

Comparison of In-Hospital Outcomes of Patients With- Versus-Without Ischemic Cardiomyopathy Undergoing Left Ventricular Assist Device Placement



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The objective of this study was to evaluate the impact of heart failure (HF) etiology (ischemic cardiomyopathy [ICM] versus nonischemic cardiomyopathy) on in-hospital outcomes in patients undergoing left ventricular assist device (LVAD) placement using the Nationwide Inpatient Sample database. We identified patients who underwent LVAD placement from 2011 to 2014. The primary end point was the effect of ICM on in-hospital mortality. Secondary end points included periprocedural vascular complications requiring surgery, postoperative myocardial infarction, stroke, and hemorrhage requiring transfusion. We also assessed length of stay and cost of hospitalization. A mixed effects logistic model was used for clinical end points and a linear mixed model was used for cost and length of stay. In 3,511 patients who underwent LVAD placement (23.32% women and 56.23 ± 13.51 years old), the incidence of ICM was 53.5%. After adjusting for patient- and hospital-level characteristics, ICM was not found to influence in-hospital mortality (odds ratio [OR] 0.98, 95% confidence interval [CI] 0.78 to 1.23). ICM was associated with an increased risk in periprocedural hemorrhage requiring transfusion (OR 1.29, 95% CI 1.08 to 1.53), vascular complications requiring surgery (OR 1.58 95% CI 1.10 to 2.28) and postoperative ST-segment myocardial infarction (OR 7.38 95% CI 5.33 to 10.24). In conclusion, ICM did not impact in-hospital mortality in patients who underwent LVAD placement but was associated with increased vascular complications, hemorrhage requiring transfusion, and postoperative myocardial infarction. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:414–418)

Left ventricular assist devices (LVADs) have become increasingly utilized in the management of patients with advanced heart failure (HF) (stage D) that is nonresponsive to optimal medical therapy. They are now an established part of the treatment algorithm for this stage of the disease either as permanent therapy or as a bridge to heart transplantation.¹ Given the increased utilization of this therapeutic modality, it becomes clinically relevant to identify various determinants of outcome. Multiple studies have shown that patients with ischemic cardiomyopathy (ICM) have decreased survival compared with patients with nonischemic cardiomyopathy (NICM),^{2–4} This has been attributed to the increased age, greater comorbidity burden, widespread atherosclerotic disease and higher incidence of arrhythmias in patients with ischemic etiology.^{2,4}

Furthermore, ischemic etiology was also found to be an independent predictor of perioperative mortality in patients with advanced HF undergoing heart transplantation.^{5,6} Heart transplantation may serve as a reasonable comparator to LVAD implantation suggesting that HF etiology may be an outcome predictor in this patient population. Only one study to date attempted to assess the impact of HF etiology on patients who underwent LVAD implantation, leaving this field underexplored.⁷ The objective of this study is to assess the impact of HF etiology (ICM vs NICM) on the in-hospital clinical outcomes in a large cohort of patients undergoing LVAD placement using the National Inpatient Sample (NIS) database.

Methods

The study was conducted using the NIS of the Health Care Utilization Project. Details of the design and description of the NIS is available online (<https://www.hcup-us.ahrq.gov/nisoverview.jsp>). Briefly, the NIS is a large all-payer inpatient care database created by the Agency of Healthcare Research and Quality as a part of the Healthcare Cost and Utilization Project. It is a 20% stratified sampling of discharges from US community hospitals, excluding rehabilitation and long-term acute care hospitals. It contains discharge data from more than 1,200 hospitals located across 45 states, representing more than 96% of the US population. Each record in the NIS includes information on

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primary and secondary discharge diagnoses and procedures, demographics, hospital characteristics, expected payment source, total charges, discharge status, length of stay, and co-morbidity measures. NIS data were queried using the International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) to identify the study variables analyses. This study was considered exempt from Institutional Review Board approval because Healthcare Cost and Utilization Project-NIS contain de-identified patient information.

All the patients who underwent LVADs (age ≥ 18 years) from 2009 to 2014 were included. ICD-9-CM procedure codes were used to identify patients with ICM (Supplemental Table 1). The primary outcome of interest was the effect of ICM on all-cause, in-hospital mortality. Secondary outcomes were the impact of ICM on post-LVAD implantation complications such as bleeding requiring transfusion, hemorrhage requiring transfusion, hemolytic anemia, hemopericardium, cardiac tamponade, vascular complications requiring surgery, ischemic stroke, respiratory complications, acute kidney injury; postoperative myocardial infarction; postoperative sepsis; and acute kidney injury (AKI) requiring transfusion. We also evaluated the length of hospital stay, discharge pattern, and hospitalization costs. A list of ICD-9-CM codes used to define in-hospital complications is included in Supplementary Table 1. Secondary outcomes were determined based on the Patient Safety Indicators (Version 4.4, March 2012) established by the Agency for Healthcare and Quality to monitor adverse events during hospitalization. These indicators are based on ICD-9-CM codes, and each Patient Safety Indicator has specific inclusion and exclusion criteria (references).

We used the following as baseline patient-level characteristics: race (Whites, Non-Hispanic Blacks, Hispanics Asians and Others), gender (female and male), health insurance type (Medicare, Medicaid, Private, Self-pay and Others), and income level based on the zip code (lowest quartile, second quartile, third quartile, and highest quartile). We also included variables for hospital-level factors: region (Northeast, Midwest, South and West), and hospital size (small, medium, and large sizes). To calculate estimated cost of hospitalization the NIS data were merged 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. Adjusted cost for each year was calculated in terms of the 2017 cost, after adjusting for inflation according to the latest consumer price index data released by US government on January 30, 2018.⁸ By doing this we standardized costs over the study period. Descriptive statistics are presented as percentages for categorical variables and as means with standard deviations for continuous variables. Baseline characteristics were compared using a chi-square test for categorical variables using surveyfreq procedure and an independent-samples *t* Test for continuous variables. We excluded all the missing variables from the analysis, and therefore, did a complete case analysis. Dichotomous outcomes (in-patient mortality, bleeding requiring transfusion, hemolytic anemia, tamponade, postoperative ST-elevation myocardial

infarction, vascular complication requiring surgery, AKI, post-operative stroke, respiratory complications, postoperative sepsis, AKI requiring dialysis and nonroutine home discharge) were modeled with multivariate logistic regressions adjusting for demographic factors-race, income level, insurance status, hospital-level factors, and Elixhauser co-morbidity index. Discrete numeric variables with an over-dispersed count distribution (length of stay) and continuous variables with a right skewed spread (total hospital cost) were modeled with generalized linear model regressions that adjusted for similar covariates as above. We reported odds ratio (OR) for binary outcomes, and mean ratios for the numeric outcomes. The trends in complication rates and mortality were computed by fitting a poisson regression model with a robust error variance to evaluate for changes in the complications and/or mortality per year. Year was kept as a continuous variable in the model.

All the data extraction and analyses was done with Statistical Analysis System (SAS V.9.4, SAS Institute Inc, Cary, NC). We chose a *p* value of <0.05 , reported the effect sizes, 95% confidence intervals (CI), and *p* values. Survey-specific techniques accounting for multistaged clustered sampling methodology of the data was used for weighting to obtain national estimates as recommended by the Agency for Healthcare Research and Quality (www.hcup-us.ahrq.gov/reports/methods/2015_09.jsp).

Results

The study population included 3,511 patients that underwent LVAD placement from 2011 to 2014. Of these, 1,880 (53.5%) had ICM, whereas 1631 (46.5%) had NICM. Patients in the ICM group were older and had a higher prevalence of several major co-morbidities including peripheral vascular disease, chronic obstructive lung disease, diabetes mellitus, and hypertension. The differences in baseline characteristics were accounted for in our propensity-matched analysis. Baseline clinical characteristics of the 2 study groups are depicted in Table 1.

With regards to in-hospital mortality, there was no significant difference between ICM and NICM cohorts (OR 0.98, 95% CI 0.78 to 1.23; *p* = 0.84) and no significant change in mortality (Table 2) or mortality trend (Table 3). ICM patients had a significantly higher risk of hemorrhage requiring transfusion (OR 1.29, 95% CI 1.08 to 1.53), vascular complications requiring surgery (OR 1.58 95% CI 1.10 to 2.28) and postoperative ST-segment myocardial infarction (OR 7.38 95% CI 5.33 to 10.24). There were no significant differences in other clinical end points including, ischemic stroke, AKI, postoperative sepsis, respiratory complications, hemopericardium, cardiac tamponade, or hemolytic anemia. Table 2 summarizes the impact of HF etiology on in-hospital outcomes in patients undergoing LVAD placement.

Discussion

The findings of our nationwide study including 3,511 patients undergoing LAVD placement maybe summarized as follows: (1) There was no difference in the primary outcome defined as in-hospital mortality between the ICM and

Table 1
Baseline characteristics of patients undergoing continuous flow ventricular assist device in the US by ischemic versus nonischemic cardiomyopathy

Variable	Total	Type of cardiomyopathy		p Value
		Ischemic	Nonischemic	
No. of observation, unweighted	3,511	1,880	1,631	
No. of observation, weighted	17,251	9,246	8,004	
Age, mean (SD)	56.23 ± 13.51	60.58 ± 10.54	51.23 ± 14.77	<0.0001
Women	815 (23.32%)	310 (16.58%)	505 (31.10%)	<0.0001
White	2,267 (64.56%)	1,356 (72.13%)	912 (55.92%)	<0.0001
Black	801 (22.81%)	288 (15.32%)	511 (31.35%)	
Hispanic	202 (5.74%)	100 (5.33%)	101 (6.20%)	
Asia	59 (1.69%)	26 (1.39%)	33 (2.03%)	
Peripheral vascular disease	305 (8.70)	226 (12.07%)	78 (4.80%)	<0.0001
Prior coronary artery bypass grafting	298 (8.49%)	291 (15.46%)	7 (0.42%)	<0.0001
Prior percutaneous coronary intervention	355 (10.12%)	345 (18.33%)	10 (0.63%)	<0.0001
Hypertension	1,503 (42.87%)	939 (49.93%)	566 (34.72%)	<0.0001
Diabetes mellitus	1,124 (32.00%)	717 (38.15%)	406 (24.89%)	<0.0001
Body mass index ≥30 Kg/m²	541 (15.42%)	251 (13.55%)	287 (17.59%)	0.001
Hypothyroidism	383 (10.92%)	217 (11.56%)	166 (10.17%)	0.161
Chronic obstructive pulmonary disease	619 (17.63%)	392 (20.84%)	227 (13.93%)	<0.0001
Renal failure	1,346 (38.35%)	747 (39.72%)	600 (36.77%)	0.081
Alcohol abuse	87 (2.47%)	44 (2.32%)	43 (2.65%)	0.549
Smokers	706 (20.12%)	457 (24.29%)	250 (15.31%)	<0.0001
Chronic liver disease	127 (3.61%)	62 (3.28%)	65 (3.99%)	0.244
Cerebrovascular disease	281 (8.08%)	169 (9.00%)	114 (7.02%)	0.036
Metastatic cancer	8 (0.23%)	2 (0.11%)	6 (0.36%)	0.115
Elixhauser score				
0	483 (13.75%)	211 (11.23%)	272 (16.65%)	<0.0001
1–3	1,337 (38.07%)	674 (35.85%)	662 (40.64%)	
≥4	1,692 (48.18%)	995 (52.92%)	696 (42.70%)	
Median household income quartile				<0.0001
1st	1,667 (47.48%)	995 (52.91%)	672 (41.22%)	
2nd	406 (11.56%)	177 (9.44%)	228 (14.00%)	
3rd	1,302 (37.07%)	632 (33.63%)	669 (41.03%)	
4th	137 (3.89%)	75 (4.02%)	61 (3.74%)	
Hospital bed size				0.055
Small	40 (1.13%)	26 (1.36%)	14 (0.87%)	
Medium	297 (8.46%)	165 (8.79%)	132 (8.09%)	
Large	3,174 (90.40%)	1,689 (89.85%)	1,492 (91.05%)	
Hospital location				
Rural	6 (0.16%)	5 (0.25%)	1 (0.06%)	0.023
Urban nonteaching	65 (1.85%)	40 (2.12%)	25 (1.55%)	
Urban teaching	3,440 (97.98%)	1,835 (97.63%)	1,605 (98.39%)	

NICM cohorts. (2) The presence of ICM was associated with an increased risk of hemorrhage requiring transfusion, vascular complications requiring surgery and postoperative myocardial infarction. (3) The remaining secondary outcomes including postoperative ischemic stroke, respiratory complications and AKI did not differ significantly between the ICM and NICM cohorts.

Numerous studies have demonstrated an increased mortality in patients with ischemic etiology compared with nonischemic etiology in HF patients treated with guideline-directed medical therapy.^{9,10} This difference of mortality was attributed to an older population, higher rates of co-morbidities, worse hemodynamic response to medical therapy, and a higher risk of ventricular arrhythmias and sudden cardiac death.^{9,10} Furthermore, ischemic etiology was also found to be an independent predictor of perioperative mortality in patients with advanced HF undergoing heart

transplantation suggesting that it may also influence outcomes in LVAD patients.^{5,6} Our analysis demonstrated that HF etiology had no impact on in-hospital mortality in LVAD patients. This was in agreement with the only study to date that assessed this topic of interest, conducted by Tsiouris et al.⁷ The authors evaluated 100 patients who underwent LVAD implantation and found no survival difference between patients with ICM and NICM. The removal of this previously demonstrated survival advantage in patients with NICM perioperatively during LVAD implantation is not entirely clear. It is possible that the extensive work up and risk factor optimization before LVAD placement plays a role in neutralization of the mortality difference between 2 study cohorts. Furthermore, the artificial improvement in systemic perfusion associated with LVAD placement may compensate for the pathophysiological factors that contribute to decreased survival in patients with ICM.¹¹

Table 2
Clinical outcomes of LVAD by ischemic versus nonischemic cardiomyopathy

Variable	Type of cardiomyopathy		OR/MR (95% CI)	p Value
	Ischemic	Nonischemic		
In-patient mortality	249 (13.24%)	219 (13.40%)	0.98 (0.78, 1.23)	0.848
Hemorrhage requiring transfusion	519 (27.60%)	367 (22.48%)	1.29 (1.08, 1.53)	0.005
Hemolytic anemia	23 (1.22%)	20 (1.20%)	1.66 (0.86, 3.22)	0.134
Hemopericardium	11 (0.58%)	10 (0.60%)	1.61 (0.32, 7.95)	0.561
Cardiac tamponade	77 (4.10%)	96 (5.86%)	0.74 (0.50, 1.09)	0.123
Postoperative ST-segment elevation myocardial infarction	14 (0.76%)	5 (0.28%)	7.38 (5.33, 10.24)	<0.0001
Vascular complication requiring surgery	133 (7.07%)	81 (4.94%)	1.58 (1.10, 2.28)	0.014
Stroke	106 (5.66%)	85 (5.23%)	0.73 (0.52, 1.03)	0.070
Respiratory complications	60 (3.21%)	75 (4.57%)	0.77 (0.49, 1.29)	0.234
Post-operative sepsis	227 (12.05%)	306 (18.78%)	0.79 (0.58, 1.06)	0.116
Acute kidney injury	1,055 (56.13%)	940 (57.66%)	1.15 (0.95, 1.39)	0.146
Acute kidney injury requiring dialysis	124 (6.62%)	101 (6.21%)	1.12 (0.74, 1.70)	0.594
Nonroutine home discharge†	1,417 (75.35%)	1,189 (72.94%)	1.03 (0.82, 1.28)	0.829
Cost (US dollars)	245,109	242,782	1.01 (0.97, 1.06)	0.678
Length of stay (Days)	33.25	37.52	0.95 (0.90, 1.00)	0.070

Our analysis revealed that patients with ICM had an increased risk of vascular complications requiring surgery and bleeding requiring transfusion. This was in agreement with previous studies that demonstrated ICM to be a predictor of bleeding in LVAD patients.^{7,12} Bleeding complicating LVAD placement has been attributed to a multitude of factors including, perioperative anticoagulant and antiplatelet use, acquired Von-Willebrand factor dysfunction, impaired platelet aggregation and lack of pulsatility associated with LVADs.¹² Although not directly derived from our study, higher bleeding rates evident in ICM patients may be related to higher incidence of preoperative antiplatelet agent use. Failure of appropriate antiplatelet agent discontinuation before surgery has been proven to increase the risk of postoperative bleeding in patients with cardiac surgery.¹³ Studies have shown that the most common source of nonsurgical bleeding in LVAD patients is the gastrointestinal tract mainly from arteriovenous malformations.^{12,14,15} ICM has been previously linked to gastrointestinal tract mainly from arteriovenous malformations, which may have led to the increased association with bleeding complications noted in our study.^{12,16} The mechanism behind this possible connection is not fully

understood but maybe related underlying diffuse vasculopathy in patients with ICM. The increased risk of vascular complications requiring surgery in ICM patients may also contribute to the increased risk of bleeding. A possible explanation for this observation is that ICM patients have a higher rate of previous cardiac surgery (15% vs 0.4% $p < 0.001$) which may be associated with the formation of postoperative intrapericardial adhesions. These adhesions may complicate technical aspects of LVAD implantation with requirement of adhesion dissection that may increase the risk of injury to the heart and blood vessels.¹⁷ Lastly, longer cardiopulmonary bypass time associated with technically complicated cardiac surgery in patients may have been associated with increased coagulopathy and higher rates of bleeding as demonstrated in previous studies.¹⁸ We also observed a higher rate of postoperative myocardial infarction in the ICM group, which is expected given the underlying coronary artery disease. Perioperative catecholamine elevation, tachycardia- and hypertension-induced shear stress and postoperative procoagulant factor synthesis have all been implicated in prompting vulnerable plaque rupture.¹⁹ Furthermore, ICM patients are more prone to perioperative supply demand

Table 3
Trends in mortality, vascular, and hemorrhagic complications from 2009 to 2014

	2009	2010	2011	2012	2013	2014	p Value
Mortality							
Total	16.91%	13.21%	14.21%	13.15%	12.41%	11.65%	0.026%
Ischemic cardiomyopathy	20.35%	12.76%	12.54%	13.47%	11.65%	11.71%	0.024
Nonischemic cardiomyopathy	13.24%	13.57%	16.48%	12.73%	13.21%	11.59%	0.319
Vascular complications requiring surgery							
Total	5.99%	5.17%	6.30%	5.68%	7.14%	5.96%	0.593%
Ischemic cardiomyopathy	7.79%	6.17%	5.08%	7.45%	8.24%	7.32%	0.517
Nonischemic cardiomyopathy	4.09%	4.07%	7.66%	3.37%	5.99%	4.27%	0.946
Hemorrhage requiring transfusion							
Total	18.40%	31.90%	26.98%	22.24%	24.34%	26.56%	0.847%
Ischemic Cardiomyopathy	19.91%	37.45%	29.83%	24.93%	25.57%	27.80%	0.818
Nonischemic cardiomyopathy	16.82%	25.79%	23.75%	18.73%	23.05%	25.00%	0.510

imbalance induced by surgical hemodynamic stress secondary to underlying atherosclerotic coronary arteries.²⁰

Our study has several limitations that need to be acknowledged. First, we used data from the NIS where variables are identified using a coding system that is subject to coding error and disparity. Nevertheless, the NIS has been extensively utilized for research in various medical subspecialties and is considered a validated tool. Second, the data we analyzed lacked information on incidence of dual antiplatelet agent use and their time of discontinuation before surgery. This limited our ability to precisely identify potential opportunities for intervention to reduce adverse outcomes. Thirdly, the NIS database does not include information quantifying the amount of transfusion, which was previously correlated with perioperative mortality in LVAD patients.²¹ Lastly, the NIS database does not include information on outcomes after discharge leading to a short follow-up duration period limiting our ability to assess mid- to long-term outcomes.

In conclusion, our study is the second but the largest study to date to examine the impact of HF etiology on in-hospital outcomes in LVAD patients. Ischemic etiology did not impact the mortality rate but did increase the risk of bleeding requiring transfusion, vascular complications requiring surgery and postoperative myocardial infarction in patients undergoing LVAD placement.

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.2018.10.039>.

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