Trends and Predictors of Transcatheter Aortic Valve Implantation Related In-Hospital Mortality (From the National Inpatient Sample Database)

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Existing surgical aortic valve replacement risk models accurately predict the post- surgical aortic valve replacement morbidity and mortality, but factors associated with post transcatheter aortic valve Implantation (TAVI) mortality are not well known. The National Inpatient Sample was queried to identify all cases of TAVI. The association of baseline comorbidities with in-hospital mortality was determined using a binary logistic regression model to obtain adjusted odds ratios (aOR). A total of 161,049 patients underwent TAVI between 2010 and 2017. Of these, 157,151 (97.6%) survived while 3,898 (2.4%) died during hospitalization. The baseline characteristics of TAVI-survivors and non-survivors showed a significant amount of variation, including age (80 vs 82 years, $p \leq 0.0001$) and female sex (46% vs 52%, $p \leq 0.0001$), respectively. The non-survivors had significantly higher adjusted odds of renal failure requiring hemodialysis (aOR 2.59, 95% CI 2.24 to 2.99, $p \leq 0.0001$), history of mediastinal radiation (aOR 2.71, 95% CI 1.02 to 7.20, $p = 0.05$), liver disease (aOR 3.04, 95% CI 2.63 to 3.51, $p \leq 0.0001$), pneumonia (aOR 2.47, 95% CI 2.15 to 2.83, $p \leq 0.0001$), cardiogenic shock (aOR 9.83, 95% CI 8.93 to 10.82, $p \leq 0.0001$), ventricular tachycardia (aOR 2.12, 95% CI 1.88 to 2.40, $p \leq 0.0001$), acute ST-elevation myocardial infarction (aOR 7.38, 95% CI 5.53 to 9.84, $p \leq 0.0001$), stroke (aOR 2.25, 95% CI 1.99 to 2.54, $p \leq 0.0001$), and acute infective endocarditis (aOR 5.74, 95% CI 3.65 to 9.02, $p \leq 0.0001$) compared to TAVI-survivors. The yearly trend of mortality showed an increase in the absolute number of TAVI procedures and mortality but the yearly rate showed a decline in mortality after an initial peak during 2012.Patients with renal failure on dialysis, ST-elevation myocardial infarction, cardiogenic shock, infective endocarditis, liver disease and pneumonia have a higher rate of in-hospital mortality post TAVI. **© 2020 Elsevier Inc. All rights reserved.** **(Am J Cardiol 2021;143:97−103)**

Transcatheter aortic valve implantation (TAVI) has proven to be a safer and effective alternative to surgical aortic valve replacement in patients with severe aortic stenosis (AS) who previously were deemed inoperable or at prohibitive surgical risk.[1] Although it seems set to expand to patients at low surgical risk, current TAVI candidates are mostly frail, having multiple comorbidities and therefore at a high risk of post-procedure mortality.[1] Recent findings of the Society of Thoracic Surgeons (STS) and American College of Cardiology Transcatheter Valve Therapies Registry revealed in-hospital all-cause mortality of about 5.3% in patients undergoing TAVI.[2] The risk prediction models produced by the STS and American College of Cardiology accounts for a wide range of baseline characteristics to accurately predict post-procedure mortality. However, these scores were primarily designed for patients undergoing surgical aortic valve replacement. Although the data for STS was derived from the National Adult Cardiac Surgery Database, it has widely been adopted as a tool to determine a patient's eligibility for TAVI. The association of individual STS components with post-TAVI mortality remains unclear. Many small-scale studies have attempted to identify this association but were subject to major methodological limitations. Some studies failed to include all potential risk factors for in-hospital mortality, others were underpowered due to their small sample size.[3−12] The present study sought to determine the association of individual components of standard STS score with TAVI-related mortality.

Methods

We retrospectively analyzed data from the National Inpatient Sample (NIS) Database. NIS is a large national database to allow for the national assessment of hospital discharges among patients of different age groups across all payer types from all United States (US) hospitals. The included data is completely de-identified and hence exempted from approval by the institutional review board. NIS contains data from almost 20 million discharges each year, representing more than a 100 million weighted

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discharges of national estimates. It is managed and closely mandated by the Agency for Healthcare Research and Quality's (AHRQ).

We utilized nationally weighted 2002−2017 NIS claims to select all US adult patients (>18 years) undergoing TAVI. The included sample was divided into two groups; those who survived the procedure and those who died during the same hospitalization. The standard International Classification of Disease, Clinical Modifications codes (ICD-CM) were used to select the population of interest. Relevant ICD-9-CM and ICD-10-CM codes were used to identify patient's baseline characteristics, in-hospital procedures, and components of STS (Supplementary Table 1). The standard risk factors of the STS scoring algorithm were used as an individual variable to determine its association with the in-hospital mortality. The mean rank of the length of stay (LOS), number of procedures, number of diagnoses on record and cost of hospitalization between the two groups were also compared between the surviving and dead patients. The patient demographics, baseline comorbidities and components of STS are given in Table 1.

All patients with severe AS undergoing TAVI were included. The crude in-hospital all-cause mortality rate and its yearly trend were calculated using descriptive statistics. Patients who survived the TAVI procedure and were discharged in a stable condition were compared to those who did not survive the procedure. Patient's demographics and baseline comorbidities between the two groups were computed using the chi-square test for categorical variables. The median, interquartile range and means with standard deviation for continuous variables were also calculated. The in-hospital outcomes for dichotomous variables were compared using unadjusted odds ratios (uOR) on Cochran −Mantel−Haenszel test. The mean of normally and non-normally distributed continuous variables were compared using independent t-test and Mann-Whitney U test analysis, respectively. To address the impact of potential confounders on mortality, differences in baseline diseases were assessed using a risk-adjusted binary logistic regression (BLR) model. The BLR was risk-adjusted for 30 potential confounders including age, gender, race, history of hypertension (HTN), peripheral vascular disease (PVD), stroke, coronary artery disease (CAD), hemodialysis, previous myocardial infarction (MI), atrial fibrillation (AF), congestive heart failure, obstructive sleep apnea, prior percutaneous coronary intervention (PCI), prior coronary artery bypass graft (CABG) and all other measurable variables of STS scoring algorithm (Supplementary Table 2). Variables with cell sizes <10 were excluded given NIS reporting guidelines. All pooled estimates were presented with 95% confidence intervals (CIs) and an alpha criterion of $p \leq 0.05$ was regarded as statistically significant. The analyses were computed using SPSS Version 24.0.

Results

A total of 161,049 patients who underwent TAVI were included in the analysis. Of these, 3,898 (2.4%) patients died and 157,151 (97.6%) survived the hospitalization. There were significant intergroup differences in the baseline characteristics as shown in Table 1. The mortality trend across different years showed an initial peak in the annual percent mortality during 2012 and then a gradual decline. There has been an exponential increase in the absolute number of TAVI procedures in recent years and a similar rising trend in the absolute number of deaths was observed. (Table 2, Figures 1 and 2)

On an unadjusted analysis, the following predictors were more frequently present among those who died compared to survivors: hemodialysis (8.9% vs 1.7%, uOR 5.5, 95% CI 6 to 6.2, $p \leq 0.0001$), history of mediastinal radiation (0.1% vs 0%, uOR 3.10, 95% CI 1.3 to 7.7, $p \leq 0.03$), liver disease (9.2% vs 1.8%, uOR 5.52, 95% CI 5 to 6.3, $p \leq 0.0001$), atrial flutter (5.1% vs 4.2%, uOR 1.23, 95% CI 1.06 to 1.41, $p \leq 0.007$), in-hospital pneumonia (8.5% vs 1.7%, uOR 5.3, 95% CI 4.76 to 6.04, $p \leq 0.0001$), cardiogenic shock (24.4% vs 1.9%, uOR 16.74, 95% CI 15.43 to 18.17, $p \leq 0.0001$), third degree heart block (13.7% vs 9.4%, uOR 1.54, 95% CI 1.39 to 1.69, $p \leq 0.0001$), ventricular tachycardia (11% vs 3.4%, uOR 3.52, 95% CI 3.18 to 3.01, $p \leq 0.0001$), ST-segment elevation MI (STEMI) (2.7% vs 0.2%, uOR 13.39, 95% CI 10.72 to 16.73, $p \leq 0.0001$), stroke (9.6% vs 3.8%, uOR 2.71, 95% CI 2.43 to 3.03, $p \leq 0.0001$), and infective endocarditis (0.8% vs 0.1%, uOR 11.07, 95% CI 7.38 to 16.59, $p \leq 0.0001$). (Table 3) The mean rank of LOS ($p \leq 0.0001$), charges per hospitalization ($p \leq 0.0001$), number of diagnoses ($p \leq 0.0001$) and number of procedures on record ($p \leq 0.0001$) were significantly higher for non-surviving TAVI patient (Supplemantary Tables 3 and 4).

A BLR model adjusted for 30 baseline characteristics mirrored the findings of unadjusted odds with few exceptions. Contrary to the pooled analysis, the odds of atrial flutter (adjusted odd ratio [aOR] 0.91, 95% CI 0.77 to 1.07, $p = 0.24$) and history of prior MI (aOR 1.05, 95% CI 0.92 to 1.19, $p = 0.5$) were identical in both groups. The nonsurvivors had significantly higher adjusted odds of the concurrent diagnosis of renal failure requiring hemodialysis (aOR 2.59, 95% CI 2.24 to 2.99, $p \leq 0.0001$), history of mediastinal radiation (aOR 2.71, 95% CI 1.02 to 7.20, $p = 0.05$), liver disease (aOR 3.04, 95% CI 2.63 to 3.51, $p \leq 0.0001$), pneumonia (aOR 2.47, 95% CI 2.15 to 2.83, $p \leq 0.0001$), cardiogenic shock (aOR 9.83, 95% CI 8.93 to 10.82, $p \leq 0.0001$), third degree heart block (aOR 1.22, 95% CI 1.10 to 1.35, $p \leq 0.0001$), ventricular tachycardia (aOR 2.12, 95% CI 1.88 to 2.40, $p \leq 0.0001$), STEMI (aOR 7.38, 95% CI 5.53 to 9.84, $p \leq 0.0001$), stroke (aOR 2.25, 95% CI 1.99 to 2.54, $p \leq 0.0001$) and infective endocarditis (aOR 5.74, 95% CI 3.65 to 9.02, $p \leq 0.0001$) compared to TAVI-survivors. Intriguingly, those who died after TAVI had consistently lower adjusted odds of HTN (aOR 0.61, 95% CI 0.57 to 0.67, $p \leq 0.0001$), PVD (aOR 0.88, 95% CI 0.78 to 0.98, $p = 0.02$),OSA (aOR 0.79, 95% CI 0.69 to 0.91, $p \leq 0.0001$), smoking (aOR 0.58, 95% CI 0.53 to 0.64, $p \leq 0.0001$), prior PCI (aOR 0.60, 95% CI 0.50 to 0.73, $p \leq 0.0001$), prior CABG (aOR 0.83, 95% CI 0.74 to 0.93, $p \leq 0.0001$), AF (aOR 0.89, 95% CI 0.83 to 0.96, $p \leq 0.0001$) and mitral stenosis (aOR 0.65, 95% CI 0.55 to 0.76, $p \leq 0.0001$) compared to the surviving patients. (Figure 3, Table 3)

Table 1
Baseline demographics of patients across the comparison groups on crude and propensity matched analysis

Variables, no. (%)	Survived (n=157151)	Died (n=3898)	p value
Men	84152 (53.6%)	1859 (47.7%)	0.0001
Women	72940 (46.4%)	2039 (52.3%)	
White	129454 (87.1%)	3149 (86.3%)	0.19
Black	6197 (4.2%)	110 (3.0%)	
Hispanic	6396 (4.3%)	210 (5.8%)	
Asians	1840 (1.2%)	40 (1.1%)	
Native American	345 (0.2%)	15 (0.4%)	
Others	4343 (2.9%)	124 (3.4%)	
Calendar Year			
2011	1131 (0.7%)	33 (0.8%)	<0.0001
2012	7280 (4.6%)	380 (9.7%)	
2013	12875 (8.2%)	650 (16.7%)	
2014	19155 (12.2%)	710 (18.2%)	
2015	26580 (16.9%)	630 (16.2%)	
2016	39485 (25.1%)	745 (19.1%)	
2017	50605 (32.2%)	750 (19.2%)	
Comorbidities			
Alcohol abuse	1492 (0.9%)	45 (1.2%)	0.56
Valvular diseases	77450 (49.3%)	1450 (37.2%)	0.0001
Peptic ulcer disease	680 (0.4%)	15 (0.4%)	0.84
Solid tumor without metastasis	3481 (2.2%)	75 (1.9%)	0.58
Deficiency Anemias	36012 (22.9%)	799 (20.5%)	0.11
collagen vascular diseases	10005 (6.4%)	160 (4.1%)	0.01
Congestive heart failure	61219 (39.0%)	1465 (37.6%)	0.43
Chronic pulmonary disease	46442 (29.6%)	1233 (31.6%)	0.21
Chronic blood loss anemia	1931 (1.2%)	30 (0.8%)	0.25
Coagulopathy	25941 (16.5%)	1358 (34.8%)	<0.0001
Drug abuse	440 (0.3%)	10 (0.3%)	0.9
Diabetes, uncomplicated	35978 (22.9%)	624 (16.0%)	<0.0001
Diabetes with chronic complications	21290 (13.6%)	411 (10.5%)	0.01
Depression	11979 (7.6%)	195 (5.0%)	0.01
Hypothyroidism	31907 (20.3%)	779 (20.0%)	0.83
Fluid and electrolyte disorder	28889 (18.4%)	2029 (52.0%)	<0.0001
Obesity	26504 (16.9%)	460 (11.8%)	<0.0001
Pulmonary circulation disorders	5590 (3.6%)	240 (6.2%)	<0.0001
Psychosis	1619 (1.0%)	20 (0.5%)	0.15
Paralysis	3507 (2.2%)	276 (7.1%)	<0.0001
Renal failure	53889 (34.3%)	1708 (43.8%)	<0.0001
Weight loss	5520 (3.5%)	545 (14.0%)	<0.0001
Metastatic cancer	954 (0.6%)	15 (0.4%)	0.43
Hemodialysis	2706 (1.7%)	345 (8.9%)	<0.0001
Drug use	1761 (1.1%)	30 (0.8%)	0.36
InfecEndocarditis	110 (0.1%)	30 (0.8%)	<0.0001
Syncope	1414 (0.9%)	25 (0.6%)	0.45
Stroke	5945 (3.8%)	376 (9.6%)	<0.0001
STEMI	324 (0.2%)	105 (2.7%)	<0.0001
Coronary artery disease	106172 (67.6%)	1919 (49.2%)	<0.0001
Mitral Stenosis	99015 (63.0%)	1709 (43.8%)	<0.0001
Ventricular Tachycardia	5341 (3.4%)	430 (11.0%)	<0.0001
Sick Sinus	4630 (2.9%)	115 (3.0%)	0.99
Third Degree Heart Block	14750 (9.4%)	535 (13.7%)	<0.0001
Atrial Flutter	6652 (4.2%)	200 (5.1%)	0.22
Atrial Fibrillation	62265 (39.6%)	1455 (37.3%)	0.19
Cardiogenic Shock	2979 (1.9%)	953 (24.5%)	<0.0001
Prior Myocardial Infarction	18278 (11.6%)	299 (7.7%)	0.001
Prior CABG	28280 (18.0%)	364 (9.3%)	<0.0001
Prior PCI	9927 (6.3%)	130 (3.3%)	0.001
Smoking	47405 (30.2%)	535 (13.7%)	<0.0001
Pneumonia	2670 (1.7%)	331 (8.5%)	<0.0001
Live Disease	2793 (1.8%)	360 (9.2%)	<0.0001
Obstructive Sleep Apnea	17215 (11.0%)	235 (6.0%)	<0.0001

(*continued*)

Table 1 (***Continued***)

Variables, no. (%)	Survived (n=157151)	Died (n=3898)	p value
Family History of CAD	8338 (5.3%)	85 (2.2%)	<0.0001
Mediastinal Radiation	65 (0.0%)	5 (0.1%)	0.25
Peripheral Vascular Disease	23078 (14.7%)	420 (10.8%)	0.002
Immunocompromised	20 (0.0%)	0 (0.0%)	0.75
Hypertension	59796 (38.1%)	880 (22.6%)	<0.0001

Table 2
Trend of mortality and TAVI procedures over the years

Year	TAVI	TAVI %	Died	Death% within calendar year	Death% With all deaths
2010	0	0	0	0	0
2011	1164	0.70%	33	2.80%	0.80%
2012	7660	4.80%	380	5.00%	9.70%
2013	13525	8.40%	650	4.80%	16.70%
2014	19865	12.30%	710	3.60%	18.20%
2015	27210	16.90%	630	2.30%	16.20%
2016	40270	25.00%	745	1.90%	19.10%
2017	51355	31.90%	750	1.50%	19.20%
Total	161049	100%	3898	21.90%	100%

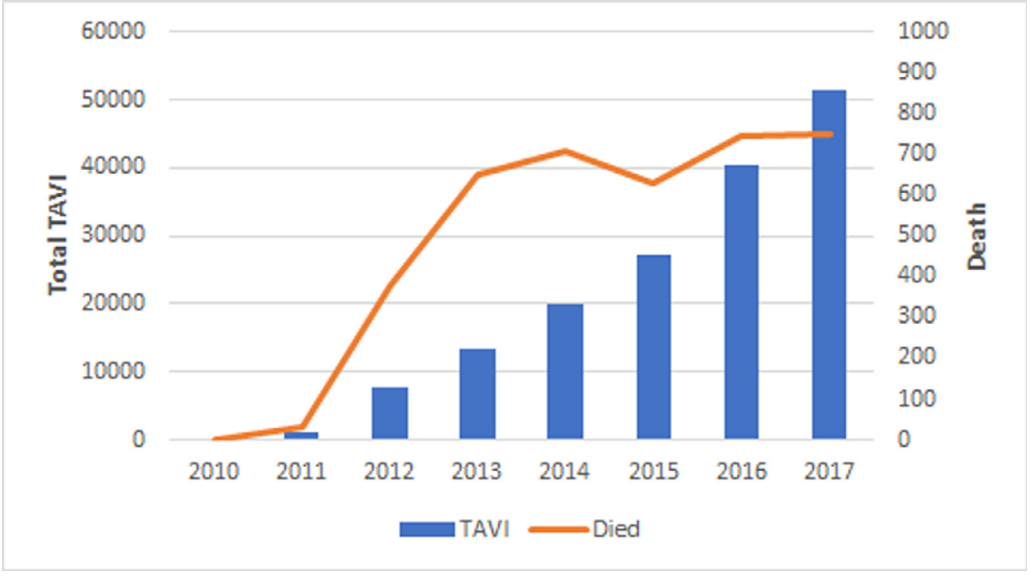

Figure 1. Yearly trend of absolute number of TAVI procedures and number of deaths.

Discussion

The present study included more than 160,000 TAVI patients from the largest available US clinical registry (2002 to 2017). Assessment of the prespecified risk factors as devised by STS revealed significant variation in its associations with TAVI-related mortality. TAVI patients with a previous history of mediastinal radiation, liver disease and third-degree heart block showed significantly higher odds of in-hospital mortality. Similarly, patients with a concurrent diagnosis of periprocedural renal failure requiring hemodialysis, pneumonia, cardiogenic shock, ventricular tachycardia, STEMI, stroke and endocarditis had higher rates of in-hospital mortality. The mean rank of the LOS, cost of hospitalization, number of diagnoses and procedures on record were also significantly higher for patients who died during hospitalization.

Many researchers have attempted to determine the association of different baseline comorbidities with TAVI mortality. The findings of these studies, however, have only added to the growing uncertainty due to conflicting results and methodological limitations.[3–10] Most studies were vastly underpowered due to small size, others were very selective in choosing the variables, limiting the widespread applicability of its results to all-TAVI patients.[4] The most common associations that were investigated by previous studies included chronic lung disease, home oxygen use, diabetes mellitus and pulmonary HTN. Some studies relied only on characteristics

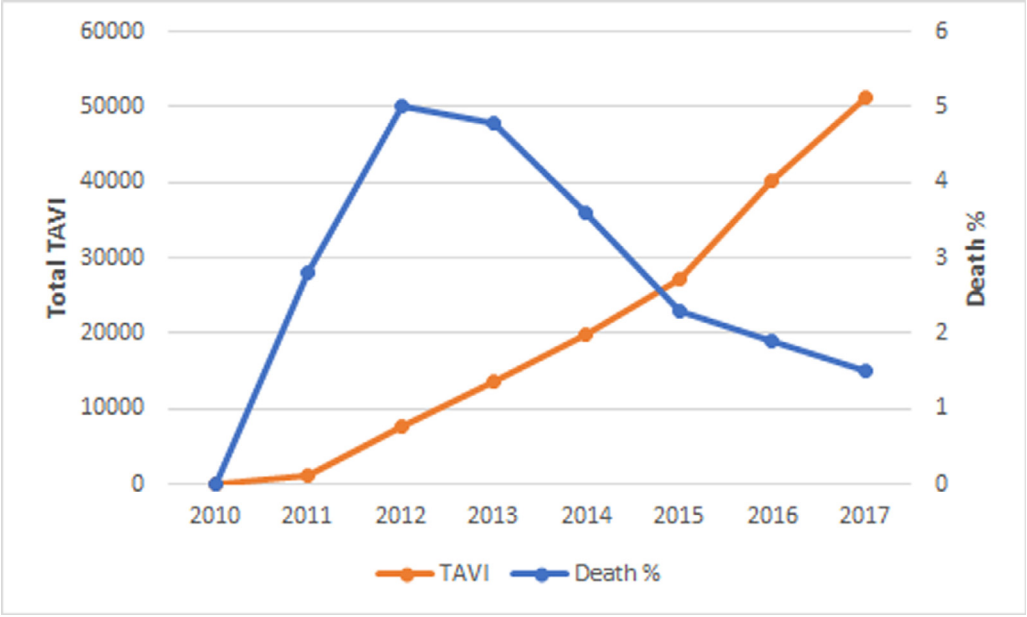

Figure 2. Yearly trend of absolute number of TAVI procedures and percentage of deaths/year.

Table 3
Unadjusted and adjusted odds ratio of predictors of in-hospital mortality in patients undergoing TAVI

Variable	Survived (n=157151)	Died (n=3898)	Unadjusted Odds	p=value	*Adjusted Odds	p=value
Hemodialysis	2706 (1.7%)	345 (8.9%)	5.5 (5-6.2)	<0.0001	2.59 (2.24-2.99)	<0.0001
Hypertension	59796 (38.1%)	880 (22.6%)	0.47 (0.44-0.51)	<0.0001	0.61 (0.57-0.67)	<0.0001
PVD	23078 (14.7%)	420 (10.8%)	0.70 (0.63-0.77)	<0.0001	0.88 (0.78-0.98)	0.02
Mediastinal Radiation	65 (0. %)	5 (0.1%)	3.10 (1.25-7.71)	0.03	2.71 (1.02-7.20)	0.05
Family history of CAD	8338 (5.3%)	85 (2.2%)	0.39 (0.32-0.49)	<0.0001	0.59 (0.46-0.75)	<0.0001
Obstructive Sleep Apnea	17215 (11.0%)	235 (6.0%)	0.52 (0.46-0.59)	<0.0001	0.79 (0.69-0.91)	<0.0001
Liver Disease	2793 (1.8%)	360 (9.2%)	5.62 (5.01-6.30)	<0.0001	3.04 (2.63-3.51)	<0.0001
Drug Use	1761 (1.1%)	30 (0.8%)	0.68 (0.48-0.98)	0.05	0.71 (0.47-1.09)	0.12
Pneumonia	2670 (1.7%)	331 (8.5%)	5.37 (4.76-6.04)	<0.0001	2.47 (2.15-2.83)	<0.0001
Smoking	47405 (30.2%)	535 (13.7%)	0.37 (0.34-0.40)	<0.0001	0.58 (0.53-0.64)	<0.0001
Prior PCI	9927 (6.3%)	130 (3.3%)	0.51 (0.43-0.61)	<0.0001	0.60 (0.50-0.73)	<0.0001
Prior CABG	28280 (18.0%)	364 (9.3%)	0.47 (0.42-0.52)	<0.0001	0.83 (0.74-0.93)	<0.0001
Prior MI	18278 (11.6%)	299 (7.7%)	0.63 (0.56-0.71)	<0.0001	1.05 (0.92-1.19)	0.5
Cardiogenic Shock	2979 (1.9%)	953 (24.4%)	16.74 (15.43-18.17)	<0.0001	9.83 (8.93-10.82)	<0.0001
Atrial Fibrillation	62265 (39.6%)	1445 (37.3%)	0.90 (0.85-0.96)	0.004	0.89 (0.83-0.96)	<0.0001
Atrial Flutter	6652 (4.2%)	200 (5.1%)	1.223 (1.06-1.41)	0.007	0.91 (0.77-1.07)	0.24
Third degree heart block	14750 (9.4%)	535 (13.7%)	1.54 (1.39-1.69)	<0.0001	1.22 (1.10-1.35)	<0.0001
Sick Sinus	4630 (2.9%)	115 (3.0%)	1.00 (0.83-1.21)	0.971	0.95 (0.77-1.17)	0.62
Ventricular Tachycardia	5341 (3.4%)	430 (11.0%)	3.52 (3.18-3.91)	<0.0001	2.12 (1.88-2.40)	<0.0001
Mitral Stenosis	99015 (63.0%)	1709 (43.8%)	0.458 (0.43-0.49)	<0.0001	0.65 (0.55-0.76)	<0.0001
CAD	106172 (67.6%)	1919 (49.2%)	0.46 (0.44-0.49)	<0.0001	0.99 (0.84-1.16)	0.85
STEMI	324 (0.2%)	105 (2.7%)	13.39 (10.72-16.73)	<0.0001	7.38 (5.53-9.84)	<0.0001
Stroke	5945 (3.8%)	376 (9.6%)	2.71 (2.43-3.03)	<0.0001	2.25 (1.99-2.54)	<0.0001
Syncope	1414 (0.9%)	25 (0.6%)	0.71 (0.48-1.06)	0.11	0.87 (0.58-1.30)	0.5
Infective Endocarditis	110 (0.1%)	30 (0.8%)	11.07 (7.38-16.59)	<0.0001	5.74 (3.65-9.02)	<0.0001

* Adjustment was done based on age, sex, race, primary payer, hemodialysis, hypertension, immunocompromised, peripheral vascular disease, mediastinal radiation, family history of CAD, obstructive sleep apnea, liver disease, drug abuse, pneumonia, smoking, prior PCI, prior CABG, prior MI, cardiogenic shock, atrial fibrillation, atrial flutter, heart block, sick sinus. Ventricular tachycardia, aortic stenosis, mitral stenosis, CAD, STEMI, stroke, syncope, endocarditis.

of the procedure such as procedural acuity and non-femoral access sites to identify the risk of post-procedure mortality.[2,6–8] There has been no concrete large scale evidence to identify the association of all potential predictors of TAVI-related mortality. Using the prespecified variables of the STS score, the present study has systematically determined the association of 30 comorbidities with the TAVI-related in-hospital mortality. The observed crude unadjusted estimates were adjusted for potential confounders such as baseline comorbidities and varying demographics of the included population.

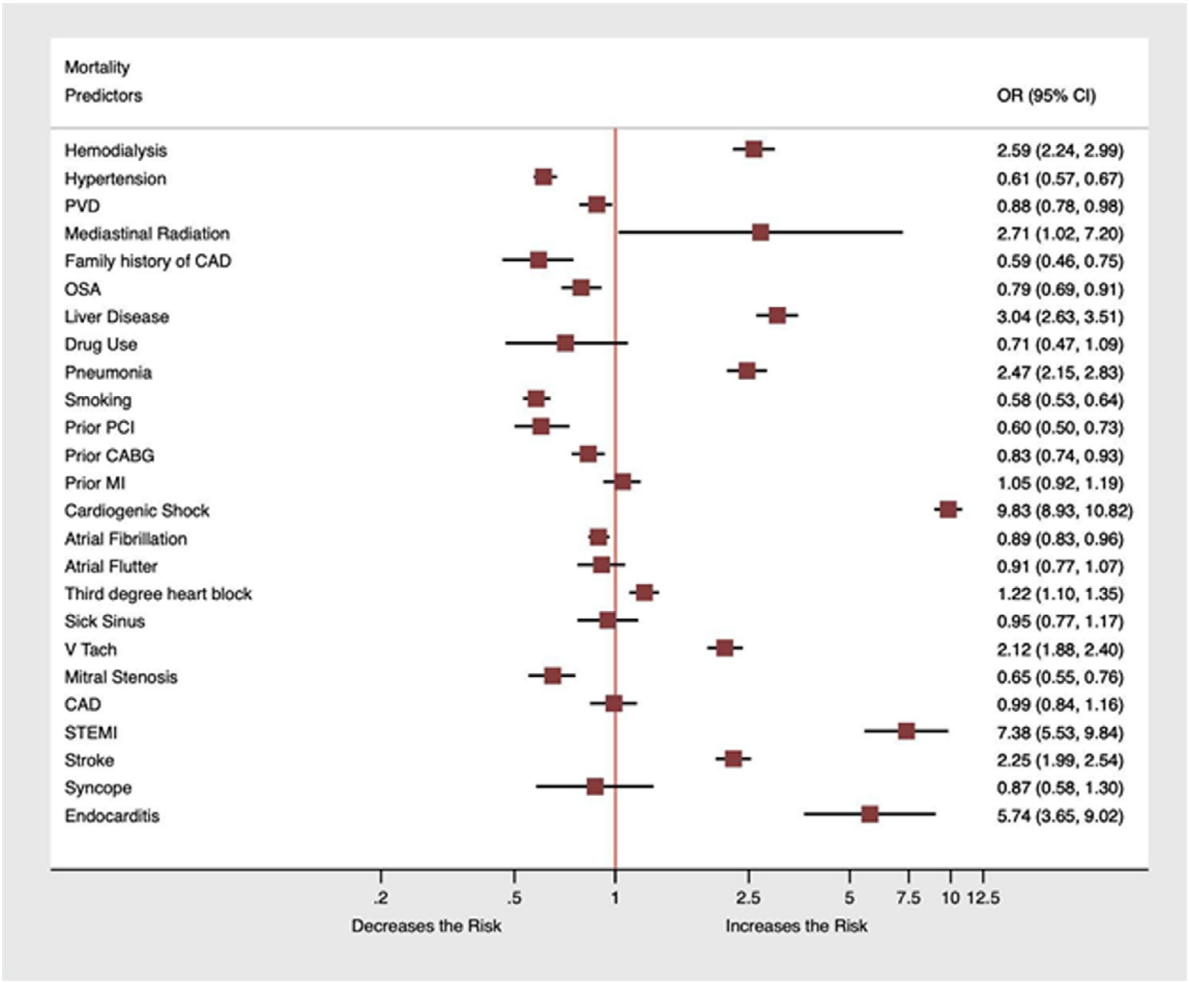

Figure 3. Forest plot showing adjusted odds of predictors of in-hospital mortality in patients undergoing TAVI.

Our study revealed that dialysis-dependent renal failure was associated with 2.5 times higher odds of in-hospital mortality. These findings were in line with previous studies, which has also demonstrated a higher rate of in-hospital mortality and major adverse cardiovascular events in patients with ESRD.[13] Similarly, patients with periprocedural infective endocarditis, STEMI and cardiogenic shock were found to have a 5, 7, and 9 fold higher adjusted odds of TAVI-related mortality. It is important to note that the landmark PARTNER trial which primarily included high-risk patients with symptomatic severe AS and predictive operative mortality of >15%, had excluded all patients with ESRD, STEMI, infective endocarditis and hemodynamic instability.[14] This injudicious utilization of TAVI procedure in the said high-risk populations partly explains the overall rising trend of TAVI-related in-hospital mortality. Although TAVI is not contraindicated in patients with a previous history of mediastinal radiation and liver disease, our study demonstrated a 3-fold increase in the adjusted odds of mortality in these patients. Together, these findings underscore the importance of consideration of baseline comorbidities while evaluating TAVI candidates.

In our study, some of the components of STS had negative or no impact on TAVI related mortality. Patients with a concomitant diagnosis of AF, PVD, prior CABG and history of PCI had 11%, 12%, 17%, and 40% lower odds of TAVI related mortality. One can speculate that these patients were more likely on anticoagulant or antiplatelet medications, putting them at a lower risk of post-TAVI thrombotic complications and lower mortality. However, large scale randomized studies are needed to validate these findings. The current results should not be used as a tool to identify candidates for TAVI; rather, they underscore the need to optimize pre-TAVI comorbidities when feasible, and to be cognizant of their implications on mortality. With the recent advancements in TAVI technology and the liberalization of procedural indications to low-risk populations, new risk assessment models are needed to yield valuable information about the evolving clinical profile of patients undergoing TAVI.

Due to the inherent limitations of cross-sectional data, we could only report the temporal associations and no definitive conclusions regarding the causality of outcomes could be made. Due to the unavailability of ICD-codes, we could not perform a subgroup analysis based on the type of valves or the TAVI procedure access. Similarly, we could not calculate the STS score for individual cases as NIS lacks data on medications and laboratory investigations.

Although our study adjusts for numerous potential confounders, the impact of unknown and unmeasurable covariates could not be determined. Using data taken entirely from the NIS and due to the lack of patient-level prospective data, the selected associations may not include covariates that might have eventually influenced mortality. Lack of information regarding medication use and metrics to assess the severity of the AS such as the NYHA class or Syntax score precluded further individualized risk assessment. Similarly, quality-of-life measures such as the Kansas City Cardiomyopathy Questionnaire and frailty indices such as the 5-m walk test of gait speed were unavailable in NIS, precluding inclusion in the adjustment variables. A larger-scale study of a randomized population followed up on the prospective scale is needed to validate our findings and to identify more objective measures to determine the risk of mortality in patients undergoing TAVI.

The utilization of the TAVI procedure has increased over the years and so has the associated mortality. Of all the STS components, hemodialysis, ventricular tachycardia, infective endocarditis, pneumonia, liver disease, STEMI, complete heart block and cardiogenic shock were associated with high in-hospital mortality in patients undergoing TAVI.

Authors' Contributions

Waqas Ullah MD: conceptualization, methodology, formal analysis, writing - review & editing; Salman Zahid MD: data curation; Ihab Hamzeh: validation, editing; Yochai Birnbaum: project administration, editing; Salim S. Virani: visualization and supervision; Mahboob Alam: critical review and supervision.

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.2020.12.031.

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