In-Hospital Outcomes of Left Ventricular Assist Device Implantation and Concomitant Valvular Surgery

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Valvular heart disease is common among left ventricular assist device (LVAD) recipients. However, its management at the time of LVAD implantation remains controversial. Patients who underwent LVAD implantation and concomitant aortic (AVR), mitral (MVR), or tricuspid valve (TVR) repair or replacement from 2010 to 2017 were identified using the national inpatient sample. End points were in-hospital outcomes, length of stay, and cost. Procedure-related complications were identified via ICD-9 and ICD-10 coding and analysis was performed via mixed effect models. A total of 25,171 weighted adults underwent LVAD implantation without valvular surgery, 1,329 had isolated TVR, 1,021 AVR, 377 MVR, and 615 had combined valvular surgery (411 had TVR + AVR, 115 TVR + MVR, 62 AVR + MVR, 25 AVR + MVR + TVR). During the study period, rates of AVR decreased and combined valvular surgeries increased. Patients who underwent TVR or combined valvular surgery had overall higher burden of co-morbidities than LVAD recipients with or without other valvular procedures. Postoperative bleeding was higher with AVR whereas acute kidney injury requiring dialysis was higher with TVR or combined valvular surgery. In-hospital mortality was higher with AVR, MVR, or combined surgery without differences in the rates of stroke. Length of stay did not differ significantly among groups but cost of hospitalization and nonroutine discharge rates were higher for cases of TVR and combined surgery. Approximately 1 in 9 LVAD recipients underwent concomitant valvular surgery and TVR was the most frequently performed procedure. In-hospital mortality and cost were lower among those who did not undergo valvular surgery. **(Am J Cardiol 2020;132:87−92)**

The implantation of axial or centrifugal flow durable left ventricular assist devices (LVAD) for either bridge to transplant or destination therapy, improves survival, rates of transplantation, and functional status among end-stage heart failure patients.[1] LVAD recipients often have valvular disease which may affect postoperative outcomes. However, the decision to intervene on a cardiac valve at the time of LVAD implantation remains controversial as it increases complexity of surgery and leads to prolonged cardiopulmonary bypass time.[2] Tricuspid and aortic valve surgeries are the most common concomitant procedures at the time of LVAD implantation. Although, earlier retrospective studies[2] showed that any valvular procedure increases mortality at the time of LVAD implantation, more recent studies did not suggest higher mortality with concomitant valvular surgeries.[3,4] In fact, emerging data suggest that concomitant tricuspid valve repair (TVR) and mitral valve repair (MVR) may improve hemodynamics and symptoms.[5−7] In view of the previously published data, we sought to analyze the trends of concomitant valvular surgeries and their impact on in-hospital outcomes and health care utilization after LVAD implantation, based on data from a nationally representative sample. Unlike, previous reports from the Interagency Registry for Mechanically Assisted Circulatory Support database (INTERMACS), our analysis focuses on trends, in-hospital outcomes and complications.

Methods

Patients who underwent LVAD implantation and concomitant aortic (AVR), mitral (MVR), or tricuspid valve (TVR) repair or replacement from 2010 to 2017 were identified using the national inpatient sample. The national inpatient sample database represents a sample of 20% of all inpatient discharges across different hospitals, including patients and hospital-level characteristics, mortality, in-hospital complications, and healthcare utilization information. Recently, the AHRQ has issued a change in the national inpatient sample design and how patient discharges are weighed to provide closer national estimates when performing trend analysis.[8,9] For the purpose of this analysis, we used NIS data from the beginning of 2010 to December 2017 and excluded patients with LVADs before 2010 because over 90% of implanted devices have been continuous-flow LVADs since 2010.[10] Since the national inpatient sample is a publicly accessed database, this study was exempted from the institutional review board.

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First, patients who underwent LVAD implantation were identified using the international classification of diseases, ninth revision, clinical modification (ICD-9-CM) of "37.66" and ICD-10 code "02HA0QZ." Second, among those patients, we identified patients with concomitant tricuspid valvuloplasty/replacement (35.14, 35.27, 35.28, 02NJxx, 027Jxx, 02QJxx, 02RJxx, 027Jxx), mitral valvuloplasty/replacement (35.12, 35.22, 35.23, 35.24, 02NGxx, 027Gxx, 02QGxx, 02VGxx, 02RGxx, 027Gxx), aortic valvuloplasty/replacement (35.11, 35.21, 02NFxx, 027Fxx, 02QFxx, 02RFxx, 02RF3xx, X2RF3xx, 02RF0xx, 02RF4xx, X2RF0xx). Patients less than 18 years, and those with missing outcomes, age, or gender were excluded from the analysis. We used a validated methodology devised by Quan et al by utilizing the coding algorithms to defining the co-morbidities in ICD-9 and ICD-10 administrative data.[11] The codes were used to calculate the Elixhauser comorbidity index.

The primary comparison groups were patients who underwent LVAD implantation without valvular surgery, LVAD with isolated AVR, MVR, TVR, or combined valvular surgery. Our main outcome was in-hospital mortality. Other outcomes included stroke, postoperative hemorrhage requiring transfusion, gastrointestinal bleeding, intracranial bleeding, infectious complications, respiratory complications, acute kidney injury leading to hemodialysis, pericardial effusion/tamponade, length of stay, total cost, and disposition (routine discharge, discharge to skilled nursing facility, or home health care). To calculate estimated cost, the national inpatient sample data were combined with cost-to-charge ratios available from the Healthcare Cost and Utilization Project. We estimated the cost of each inpatient stay by multiplying the total hospital charge with cost-to-charge ratios.

For our analysis, we adhered to the main practices provided by Khera et al[12] on statistical and research methodologies using the NIS database. We excluded all the missing variables from the analysis, and therefore, performed a complete case analysis. Trend weights were used to estimate national hospitalizations. Baseline demographics, comorbidities, and hospital characteristics among groups were compared using the Pearson chi-square test for categorical variables and one-way ANOVA for continuous variables. Categorical and continuous variables were reported as percentages and mean ± standard deviation (SD), respectively. For trend analysis, hospitalizations and outcomes were reported as absolute values for each calendar year and compared using one-way ANOVA. First, we evaluated baseline characteristics of patients who underwent LVAD alone or with concomitant AVR, MVR, TVR or combined valvular surgery. Then a subgroup analysis was performed to report the incidence of mortality and other major secondary complications based on each surgical subtype. Binary outcomes (in-hospital mortality, discharge disposition, stroke, postoperative hemorrhage requiring transfusion, gastrointestinal bleeding, intracranial bleeding, infectious complications, respiratory complications, acute kidney injury leading to hemodialysis, and pericardial effusion/tamponade) were modeled with binomial logistic regressions. A nonparsimonious multivariable logistic regression model was formed after adjusting for age, gender, coronary artery disease, and all the co-morbidities extracted from Elixhauser scoring system. Bonferroni adjustment was applied for multiple comparisons correction. All data extraction and analyses were conducted using Stata 16.0 (StataCorp 2019, Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC). Two-sided p value <0.05 was used for statistical significance.

Results

A total of 25,171 weighted adults underwent LVAD implantation without valvular surgery, 1,329 had isolated TVR, 1,021 AVR, 377 MVR, and 615 had combined valvular surgery (411 had TVR + AVR, 115 TVR + MVR, 62 AVR + MVR, 25 AVR + MVR + TVR) in the United States from 2010 to 2017. The mean age of patients was highest among those who underwent LVAD with isolated AVR (62.5 years) and those who underwent LVAD with combined valvular surgery (60.7 years), the rate of female patients was highest among those who underwent LVAD with isolated MVR (36.6%), and the mean Elixhauser comorbidity score was highest in LVAD with isolated TVR and those who underwent LVAD with combined valvular surgery (Table 1). During the study period, rates of AVR decreased and combined valvular surgery increased significantly (Figure 1).

The main study in-hospital outcomes are reported in Table 2. In-hospital mortality was higher among those who underwent combined valvular surgery, MVR, and AVR compared with those who underwent LVAD without valvular surgery and TVR (Table 2). However, no differences were observed in the rates of stroke among the study groups. Postoperative bleeding was more frequent among those who underwent AVR (27%), whereas TVR and combined valvular surgery were associated with higher gastrointestinal bleeding (14.1%, 12.9%, respectively) and acute kidney injury requiring hemodialysis (9.2%, 8.8%, respectively). Respiratory complications (14.6%) and pericardial effusion/tamponade (12.8%) were also more frequent among those who underwent combined valvular surgery. There was no significant difference in the rates of intracranial bleeding and infectious complications among groups. Length of stay did not differ significantly among the study groups but it was numerically higher in the combined valvular surgery group. In contrast, total cost in cases of combined surgery was significantly higher compared with other groups ($313,692 ± 196,551). Disposition patterns were different among groups (Table 3). Routine discharges (routine discharge is defined as discharge to home rather than a health care facility after surgery) with or without home health care were highest among those who underwent LVAD without valvular surgery (26.6%, 38.9%, respectively), whereas transfer to skilled nursing facility/nursing home was more frequent for cases of TVR and combined surgery (65.0%, 69.2%, respectively).

A multivariable logistic regression for in-hospital mortality with adjustment for age, gender, and Elixhauser comorbidities, showed that those who underwent AVR, MVR, and combined valvular surgery were associated with significantly higher in-hospital mortality compared with those who underwent LVAD without valvular surgery (Table 4).

Table 1
Patient characteristics of patients with left ventricular assist devices

Characteristics	LVAD	Isolated TVR	Isolated AVR	Isolated MVR	Combined valvular surgery	p value
Weighted	25,171	1,329	1,021	377	615	
Unweighted	5068	268	207	76	124	
Number/year						
2010	2128	91	187	5	15	
2011	2293	113	169	36	40	
2012	2730	190	155	65	35	
2013	3020	235	185	45	70	
2014	3395	165	200	55	40	
2015	3690	170	120	50	90	
2016	3865	145	0	60	190	
2017	4050	220	5	60	135	
Age, mean (SD), (years)	54.9 (15.3)	55.8 (15.2)	62.5 (12.8)	57.9 (16.4)	60.7 (12.1)	<0.001
Female	23.1%	27.6%	17.8%	36.6%	25.0%	0.0082
Hypertension	59.8	56.9	52.9	48.8	61.4%	0.0789
Diabetes	34.4	33.3	32.9	21.2	25.0%	0.0437
Coronary artery disease	44.0	37.5	43.2	43.3	43.4%	0.3651
Atrial fibrillation	42.9	51.2	44.8	41.9	49.4	0.0564
Pulmonary circulation disorder	40.0	43.4	32.9	39.7	38.0	0.2298
Chronic pulmonary disease	38.4	42.2	43.0	40.8	24.1	0.0068
Neurological disorders	12.9%	13.7	17.3	19.8	17.9	0.1085
Hypothyroidism	10.5	15.4	14.9	6.6	8.1	0.0224
Chronic kidney disease	44.9	52.0	44.0	33.0	53.3	0.0121
Liver disease	18.1	20.5	21.8	22.6	21.1	0.3753
Cancer	2.0	3.4	4.3	2.7	1.6	0.0952
Obesity†	16.7	15.0	10.2	8.0	8.1	0.0021
Prior CABG	9.2	7.8	9.1	7.8	7.9	0.9014
Mean Elixhauser score (SD)	6.8 (2.2)	7.6 (2.3)	7.0 (2.3)	6.6 (2.3)	7.3 (2.0)	<0.001
Hospital tertiles by volume of LVAD						0.3720
Lowest	6.6	7.1	10.7	10.5	10.6	
Intermediate	23.6	21.5	22.0	20.1	21.9	
Highest	69.8	71.4	67.3	69.4	67.5	
Insurance						0.0002
Medicare	46.7	53.8	62.9	43.1	55.5	
Medicaid	12.9	13.4	6.3	13.6	6.5	
Private	36.2	30.2	26.4	38.0	36.3	
Uninsured	4.2	2.6	4.4	5.3	1.6	
Median income (quartile)						0.0054
0-25th	27.4	33.4	25.1	37.0	23.8	
26-50th	26.0	23.5	19.6	20.4	19.5	
51-75th	25.3	22.1	27.6	13.8	21.8	
>75th	21.3	21.1	27.78	28.8	34.9	

AVR = aortic valve repair/replacement; CABG = coronary artery bypass graft; LVAD = left ventricle assist device; MVR = mitral valve repair/replacement; SD = standard deviation; TVR = tricuspid valve repair/replacement.

Discussion

The salient findings of this analysis of a nationally representative sample of patients who underwent LVAD placement with or without concomitant valvular surgery can be summarized as follows: (1) approximately 1 in 9 LVAD recipients underwent concomitant valvular surgery, (2) TVR was the most frequently performed procedure, (3) rates of AVR decreased and combined valvular surgeries increased during the study period, (4) in-hospital mortality and cost were lower among those who did not undergo valvular surgery, and concomitant TVR had lower risk of in-hospital mortality than other surgeries, (5) combined valvular surgery was associated with higher in-hospital mortality, tamponade, respiratory complications, length of stay, and cost of hospitalization.

Aortic insufficiency is a well-documented complication in patients supported with long-term LVAD. The constant increase of afterload and decrease of left ventricle end-diastolic pressure causes aortic valve closure and stretching, which induce pathologic change in the leaflets, the aortic wall and the root dimensions.[13,14] AI progresses with time and it is associated with worse hemodynamics, hospitalization and survival.[15] Any degree of severity above mild warrants intervention. A previous INTERMACS analysis suggested that aortic valve repair is associated with higher rates of AI recurrence and valve closure with increased mortality compared with replacement.[16] These findings along with an increase of combined valvular procedures which mainly include AVR, may explain the decline in the number of isolated AVR

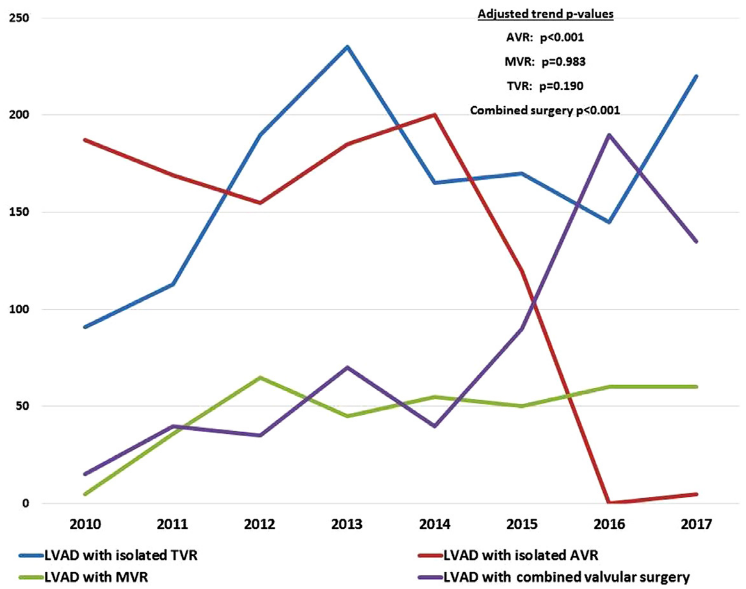

Figure 1. Trend of each procedure performed from 2010 to 2017.
AVR = aortic valve repair/replacement, LVAD = left ventricle assist device, MVR = mitral valve repair/replacement, TVR = tricuspid valve repair/replacement.

Table 2
In-hospital outcomes

	LVAD	Isolated TVR	Isolated AVR	Isolated MVR	Combined valvular surgery	p value
In-hospital mortality	11%	13.7%	20.3%	22.2%	25.2%	<0.001
Postoperation hemorrhage requiring transfusion	17.6%	20.0%	27.0%	9.1%	8.8%	<0.001
GI bleeding	8.0%	14.1%	10.1%	5.3%	12.9%	0.001
Intracranial bleeding	2.5%	2.6%	3.4%	1.3%	3.3%	0.86
Infectious complications	5.9%	4.8%	2.4%	8%	8.7%	0.10
Respiratory complications	6.7%	8.3%	5.4%	8%	14.6%	0.009
AKI leading to HD	5.0%	9.2%	7.2%	6.6%	8.8%	0.017
Pericardial effusion/tamponade	5.2%	8.2%	3.5%	9.1%	12.8%	<0.001
Stroke	4.4%	2.6%	4.7%	2.7%	4.8%	0.61
Length of stay mean (SD), days	36.7 (29.9)	38.8 (24.5)	34.2 (25.5)	36.1 (22.1)	42.4 (29.2)	0.22
Total cost, mean (SD), dollars	251,647 (180,319)	279,504 (154,938)	259,759 (172,546)	255,270 (111,142)	313,692 (196,551)	<0.001

AKI = acute kidney injury; AVR = aortic valve repair/replacement; CABG = coronary artery bypass graft; GI = gastrointestinal; HD = hemodialysis; LVAD = left ventricle assist device; MVR = mitral valve repair/replacement; SD = standard deviation; TVR = tricuspid valve repair/replacement.

Table 3
Patients disposition

Discharge status (%)	LVAD	LVAD with isolated TVR	LVAD with isolated AVR	LVAD with isolated MVR	LVAD with combined valvular surgery	p value
Routine	26.6	18.4	21.3	21.0	13.1	<0.001
SNF/NH	22.1	29.6	27.5	25.2	34.8	
Home healthcare	38.9	35.4	28.7	30.2	24.4	

AVR = aortic valve repair/replacement; LVAD = left ventricle assist device; MVR = mitral valve repair/replacement; NH = nursing home; SNF = skilled nursing facility; TVR = tricuspid valve repair/replacement.

during the study period. A recent expert consensus by the European Association for Cardio-Thoracic Surgery recommends biologic aortic valve replacement rather than closure or repair in LVAD recipients with more than mild AI or mechanical aortic valve.[17] Recently, transcatheter AVR has emerged as an alternative strategy for the treatment of aortic insufficiency (de novo or pre-existing) among LVAD recipients. Case-series reported successful treatment of aortic insufficiency with transcatheter AVR[18,19] and with the advances in transcatheter AVR technology large prospective studies of this procedure are warranted.

Table 4
A multivariable logistic regression for in-hospital mortality

Procedure	OR [CI]	p value	Bonferroni adjusted p value
LVAD alone	-	-	-
LVAD with TVR	1.32 [0.85-2.07]	0.22	0.86
LVAD with AVR	2.13 [1.39-3.28]	0.001	0.0023
LVAD with MVR	2.36 [1.18-4.72]	0.016	0.062
LVAD with combined valvular surgeries	2.30 [1.35-3.93]	0.002	0.009

AVR = aortic valve repair/replacement; CI = confident interval; LVAD = left ventricle assist device; MVR = mitral valve repair/replacement; OR = odds ratio; TVR = tricuspid valve repair/replacement.

Mitral regurgitation is common in patients who undergo LVAD implantation (40% to 70%).[20] LVAD implantation decreases the severity of mitral regurgitation by unloading the left ventricle and improving mitral leaflet coaptation.[21] However, persistent mitral regurgitation in LVAD patients can have detrimental hemodynamics and associated with worse function and death.[22] Therefore, concomitant MVR at the time of LVAD is performed occasionally, but it is not associated with any survival benefits. A meta-analysis of 8 retrospective studies showed concomitant MVR for patients with moderate to severe or severe mitral regurgitation did not improve residual mitral regurgitation, perioperative outcomes, short- and long-tern survival.[23] Similarly, an INTERMACS database analysis showed concomitant MVR did not improve survival but may confer benefits such as lower hospital re-admission and improved quality of life in selected patients.[4] Our analysis showed significant increase in in-hospital mortality among patients who underwent concomitant MVR. Since the severity of MR potentially improves after LVAD implantation alone, concomitant MVR has limited role at the time of LVAD implantation.

Moderate to severe functional tricuspid regurgitation is present in about 40% to 50% of patients at the time of LVAD implantation.[24] Although LVAD implantation alone reduces right ventricular afterload, which might result in decreased tricuspid regurgitation in theory, the severity of tricuspid regurgitation does not always improve after LVAD implantation. It is known that presence of significant tricuspid regurgitation is associated with worse outcomes for patients who undergo LVAD implantation. A propensity-score match analysis of the EUROMACS registry showed that concomitant TVR did not improve short- and long-term mortality, hospital stay, unexpected hospital readmission, and probability of moderate-to-severe TR within 1.5 years of follow-up.[6] In our analysis, although it was associated with increased rates of acute kidney injury requiring dialysis likely related to associated right ventricular failure, concomitant TVR exhibited similar in-hospital mortality compared with LVAD implantation alone. Since concomitant TVR offers hemodynamic benefit,[5–7] these findings support concomitant TVR at the time of LVAD implantation. However, a high failure late rate of concomitant TVR (38% at median follow-up of 23 months) has been reported,[25] and it could be related to late right ventricular failure, residual pulmonary hypertension and/or presence of pacemaker/defibrillator leads in the right ventricle.

Our analysis included patients who underwent combined valvular surgery at the time of LVAD implantation, which was associated with increased in-hospital morbidity and mortality. In aggregate these data suggest that AVR and TVR could be performed if indications are met, MVR and particularly combined valvular surgeries should be discouraged unless there is a compelling reason to proceed.

Although length of stay did not differ significantly among groups, cost of hospitalization and non-routine discharge rates were higher for cases of TVR and combined surgery, which should be taken into account during the decision-making process. However, concomitant valvular surgery may decrease re-admissions,[26] and therefore, long-term total cost for each strategy should be investigated further.

There are several limitations in our analysis. First, the national inpatient sample is a de-identified administrative database which makes it impossible to validate individual ICD codes, which significantly affects the sensitivity and specificity when applying the diagnostic codes. Additionally, the retrospective observational nature of the study carries an inherent risk of selection bias and confounding that might have contributed to reporting of adverse effects. However, these limitations are counteracted by the large sample size because the national inpatient sample is the largest publicly available all-payer inpatient database representing >95% of the US inpatient population.

In conclusion, approximately 1 in 9 LVAD recipients underwent concomitant valvular surgery and TVR was the most frequently performed procedure. AVR, MVR, and combined valvular surgery at the time of LVAD implantation are associated with significantly higher in-hospital mortality.

Disclosures

The authors have no conflicts of interest to disclose.

Credit author statement

Alexandros Briasoulis-conceived the project, wrote manuscript. Yujiro Yokoyama-participated in the draft of the manuscript. Toshiki Kuno-participated in data analysis. Hiroki Ueyama-participated in manuscript preparation. Suchith Shetty-participated in data analysis. Paulino Alvarez-participated in draft preparation. Aaqib Malik-supervised work, performed data analysis.

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