

In-hospital outcomes of transapical versus surgical aortic valve replacement: from the U.S. national inpatient sample

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ABSTRACT

OBJECTIVE To compare the outcomes of transapical transcatheter aortic valve replacement (TA-TAVR) and surgical aortic valve replacement (SAVR) using a large US population sample.

METHODS The U.S. National Inpatient Sample was queried for all patients who underwent TA-TAVR or SAVR during the years 2016–2017. The primary outcome was all-cause in-hospital mortality. Secondary outcomes were in-hospital stroke, pericardiocentesis, pacemaker insertion, mechanical ventilation, vascular complications, major bleeding, acute kidney injury, length of stay, and cost of hospitalization. Outcomes were modeled using multi-variable logistic regression for binary outcomes and generalized linear models for continuous outcomes.

RESULTS A total of 1560 TA-TAVR and 44,280 SAVR patients were included. Patients who underwent TA-TAVR were older and frailer. Compared to SAVR, TA-TAVR correlated with a higher mortality (4.5% vs. 2.7%, effect size (SMD) = 0.1) and higher peri-procedural complications. Following multivariable analysis, both TA-TAVR and SAVR had a similar adjusted risk for in-hospital mortality. TA-TAVR correlated with lower odds of bleeding with (adjusted OR (aOR) = 0.26; 95% CI: 0.18–0.38; $P < 0.001$), and a shorter length of stay (adjusted mean ratio (aMR) = 0.77; 95% CI: 0.69–0.84; $P < 0.001$), but higher cost (aMR = 1.18; 95% CI: 1.10–1.28; $P < 0.001$). No significant differences in other study outcomes. In subgroup analysis, TA-TAVR in patients with chronic lung disease had higher odds for mortality (aOR = 3.11; 95%CI: 1.37–7.08; $P = 0.007$).

CONCLUSION The risk-adjusted analysis showed that TA-TAVR has no advantage over SAVR except for patients with chronic lung disease where TA-TAVR has higher mortality.

Trans-apical aortic valve replacement (TA-TAVR) is typically reserved for patients who have unfavorable transfemoral approach.^[1] Several studies investigated the clinical outcomes of transfemoral-(TF) TAVR vs. surgical aortic valve replacement (SAVR); but there is paucity of data about the outcomes of TA-TAVR compared to SAVR.

The STACCATO trial was the first randomized controlled trial to compare TA-TAVR versus SAVR. Though it was small trial (included only 70 oper-

able patients) and was terminated prematurely (due to major adverse events in the TA-TAVR), it heralded a better outcome of SAVR when compared to TA-TAVR.^[2] Current trends in the U.S. show a steady decline in TA-TAVR procedures with a decrease in the rates of TAVR-related complications, such as stroke and need for pacemaker insertion. However, there has been no change in the risk of mortality or other peri-procedural complications.^[3]

In this study, we aim to elucidate the applicability and safety of TA-TAVR when compared with SAVR.

To our knowledge, this is the first retrospective cohort in the literature that compares the outcomes of TA-TAVR vs. SAVR in a national sample representative of the U.S. population.

METHODS

This study was conducted using the National Inpatient Sample (NIS) of the Health Care Utilization Project (HCUP) sponsored by the Agency for Healthcare Research and Quality (AHRQ). The NIS is a publicly available national registry that receives data from all US community hospital discharges, the NIS includes administrative as well as

demographic data from a 20% sample of inpatient hospitalizations in the United States. NIS provides hospitalization information for over 7 million hospital stays each year with a weighted estimate of more than 35 million hospitalizations annually.^[4]

We included all adult patients who underwent either SAVR or TA-TAVR during 2016 and 2017 calendar years. These patients were identified using the International Classification of Diseases – Tenth Revision, Procedure Codes (ICD-10-PCS for TA-TAVR (02RF37H 02RF3JH 02RF38H 02RF3KH) and SAVR (02RF07Z 02RF08Z 02RF0JZ 02RF0KZ) (online Supplementary Table 1). Frailty was measured using the Hospital Frailty Risk Score (HFRS) cre-

Table 1 Demographics and risk factors among study population.

	SAVR% (n = 8,856; N = 44,280)	TA-TAVR% (n = 312; N = 1,560)	SDM
Age in years	69.0 [61.0–75.0]	81.0 [74.0–85.0]	1.2
Gender			0.2
Males	60.5%	49.4	
Females	39.5%	50.6	
Race			0.2
Caucasian	78.2%	83.7	
African-American	5.2%	4.2	
Hispanic	7.2%	2.2	
Asian or Pacific Islander	1.5%	1.6	
Native American	0.4%	0.3	
Comorbidities			
Diabetes mellitus	30.6%	35.3%	0.1
Hyperlipidemia	58.9%	65.1%	0.1
Hypertension	67.9%	67.6%	0.0
Hypothyroidism	14.0%	21.8%	0.2
Obesity	28.6%	16.0%	0.3
Obstructive sleep apnea	16.7%	13.8%	0.1
Depression	9.3%	6.7%	0.1
Deficiency anemias	14.7%	24.7%	0.3
Blood loss anemia	1.3%	1.3%	0.0
Congestive heart failure	34.2%	73.1%	0.9
Chronic pulmonary disease	21.5%	37.8%	0.4
Alcohol abuse	2.8%	1.0%	0.1
Drug abuse	2.5%	0.6%	0.2
Liver disease	4.7%	5.8%	0.1
Chronic renal failure	14.6%	33.3%	0.5
Peripheral vascular disease	24.2%	44.2%	0.4
Atrial fibrillation	44.0%	46.8%	0.1



Continued

	SAVR% (n = 8,856; N = 44,280)	TA-TAVR% (n = 312; N = 1,560)	SDM
Coronary artery disease	37.1%	68.6%	0.7
Prior stroke	6.7%	15.1%	0.3
Elective admission	75.5%	80.6%	0.1
Frailty index	3.3 [1.5–6.0]	4.1 [1.8–7.4]	0.3
Median household income			0.1
0–25 th percentile	23.1%	23.1%	
26 th to 50 th percentile	26.2%	24.0%	
51 st to 75 th percentile	25.8%	26.6%	
76 th to 100 th percentile	23.1%	22.8%	
Insurance category			0.7
Medicare	62.6%	91.3%	
Medicaid	6.4%	1.6%	
Private insurance	27.2%	5.8%	
Self-pay	1.6%	0.6%	
No charge	0.2%	0.0%	
Hospital bed size			0.2
Small	9.0%	4.8%	
Medium	23.4%	22.8%	
Large	67.5%	72.4%	
Hospital location and teaching status			0.2
Rural	2.0%	0.6%	
Urban nonteaching	14.6%	9.3%	
Urban teaching	83.4%	90.1%	

Data are presented as median (IQR) for continuous measures, and % for categorical measures. *n*: computed sample size; *N*: weighted estimate of population; SAVR: surgical valve replacement; SDM: Standardized mean difference; TA-TAVR: transcatheter aortic valve replacement.

ated by Gilbert, *et al.*,^[5] where a certain number of points ranging from 0.1 to 4.4 are assigned for each ICD-10 code, then summated to create a final frailty risk score. Exclusion criteria were records with missing data, history of prior coronary artery bypass grafting (CABG) or SAVR, history of aortic insufficiency, records with concurrent cardiac surgery (including mitral, tricuspid, or pulmonary valve surgery), and patients who underwent coronary revascularization through either CABG or percutaneous coronary intervention during the same admission (Figure 1).

The primary outcome was all-cause in-hospital mortality. Secondary outcomes included the incidence of in-hospital stroke, pericardiocentesis, pacemaker insertion, major bleeding, vascular complications, acute kidney injury, sepsis, mechanical ventilation. We also compared the length of stay and cost

of hospitalization for both procedures.

We reported percentages for categorical variables and mean \pm SE or median \pm interquartile ranges for approximately symmetric or skewed continuous variables, respectively. The standardized mean difference effect size (SMD) was obtained for each variable. Effect size is considered large, moderate, small, or trivial for values ≥ 0.5 , 0.3–0.5, 0.1–0.3 and < 0.1 , respectively.^[6] Binary outcomes were modeled using multivariable logistic regression. Original models included variables for age, gender, race, clinical comorbidities, degree of frailty, health insurance type, and hospital factors including hospital size, teaching status, and ownership (All variables in Table 1). Non-consequential variables were removed using backward selection based on their contribution to the Akaike Information Criterion (AIC) of the model.



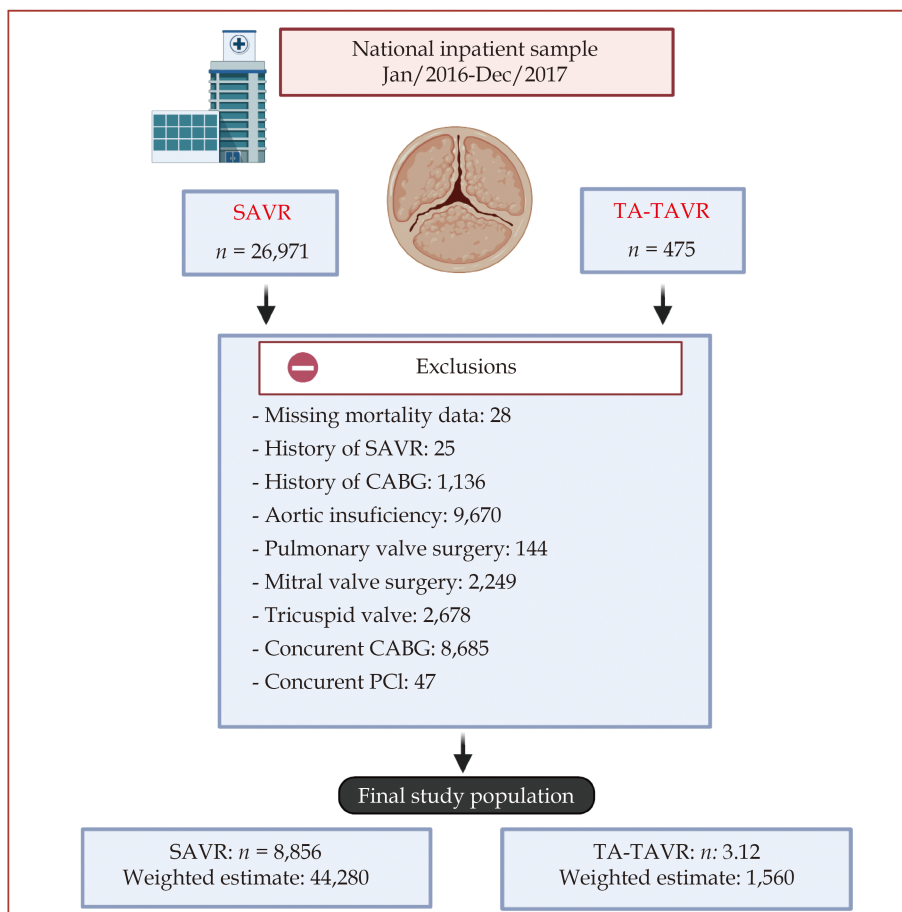


Figure 1 Algorithm for selection of study population. CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention; SAVR: surgical aortic valve replacement; TA-TAVR: transapical transcatheter aortic valve replacement.

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 (PRR) and its inferential properties. 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. 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 then weighed using parameters of the survey design to account for non-response bias.^[7]

We performed subgroup analyses by including interaction terms between TA-TAVR and gender, age groups (> 75 , ≤ 75 years), degree of frailty, comorbidities including congestive heart failure, chronic lung disease, chronic renal failure, peripheral arterial disease, coronary artery disease in the logistic models that predict the odds for mortality. Covariate-adjusted group-specific odds ratios

with 95% CI were reported and the significance of each interaction was evaluated using a likelihood ratio test. Outcomes of hospitalization were modeled using logistic regression for binary outcomes for binary outcomes and incidence rate ratios (IRR), also referred to as means ratios, with 95% CI for the numeric outcomes. Calculated mean ratios represent the increase or decrease in percent association with length of stay and cost.^[8,9] For example, IRR of 1.1 for the length of stay represents a 10% increase in the mean length of stay. Descriptive analyses and statistical models were carried out using STATA 15 (STATA Corp) and R (R Core Team, 2019), respectively.^[10]

RESULTS

Participants

A total of 1 560 patients underwent TA-TAVR



and 44,280 patients who underwent SAVR were included. Table 1 summarizes the baseline characteristics of study population. The TA-TAVR population were older (81 years [IQR: 74–85] vs. 69 years [IQR: 61–75], SMD = 1.2). Overall, recipients of TA-TAVR were sicker, scored higher hospital frailty index (4.1 [IQR: 1.8–7.4] vs. 3.3 [IQR: 1.5–6], SMD = 0.3), and had higher prevalence of comorbidities compared to the SAVR group (congestive heart failure (73.1% vs. 34.2%, SMD = 0.8), coronary artery disease (68.6% vs. 37.1%, SMD = 0.7), chronic renal failure (44.2% vs. 24.2%, SMD = 0.5), chronic lung disease (37.8% vs. 21.5%, SMD = 0.4), peripheral vascular disease (44.2% vs. 24.2%, SMD = 0.4), stroke (15.1% vs. 6.7%, SMD = 0.3), and iron-deficiency anemia (24.7% vs. 14.7%, SMD = 0.3). TA-TAVR recipients also had significantly less Medi-

caid (1.6% vs. 6.4%, SMD = -0.2) and private insurance (5.8% vs. 27.2%, SMD = -0.6).

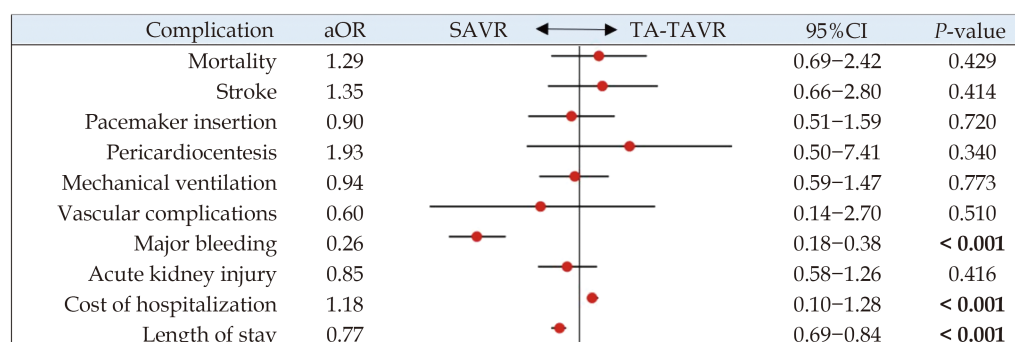
Primary Outcomes

On univariate analysis, TA-TAVR was associated with higher mortality rates compared to SAVR (4.5% vs. 2.7%, SMD = 0.1) (Table 2). However, there was no significant difference in mortality between recipients of TA-TAVR versus SAVR following risk factors adjustments on multivariable analysis (Figure 2). Subgroup analyses revealed significant interactions between TA-TAVR and presence of chronic lung disease. Patients with chronic lung disease had higher mortality risk following TA-TAVR than SAVR (aOR = 3.11, 95%CI: (1.37–7.08), P = 0.007). Otherwise, neither treatment strategy had a clear advantage in any of the analyzed sub-

Table 2 Complication rates among TA-TAVR versus SAVR.

	SAVR % (n = 8,856; N = 44,280)	TA-TAVR % (n = 312; N = 1,560)	SDM
Mortality	2.7%	4.5%	0.1
Stroke	3%	3.8%	0.0
Pacemaker insertion	5.4%	5.8%	0.0
Pericardiocentesis	0.3%	0.6%	0.1
Mechanical ventilation	7%	7.7%	0.0
Vascular complications	0.8%	0.6%	0.0
Major bleeding	11.4%	4.8%	-0.2
Acute kidney injury	18.8%	25.3%	0.2
Length of stay	7 (5–10)	5 (3–9)%	-0.2
Cost of hospitalization, \$	42,396 (32,564–59,339)	53,255 (39,028–73,295)	0.2

Data are presented as median (IQR) for continuous measures, and % for categorical measures. n: computed sample size. N: weighted estimate of population; SAVR: surgical valve replacement; SDM: Standardized mean difference; TA-TAVR: transcatheter aortic valve replacement.



Results of multivariable logistic regression analysis with adjustment for age, gender, race, comorbidities, median household income, insurance type, hospital characteristics including bed size, location, and teaching status.

Figure 2 Adjusted complication rates among TA-TAVR vs. SAVR. SAVR: surgical valve replacement; TA-TAVR: transcatheter aortic valve replacement.



groups including age category, frailty index, gender, and comorbidities (congestive heart failure, coronary artery disease, kidney failure, or peripheral vascular disease) (Table 3).

Secondary Outcomes

The rates of stroke, need for pacemaker insertion, vascular complications, and mechanical ventilation were similar in both TA-TAVR and SAVR groups. However, TA-TAVR was correlated with statistically-significant higher rates of pericardiocentesis (0.6% vs. 0.3%, SMD = 0.1) and acute kidney injury (25.3% vs. 18.8%, SMD = 0.2), but lower rates of major bleeding (4.8% vs. 11.4%, SMD = -0.2) com-

pared to SAVR. Regarding resources utilization, TA-TAVR correlated with higher cost of hospitalization (53,255 \$; [IQR: 39,028–73,295] vs. 42,396 USD [IQR: 32,564–59,339], SMD = 0.2) and lower length of stay (5 days [IQR: 3–9] vs. 7 days [IQR: 5–10], SMD = -0.2). No significant difference in other study outcomes (Table 2).

Following multivariable analysis, TA-TAVR correlated with significantly lower odds of major bleeding (aOR = 0.26; 95% CI: 0.18–0.38; $P < 0.001$) and shorter length of stay (aMR = 0.77; 95% CI: 0.69–0.84; $P < 0.001$) but an 18% higher cost (aMR = 1.18; 95% CI: 1.10–1.28; $P < 0.001$).

Table 3 The impact of Interaction between selected categories and TA-TAVR versus SAVR on the risk for mortality.

	aOR	95% CI	Interaction <i>P</i> value
Age			0.703
> 75 yrs	1.33	[0.67–2.67]	
≤ 75 yrs	1.08	[0.27–4.30]	
Sex			0.719
Females	1.17	[0.48–2.87]	
Males	1.48	[0.60–3.63]	
Frailty			0.287
Low	2.33	[0.88–6.17]	
High	1.07	[0.51–2.24]	
Diabetes mellitus			0.437
Yes	1.73	[0.71–4.23]	
No	1.14	[0.49–2.65]	
Congestive heart failure			0.368
Yes	1.52	[0.78–2.98]	
No	0.50	[0.06–4.33]	
Chronic lung disease			0.007
Yes	3.11	[1.37–7.08]	
No	0.52	[0.18–1.52]	
Chronic renal failure			0.325
Yes	1.93	[0.80–4.66]	
No	0.99	[0.38–2.60]	
Peripheral vascular disease			0.250
Yes	1.83	[0.78–4.36]	
No	0.95	[0.40–2.24]	
Coronary artery disease			0.859
Yes	1.26	[0.56–2.85]	
No	1.40	[0.53–3.69]	

Results of multivariable logistic regression analysis with adjustment for all variables listed in Table 1. aOR: adjusted odds ratio; SAVR: surgical valve replacement; TA-TAVR: transcatheter aortic valve replacement.



DISCUSSION

In this study, outcomes of TA-TAVR and SAVR were compared at the population level using a large national database. Following adjustment of baseline clinical characteristics, TA-TAVR and SAVR had similar rates of all-cause in-hospital mortality, stroke, need for pacemaker insertion, vascular complications, and acute kidney injury. Moreover, TA-TAVR had significantly fewer rates for major bleeding and a shorter length of stay but correlated with higher cost. Patients with chronic lung disease tend to have favorable outcomes with SAVR more than TA-TAVR.

Patients who underwent TA-TAVR were significantly older, sicker, frailer, and had a higher burden of comorbidities than those who underwent SAVR. These baseline differences might have contributed to the higher all-cause mortality and periprocedural cardiac complications following TA-TAVR on the univariate analysis (Table 1). However, when baseline characteristics were adjusted, no significant difference in mortality, stroke, or cardiac complications was detected between the two study groups.

To date, the largest study comparing the outcomes of TA-TAVR versus SAVR was done in Germany, in which claim-based hospitalization records of 19,016 isolated SAVR and 6 432 TA-TAVR patients were analyzed.^[11] TA-TAVR group had a lower adjusted risk for stroke, acute kidney injury, major bleeding, and need for prolonged mechanical ventilation. However, there was no significant difference in the adjusted risk of mortality between TA-TAVR and SAVR groups. Notably, in the subgroup analysis, SAVR was superior to TA-TAVR in patients < 75 years old, females, and in those with a European System for Cardiac Operative Risk Evaluation score (EuroSCORE) of 4-9. Conversely, TA-TAVR was superior to SAVR in patients with chronic renal failure.^[11]

When compared to our study, TA-TAVR correlated with higher mortality risk among patients with chronic lung disease. Both procedures had similar mortality rates in all other subgroups including patients \leq 75 years, females, and in those with chronic kidney disease. While it was not possible to calculate a surgical-risk score due to the intrinsic charac-

teristics of the NIS database, TA-TAVR correlated with a higher adjusted mortality risk than SAVR among patients who were less frail. Though, the relationship was not significant (aOR = 2.33, 95% CI: 0.88–6.17, $P = 0.088$).

According to current literature, stroke remains a significant, and more common, complication in recipients of TA-TAVR when compared with other TF-TAVR or SAVR.^[12] In our study, patients who underwent TA-TAVR had higher rates for stroke before risk adjustment, but, there was no significant difference in stroke risk between the TA-TAVR and SAVR groups after adjusting for comorbidities, a similar phenomenon occurred for the need for pericardiocentesis, pacemaker insertion, and mechanical ventilation. It might infer to the fact that the occurrence of stroke, though happened peri-procedurally, might be a consequence of patients' underlying comorbidities rather than a result of the TA-TAVR procedure itself.

Our findings of significantly lower bleeding complication rates following TA-TAVR than with SAVR are consistent with current literature. Among high-risk aortic stenosis patients enrolled in the PARTNER I randomized trial, bleeding complications were more common after SAVR than TAVR and were also associated with worse long-term prognosis.^[13] Tchetché, *et al.*^[14] recently reported bleeding rates in TAVR patients at 13.9% for life-threatening bleeding and 20.9% for major bleeding, with 38.9% of patients receiving at least one transfusion. Tamburino, *et al.*^[15] reported 30-day rates of life-threatening bleeding of 5.5% and 9.0% after TAVR and SAVR, respectively. Génèreux, *et al.*^[13] reported that SAVR was associated with a significantly higher 30-day rate of transfusion (17.9%) than either TF-TAVR (7.1%) or TA-TAVR (4.8%), $P < 0.0001$.

In terms of risk for acute kidney injury (AKI), there is conflicting evidence in current literature. Wenaweser, *et al.*^[16] found that patients undergoing TAVR are more frequently to suffer RIFLE stage 3 renal failure when compared to SAVR, whereas, Latib, *et al.*^[17] concluded that AKI was more frequent after SAVR. In our study, recipients of TA-TAVR had higher rates of acute kidney injury than those who underwent SAVR. However, when adjusted to other comorbidities in a multivariable ana-



lysis, the risk for AKI was similar in both groups suggesting it is likely to underlying medical conditions rather than the procedure itself.

Our study has a number of limitations, the use of ICD codes can lead to inaccuracies in estimating the diagnosis of certain comorbidities and complications. To improve accuracy, a set of ICD codes that were previously validated in other studies was utilized. Due to database characteristics, it was not possible to calculate the Society of Thoracic Surgeons (STS) score or EuroSCORE, the technical details of the procedures under study, patients' hemodynamic status, laboratory and radiological data, or echocardiographic parameters such as aortic valve area, mean gradient, left ventricular ejection fraction, etc. However, we mitigated the confounding bias by using a multivariable analysis with adjustment for a wide range of variables including patient demographics, several comorbidities, degree of frailty, and hospital characteristics.

In conclusion, recipients of TA-TAVR were at baseline sicker, had higher rates of mortality and postprocedural complications compared to SAVR recipients. The risk-adjusted analysis showed that TA-TAVR and SAVR are similar in terms of mortality, risk of AKI, and periprocedural cardiac complication rates. However, patients with COPD are at higher risk for mortality following TA-TAVR compared to SAVR.

CONFLICTS OF INTEREST

None

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None

AUTHOR CONTRIBUTION

A.A: concept and study design; acquisition, analysis, and interpretation of the data; drafting and critical revision of the manuscript. O.H, A.T, A.S, H.D, E.I: Writing and critical revision of the manuscript. S.A: Methodology, Statistical analysis and critical revision of the manuscript. L.K: Supervision, critical revision of the manuscript.

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