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Contemporary trends and outcomes in aortic valve replacement in patients with end-stage liver disease

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Abstract

Objective: Even in high-risk trials pertaining to transcatheter aortic valve replacement (TAVR), patients with end-stage liver disease (ESLD) have been under-represented. We sought to study this population group from a large national United States population database.

Methods: We used National Inpatient Sample (NIS) database from January 2005 to August 2015. Patients with ESLD were extracted using Goldberg's algorithm. Propensity match analysis was done for comparative analysis between surgical aortic valve replacement (SAVR) and TAVR groups. Logistic regression analysis was used for predictors of in-hospital mortality.

Results: Out of 309,959 ESLD patients, 1,375 underwent aortic valve replacement and 1,199 patients were included in our study. Mean age was 66.1 (*SD*, 9.1) years. In matched data, the in-hospital mortality was 5.5% in TAVR group when compared to 19.4% in SAVR group. Ventilator use (16.1 vs. 27.2%, $p < .01$), tracheostomy (<4 vs. 7.2%, $p < .01$), and vasopressin use (0 vs. 7.4%, $p < .01$) were utilized less in TAVR group as compared to SAVR group. The proportion of TAVR has increased from almost zero in 2011 to 51.3% in 2015. Mean cost for hospital stay has increased in SAVR group (from 254,427\$ in 2005 to 321,791\$ in 2015, $p < .01$). Similarly, a large decrease in length of stay has been observed for TAVR group (14.5 days in 2011 to 5.4 days in 2015, $p < .01$). TAVR (odds ratios [OR]: 0.42, 95% confidence interval [CI]: 0.20–0.87, $p = .02$) was associated with lower in-hospital mortality.

Conclusion: TAVR was associated with lower in-hospital mortality, morbidity, and resource utilization in high-risk ESLD patients.

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CONFLICT OF INTERESTS

The authors declare no conflicts of interest.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

Keywords

end-stage liver disease; outcomes; surgical aortic valve replacement; transcatheter aortic valve replacement

1 | INTRODUCTION

With the widespread availability and utilization of transcatheter valve replacement (TAVR), there has been a paradigm shift in treatment of aortic stenosis.¹ While TAVR is now well established for high-risk aortic valve replacement (AVR), recent randomized trials^{2,3} even favor TAVR in low risk patients.⁴ Despite having a significant burden of patients with advanced liver disease and coexisting aortic valve stenosis, current risk prediction models such as Society of Thoracic Surgeons (STS) risk score (lack criteria to include this high-risk population. Previously reported studies have analyzed patients with cirrhosis;^{5–8} however, there is paucity of data on utilization and clinical outcome of TAVR and surgical aortic valve replacement (SAVR) in population with end-stage liver disease (ESLD).⁷ The objectives of our study are to evaluate contemporary trends in patients with ESLD undergoing TAVR or SAVR by incorporating a well-validated definition⁹ of patients with ESLD in our analysis.

2 | METHODS

2.1 | Study data

National Inpatient Sample (NIS) was used. NIS is part of Healthcare Cost and Utilization Project (HCUP) databases and is made possible by a Federal-State-Industry partnership sponsored by the Agency for Healthcare Research and Quality (AHRQ). The NIS is derived from all states for national estimates of healthcare utilization, costs, and outcomes.¹⁰ Since NIS is compiled annually, the data can be used for analysis of disease trends over time. Institutional Review Board approval and informed consents were not required for this study given the deidentified nature of the NIS database and public availability.

2.2 | Study population and design

We analyzed NIS data from January 2005 to August 2015 using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes. For better comparable groups between TAVR and SAVR, young patients (patients <50 years) were excluded. ESLD is defined as patients with cirrhosis having an acute decompensating event like clinical ascites, variceal hemorrhage, hepatic encephalopathy, or renal impairment. Patients with ESLD were identified using ICD-9 codes of Goldberg's third algorithm,⁹ a well-validated method for identifying ESLD from administrative datasets, generating a positive predictive value of cirrhosis, ESLD, and hepatic decompensation event at 93.9, 89.8, and 82.3% respectively. First, ICD-9-CM codes were used to select chronic liver disease (070.20–21, 070.23, 070.30–33, 070.40, 070.42, 070.49, 070.52, 070.59–60, 070.70–71, 070.90, 571.1, 571.40–41, 571.8, and 571.9), then a concurrent diagnosis code of cirrhosis was added (571.2, 571.5, or 571.6) and finally at least one concurrent diagnostic code of hepatic decompensating defining event was added (456.0, 456.20 for esophageal varices with bleeding; 456.1, 456.21 for esophageal varices without bleeding; 789.5, 789.59 for

ascites; 572.2 for hepatic coma, 567.0, 567.2, 567.21, 567.21, 567.29, 567.8, 567.89, 567.9 for peritonitis; or 572.4 for hepatorenal syndrome). Hepatic decompensating event was defined as per American Association for the Study of Liver Diseases (AASLD).¹¹ Given there are no validated data extraction designs for ICD-10 codes, the available NIS data for year 2016 was not used. Patients with ESLD were grouped into two cohorts of patients, who underwent TAVR (ICD-9-CM codes 35.05 and 35.06) or SAVR (ICD-9 CM codes 35.21 and 35.22) (Figure 1). Baseline characteristics of patients undergoing TAVR and SAVR with ESLD along with hospital outcomes were derived (Table 1).

2.3 | Study end points

The primary end point of the study was in-hospital mortality. Secondary end points were discharge disposition, length of stay, and cost of stay.

2.4 | Statistical analysis

Descriptive statistics were presented as frequencies with percentages for categorical variables and as means with standard deviations for continuous variables. Baseline characteristics were compared using a Pearson's chi-squared test and Fisher's exact test (when output was expected to be <5) for categorical variables and independent samples *t* test for continuous variables. Linear regression was done for trends where appropriate. Trends; including length of stay and cost were calculated in the overall cohort given the smaller data size in matched cohort. To account for potential confounding factors and selection bias, a propensity score-matching model was developed using logistic regression to derive two matched groups for comparative outcome analysis. Given larger SAVR group and to minimize losses, a nearest neighbor 1:2 variable ratio, parallel, balanced propensity-matching model was made using a caliper width of *SD* 0.2. Univariate (multivariable), single step, logistic regression was performed to estimate odds ratios (ORs) with 95% confidence intervals (CIs) to determine predictors for in-hospital mortality in AVR in ESLD. Chi-square test was used for regression model testing. A type I error rate of <0.05 was considered statistically significant. All statistical analyses were performed using statistical package for social science (SPSS) version 26 (IBM Corp) and R 3.5 for propensity matching using "MatchIt" package.

3 | RESULTS

3.1 | Outcomes in TAVR as compared to SAVR in match and unmatched cohort

A total of 1,199 patients with either TAVR or SAVR were identified. Baseline characteristics of the study population are shown in Table 1. Mean age was 66.1 (*SD*, 9.1) years. Mean age for TAVR was 1.7 years greater than SAVR. Of these, 28.4% patients were women: 83.3% were Caucasian, 1.8% were African American, and 10.7% were Hispanics. Crude in-hospital mortality was 6.7% in TAVR group and 18.7% in SAVR group (Table 2). After 2:1 propensity matching 404 patients in SAVR group were matched to 273 patients in TAVR group. Baseline characteristics after propensity score matching are shown in supplementary. In matched data, the in-hospital mortality was 5.5% in TAVR group as compared to 19.4% in SAVR group. TAVR had significantly superior outcomes in several major matrices

including discharge disposition to self-care, hospital length of stay, cost of stay as well as less complications of myocardial infarction and dialysis-dependent renal failure (Table 3).

3.2 | Trends in in-hospital mortality in SAVR and TAVR

In-hospital mortality has decreased over the years (see Figure 2). The use of SAVR has gradually decreased over time. The proportion of TAVR in AVR has increased from almost zero in 2011 to 51.3% in 2015 (Figure 3a), noting that TAVR was commercially available in USA after August 2011. In-hospital mortality in SAVR group has decreased from 29.2% in 2005 to 26.3%. The in-hospital mortality in TAVR group has fluctuated over the years but has decreased rapidly since 2013, such that in-hospital mortality was zero in 2014 and 2015 from 27.3% in 2013. The overall in-hospital mortality in combined SAVR and TAVR has decreased from 29.2 to 12.8%. The number of AVR procedures has gone up especially since introduction of TAVR (Figure 3b).

3.3 | Trends in resource utilization and cost

There has been increase trend in mean cost for hospital stay over the years, this cost has increased in SAVR group (from 254,427\$ in 2005 to 321,791\$ in 2015) but decreased in TAVR group (from 313,116\$ in 2012 to 228,096\$ in 2015) (Figure 4a). Similarly, a large decrease in length of stay has been seen for TAVR group (14.5 days in 2011 to 5.4 days in 2015). In SAVR group the length of stay has initially decreased and then somewhat plateaued (24.9 days in 2005 to 17.5 days in 2011, and then to 17.1 days in 2015) (Figure 4b).

3.4 | Predictor for in-hospital mortality in AVR

Predictors of in-hospital mortality for patients with ESLD undergoing AVR are shown in Figure 5. TAVR (OR: 0.42[95% CI: 0.20–0.87], $p = .02$) and recent year of procedure (OR: 0.87[95% CI: 0.81–0.93], $p < .01$) was associated with lower in-hospital mortality. While female gender (OR: 2.79 [95% CI: 1.72–4.55], $p = .01$), diabetes (OR: 1.92 [95% CI: 1.13–3.24], $p = .02$). Renal failure (OR: 3.74 [95% CI: 2.23–6.28], $p < .01$) were associated with high in-hospital mortality.

4 | DISCUSSION

In our analysis from the NIS including data till 2015, we found that utilization of TAVR as compared to SAVR in patients with aortic stenosis and ESLD has increased significantly. We found that from 2011 to 2015, utilization of TAVR increased from nonexistent to 50% of all AVR in this population. We also found that in propensity matched cohorts, in comparison to TAVR, patients undergoing SAVR had a 3.5 times higher in-hospital mortality. Similarly, length of stay was longer and cost was higher for patients undergoing SAVR as compared TAVR. There was a significant reduction in post procedure complications such as dialysis dependent renal failure, red blood cell transfusion, and myocardial infarction in TAVR group as compared to SAVR group.

ESLD has a major impact on post cardiac surgical morbidity and mortality; however, current STS predicted risk calculation may underestimate risk of aortic valve surgery in this

population as it does not incorporate underlying liver disease in the calculator. Thielmann et al¹² report the model for end-stage liver disease (MELD) score as a more reliable predictor of mortality in patients with liver disease undergoing cardiac surgery as compared to Child-Pugh and EuroSCORE. Thielmann et al¹³ have compared prediction tools in patients with chronic liver disease undergoing TAVR and found MELD-XI a more accurate predictor of mortality compared to STS, EuroSCORE, and EuroSCORE II.

In our study, several predictors of in-hospital mortality in ESLD patients undergoing AVR were identified including renal failure, diabetes, and female gender. Our results are consistent with previous studies^{5,7,8} that evaluated outcomes in cirrhotic patients, however, we are the first study to report these findings through a well-validated algorithm for ESLD⁹ and confirm significant complications with SAVR as compared to TAVR. Findings from Reference 6 reported no increase in risk of in-hospital mortality for cirrhotic patients undergoing TAVR, however, it lacked a comparative analysis with SAVR. Reference 7 analyzed NIS data from 2003 to 2014 and concluded that overtime there was a threefold increase in cirrhotic patients undergoing AVR. Their analysis showed a twofold increase in in-hospital mortality for SAVR as compared with TAVR, which is lower than our analysis though we included a larger sample size and validated data.

Although TAVR is now considered standard of care in patients with prohibitive surgical risk, patients with chronic liver disease have been under-represented in these high-risk randomized trials.¹⁴⁻¹⁸ In comparison with TAVR, SAVR was associated with increased procedural related morbidities. A recent pooled analysis¹⁹ of clinical outcomes found significantly lower odds of in-hospital, blood transfusion and periprocedural hospital length of stay, reduced cost of hospitalization, and reduced acute kidney injury in TAVR as compared to SAVR in patients with cirrhosis.

Several factors both intrinsic and extrinsic likely contributed to lower complications and morbidity in patients undergoing TAVR with underlying chronic liver disease including less invasive nature, early mobilization, reduced mechanical ventilation, and bleeding. This translates into a lower hospital length of stay, lower cost, as well as lower complication rate. Since patients with ESLD are at high-risk of postoperative complications due to several pathophysiological factors²⁰ including coagulopathy, increased risk of infection, fluid and electrolyte shifts, with limited respiratory and renal reserve, they are very likely to benefit from less invasive option provided by TAVR.²¹⁻²³ Therefore, in conclusion, our study supports TAVR is a safe option and a viable treatment options for aortic valve stenosis in patients with ESLD.

Our study has several limitations. NIS is an administrative claim-based database that uses ICD-9-CM codes for diagnosis that may be subject to error. Use of ICD insurance-based administrative data have validity issues, however, this study is based upon highly validated data.⁹ NIS collects data on in-patient discharges and each admission is registered as an independent event. NIS samples are not designed to follow patients longitudinally so long-term outcomes could not be assessed from the present data set. Like any retrospective database study association does not mean causation and conclusion should be drawn cautiously. We used propensity match analysis to equally match both the cohorts; however,

residual confounding cannot be ruled out entirely with certainty. For example, we did not match for calendar year, given small data size selected variables of clinical significance were chosen for propensity matching. Similarly, ICD-9 codes do not differentiate between nature of implanted surgical aortic valve (metallic or biological). We did not include data from available NIS 2016 due to lack of validation of ICD-10 for ESLD. Also, various models that are currently utilized in prognostication of patients with ESLD such as MELD score and Child-Pugh score could not be computed from present dataset. ESLD is a known risk factor for worsened mortality in patients with infective endocarditis (IE). These patients are usually managed with SAVR provided they are candidates for such procedure. Increase mortality in SAVR group may in part be related to high prevalence of IE in this cohort. Unfortunately, data on IE were not readily available from NIS so we were unable to assess this important disease entity for our multivariate analysis.

5 | CONCLUSION

In summary, TAVR appears to be a safe procedure in ESLD and is associated with lower in-hospital mortality, morbidity, length of stay, and health care cost as compared to SAVR.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Abbreviations:

AHRQ	Agency for Healthcare Research and Quality
AVR	aortic valve replacement
ESLD	end-stage liver disease
HCUP	Healthcare Cost and Utilization Project
ICD-9-CM	International Classification of Diseases, Ninth revision, Clinical Modification
NIS	National Inpatient Sample
SAVR	surgical aortic valve replacement
TAVR	transcatheter aortic valve replacement

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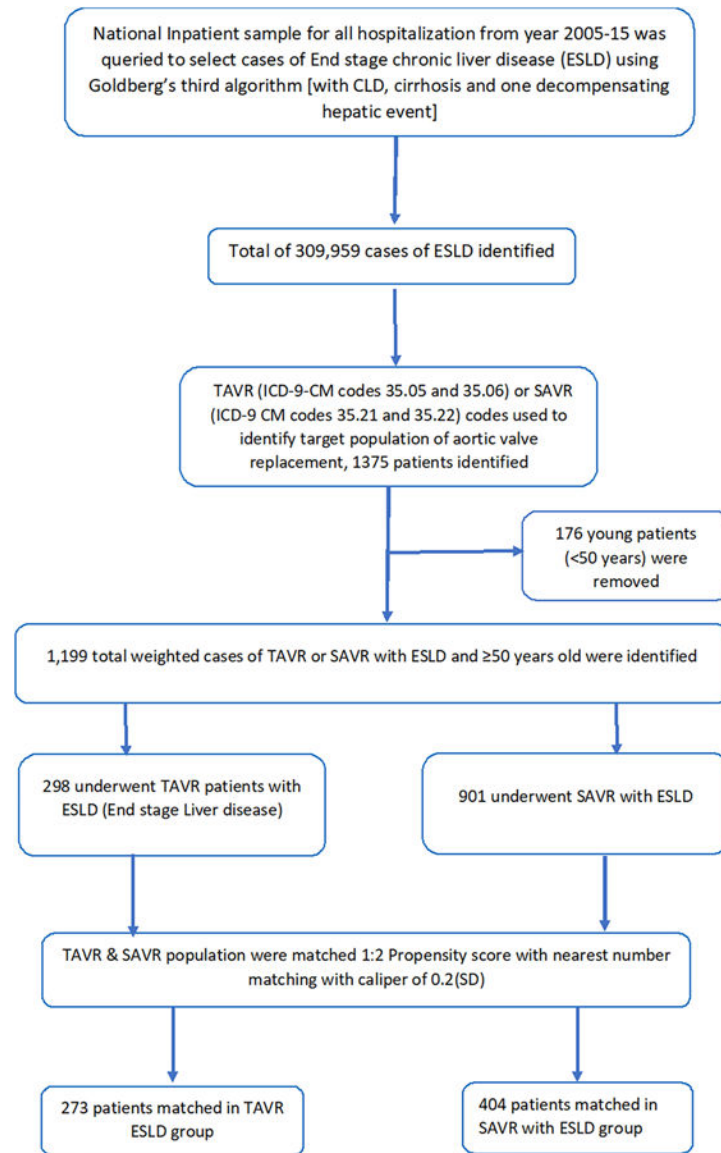


FIGURE 1. Flow sheet [Color figure can be viewed at wileyonlinelibrary.com]

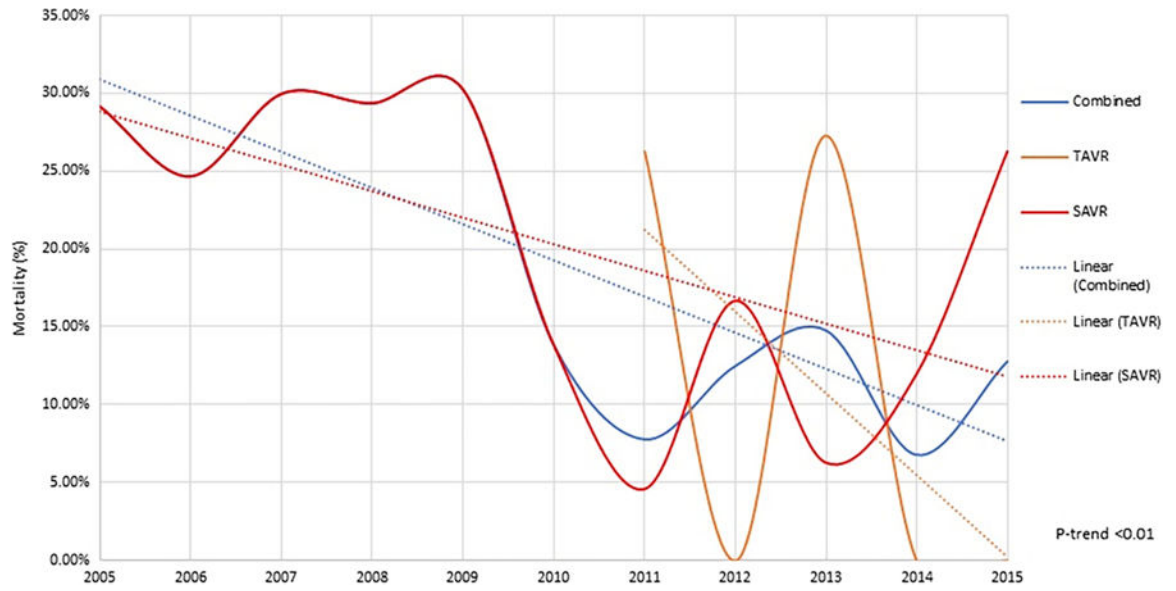


FIGURE 2. In-hospital mortality trends in patients of ESLD undergoing aortic valve replacement. ESLD, end-stage liver disease [Color figure can be viewed at wileyonlinelibrary.com]

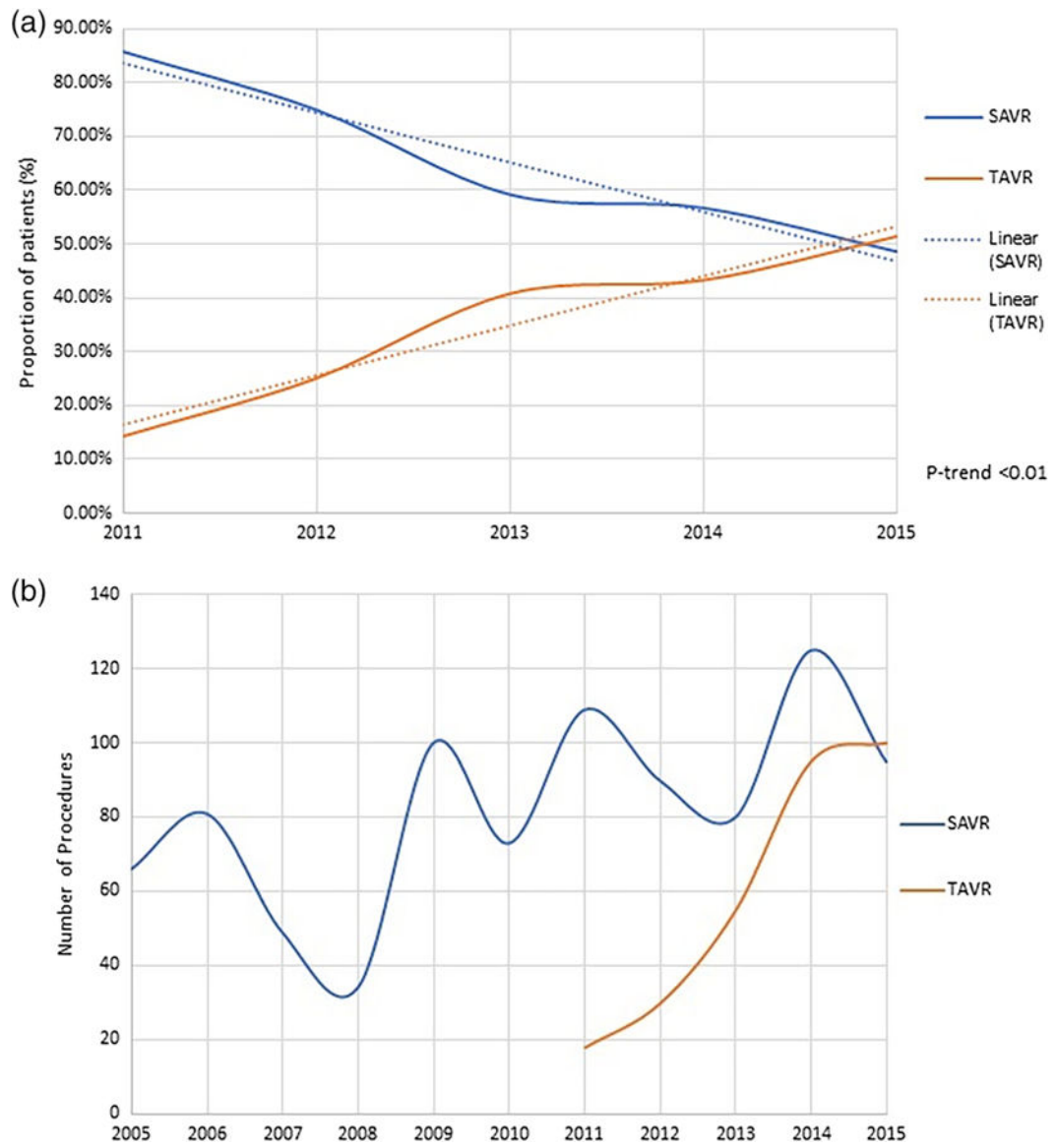


FIGURE 3. (a) Trends in aortic valve replacement in ESLD and (b) number of aortic valve replacements in ESLD. ESLD, end-stage liver disease [Color figure can be viewed at wileyonlinelibrary.com]



FIGURE 4. (a) Length of stay in aortic valve replacement and (b) cost of stay in aortic valve replacement [Color figure can be viewed at wileyonlinelibrary.com]

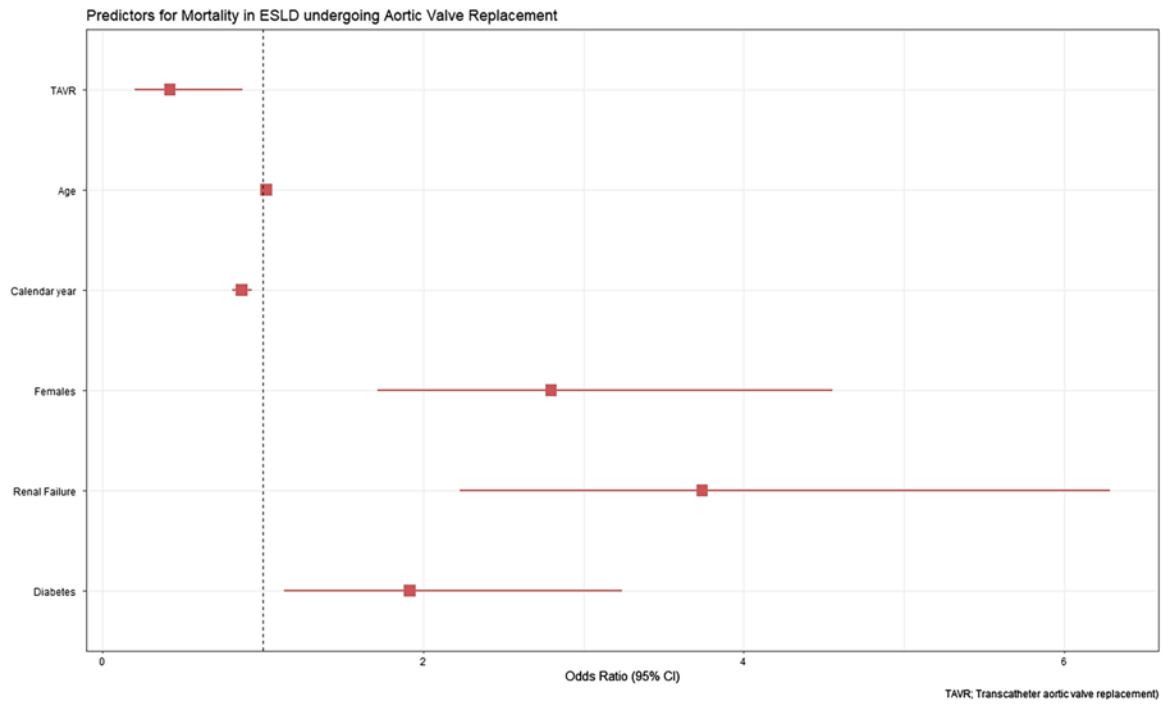


FIGURE 5. Predictors for in-hospital mortality in end-stage liver disease undergoing aortic valve replacement [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1

Baseline characteristics of the study population

Variable	TAVR (n = 298)	SAVR (n = 901)	All ESLD (n = 1,199)	p value
Age (mean [SD]) years	67.4 (8.6)	65.7 (9.3)	66.1 (9.1)	<.01
Female	85 (28.4%)	256 (28.4%)	341 (28.4%)	.98
Race				
Caucasian	258 (92.8%)	667 (80.1%)	925 (83.3%)	<.01
African American	<11 (3.5%)	<11 (<1.2%)	20 (1.8%)	
Hispanics	<11 (3.5%)	109 (13.1%)	119 (10.7%)	
Asian or Pacific Islander	0	15 (1.8%)	15 (1.4%)	
AHRQ medical comorbidity				
Alcohol abuse	40 (13.4%)	246 (27.3%)	286 (23.8%)	<.01
Anemia	15 (5%)	19 (2.1%)	34 (2.8%)	<.01
Collagen vascular diseases	<11 (<3.5%)	12 (1.3%)	22 (1.8%)	<.01
Congestive heart failure	25 (8.4%)	34 (3.8%)	59 (4.9%)	<.01
Chronic pulmonary disease	89 (29.8%)	231 (25.6%)	320 (26.6%)	.16
Coagulopathy	194 (64.9%)	557 (61.8%)	751 (62.5%)	.32
Diabetes	145 (48.5%)	251 (27.9%)	396 (33.0%)	<.01
Hypertension	145 (48.5%)	251 (27.9%)	396 (33.0%)	<.01
Fluid and electrolyte disorders	104 (34.9%)	422 (46.8%)	526 (43.9%)	<.01
Metastatic cancer	0	<11 (<1.2%)	<11 (<1.2%)	<.01
Neurological disorders	<11 (3.5%)	30 (3.3%)	40 (3.3%)	<.01
Peripheral vascular disorders	55 (18.5%)	113 (12.5%)	168 (14.0%)	<.01
Renal failure	95 (31.8%)	164 (18.2%)	259 (21.6%)	<.01
Solid tumor without metastasis	25 (8.4%)	35 (3.9%)	60 (5.0%)	<.01
Hospital location				
Rural	0	25 (2.8%)	25 (2.1%)	<.01
Urban nonteaching	<11 (3.5%)	203 (22.5%)	213 (17.8%)	
Urban teaching	288 (96.6%)	673 (74.7%)	961 (80.2%)	
Bed size of the hospital				
Small	20 (6.7%)	34 (3.8%)	54 (4.5%)	<.01
Medium	60 (20.1%)	131 (14.5%)	191 (15.9%)	

Variable	TAVR (n = 298)	SAVR (n = 901)	All ESLD (n = 1,199)	p value
Large	218 (73.2%)	737 (81.7%)	955 (79.6%)	
Region (%)				
Northeast	74 (24.7%)	290 (32.2%)	364 (30.3%)	<.01
Midwest	80 (26.8%)	372 (41.2%)	452 (37.6%)	
South	90 (30.1%)	155 (17.2%)	245 (20.4%)	
West	55 (18.4%)	85 (9.4%)	140 (11.7%)	
Median household income percentile				
0–25th	45 (15.1%)	164 (19.0%)	209 (18.0%)	.02
26–50th	110 (36.8%)	236 (27.3%)	346 (29.8%)	
51–75th	70 (23.4%)	233 (27.0%)	303 (26.1%)	
76–100th	74 (24.7%)	231 (26.7%)	305 (26.2%)	

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; ESLD, end-stage liver disease; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement.

TABLE 2

Hospital encounter outcomes and resource utilization of the study cohort

Variables	TAVR (n = 298)	SAVR (n = 901)	All ESLD (n = 1,199)	p value
Died at discharge	20 (6.70%)	169 (18.7%)	189 (15.70%)	<.01
Discharge disposition of surviving patients				
Routine/self-care	135 (48.4%)	158 (21.6%)	293 (29.0%)	<.01
Short-term hospital	0	15 (2.0%)	15 (1.5%)	
Another type of facility	45 (16.1%)	273 (37.2%)	318 (31.4%)	
Home health care	99 (35.5%)	287 (39.2%)	386 (38.1%)	
Resource utilization, mean (SD)				
Length of stay, mean (SD), days	8.6 (8.0)	19.7 (14.9)	16.9 (14.4)	<.01
Cost of hospitalization-mean (SD), \$	241,666 (125,290)	299,993 (242,087)	285,483 (220,331)	<.01
Procedures during stay				
Acute myocardial infraction	<11 (3.5%)	58 (6.4%)	63 (5.3%)	<.01
Atrial fibrillation	94 (31.5%)	434 (48.2%)	528 (44.0%)	<.01
Cardiac arrest	<11 (3.5%)	30 (3.3%)	35 (2.9%)	.14
Cardiogenic shock	20 (6.7%)	31 (3.4%)	51 (4.2%)	.02
Gastrostomy	<11 (3.5%)	20 (2.2%)	30 (2.5%)	.27
Left heart catheterization	94 (31.5%)	434 (48.2%)	528 (44.0%)	<.01
Per cutaneous coronary intervention	<11 (3.5%)	<11 (<1.2%)	15 (1.3%)	.44
Hemodialysis	0	85 (9.4%)	85 (7.1%)	<.01
Hepatorenal syndrome	<11 (3.5%)	88 (9.8%)	93 (7.8%)	<.01
Hyponatremia	40 (13.4%)	179 (19.8%)	219 (18.3%)	.01
Septic shock	<11 (3.5%)	69 (7.6%)	74 (6.2%)	<.01
Stroke	15 (5.0%)	90 (10.0%)	105 (8.7%)	<.01
Vasopressin use	0	45 (5.0%)	45 (3.8%)	<.01
Tracheostomy	<11 (3.5%)	68 (7.5%)	73 (6.1%)	<.01
Red blood cells transfusion	55 (18.4%)	410 (45.5%)	465 (38.7%)	<.01
Ventilator	49 (16.4%)	219 (24.3%)	268 (22.3%)	<.01

Abbreviations: ESLD, end-stage liver disease; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement.

TABLE 3

Outcomes and resource utilization after 1:2 propensity match in ESLD

Variables	TAVR (n = 273)	SAVR (n = 404)	p value
Died at discharge	15 (5.5%)	78 (19.4%)	<.01
Discharge disposition of surviving patients			
Routine/self-care	125 (48.3%)	44 (13.5%)	<.01
Another type of facility	45 (17.4%)	118 (36.3%)	
Home health care	89 (34.4%)	163 (50.2%)	
Resource utilization, mean (SD)			
Length of stay, mean (SD), days	9.0 (8.3)	20.0 (16.1)	<.01
Cost of hospitalization-mean (SD), \$	248,989 (126,068)	312,839 (255,856)	<.01
Procedures during stay			
Acute myocardial infarction	<11 (<2%)	35 (8.7%)	<.01
Atrial fibrillation	84 (30.8%)	210 (52.1%)	<.01
Cardiac arrest	5 (1.8%)	20 (5.0%)	.04
Cardiogenic shock	20 (7.3%)	20 (5.0%)	<.01
Left heart catheterization	58 (21.2%)	120 (29.8%)	.01
Per cutaneous coronary intervention	<11 (<2%)	<11 (<2%)	.5
Hemodialysis	0	50 (12.4%)	<.01
Hepatorenal syndrome	<11 (<2%)	29 (7.2%)	<.01
Vasopressin use	0	30 (7.4%)	<.01
Tracheostomy	<11 (<2%)	29 (7.2%)	<.01
Red blood cells transfusion	55 (20.1%)	185 (45.9%)	<.01
Ventilator	44 (16.1%)	110 (27.2%)	<.01

Abbreviations: ESLD, end-stage liver disease; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement.