# Outcomes of Transcatheter Aortic Valve Replacement With Percutaneous Coronary Intervention versus Surgical Aortic Valve Replacement With Coronary Artery Bypass Grafting

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**We aimed to compare the outcomes of combined surgical aortic valve replacement (SAVR) with coronary artery bypass grafting (CABG) to concurrent transcatheter aortic valve replacement (TAVR) with percutaneous coronary intervention (PCI) in a large U.S. population sample. The National Inpatient Sample was queried for all patients diagnosed with aortic valve stenosis who underwent SAVR with CABG or TAVR with PCI during the years 2016 to 2017. Study outcomes included all-cause in-hospital mortality, acute stroke, pacemaker insertion, vascular complications, major bleeding, acute kidney injury, sepsis, non-home discharge, length of stay and cost. Outcomes of hospitalization were modeled using logistic regression for binary outcomes and generalized linear models for continuous outcomes. Overall, 31,205 patients were included (TAVR + PCI = 2,185, SAVR + CABG = 29,020). In reference to SAVR + CABG, recipients of TAVR + PCI were older with mean age 82 versus 73 years, effect size (d) = 0.9, had higher proportions of females 47.6% versus 26.6%, d = 0.4 and higher prevalence of congestive heart failure and chronic renal failure. On multivariable analysis, TAVR + PCI was associated with lowers odds for mortality adjusted OR: 0.32 (95% CI: 0.17 to 0.62) p = 0.001, lower odds for acute kidney injury, sepsis, non-home discharge, shorter length of stay and higher odds for vascular complications, need for pacemaker insertion and higher cost. The occurrence of stroke was similar between both groups. In conclusion, results from real-world observational data shows less rates of mortality and periprocedural complications in TAVR + PCI compared to SAVR + CABG.**  **(Am J Cardiol 2020;137:83−88)**

Surgical aortic valve replacement (SAVR) and concurrent coronary artery bypass grafting (CABG) has been the standard management strategy for patients with severe symptomatic aortic stenosis (AS) and coronary artery disease (CAD).[1] A paradigm shift on the management of severe AS accompanied the introduction of transcatheter aortic valve replacement (TAVR). In light of noninferiority results with TAVR seen in clinical trials, TAVR has been granted the U.S. Food and Drug Administration approval in patients with severe AS across different risk profiles.[2,3,4,5] There is no consensus on the management of severe CAD in this setting. Given the limited literature on this topic, we aimed to investigate the in-hospital clinical outcomes of combined SAVR + CABG versus concurrent TAVR + percutaneous coronary intervention (PCI) using a national database.

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See page 87 for disclosure information.

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## Methods

This is a retrospective study conducted using an administrative database provided by the National Inpatient Sample (NIS) of the Health Care Utilization Project sponsored by the Agency for Healthcare Research and Quality. The NIS registry is available publicly and includes data from all US community hospital discharges.[6] The NIS includes administrative as well as demographic data from a 20% sample of inpatient hospitalizations in the United States.

All patients who underwent TAVR or SAVR during the year 2016 to 2017 were identified based on the International Classification of Diseases, Clinical Modification (ICD-10-CM) diagnosis codes: (Supplement). Patients who received TAVR with PCI or SAVR with CABG compromised the study groups (Figure 1). Study variables including baseline comorbidities and complications were defined based on ICD-10.

The frailty risk score was calculated by using a previously validated ICD-10-point system. Variables included in the score covered multiple aspects of physical and cognitive decline that were linked to frailty. A certain number of points (ranging from 0.1 to 4.4) were awarded for each ICD-10 code and added together to create the final frailty risk score.[7] Hospitals included in the study were classified by Health Care Utilization Project using hospital active and staffed bed numbers into small, medium, or large hospitals,

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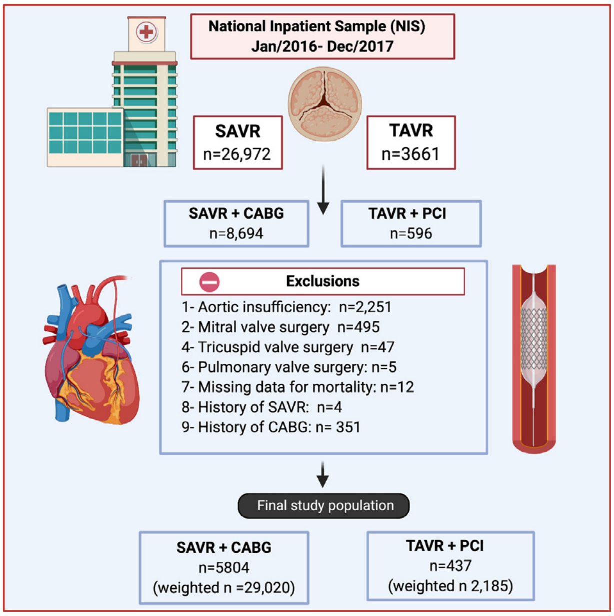


Figure 1. Algorithm for selectin of study population.

by region of the US, the urban-rural designation of the hospital, and teaching status based on the presence of 1 or more Accreditation Council for Graduate Medical Education approved residency programs or membership of the Council of Teaching Hospitals. We excluded the following patients: (1) patients <18 years old, (2) Patients who underwent transapical-TAVR, (3) patients who underwent concomitant cardiac surgery apart from CABG and SAVR, (4) patients who received TAVR for the management of aortic insufficiency as this is not currently an Food and Drug Administration approved indication.

The primary outcome of the current study was all-cause in-hospital mortality. Secondary outcomes included in-hospital stroke (defined as acute cerebral infarction or nontraumatic intracranial bleeding), pericardiocentesis, need for pacemaker insertion, major bleeding (defined as postprocedural blood loss requiring blood transfusion), vascular complications (presence of either vessel injury, arteriovenous fistula, or hematoma), acute kidney injury, sepsis, and nonhome discharge as well measures of resource utilization including the length of stay, and cost of hospitalization. (Supplement) The cost for each in-patient hospitalization record was calculated by multiplying the total hospital charge with the cost-to-charge ratio provided by the NIS database.

We computed descriptive statistics for patient demographics, comorbidities, and hospital characteristics, in the overall sample and stratified by TAVR + PCI versus SAVR + CABG. We reported percentages for categorical variables and mean ± standard error or median ± interquartile ranges for approximately symmetric or skewed continuous variables, respectively. The standardized mean-difference effect size (d) was obtained for each variable. Effect size (d) ≥0.5 standard deviation units is considered large. Effect size is considered moderate, small and trivial for values 0.3 to 0.5, 0.1 to 0.3 and <0.1 respectively.[8]

The covariate-adjusted effects of TAVR + PCI on all-cause mortality was modeled using multivariable logistic regression. The model originally included variables for age, gender, race, clinical comorbidities, degree of frailty, insurance type, and hospital factors including hospital size, teaching status, and ownership. We then performed backward selection to remove nonconsequential variables based on their contribution to the Akaike Information Criterion of the model. Adjusted odds-ratios, their 95% confidence intervals, and associated p values were obtained. We then applied a similar approach to model the effects of the primary exposure on secondary binary outcomes. In the case of hospital length-of-stay, which is a discrete, right-skewed outcome, we used a quasi-Poisson model with a natural log link function to estimate the prevalence rate ratio and its inferential properties. For the cost, we used a Gamma model with a natural log link to estimate the percent difference in relative cost. Each model above was weighed using parameters of the survey design to account for nonresponse bias.[9] Descriptive analyses and statistical models were carried out using STATA 15 (STATA Corp) and R (R Core Team, 2019), respectively.[10]

## Results

Table 1 summarizes the baseline characteristics of the study population. Overall, a total of 31,205 patients were included (SAVR + CABG = 29,020, TAVR + PCI = 2,185) (Figure 1). Compared to patients who had SAVR + CABG, those who received TAVR + PCI were older, had higher proportions of females and had higher prevalence of congestive heart failure and chronic renal failure. Table 2 and Figure 2 summarize the in-hospital outcomes of TAVR + PCI versus SAVR + CABG. In reference to

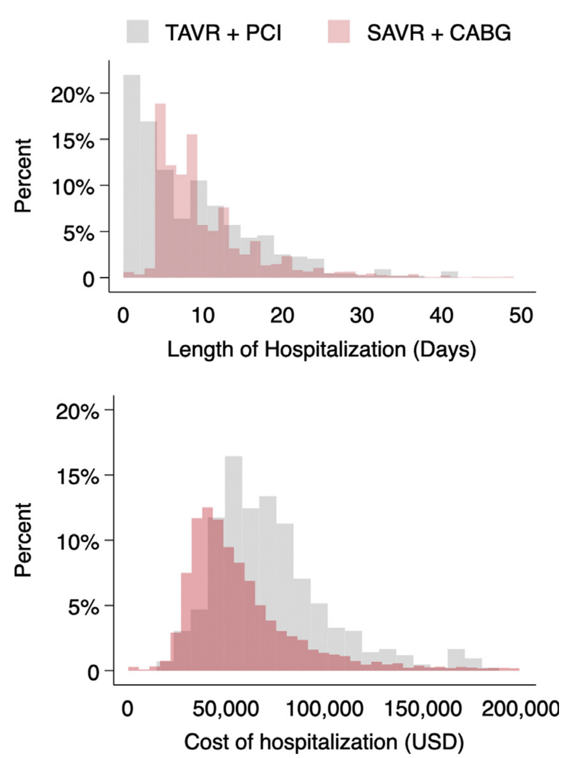


Figure 2. Cost of hospitalization and length of stay following TAVR + PCI versus SAVR + CABG.

Table 1.
Baseline characteristics of study population

| Variable | TAVR + PCI (N = 437n =2,185) | SAVR + CABG (N = 5804n = 29,020) | SMD |
|---|---|---|---|
| Age (years) (IQR) | 82.0 [74.0, 87.0] | 73.0 [67.0, 78.0] | 0.9 |
| Women | 47.6% | 26.6% | 0.4 |
| White | 88.1% | 86.9% | 0.1 |
| Black | 2.4% | 3.3% | |
| Hispanic | 3.8% | 5.8% | |
| Asian or Pacific Islander | 2.1% | 1.4% | |
| Native American | 0.2% | 0.5% | |
| Deficiency anemia | 26.3% | 16.4% | 0.3 |
| Blood loss anemia | 1.1% | 1.3% | 0.0 |
| Congestive heart failure | 77.6% | 37.6% | 0.9 |
| Chronic pulmonary disease | 28.6% | 22.8% | 0.1 |
| Diabetes mellitus | 40.7% | 41.8% | 0.0 |
| Hypertension | 66.8% | 73.2% | 0.1 |
| Hypothyroidism | 22.9% | 12.7% | 0.3 |
| Alcohol abuse | 1.1% | 3.0% | 0.1 |
| Liver disease | 5.5% | 4.9% | 0.0 |
| Chronic Renal failure | 36.8% | 21.0% | 0.4 |
| Obesity | 17.6% | 26.5% | 0.2 |
| Peripheral vascular disease | 28.4% | 22.4% | 0.1 |
| Depression | 7.8% | 6.9% | 0.0 |
| Atrial fibrillation | 37.3% | 49.3% | 0.2 |
| Coronary artery disease | 90.4% | 95.3% | 0.2 |
| Hyperlipidemia | 66.1% | 71.5% | 0.1 |
| Obstructive sleep apnea | 10.8% | 15.1% | 0.1 |
| Prior stroke | 10.8% | 8.2% | 0.1 |
| Degree of frailty (IQR) | 3.9 [1.5, 6.9] | 3.9 [1.8, 6.8] | 0.0 |
| Median household income (percentile) | | | 0.2 |
| 0-25th | 18.0% | 24.2% | |
| 26th to 50th | 27.8% | 27.1% | |
| 51st to 75th | 25.2% | 26.8% | |
| 76th to 100th | 29.0% | 21.9% | |
| Primary expected payer | | | 0.4 |
| Medicare | 89.5% | 76.1% | |
| Medicaid | 1.8% | 3.5% | |
| Private insurance | 6.4% | 17.0% | |
| Self-pay | 0.7% | 1.0% | |
| Bed size of hospital | | | 0.2 |
| Small | 5.3% | 9.0% | |
| Medium | 20.8% | 25.7% | |
| Large | 73.9% | 65.3% | |
| Location/teaching status of hospital | | | 0.3 |
| Rural | 0.2% | 2.2% | |
| Urban nonteaching | 8.7% | 16.9% | |
| Urban teaching | 91.1% | 80.9% | |

IQR = interquartile range; N = calculate sample size; n = weighted population estimate.

SAVR + CABG, recipients of TAVR + PCI had lower rates for mortality, acute kidney injury, major bleeding, sepsis, and non-home discharge. Conversely, recipients of TAVR + PCI had higher rates for pericardiocentesis, vascular complications and need for pacemaker insertion, higher cost and less length of stay. The occurrence of stroke was similar between both groups. Similar findings were reported following multivariate analysis (Table 3).

## Discussion

In this retrospective study, patients with AS and CAD who had TAVR with PCI were compared to those who had SAVR with CABG. Following multivariable analysis, those who had TAVR with PCI had lower odds for mortality, acute kidney injury, sepsis, non-home discharge and shorter length of stay and higher odds for vascular complications, need for pacemaker insertion and higher hospitalization cost. There was no significant difference in the risk of stroke. Findings from this study were driven from a relatively large sample and are more representative of the real-world data.

Among the intermediate-risk patients, the SURTAVI trial showed that both TAVR and SAVR had similar risk for mortality and stroke.[11] In sub-group analysis from the SURTAVI trial, hybrid TAVR and PCI had similar rates of all-cause mortality and stroke compared to SAVR and CABG.[12] Conversely, Baumbach et al., found that SAVR

Table 2.
In-hospital outcomes of TAVR + PCI versus SAVR + CABG

| | TAVR + PCI (N = 437n = 2,185) | SAVR + CABG (N = 5,804n = 29,020) | Effect size (d) |
|---|---|---|---|
| Mortality | 2.7% | 4.5% | 0.1 |
| Pericardiocentesis | 1.1% | 0.2% | −0.1 |
| Stroke | 2.5% | 2.9% | 0.0 |
| Acute kidney injury | 19.7% | 25.6% | 0.1 |
| Major bleeding | 4.3% | 14.6% | 0.4 |
| Vascular complication | 2.1% | 0.7% | −0.1 |
| Pacemaker insertion | 9.4% | 5% | −0.2 |
| Sepsis | 2.7% | 3.8% | 0.1 |
| Non-home discharge | 27.2% | 34.5% | 0.2 |
| Cost of hospitalization | 68,043 | 50,258 | -0.3 |
| Median $ (25th-75th IQR) | (52,571-85,899) | (38,461-68,592) | |
| Length of Hospitalization | 6 (3-12) | 8 (6-13) | 0.3 |
| Median days (25th-75th IQR) | | | |

IQR = interquartile range; N = calculate sample size; n = weighted population estimate.

and CABG had lower in-hospital mortality than TAVR with CABG group but there was no significant difference in the rate for stroke.[13] However, results from Baumbach et al. were limited by a significant selection bias for both SAVR and PCI groups, as the study had only low to moderate surgical risk patients. Also, those with significant calcification burden were excluded from the TAVR group.[14] In between these discrepancies, our study showed that TAVR with PCI was associated with a lower odd for all-cause in-hospital mortality but no significant difference in the rate of stroke.

The prevalence of pacemaker implantation following SAVR and TAVR ranges between 6.6% and 16.5 respectively.[15,16,17] In agreement with prior studies, in the current analysis the postprocedural risk for pacemaker implantation was higher in the TAVR with PCI than SAVR with CABG group.[15] Risk factors for pacemaker implantation following either approach include advanced age, presence of underlying comorbidities, and conduction system defect. In addition, prior cardiac surgery and the depth of implantation increases the risk for pacemaker insertion following SAVR and TAVR respectively.[18,16,19] In the current study, we adjusted for the majority of these factors, except for technical procedural variables that were not available on the database.

Table 3.
Multivariable analysis of In-hospital outcomes of TAVR + PCI versus SAVR + CABG

| | Adjusted OR* | 95% CI | p value |
|---|---|---|---|
| Mortality | 0.32 | 0.17 − 0.62 | 0.001 |
| Pericardiocentesis | 5.27 | 1.16 − 23.91 | 0.031 |
| Stroke | 0.73 | 0.37 − 1.44 | 0.364 |
| Acute kidney injury | 0.40 | 0.30 − 0.54 | <0.001 |
| Major bleeding | 0.24 | 0.15 − 0.39 | <0.001 |
| Vascular complication | 2.65 | 1.22 − 5.75 | 0.014 |
| Pacemaker insertion | 1.92 | 1.34 − 2.74 | <0.001 |
| Sepsis | 0.39 | 0.19 − 0.79 | 0.009 |
| Non-home discharge | 0.47 | 0.36 − 0.60 | <0.001 |
| Length of Hospitalization | 0.68 | 0.62 − 0.75 | <0.001 |
| Cost of hospitalization | 1.12 | 1.05 − 1.19 | <0.001 |

* Calculated odd ratio was adjusted for age, gender, race, components of Elixhauser comorbidity index, insurance type, hospital location, bed-size and teaching status.

Patients with severe AS and CAD have a higher prevalence of chronic renal insufficiency and are more prone to develop acute kidney injury following cardiac procedures, particularly when contrast material is used.[20] The results from the PARTNER-1 trial, showed no difference in the rate of acute kidney injury between TAVR and SAVR. The risk for acute kidney injury following TAVR was more linked to procedural factors that were successfully mitigated with more refinements in TAVR technology and the use of 3D echocardiography.[20] Accordingly, national trends showed a significant reduction in rates of acute kidney injury following TAVR.[17] Conversely, the acute kidney injury following SAVR remained relatively unchanged as the risk was more linked to the patient risk profile than procedural factors. In a recent meta-analysis, TAVR had an almost 50% reduction in the incidence of acute kidney injury compared to SAVR.[20] Our findings go in alignment with the current literature.

The reported incidence of vascular complications following TAVR has ranged from 1.9% to 30.7%.[21] Despite the adoption of wide innovative technologies and the use of lower-profile delivery systems, the risk for vascular complications remains higher in TAVR than in SAVR.[22] This is in accordance with the current data. In contrast, a major bleeding event requiring blood transfusion was higher following SAVR with CABG.

Generally, cardiac surgery is linked to a higher risk of postoperative infections. Relative to SAVR, combining both SAVR and CABG further increases the risk.[23] In agreement with previous literature, our study showed that SAVR with CABG had higher rates for infection than TAVR with PCI.[24] The increased risk for infection seen with surgery is linked to multiple factors including surgical incision, and perioperative blood transfusion, together with the use of central venous lines and urinary catheter placement. In addition, higher hospital stays, as seen in SAVR with CABG group increase the risk for nosocomial infection.[24]

As expected, the length of stay was higher in those who had SAVR with CABG. However, in terms of cost, the hospitalization cost for TAVR with PCI was higher. Osnabrugge et al. reported similar findings where the higher cost for TAVR was attributed to the increased cost of the material used for the TAVR procedure.[25]

Our study has limitations. First, the study was retrospective and based on administrative claim data. The use of ICD codes may have led to inaccuracies in estimating the burden of some comorbidities and complications. The multivariable analysis was limited to variables available within the NIS registry. The lack of angiographic, laboratory and imaging data did not allow for measurement of the severity and complexity of CAD and the underlying heart function. Thus, operative risk based on angiographic data was not measured and the frailty risk score was used as a surrogate. Recipients of staged PCI and TAVR who had PCI in different hospitalization were not included in the study. Since the data is based on a single hospitalization events only, it was not possible to measure the long-term complications.

In conclusion, relative to SAVR and CABG surgery, TAVR and PCI procedure, had lower rates for in-hospital mortality, acute kidney injury, sepsis, a shorter length of stay and higher rates of vascular injury, need for pacemaker insertion, and cost with no difference on the rate of stroke.

## Authors' Contributions

A.A: Concept and study design; acquisition, analysis, and interpretation of the data; drafting and critical revision of the manuscript; M.O: Study design, Methodology, editing and critical revision of the manuscript; S.A: Statistical analysis, editing and critical revision of the manuscript; L. K: Supervision, editing and critical revision of the manuscript.

## 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.2020.09.040.


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