Trends in Readmission and Costs After Transcatheter Implantation Versus Surgical Aortic Valve Replacement in Patients With Renal Dysfunction

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Patients with renal dysfunction are at increased risk for developing aortic valve pathology. In the present era of value-based healthcare delivery, a comparison of transcatheter and surgical aortic valve replacement (SAVR) readmission performance in this population is warranted. All adult patients who underwent transcatheter or SAVR from 2011 to 2014 were identified using the Nationwide Readmissions Database, containing data for nearly 50% of US hospitalizations. Patients were further stratified as chronic kidney disease stage 1 to 5 as well as end-stage renal disease requiring dialysis. Kaplan-Meier, Cox Hazard, and multivariable regression models were generated to identify predictors of readmission and costs. Of the 350,609 isolated aortic valve replacements, 4.7% of patients suffered from chronic kidney disease stages 1 to 5 or end-stage renal disease. Transcatheter aortic valve patients with chronic kidney disease stages 1 to 5/or end-stage renal disease were older (81.9 vs 72.9 years, p <0.0001) with a higher prevalence of heart failure (15.2 vs 4.3%, p = 0.04), and peripheral vascular disease (31.1 vs 22.8%, p <0.0001) compared to their SAVR counterparts. Transcatheter aortic valve replacement in chronic kidney disease stage 1 to 3 patients had a higher rate of readmission due to heart failure and pacemaker placement than SAVR. Transcatheter aortic valve replacement was associated with increased costs compared with SAVR for all renal failure patients. In conclusion, in this national cohort of chronic and end-stage renal disease patients, transcatheter aortic valve implantation was associated with increased mortality, readmissions for chronic kidney disease stages1 to 3, and index hospitalization costs. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:1481−1488)

Patients with creatinine clearance <20cc/min or hemodialysis-dependence have been excluded from all early pivotal clinical trials comparing transcatheter aortic valve implantation (TAVI), surgical aortic valve replacement (SAVR), and medical treatment.[1−3] Those with end-stage renal disease (ESRD) are prone to premature valvular calcification and have been demonstrated to have worse mortality with medical management of aortic stenosis compared to their non-ESRD counterparts.[4,5] Furthermore, the presence of other major co-morbidities in patients with advanced renal disease theoretically makes TAVI an attractive option given its inherently less invasive nature and obviation of cardiopulmonary bypass.[6] Patients with renal disease, in particular, present a challenging cohort with more frequent unplanned rehospitalization and increased resource utilization.[7] With the rapid expansion of TAVI and the increasing use of postoperative readmission rate as a surrogate marker for quality of care, characterization of clinical outcomes and hospital readmissions in patients with varying degrees of renal insufficiency is necessary to ensure value-based strategies for the treatment of valvular disease.[8,9] We hypothesized that patients who underwent TAVI would have higher overall, early, and intermediate readmission rates for all stages of renal failure compared with SAVR. We used the Nationwide Readmissions Database (NRD), the largest available readmissions repository in the United States, to provide a contemporary national landscape of mortality and readmission outcomes for surgical replacement and TAVI in patients with chronic kidney disease and ESRD.

Methods

The 2011 to 2014 NRD, the largest publicly available all-payer discharge database maintained by the Agency of Healthcare Research and Quality, was used to identify candidate patients.[10] Hospitalization episodes in the NRD are accrued from individual State Inpatient Databases containing patient identifiers allowing for linked visits to inpatient facilities, excluding rehabilitation and long-term acute hospitals.[10] The NRD accounts for up to 57.8% of all US discharges. National estimates are obtained using discharge weights assigned to each sampled institution. This study was deemed exempt from review by the Institutional Review Board at the University of California, Los Angeles.

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The study cohort was derived from the approximately 17 million annual unweighted discharges in the NRD using International Classification of Disease (ICD9) administrative coding. All adult patients (≥18 years) who underwent TAVI (*ICD 35.05 and 35.06*) and SAVR (*ICD9 35.21 and 35.22*) with the diagnosis of Aortic Stenosis (*ICD9 39.50, 39.52, 42.41, and 74.63*) within the NRD were identified. ICD9 coding was used to exclude patients who underwent concomitant coronary artery bypass grafting, valve repair/replacement, aortic arch interventions, left atrial appendage ligation, and ventricular assist device or transplant during the same hospitalization. Severity of renal insufficiency was defined using the National Kidney Foundation Kidney Disease Quality Outcome Initiative.[11] Patients were then grouped based on degree of chronic kidney disease for all analyses as follows: Non-CKD, Stage 1-3 (CKD1-3), Stage 4-5 (CKD4-5), and ESRD, representing renal dysfunction requiring dialysis (Figure 1). NRD definitions were used for patient and hospital level variables including age, gender, co-morbidities present on admission and hospital bedsize.[10,12] The previously validated Elixhauser co-morbidity index was calculated to estimate extent of chronic diseases within this administrative database.[13] High TAVI volume institutions were defined as those performing at least 50 TAVI per NRD year. Diagnosis-Related Groups (DRGs) were used to categorize the primary indication for readmission.

The primary outcome of this study was the rate of all-cause 30- and 31-90 day readmission after discharge. Additional outcomes included index hospitalization mortality, length of stay (LOS), and costs. Costs were calculated from hospital charges using the NRD Cost-to-Charge ratios and gross-domestic product adjustments published by the US Bureau of Labor Statistics Consumer Price Index.

All statistical analyses were performed using Stata 15 (StataCorp, College Station, Tx). Survey-weighted chi-squared analysis of categorical variables and Adjusted Wald Test for continuous measurements were performed. Kruskal-Wallis test was used for variables with left-skewed distribution. Cox proportional hazard and Kaplan-Meier analyses were used to identify patient and hospitalization characteristics associated with readmission. Linear regression models including patient co-morbidities, age, gender, perioperative complications, hospital stratification as high TAVI volume, and hospital control, as provided by the NRD, were generated to assess the primary and secondary outcomes. Outcome trends were determined using a PTREND analysis.[14]

Results

Of the 350,609 patients who underwent aortic valve replacement, 155,579 patients met inclusion criteria (TAVI = 36,070 and SAVR = 119,509). Extent of renal insufficiency among the cohort was shown in Figure 1. Compared with SAVR, TAVI patients had a greater proportion of CKD1-3 (12.1 vs 5.8 %, p <0.0001), CKD4-5 (3.5 vs 1.0%, p <0.0001), and ESRD (2.9 vs 1.5%, p <0.0001). On average, TAVI patients with ESRD were older, and had higher rates of heart failure, chronic obstructive pulmonary disease, and peripheral vascular disease than their SAVR counterparts. ESRD TAVI patients had lower rates of baseline neurologic dysfunction and chronic blood loss anemia without any significant difference in obesity and hematologic malignancies. Differences between TAVI and SAVR patients grouped by extent of kidney disease, including rates of heart failure, history of myocardial infarction, peripheral vascular disease, and univariate index and readmission outcomes are shown in Table 1.

Of the 2,189 hospitals included in the study, 721 performed both SAVR and TAVI. Among all CKD1-5 and ESRD patients, 73% underwent TAVI at hospitals within major metropolitan (>1 million residents) areas. Overall the rate of TAVI utilization (PTREND < 0.0001) increased, with a more rapid growth in patients with CKD1-5 and ESRD (Figure 2). Any degree of renal dysfunction was associated with increased odds of in-hospital mortality for TAVI and SAVR (Figure 3). TAVI was associated with significantly higher odds of in-hospital risk-adjusted mortality compared with SAVR at every stage of renal insufficiency. CKD1-3 had significantly lower odds of mortality compared with CKD4-5 and ESRD for both TAVI and SAVR. However, the differences between in-hospital mortality for each surgical approach did not significantly vary between CKD4-5 and ESRD. Age greater than 85 (odds ratio [OR] 2.8, 95%CI 2.2 to 39), female gender (OR 1.9, 95%CI 1.6 to 2.2) and heart failure (OR 1.7, 95%CI 1.3 to 2.2) were all significant predictors of index hospitalization mortality. Mortality regression excluding these predictors demonstrated a similar association between TAVI and mortality (Supplement A). Surgical complications increased likelihood of mortality by 13-fold (OR 12.9, 95%CI 11.1 to 15.1) while infectious complications were associated with a 10-fold increase in mortality (OR 10.2, 95% CI 7.8 to 13.4).

Following TAVI and SAVR, the overall rates of stroke for the entire population including, non-ESRD patients, were 3.0% and 1.8%, respectively (p < 0.0001). Those with CKD stage 4-5 had the highest risk of in-hospital stroke (2.9 vs 3.8%, p = 0.36) with similar rates for CKD1-3 (2.3 vs 2.0%, p = 0.73) and ESRD (1.8 vs 1.9%, p = 0.91) after TAVI and SAVR, respectively. However, after risk
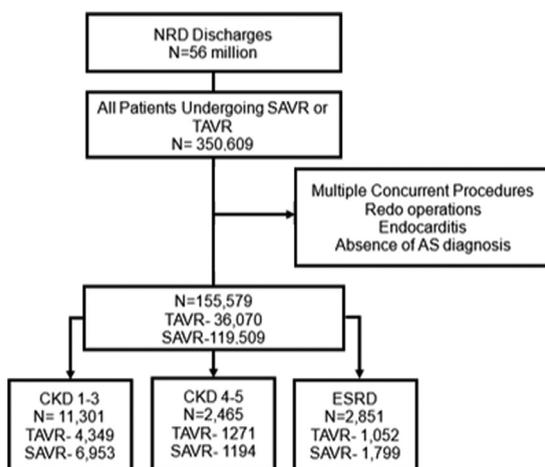

Figure 1. Patient cohort inclusion and exclusion criteria.

Table 1
Patient characteristics, index and readmission outcomes by surgical approach and stage of renal failure

Variable	Non-CKD			CKD stage 1 to 3			CKD stage 4 to 5			ESRD		
	TAVI (N = 26,942)	SAVR (N = 104,753)	p	TAVI (N = 4,349)	SAVR (N = 6,953)	p	TAVI (N = 1,271)	SAVR (N = 1,194)	p	TAVI (N = 1,052)	SAVR (N = 1,799)	p
Age (mean, years)	81.7	68.8	<0.0001	83.0	74.6	<0.0001	82.5	74.4	0.41	76.4	64.9	<0.0001
Elixhauser (score)	6.1	4.9	<0.0001	7.2	6.8	<0.0001	7.2	7.4	0.49	7.4	7.2	0.24
Women	53.6 (%)	42.5(%)	<0.0001	45.7(%)	38.4(%)	<0.0001	48.3(%)	45.3(%)	0.01	43.0(%)	36.7(%)	0.06
Heart failure	12.4(%)	2.0(%)	<0.0001	14.7(%)	4.2(%)	<0.0001	13.0(%)	7.0(%)	0.01	16.3(%)	9.9(%)	0.02
Atrial fibrillation	35.0(%)	35.3(%)	0.66	33.2(%)	37.8(%)	0.004	31.1(%)	32.6(%)	0.73	32.5(%)	29.4(%)	0.26
Prior MI	8.3(%)	3.9(%)	<0.0001	11.7(%)	6.1(%)	<0.0001	6.3(%)	5.2(%)	0.50	8.0(%)	5.0(%)	0.06
CPD	34.5(%)	21.2(%)	<0.0001	36.0(%)	25.1(%)	<0.0001	33.8(%)	33.4(%)	0.92	37.5(%)	21.8(%)	<0.0001
Coagulopathy	23.9(%)	28.8(%)	<0.0001	26.8(%)	36.5(%)	<0.0001	26.8(%)	33.9(%)	0.05	29.3(%)	38.4(%)	0.0
Depression	7.9(%)	8.1(%)	0.5895	7.6(%)	7.5(%)	0.9	4.3(%)	6.6(%)	0.12	6.7(%)	7.5(%)	0.6
Diabetes Mellitus	26.0(%)	24.9(%)	0.0546	26.6(%)	28.5(%)	0.2	28.7(%)	28.7(%)	0.98	28.0(%)	23.6(%)	0.1
Hypertension	77.9(%)	73.3(%)	<0.0001	84.6(%)	84.8(%)	0.8	81.9(%)	82.9(%)	0.72	90.1(%)	88.6(%)	0.5
Liver disease	2.9(%)	1.9(%)	<0.0001	3.2(%)	2.3(%)	0.1	3.0(%)	1.1(%)	0.02	4.4(%)	4.9(%)	0.7
Lymphoma	1.7(%)	0.7(%)	<0.0001	2.2(%)	0.8(%)	0.0002	1.8(%)	1.6(%)	0.83	2.2(%)	1.4(%)	0.4
Neurologic Dysfunction	6.5(%)	4.8(%)	<0.0001	7.1(%)	6.0(%)	0.2	6.3(%)	8.7(%)	0.23	4.6(%)	9.1(%)	0.01
Obesity	15.3(%)	21.7(%)	<0.0001	18.4(%)	27.6(%)	<0.0001	16.0(%)	23.8(%)	0.01	14.0(%)	17.5(%)	0.1
Chronic blood loss anemia	1.3(%)	1.3(%)	0.87	2.4(%)	1.6(%)	0.09	1.7(%)	1.6(%)	0.41	0.5(%)	2.3(%)	0.0
Peripheral vascular disease	28.0(%)	13.4(%)	<0.0001	30.4(%)	19.7(%)	<0.0001	30.9(%)	18.9(%)	0.95	32.7(%)	20.2(%)	<0.0001
Index outcomes												
Mortality	4.5(%)	1.8(%)	<0.001	4.2(%)	2.7(%)	0.02	7.3(%)	5.4(%)	0.28	8.9(%)	7.3(%)	0.36
LOS (days, SE)	8.9 (0.18)	8.9 (0.86)	0.82	9.7 (0.37)	11.5 (0.31)	0.002	12.6 (0.68)	15.3 (0.74)	0.003	13.1 (0.81)	19.1 (0.91)	<0.0001
Costs ($, SE)	$59,393 (791)	$45,214 (385)	<0.001	$60,898 (1,306)	$51,702 (1,140)	<0.001	$67,659 (1,975)	62,305 (2,689)	0.11	$73,493 (3130)	$78,476 (2827)	0.23
Readmission outcomes												
30-day Readm	18.6(%)	13.6(%)	<0.001	27.0(%)	28.5(%)	0.63	24.1(%)	21.7(%)	0.51	20.6(%)	18.0(%)	0.08
31 - 90-day Readm	9.9(%)	6.1(%)	<0.001	10.7(%)	8.7(%)	0.89	13.1(%)	13.1(%)	0.98	15.0(%)	15.3(%)	0.13

*CPD = chronic pulmonary disease; MI = myocardial infarction; LOS = length of stay; Readm = readmission; Obesity defined based on ICD9 comorbidity software coding as obesity unspecified, morbid obesity.
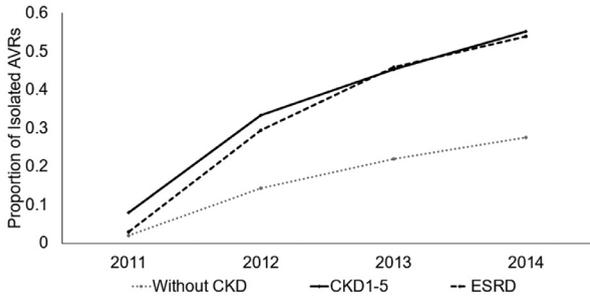
Figure 2. Increasing utilization of TAVI for overall, CKD1-5, and ESRD population. ESRD = end-stage renal disease.

adjustment odds of stroke did not significantly vary in the renal failure nor aortic valve intervention groups. Nonetheless, occurrence of neurologic complications significantly increased odds of index mortality (OR 3.7, 95% CI 2.7 to 5.1).

Rates of inpatient pacemaker implantation were consistently higher for patients who underwent TAVI compared with SAVR (CKD1-3, 10.7 vs 5.0%, p <0.0001; CKD4-5 12.6 vs 5.1%, p <0.0001; ESRD 10.6 vs 5.7%, p = 0.002). Risk-adjusted analysis of pacemaker implantation at the

index hospitalization further demonstrated increased odds of this event with TAVI for patients with CKD1-3 (OR 2.1 95% CI 1.5 to 3.1), CKD4-5 (OR 2.7, 95% CI 1.4 to 5.5), ESRD (OR 2.2, 95% CI 1.3-3.8) and those without renal disease (OR 1.8, 95% CI 1.5 to 2.1).

Mean index LOS was significantly longer for SAVR across all renal failure groups except for CKD1-3 while unadjusted index costs were significantly lower for SAVR CKD1-3 but similar for CKD4-5 and ESRD (Table 1). Risk-adjusted analysis demonstrated significantly increased incremental cost with TAVI technology and increasing severity of renal failure (Figure 4).

Kaplan-Meier curves for freedom from readmission are shown in Figure 5 with TAVI performing worse in patients with CKD1-3 compared with SAVR but similarly for all other categories. At 1 year after discharge, 34.6% of TAVI and 32.7% of SAVR patients with renal disease were readmitted at least once (p = 0.51). ESRD patients had the greatest overall readmission rate when compared with CKD1-3 (46.7 vs 29.6%, p <0.0001) and CKD4-5 (46.7 vs 32.7%, p = 0.002). The median days to first readmission did not differ significantly (all p >0.5) between TAVI and SAVR patients across all stages of renal failure (CKD1-3: 21 vs 26 days; CKD45:
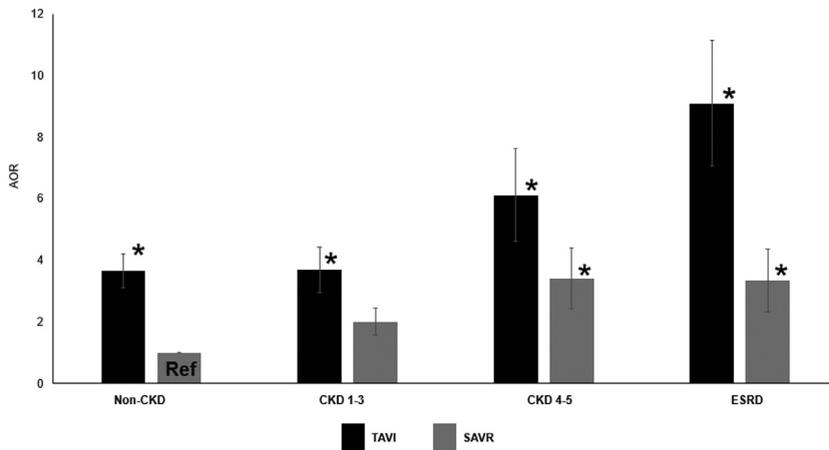

Figure 3. Index mortality by surgical approach and CKD stage. *model adjusted for age, gender, patient comorbidities, hospital characteristics, inpatient complications, presence of high-volume TAVI program. C-statistic: 0.91.
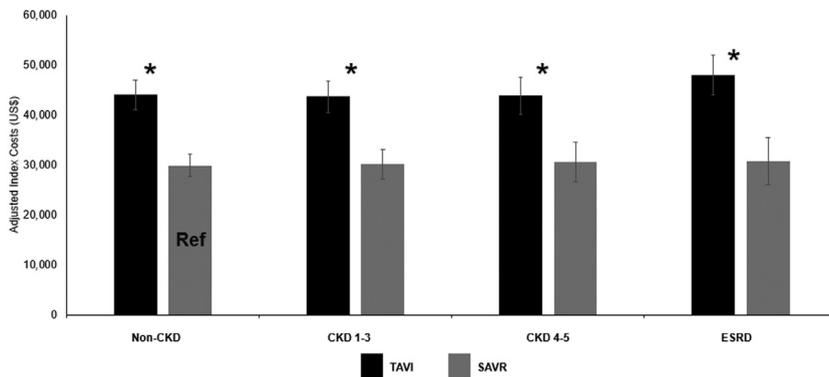

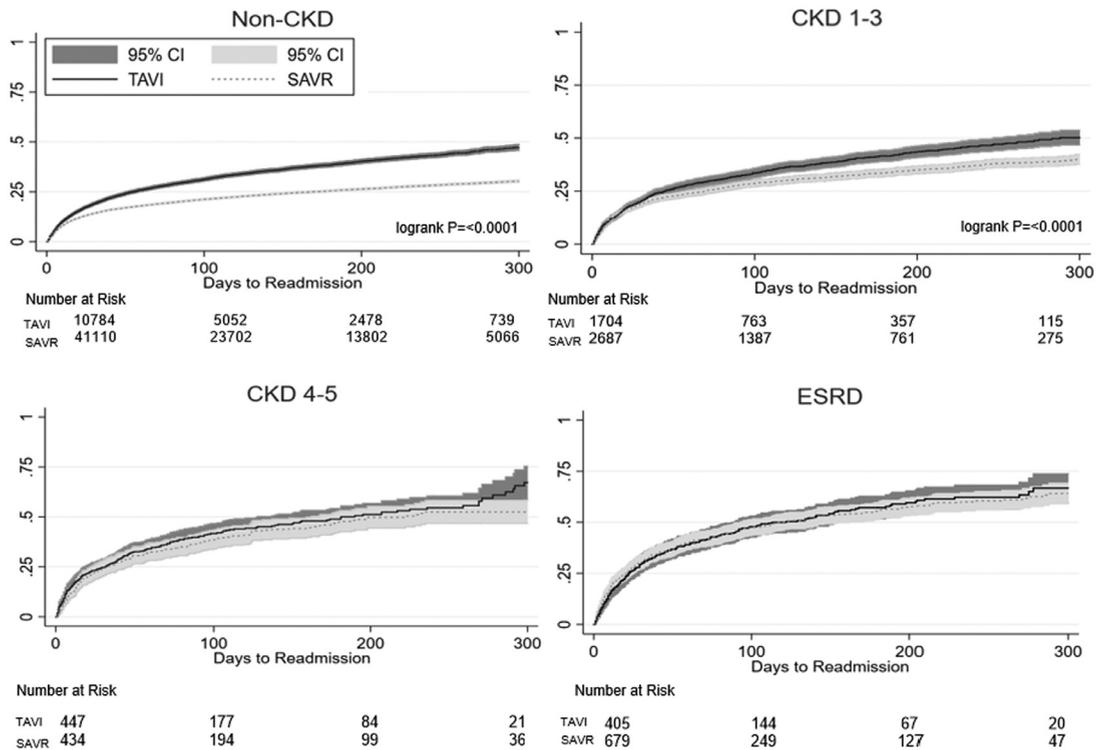Figure 4. Risk-adjusted index cost analysis by surgical approach and CKD stage.

Figure 5. Kaplan-Meier readmission analysis by surgical approach.

26 vs 25 days; ESRD 26 vs 22 days). At 1 year, SAVR patients had fewer readmission episodes compared with TAVI only for the CKD4-5 group (1.4 vs 1.8 visits, p = 0.008). Kaplan-Meier analysis by severity of renal disease yielded a similar relation for CKD1-3 (log-rank p <0.0001) but not for CKD4-5 or ESRD patients (Figure 5). After adjusting for patient co-morbidities, discharge disposition, and index complications, SAVR was associated with a significantly lower readmission hazard ratio (hazard ratio [HR] 0.72, 95% confidence interval [CI] 0.60 to 0.85, p <0.001) compared with TAVI for patients with CKD1-3. This association was

not significant for CKD4-5 (HR 0.79, 95% CI 0.58 to 1.07, p = 0.12) nor ESRD (HR 0.93, 95% CI 0.74 to 1.18, p = 0.57) patients.

Risk-adjusted odds of early readmission were significantly higher for TAVI across all renal failure groups (Figure 6). Even after exclusion of patients returning for pacemaker or with historically higher risk for readmissions such as the elderly (age ≥ 85, female gender, and heart failure), TAVI patients had higher odds of 30-day readmission (Supplement B). At 90 days after hospital discharge, TAVI was consistently associated with higher odds of readmission compared with SAVR (Figure 7) while the odds of
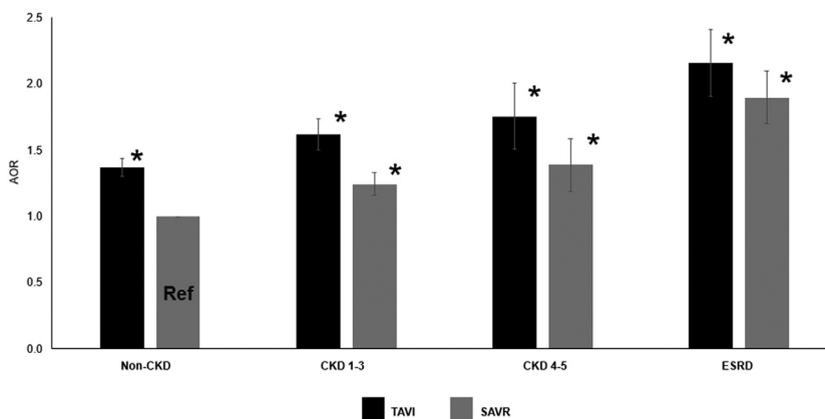

Figure 6. Risk-adjusted odds of 30-day readmission by surgical approach and CKD stage. *model adjusted for age, gender, patient comorbidities, hospital characteristics, inpatient complications, discharge disposition, presence of high-volume TAVI program. C-statistic: 0.63.
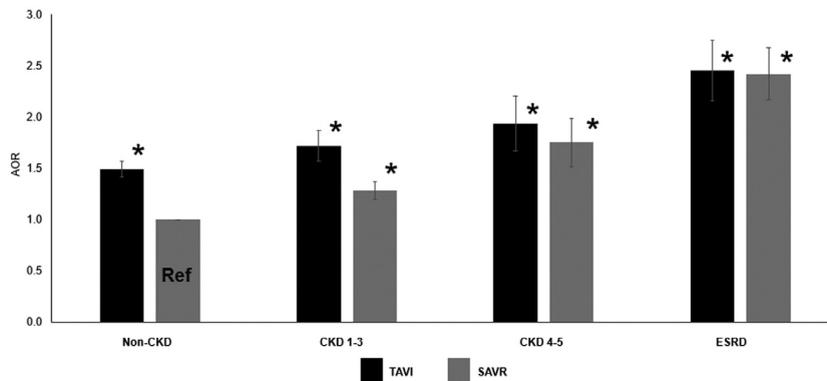
Figure 7. Risk-adjusted odds of 90-day readmission by surgical approach and CKD stage. *model adjusted for age, gender, patient comorbidities, hospital characteristics, inpatient complications, discharge disposition, presence of high-volume TAVI program. C-statistic: 0.64.

readmission increased with worsening renal disease. Cumulative costs of up to 2 readmission visits within the first 90 days after discharge demonstrated greater financial burden with TAVI except for the ESRD group (CKD1-3 − $69,442 vs $58,911; CDK4-5 − $77,001 vs $69,062; ESRD $85,942 vs $90,439). Annually, readmissions after surgical aortic valve replacement cost an average 8.6 million dollars (TAVI $6.2 million, SAVR $2.4 million).

Cardiac-related diagnoses were the most common reasons for rehospitalization across all kidney disease stages and aortic valve replacement techniques. Readmission within 30-days for heart failure exacerbation was frequent for both TAVI and SAVR across CKD Stage 1 to 5 (4.6 vs 3.6%, p = 0.2) and ESRD (4.9 vs 3.1%, p = 0.13). For CKD stage 1 to 3, SAVR patients more commonly presented with arrhythmias (1.4 vs 0.25%, p = 0.004). However, CKD1-3 TAVI patients were more commonly readmitted within 30 days for pacemaker placement (1.1 vs 0.16 %, p = 0.0001). In contrast, readmission for ischemic or hemorrhagic stroke occurred more frequently for TAVI than SAVR ESRD patients within the first 30 days (0.98 vs 0.34%, p = 0.0001).

Since its introduction in late 2011, in-hospital mortality for TAVI rose to 14% but decreased to 2.3% in the final year of the study (p <0.0001) while 30-day readmissions rates remained steady between 23% and 28% (p = 0.47). SAVR in-hospital mortality (5.1% to 1.9%, p = 0.43) and 30-day readmission rates (26.1% to 31.2%, p = 0.19) were stable during the study period.

Discussion

Given their burden of concomitant cardiovascular comorbidities, patients with chronic or end-stage kidney disease represent a particularly high-risk group for SAVR. The existing literature comparing outcomes of SAVR and TAVI provides little data regarding the relative quality metrics of these modalities in patients with renal disease. In this nationwide study, we have made several observations. Firstly, TAVI was associated with greater risk of readmission compared with SAVR for CKD1-3 patients at 30 and 90 days after discharge. Second, while SAVR LOS was longer, it was associated with significantly lower adjusted costs

for CKD1-5 and ESRD compared with TAVI. And finally, decrements in renal function were associated with worse mortality, and increased costs, LOS and readmissions in a stepwise manner.

Several groups have previously examined acute outcomes in TAVI patients and found a higher prevalence of ESRD and increased age compared with SAVR. Using a nationally representative sample, we found a similar age distribution in the groups, but encountered a lower incidence of ESRD in the TAVI cohort. As expected, patients with CKD who underwent TAVI had an increased burden of co-morbidities compared with SAVR. This is consistent with several previous studies confirming the disparate baseline co-morbid conditions in the groups, attributable to the selection process. Taken together, the inferior readmission results obtained with TAVI and SAVR in patients with advanced kidney disease may stem from differences in co-morbid risk profiles rather than renal disease *per se*.

In the present study, risk-adjusted mortality was significantly greater with TAVI patients across all stages of renal insufficiency. These findings are in contrast with a recent propensity matched analysis of 195 patient pairs with comparable Society of Thoracic Surgeons mortality scores and glomerular filtration rates, which demonstrated no significant difference between TAVI and SAVR with respect to in-hospital death, kidney injury or the need for dialysis.[15] Extending this analysis, Korbin et al. showed comparable 30-day mortality and perioperative adverse events for ESRD patients receiving TAVI and SAVR.[16] Although the present study was limited in assessment of many clinical variables, it provides the largest, postmarket experience with TAVI and SAVR in patients with renal disease, nationally. Despite the use of TAVI-program volume in our adjusted analyses, we were unable to identify individual provider level experience in the present study, which has been shown to be strongly associated with in-hospital outcomes.[17,18] Nonetheless, patients who underwent TAVI during the study period were predominantly patients with prohibitive SAVR risk. This possible treatment selection bias, not fully corrected for by multivariable risk adjustment using administrative variables, may explain the mortality results observed in the present study.

Compared with SAVR, TAVI resulted in similar rates of index hospitalization stroke but a significantly higher risk of index pacemaker implantation. Although the increased rate of pacemaker implantation with TAVI has been previously reported, our stroke findings are not consistent with the literature.[19] In contrast with a recent propensity matched analysis, SAVR was associated with an increased rate of perioperative stroke and all-cause mortality.[19] Of note, this publication by Doshi reported nearly double the rate of pacemaker implantation during the index stay compared with the present study.[19] This discordance in regards to replacement approach and increased stroke rate may be attributed to differences in morbidity and operative aspects, such as valvular calcification, not accounted for in regression or propensity matched analyses. Independent of which approach is associated with increased cerebrovascular events, the increased need for pacemaker implantation after TAVI has been well established previously and confirmed in the present study, prompting further optimization of valve delivery, placement and postoperative monitoring to await return of intrinsic conduction-system function.

Interestingly, worsening kidney function increased the odds of readmission linearly for both SAVR and TAVI groups in the present investigation. Several studies have examined short- and long-term readmission outcomes in TAVI versus SAVR patients.[20,21] Hannan et al found that the 30-day readmission rates after TAVI and SAVR were similar, even after propensity matching.[21] Furthermore, several recent studies have demonstrated increased early and long-term TAVI morbidity and mortality with worsening renal dysfunction, although few have specifically examined readmissions along the spectrum of CKD.[22,23] These findings are in contrast to our risk-adjusted comparison of TAVI and SAVR readmissions, which found higher likelihood of readmission for TAVI rather than SAVR in patients without CKD and those with CKD1-3.[6] Lack of significant association between TAVI and odds of readmission in CKD4-5 and ESRD cohorts may be attributable to the relatively smaller sample size in these subgroups and dominance of CKD4-5 and ESRD over procedure type in directing readmission performance. Moreover, TAVI patients in the present study had significantly shorter index LOS, a factor that may predispose this group to increased readmissions.[24]

Our study has several important limitations inherent to its retrospective nature and use of an administrative database. Although, we used robust regression models to account for disease severity, variables such as severity of heart failure and aortic stenosis, among others, were not available and may limit the applicability of our results. Given that linkage numbers are not uniform throughout each year of the NRD, the duration of follow-up is limited for operations that occurred toward the end of the year. We were also unable to characterize the incidence of hemorrhagic events postoperatively due a limited incidence among each of the renal failure subgroups. Furthermore, using administrative codes for defining chronic kidney disease rather than estimated glomerular filtration, preferential selection of patients with more severe kidney diseases may have occurred.

In summary, readmissions after TAVI and SAVR demonstrated an incremental increase with advancing renal dysfunction. TAVI was associated with increased odds of mortality across all stages of renal failure and readmission only for patients with CKD1-3. And finally, the increase in 90-day readmissions with TAVI resulted in expenditures of nearly $6 million annually in the United States.

Disclosures

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2019.01.047.

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