Transcatheter Versus Surgical Aortic Valve Replacement in the United States (From the Nationwide Readmission Database)

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Clinical outcomes of transcatheter aortic valve implantation (TAVI) have significantly improved with the accumulation of operator and institution experience as well as the wide use of newer generation devices. There is limited data on TAVI outcomes compared with surgical aortic valve replacement (SAVR) in contemporary practice in the United States. We queried the 2018 Nationwide Readmission Database of the United States. International Classification Diagnosis code 10 was used to extract TAVI and SAVR admissions. A propensity-matched cohort was created to compare TAVI and SAVR outcomes. A weighted 48,349 TAVI and 24,896 SAVR for aortic stenosis were included and 4.9% of TAVI were performed with an embolic protection device. In propensity-matched cohort (12,708 TAVI and 12,708 SAVR), TAVI conferred lower in-hospital mortality (1.7% vs 3.8%), acute kidney injury (11.3% vs 22.9%), and transfusion rate (5.9% vs. 20.6%) whereas new pacemaker rate was higher in TAVI compared with SAVR (10.5% vs. 7.0%) (all p values < 0.001). Stroke rate was similar between TAVI and SAVR (1.5% vs. 1.5%) (p value = 0.79). The routine discharge was more frequent (66.9% vs 25.8%) and length of stay was shorter (4.8 vs. 9.8 days) in TAVI than SAVR. Hospitalization cost was higher in SAVR than TAVI (51,962 vs 57,754 U.S. dollars) (all p values < 0.001). In-hospital mortality was also lower in TAVI compared with isolated SAVR. TAVI was performed more frequently than SAVR in 2018 in the United States with lower in-hospital mortality of TAVI compared with both SAVR and isolated SAVR.
(Am J Cardiol 2021;148:110−115)

Case volume of transcatheter aortic valve replacement (TAVI) has recently surpassed that of surgical aortic valve replacement (SAVR) in the United States (US).[1-3] TAVI is considered less invasive and therefore could offer a perioperative outcome advantage over SAVR, however, previous studies have shown similar short-term mortality between TAVI and SAVR.[4-6] This could be because that TAVI experiences were still developing. Recent large registry from the US showed that thirty-day mortality of TAVI has decreased significantly from 7.2% in 2011 to 2.5% in 2019[1] but it remains unknown whether TAVI confers improved short-term mortality over SAVR from large database especially in an era where case selections and managements of TAVI have become more matured. The purpose of our study was to compare TAVI and SAVR outcomes in 2018 from the Nationwide Readmission Database (NRD) of the United State.

Methods

The latest data from NRD 2018 were used from the Agency for Healthcare Research and Quality's (AHRQ) Healthcare Cost and Utilization Project (HCUP). Details are provided in previous studies. Briefly, the NRD includes a large sample size, which provides sufficient data for analysis across hospital types and the study of readmissions for relatively uncommon disorders and procedures. Discharge data from 28 geographically dispersed states, accounting for 59.7% of the total US resident population and 58.7% of all US hospitalizations is available. Discharge weights are provided in the form of a variable 'DISCWT' to obtain national estimates. Unweighted, the NRD contains data from approximately 18 million discharges each year. Weighted, it estimates roughly 35 million discharges. This study was deemed exempt from the Institutional Review Board as the NRD is a publicly available database that contains de-identified patient information.

We used the ICD-PCS (Procedure Coding System) codes of 02RF3JZ, 02RF3KZ, 02RF38Z, and 02RF37Z, to identify all hospitalizations for TAVI and SAVR from 2018. We excluded patients <= 65 years of age, patients with a primary diagnosis of infective endocarditis, and who had both TAVI and SAVR performed during the same

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There was no external funding for this study.

See page 114 for disclosure information.

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https://doi.org/10.1016/j.amjcard.2021.02.031

hospitalization, and those who underwent transapical TAVI. Figure 1 depicts the flowsheet for the selection including inclusion and exclusion criteria. Further to this we also compared TAVI with isolated SAVR after excluding coronary bypass graft surgery and surgeries on other valves. Because the NRD is a yearly database, all the patients who underwent TAVI in the first 11 months were included in the study so that we could track 30-day readmission outcomes. Readmissions within the 30-days were identified in survivors of the index admission using the 'nrd_visitlink' variable. Patients who got readmitted more than once within the designated time-period were counted once for their index readmission. Time to readmission was calculated as the number of days between hospital discharge after index TAVI procedure and the first day of hospital readmission.

For each of the above two cohorts, we extracted baseline patient and hospital characteristics. Patient characteristics included age, sex, race, median household income, and relevant comorbidities such as hypertension, diabetes mellitus, congestive heart failure, chronic lung disease, peripheral vascular disease, chronic kidney disease stage, prior myocardial infarction, prior percutaneous coronary intervention, prior coronary artery bypass grafting, previous valve surgery, prior pacemaker implantation, liver disease, coagulopathy, atrial fibrillation, and obesity. We also gathered data on elective admissions and compared them based on their baseline frailty status divided into low intermediate and high using a validated method for an administrative database.[7] We used the well-validated methodology devised by Quan et al.[8] by utilizing the coding algorithms with ICD-10 for defining the comorbidities. Additionally, we extracted the data on hospital characteristics such as location, teaching status, and bed size. The hospital was considered a teaching facility when it had an American Medical Association approved residency program. It was a member of the Council of Teaching Hospitals and Health Systems. It had full-time equivalent interns and residents to bed ratio of 0.25 or greater.

Our primary outcome of interest was all-cause in-hospital mortality. Other in-hospital outcomes of interest were acute kidney injury, need for transfusion, stroke, and new pacemaker implantation. Finally, we also investigated routine home discharge, hospital length-of-stay, and total hospital cost in US dollars for the indexed intervention. Total hospital charges (the amount hospitals billed for the stay) are reported in the core NRD file, although they do not reflect the actual cost of care. The HCUP provides cost-to-charge ratios filed based on all-payer inpatient costs. This cost information is obtained from the hospital accounting reports collected by the Centers for Medicare and Medicaid Services. Using this information, total hospital costs were calculated by multiplying total hospital charges with the corresponding cost-to-charge ratio.

NRD data design is based on a complex survey design that includes stratification, clustering, and weighting adjustment. We utilized weighting to produce nationally representative unbiased results, variance estimates, and p values. Baseline patient and hospital characteristics, in-hospital procedures, and complications were initially compared between an unmatched population using a test of independence based on the Pearson $\chi 2$ statistic. To account for survey design, the Pearson statistic was converted into an F-statistic with noninteger degrees of freedom by using a second-order Rao and Scott correction. Continuous variables were compared between different groups using a t-test, as appropriate. All p values were two-sided, with a conventional significance threshold of p value < 0.05. Categorical variables are expressed as percentages and continuous variables as mean$\pm$SD. A propensity score-matched analysis

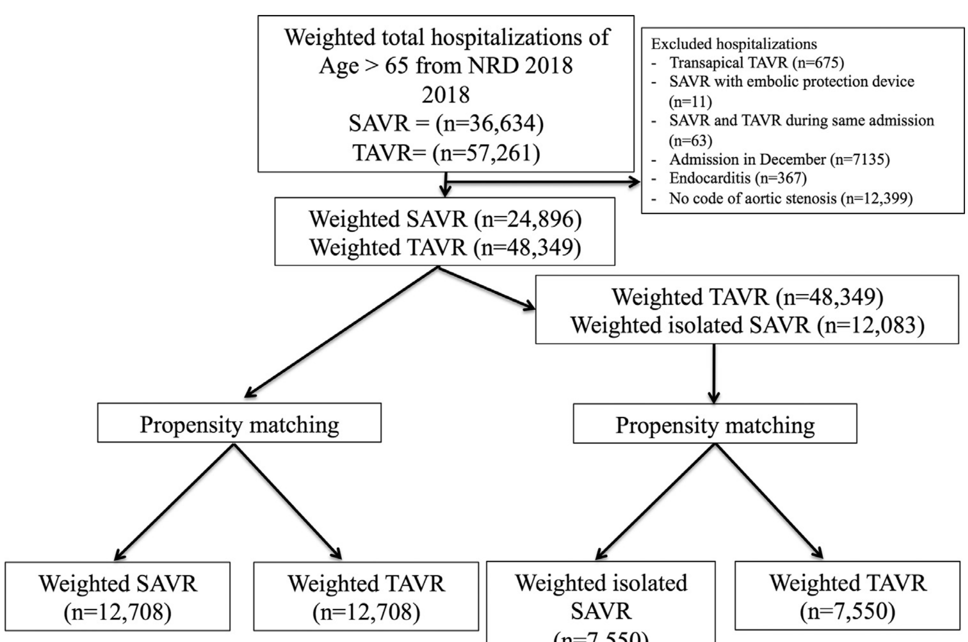

Figure 1. Patient selection flow chart
NRD = Nationwide Readmission Database, SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.

was performed to adjust for potential confounders (including all the variables mentioned in Table 1. Propensity-score matching was performed in R statistical software using 'nearest neighbor matching.' Logistic regression was employed to estimate the distance measure. Matching was performed with a caliper set at 0. 1. Cases were matched with controls without replacement and with common support. All the comparison analyses were repeated in the matched cohort. Data were complete on all covariates except for cost. Missing values were replaced with the dominant category. This approach has been used in prior studies.[9] Statistical analyses were performed using Stata 16.0 (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC.) and R (R Development Core Team, Vienna, Austria).

Results

A weighted 48,349 TAVI and 24,896 SAVR were performed in the US in 2018 (Figure 1). TAVI patients were older and had a higher percentage of the female sex, hypertension, prior coronary bypass or percutaneous coronary intervention, myocardial infarction, chronic kidney disease, and congestive heart failure. The bicuspid aortic valve was more frequently observed in SAVR patients. Concomitant coronary bypass, mitral valve, and combined coronary bypass and mitral valve surgery were performed in 42.5%, 5.4%, and 2.8% of SAVR patients. TAVI was performed more often at teaching hospitals and hospitals with large bed size. Embolic protection device was used in 4.9% of TAVI admissions. Baseline characteristics of TAVI, SAVR, and isolated SAVR are summarized in Table 1 and supplemental Table 1.

In an unadjusted cohort, TAVI conferred lower in-hospital mortality (1.4% vs 3.1%), acute kidney injury (9.2% vs 22.2%), and transfusion rate (5.1% vs 20.0%) than SAVR (all p values < 0.001). Contrary, TAVI had higher rate of new pacemaker (10.2% vs 6.6%) (p value <0.001). Stroke rate was similar between TAVI and SAVR (1.3% vs 1.3%, p value = 0.97). The routine discharge was more frequent (67.1% vs 28.9%), length of stay was significantly shorter (3.9 vs 9.6 days) and hospitalization cost was lower (49,022 vs 56,976 US dollars) in TAVI compared with SAVR (all p values<0.001).

In propensity-matched cohort (12,708 TAVI and SAVR), TAVI had significantly lower incidence of in-hospital mortality (1.7% vs 3.8%), acute kidney injury (11.3% vs 22.9%),and blood transfusion rate (5.1% vs 20.0%) whereas new pacemaker rate was higher in TAVI compared with SAVR (10.5% vs 7.0%) (all p value < 0.001). Stroke

Table 1.
Baseline characteristics of TAVI and SAVR in unadjusted and propensity-matched admissions

Variable	Unadjusted		P-value	Propensity-matched		p value
	TAVI (N = 48,349)	SAVR (N = 24,896)		TAVI (N = 12,708)	SAVR (N = 12,708)	
Age mean (SD) (Years)	81.0 (6.6)	74.0 (5.2)	<0.001	76.0 (6.2)	76.0 (5.2)	0.88
Men	53.9%	65.8%	<0.001	59.8%	60.1%	0.69
Bicuspid aortic valve	0.4%	3.6%	<0.001	1.1%	1.1%	0.68
Hypertension	90.4%	86.7%	<0.001	88.4%	88.6%	0.82
Diabetes mellitus	38.1%	37.5%	0.54	41.6%	40.9%	0.52
Obesity	19.2%	27.1%	<0.001	26.6%	26.1%	0.67
Prior percutaneous coronary intervention	23.2%	11.3%	<0.001	15.1%	15.1%	0.92
Prior coronary bypass	16.3%	5.3%	<0.001	8.1%	7.8%	0.66
Prior valve replacement	2.3%	3.6%	<0.001	3.6%	3.8%	0.63
Prior myocardial infarction	12.5%	8.2%	<0.001	10.3%	9.5%	0.13
Prior pacemaker	10.1%	3.8%	<0.001	5.5%	5.6%	0.83
Congestive heart failure	74.2%	41.5%	<0.001	57%	56.2%	0.68
Chronic kidney disease III-V	35%	21.6%	<0.001	27.9%	27.5%	0.74
Chronic lung disease	27.2%	20.8%	<0.001	25.8%	24.7%	0.17
Prior stroke	14.9%	8.9%	<0.001	10.7%	11%	0.59
Peripheral vascular disease	21.7%	20.3%	0.54	20.8%	20.5%	0.8
Liver disease	2.8%	3.5%	0.001	4.2%	4.1%	0.81
Coagulopathy	11%	37.4%	<0.001	23.2%	23.4%	0.91
Atrial fibrillation	40.1%	53.9%	<0.001	46.5%	47.1%	0.52
Embolic protection device	4.9%	0%	0.004	0%	0%	0.32
Low frailty	66%	53.2%	<0.001	57.1%	57.2%	0.95
Intermediate frailty	32.9%	44.9%	<0.001	41.1%	40.8%	0.80
High frailty	1.1%	1.9%	<0.001	1.7%	1.9%	0.40
Elective admissions	83.4%	78.6%	<0.001	79%	78.8%	0.93
Teaching hospital	89%	83.5%	<0.001	85.8%	86.2%	0.78
Hospital area						
Large metropolitan	60.3%	54.6%	0.003	55.9%	56.9%	0.70
Small metropolitan	39%	43.2%	0.028	42.8%	41.9%	0.73
Micropolitan	0.6%	2.1%	<0.001	1.3%	1.2%	0.83
Non-metropolitan	0%	0.1%	<0.001	0%	0%	0.93

SAVR = surgical aortic valve replacement; SD = standard deviation; TAVI = transcatheter aortic valve implantation.
Obesity = body mass index≥30kg/m^2.

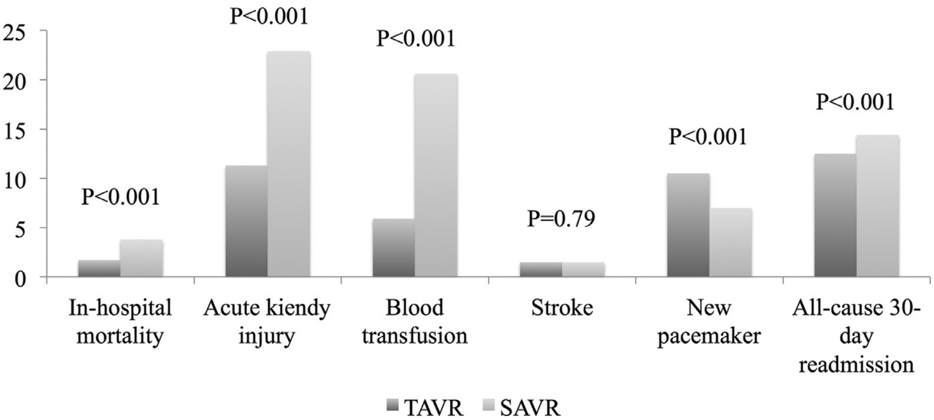

Figure 2. Clinical outcomes of TAVI vs SAVR in 2018. The rate of in-hospital mortality, acute kidney injury, blood transfusion, and all-cause 30-day readmission was lower in TAVI whereas new pacemaker was higher in TAVI compared with SAVR.
SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.

rate was similar between TAVI and SAVR (1.5% vs 1.5%) (p value = 0.79) (Figure 2). The routine discharge was significantly higher (66.9% vs 25.8%) and length of stay was shorter (4.8 vs 9.8 days) in TAVI than SAVR. Hospitalization cost was higher in SAVR than TAVI (57,754 vs 51,962 US dollars) (all p values < 0.001). All-cause 30-day readmission rate was lower in TAVI than SAVR (12.5% vs 14.4%, p value = 0.005)

Baseline characteristics of TAVI and isolated SAVR are summarized in supplemental Table 1. In propensity-matched cohort (7,550 TAVI and isolated SAVR), TAVI had significantly lower rate of in-hospital mortality (1.5% vs 2.5%), acute kidney injury (9.4% vs 17.0%), and transfusion (5.7% vs 16.4%) while had higher incidence of new pacemaker (10.3% vs 6.1%) (all p values < 0.001) compared with isolated SAVR. Stroke rate was similar between TAVI and isolated SAVR (1.4% vs 1.1%) (p value = 0.25) (Figure 3). TAVI were more frequently discharged routinely (68.9% vs 30.7%), spend fewer days in the hospitals (4.4 vs 8.1 days) (both p values < 0.001), and similar hospitalization cost (51,335 vs 48,525 US dollars) (p value = 0.053) compared with isolated SAVR. All-cause 30-day readmission rate was similar between TAVI and SAVR (11.2% vs 12.0%, p value = 0.29).

Discussion

From the Nationwide Inpatient Sample database of United States 2018, our main findings were: 1) in-hospital mortality was significantly lower in TAVI compared with SAVR or isolated SAVR; and 2) acute kidney injury and transfusion were significantly higher in SAVR or isolated SAVR compared with TAVI whereas new pacemaker was higher in TAVI. Stroke rate of TAVI was similar compared with SAVR or isolated SAVR. Thirty-days all-cause readmission rate was lower in TAVI compared with SAVR but similar when compared with isolated SAVR

Outcomes of TAVI compared with SAVR since the wide use of newer-generation transcatheter heart valves from a national perspective in the United States are limited. Our results showed that in-hospital mortality was lower in TAVI compared with both SAVR and isolated SAVR. Reason for lower mortality could include lower perioperative complication rates, improved periprocedural management

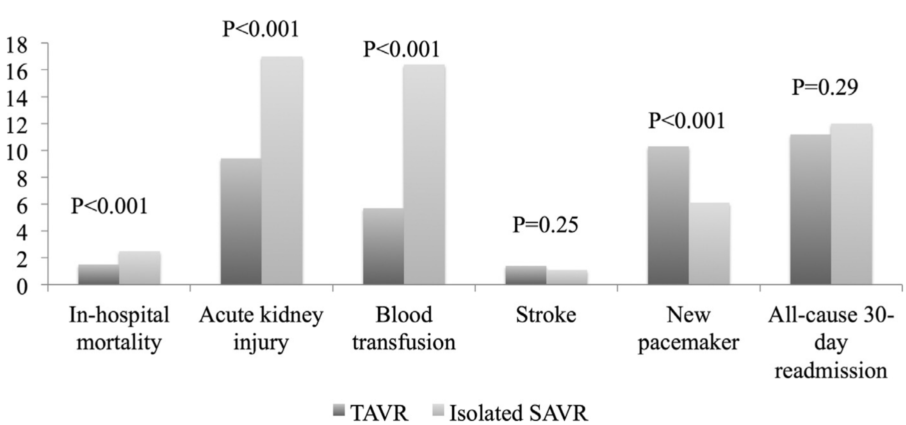

Figure 3. Clinical outcomes of TAVI vs isolated SAVR in 2018. The rate of in-hospital mortality, acute kidney injury, blood transfusion was lower in TAVI whereas the new pacemaker was higher in TAVI compared with isolated SAVR. The rate of stroke and all = cause 30-day readmission was similar between both groups.
SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.

post-TAVI, accumulation of operator experience, and better patient selection. In-hospital mortality (3.4% for TAVI vs. 2.5% for SAVR) was similar between TAVI and SAVR in 2011 from the United States Nationwide Inpatient Sample database.[5] From Germany's national database, TAVI and isolated SAVR outcomes from 2018 showed lower in-hospital mortality of non-transapical TAVI compared with isolated SAVR (2.5% vs 3.1%).[10] Our study is unique in that we used the nationwide database of the US from 2018 and we have directly compared in-hospital outcomes of both TAVI and SAVR or isolated SAVR in a propensity-matched cohort. When concomitant surgery is required, SAVR should be the first option for aortic valve replacement. However, our study raises the important question of when should isolated SAVR be performed? One concern is the durability of the transcatheter heart valve but the rate of structural valve deterioration of transcatheter heart valve Sapien 3 did not differ from SAVR at 5-year.[11] Another study suggested that structural valve degeneration was higher in SAVR.[12] With short and long-term outcomes favoring TAVI, TAVI could be a more promising treatment option compared with isolated SAVR. However, reliable, long-term valve durability data over 10-year data is warranted for further consideration especially in the low-risk patient.

The strength of our study is that we used the national database and our results provide the landscape of TAVI vs. SAVR outcomes in the US during where the wide use of newer-generation transcatheter valves are used. However, there are several limitations to this analysis. First, ICD-10 codes were used to identify baseline comorbidities, procedures, and clinical outcomes and the possibility of code missing or errors cannot be excluded. Second, although we used the propensity-matching method, the severity of comorbidities may differ between the two groups. Third, this was a retrospective study of NRD and is subject to all the inherent biases of retrospective study such as selection bias and unmeasured confounding. Fourth, the approach site could not be further delineated as the ICD-10 code does not specify the access site. However, a large proportion of TAVI was transfemoral in the United States in.[1] Fifth, the NRD only contain outcomes of in-hospital events or readmission events within 30-days. Lastly, details of TAVI and SAVR are not available such as used type of valves, size, and echocardiographic data. In addition, data of medications were unavailable. However, recent study showed that there were no major differences in short-term outcomes between balloon-expandable and self-expandable valves.[13].

Authors' Contributions

Tomo Ando: Conceptualization, methodology, Writing − original draft, writing review and editing. Takayuki Onishi: Supervision. Toshiki Kuno, Conceptualization, methodology. Alexandros Briasoulis: Writing, review, and editing. Hisato Takagi: Supervision. Cindy L. Grines: Supervision. Kei Hatori: Conceptualization, writingHisato Takagi: Supervision. Tetsuya Tobaru: Supervision Aaqib Malik: Methodology, software, formal analysis, data curation Alexandros Briasoulis: Supervision. Hasam Ahmad: Supervision

Disclosures

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2021.02.031.

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