43.5%)	<0.001
Nursing home/facility	36,037 (42.5%)	9,220 (30.1%)	26,912 (49.6%)		5,693 (28.8%)	10,866 (55.1%)	
Transfer to another hospital	975 (1.1%)	260 (0.8%)	705 (1.3%)		175 (0.8%)	262 (1.3%)	

0.89; p = 0.002), and blood transfusions (19.9% vs 46.8%, RR: 0.28, 95% CI:0.25 to 0.32; p <0.001). Need for permanent pacemaker placement was more likely in the TAVI group (11.9% vs 8.1%, RR: 1.54, 95% CI: 1.34 to 1.76; p <0.001). Hospital LOS was significantly lower in patients that under TAVI (7.1 vs 12.3 days, p <0.001), as well as hospital costs (US$ 59,205 vs US$ 65,146, p <0.001). Patient that underwent SAVR was more likely to be discharged to a nursing home or acute care facility (28.9% for TAVI vs 55.1% for SAVR) instead of being discharged home (70.2% vs 43.5%, p <0.001).

Discussion

In this large observational nationwide study, we report a comprehensive analysis between TAVI and SAVR in patients 80 years and older in the United Stated from 2011 to 2015. The key findings of our study are: (1) TAVI is

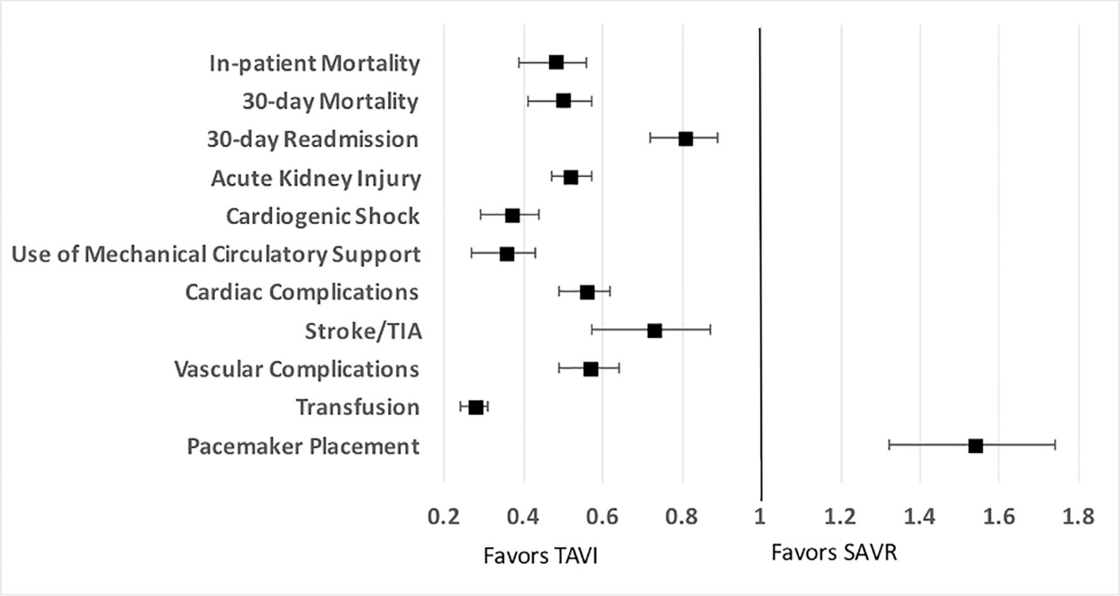

Figure 1. Forest plot showing the outcomes of patients who underwent TAVI vs SAVR in propensity-matched groups.

associated with a significantly lower all-cause in-hospital mortality when compared with a matched-group who underwent SAVR, (2) 30-day readmission is significantly less common after TAVI, and the most common cause for readmission for TAVI and SAVR patients is HF. TAVI is associated with both a significant decrease in LOS by 5 hospital days (7 vs 12 days), and also fewer major in-hospital complications (cardiogenic shock, AKI, use of MCS, cardiac, and vascular complications), and (4) TAVI is performed more frequently with increased patient age and there was an exponential overall increase in the use of TAVI during the study period.

Our cohort showed that TAVI patients had a 52% decreased risk of mortality when compared with SAVR (3.4% vs 6.8%) after propensity match. Similar results were seen in PARTNER A trial[13] with high-risk patients, a 30-day mortality for TAVI of 3.4% versus 6.5% for SAVR. PARTNER 2 trial[4] showed no significant difference in mortality for intermediate risk patients. A meta-analysis by Tam et al,[6] comparing TAVI versus SAVR in low-intermediate risk patients found similar rates of early stroke, with higher percentage in the SAVR patients (TAVI 3.0% and SAVR 3.9%). Similarly, they found fewer rates of cardiogenic shock and AKI in patients who underwent TAVI.

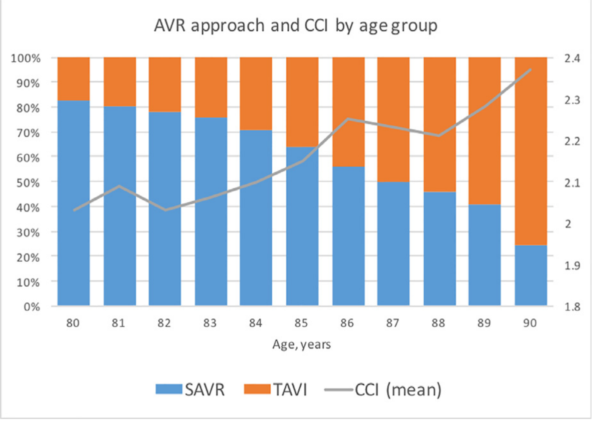

Figure 2. Method of aortic valve replacement and charlson comorbitidy index by age.

Older patients who undergo TAVI have significantly fewer hospital days and are more likely to be discharged home. Although not evaluated in our study, this might be explained by hospital and procedural factors such as anesthesia use (conscious sedations vs general anesthesia), early mobility postprocedure, decrease use of vasoactive drugs, and fewer ICU days.[14]

In our unmatched cohort, patients who underwent TAVI had a significantly higher number of co-morbidities with a mean CCI score of 2.7 compared with 1.8 for the SAVR group. Similar findings have been previously reported[15] confirming that TAVI patients consistently have a higher risk with more co-morbidities and are therefore prone to worse outcomes. Nevertheless, as reported by previous studies,[13,16,17] our study is consistent with multiple others in showing that TAVI is an effective and safer method that SAVR particularly in an older and high risk cohort. We also found that patients with history of previous CABG were more likely to undergo TAVI, which can be explained by the inherent risk in redo sternotomies. Gupta et al[14] similarly described that TAVI is increasingly performed in patients with previous CABG and is associated with lower rates of in-hospital complications when compared with SAVR.

In our unmatched cohort, HF was the most common etiology for 30-day readmission in both TAVI and SAVR patients. Similar findings were described by Kolte et al,[18] showing HF as a readmission diagnosis in 22.5% of patients readmitted after TAVI. We found that patients who underwent SAVR had a higher readmission rates for atrial fibrillation and other arrhythmias as well as postoperative complications; this has been showed in previous

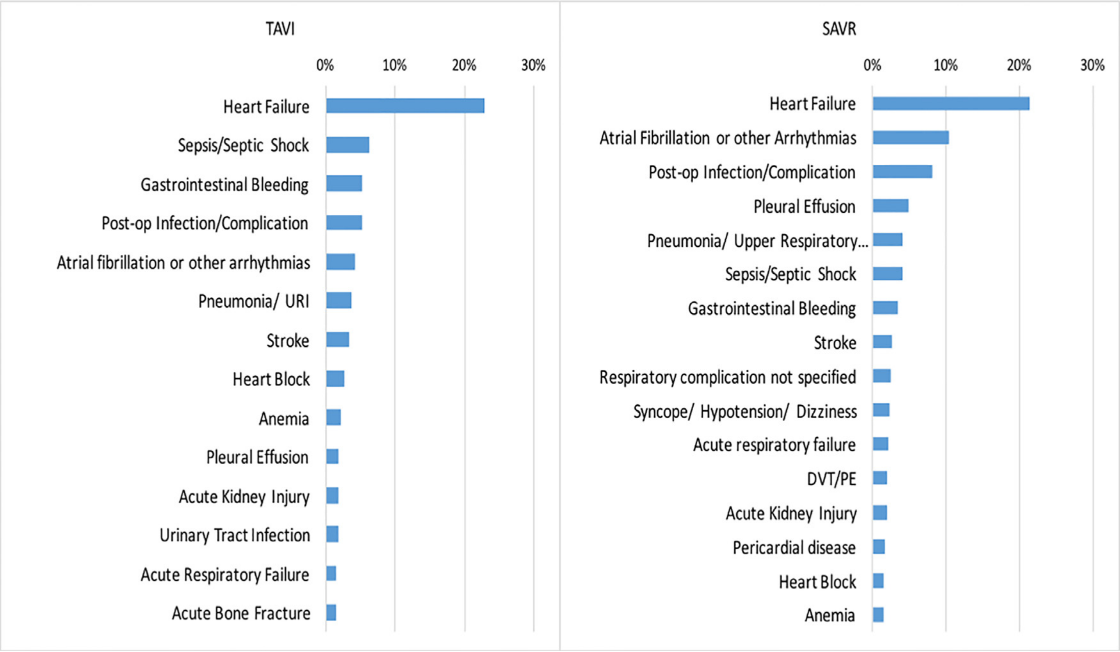

Figure 3. Etiologies of 30-day readmission in TAVI and SAVR patients.

studies and atrial fibrillation is a well-known complication after cardiac surgery.[19,20] Patients that underwent TAVI, however, had higher readmission rates due to sepsis and gastrointestinal bleeding. Readmission due to gastrointestinal bleeding in TAVI patients could be explained by the use of dual antiplatelet therapy, and often the use of anticoagulation for those patients with underlying atrial fibrillation.[21,22]

There are several limitations to the pesent study due to the nature and well described short comings of this database.[18] The mortality data does not distinguish between cardiac and noncardiac causes of death. In addition, the study is limited to in-hospital outcomes only and the outcome data are not available for patients after hospital discharge. In addition, it is not possible to reliably distinguish in-hospital complications from comorbidities with this administrative database. NRD data is based on ICD-9-CM codes, and there is a possibility of coding error. The lack of information about laboratory results, medications, valve type and size, access site, echocardiographic findings, and STS score is also a limitation. Despite these limitations, our results are comparable with previous studies and provide a comprehensive assessment between the TAVI and SAVR in an older cohort.

In conclusion, in octo- and nonagenarians, TAVI is an effective and safer alternative to SAVR as it is associated with lower in-hospital mortality, lower major in-hospital complications, and lower 30-day readmission rate. Patients that underwent TAVI had shorter LOS, hospital costs and were more likely to be discharged home rather than a skilled nursing facility. HF remains a common cause of readmission in this population regardless of AVR procedure.

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.2019.03.006.

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