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Clinical Impact of Diabetes Mellitus on Short-Term Outcomes and In-Hospital Mortality of Cardiac Mechanical Support with Left Ventricular Assist Device (LVAD): A Retrospective Study from a National Database☆,☆☆

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ABSTRACT

Background: Cardiac support with left ventricular assist devices (LVAD) is a growing field. LVAD are increasingly used for patients with advanced congestive heart failure. Multiple studies have evaluated the outcomes of cardiac support with LVAD in patients with and without diabetes mellitus (DM), yet we still have conflicting results. This study aimed to assess the clinical impact of diabetes mellitus on patients undergoing cardiac support with LVAD.
Methods: Diabetic patients who underwent mechanical support with LVAD between 2011 and 2014 were identified in the National Inpatient Sample (NIS) database using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). The primary outcome was the effect of diabetes mellitus on inpatient mortality. Secondary outcomes were the impact of diabetes on other immediate post-LVAD complications and the cost of hospitalization. Multivariable logistic regression models analysis was performed to address potential confounding.
Results: After adjusting for patient-level and hospital-level characteristics, diabetic patients who underwent cardiac support with LVAD have no significant increase in in-hospital mortality (OR: 0.79, 95% CI (0.57–1.10), $p = 0.166$), post-LVAD short-term complications and cost of hospitalization (OR: 0.97, 95% CI (0.93–1.01), $p = 0.102$).
Conclusion: Cardiac mechanical support with LVAD implantation is feasible and relatively safe in patients with diabetes and stage-D heart failure as a bridge for transplantation or as destination therapy for patients who are not candidates for transplantation. However, further trials and studies using bigger study sample and more comprehensive databases, need to be conducted for a stronger and more valid evidence.

1. Introduction

Insulin resistance (IR) prevalence in the developed world is tremendously increasing [1]. Diabetes mellitus is a major risk factor for morbidity and mortality in patients with heart failure [2]. Diabetics are at exponential risk to develop congestive heart failure (CHF), which despite the advances on medical therapy, might advance to stage D where they will need mechanical support with LVADs, either as a bridge for heart transplantation or as destination therapy [3]. CHF and IR are strongly linked in many ways. Interestingly, some studies even showed a possibility of CHF causing insulin resistance [4]. With such a bidirectional link and temporal etiology, IR and CHF overlap in many patients. However, there is evidence that LVAD implantation in CHF diabetic patients, in fact improves glycemic control in these patients [5,6]. In general, Diabetics might be at higher cardiac risk than non-diabetics with heart failure, given the expected burden of microvascular and macrovascular changes. The Food and Drug Administration (FDA) approved left ventricular assist devices as relatively safe therapeutic options to bridge stage D CHF patients for transplantation or as a final destination for patients who are not eligible candidates for

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transplantation. Therefore, cardiac mechanical support with LVAD implantation has been increasingly performed in health facilities across the United States in the last decade. Considering recent technological advances, improvement in healthcare and growing older population, it is expected that LVADs will be increasingly used in the future. Our study aims to review in-hospital mortality associated with cardiac mechanical-support with LVADs, postprocedural complications and cost of care in diabetic patients as compared with non-diabetic patients using real practice data derived from the Nationwide Inpatient Sample (NIS).

2. Methods

Our study was conducted utilizing the National Inpatient Sample (NIS) database which is part of the Healthcare Cost and Utilization Project (HCUP) [7]. NIS is the largest all-payer inpatient stays database in the United States [7]. It represents a 20% stratified sample of all discharges from community hospitals in the United States excluding rehabilitation and long-term acute care hospitals [7]. NIS data were queried using the ICD-9-CM to identify the study variables. All the patients who underwent LVADs (age ≥ 18 years) from 2011 to 2014 were included. DM patients were identified using the ICD-9 diagnosis code 250. The primary outcome was the effect of diabetes on inpatient mortality. Secondary outcomes were the impact of diabetes on post-LVAD implantation complication like bleeding requiring transfusion, cardiac, vascular complications requiring surgery, ischemic strokes, respiratory complications, acute kidney injury; postoperative deep venous thrombosis/pulmonary embolism; sepsis; and the requirement for a new pacemaker. We also evaluated discharge pattern, and hospitalization costs.

To account for demographic factors, we included 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 (CPI) data released by US government on January 30, 2018 [8]. By doing this we standardized costs over the study period. All the diabetic patients were diagnosed as diabetic before the LVAD implantation. Variables related to clinical status of the study population, including NYHA class, inotrope dependence, emergency versus non-emergency LVAD insertion, and indication for LVAD (destination versus bridge to transplantation), are unavailable from NIS database, although theses variables may have some effects on mortality and complications after LVAD insertion. The ICD codes used to identify these complications are available in Supplementary Table 1. Secondary outcomes were determined based on the Patient Safety Indicators (PSIs) (Version 4.4, March 2012) established by the AHRQ to monitor adverse events during hospitalization. These indicators are based on ICD-9-CM codes, and each PSI has specific inclusion and exclusion criteria [9,10].

2.1. Statistical analysis

For the baseline characteristics, the categorical variables are calculated with frequencies (chi-square). Count and continuous variables are estimated with median/mean based on their distribution, and then Wilcoxon and Kruskal Wallis tests for non-normally distributed 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, post-operative STEMI, vascular complication requiring surgery, acute kidney injury, post-operative stroke, respiratory complications, post-operative sepsis, acute kidney injury requiring dialysis and non-routine home discharge) were modeled with multivariate logistic regressions adjusting for demographic factors-race, income level, insurance status, hospital-level factors, and Elixhauser comorbidity index. Discrete numeric variables with an over-dispersed count distribution and continuous variables with a right skewed spread (total hospital cost) were modeled with generalized linear model regressions, with a negative binomial function and gamma function respectively. We reported adjusted odds ratio (aOR) for our binary outcome, and adjusted mean ratios (aMR) for the numeric outcomes. All the data extraction and analyses was done with Statistical Analysis System (SAS V.9.4, SAS Institute Inc., Cary, NC, US). We chose a p-value of <0.05, reported the effect sizes, 95% confidence intervals (CI), and p-values. All models accounted for the multi-staged randomized clustered sampling methodology implemented by HCUP to acquire the data.

3. Results

The study population included 2596 patients from the NIS registry; all underwent mechanical support with LVAD implantation from 2011 to 2014. Of these (23.74% women and 55.4 ± 14.7 years old), the

Table 1
Baseline characteristics of patients undergoing cardiac mechanical support with LVAD implantation in the United States, according to the presence or absence of diabetes mellitus.

Diabetes mellitus				
Variables	Total	Yes	No	p value
No. of observation, unweighted	2596	885	1711	
No. of observation, weighted	12,754	4358	8397	
Age, mean (standard deviation)	55.4 (14.7)	59.0 (10.7)	53.7 (16.0)	<0.001
Female	23.74%	21.04%	25.15%	0.018
Race/ethnicity				0.777
White	64.36%	64.21%	64.43%	
Black	23.34%	23.29%	23.37%	
Hispanic	5.51%	6.04%	5.23%	
Asia	1.44%	1.12%	1.62%	
Peripheral vascular disease	9.23%	10.73%	8.45%	0.050
Prior coronary artery bypass graft surgery	9.09%	11.61%	7.79%	0.001
Prior percutaneous coronary intervention	11.13%	14.88%	9.18%	<0.0001
Hypertension	44.49%	59.66%	36.61%	<0.0001
Obese	16.87%	24.16%	13.09%	<0.0001
Hypothyroidism	11.81%	13.74%	10.82%	0.027
Chronic obstructive pulmonary disease	18.30%	20.98%	16.91%	0.024
Renal failure	40.44%	49.79%	35.59%	<0.0001
Alcohol abuse	2.58%	1.81%	2.98%	0.076
Smoking	21.52%	23.91%	20.28%	0.034
Chronic liver disease	3.74%	3.85%	3.69%	0.832
Ischemic cardiomyopathy	54.23%	63.65%	49.35%	<0.0001
Cerebrovascular disease	7.57%	6.64%	8.05%	0.227
Dyslipidemia	35.36%	50.68%	27.40%	<0.0001
Metastatic cancer	0.19%	0.23%	0.17%	0.758
Elixhauser score				<0.0001
0	11.75	1.37	17.13	
1–3	36.75	21.81	44.51	
≥4	51.50	76.81	38.36	
Median household income				<0.0001
1st quartile	49.52%	56.61%	45.84%	
2nd quartile	11.50%	8.52%	13.06%	
3rd quartile	35.35%	31.81%	37.20%	
4th quartile	3.62%	3.06%	3.91%	
Hospital bed size, %				
Small				0.012
Small	1.18	1.72	0.89	
Medium	10.04	10.43	9.84	
Large	88.78	87.85	89.27	
Hospital location				
Rural	0.12	0.00	0.18	
Urban non-teaching	1.63	1.49	1.71	
Urban teaching	98.25	98.51	98.11	

Table 2
Clinical outcomes and short-term in-hospital complications of cardiac mechanical support with LVAD implantation, according to presence or absence of diabetes mellitus.

Variables	Diabetes mellitus/adjusted rate	No diabetes mellitus/adjusted rate	aOR/aMR (95% CI)	p value
In-patient mortality	9.34%	14.49%	0.79 (0.57, 1.10)	0.166
Hemorrhage requiring transfusion	24.71%	26.61%	0.93 (0.75, 1.17)	0.553
Hemolytic anemia	0.79%	1.09%	0.56 (0.26, 1.23)	0.148
Hemopericardium	0.41%	0.82%	0.62 (0.13, 3.09)	0.561
Post op STEMI	10.84%	14.46%	0.88 (0.66, 1.19)	0.403
Vascular complication requiring surgery	6.06%	4.86%	1.22 (0.86, 1.75)	0.266
Post-operative stroke	5.57%	5.41%	0.96 (0.59, 1.59)	0.886
Respiratory complications	3.40%	2.83%	1.44 (0.83, 2.49)	0.195
Post-op sepsis	9.45%	11.87%	0.78 (0.56, 1.07)	0.123
Acute kidney injury	59.37%	58.25%	1.02 (0.82, 1.28)	0.846
Acute kidney injury requiring dialysis	6.20%	5.42%	1.23 (0.83, 1.84)	0.304
Non-routine home discharge[a]	73.77%	75.15%	0.98 (0.77, 1.25)	0.884
Cost	209,360	216,362	0.97 (0.93, 1.01)	0.102

aOR represents Adjusted Odds Ratio (with 95% CI), aMR: represents Adjusted Mean Ratio for cost and length of stay.
[a] Non-routine home discharge include home with health care, transfer to short term hospital or other intermediate or long-term care facility.

prevalence of diabetes was 34%. The mean age for the LVAD group with diabetes was 59.0 ± 10.7 years versus 53.7 ± 16 years for the group without diabetes. The group with DM was older and had higher rates of smoking, hypertension, COPD, renal failure, and prior CABG/PCI, all of which are risk factors for higher complication rates and mortality after major procedures. Also the Elixhauser score was much higher in the DM group. Baseline clinical characteristics between the two groups are depicted in Table 1.

After adjusting for patient- and hospital-level characteristics, mechanical support with LVADs in-hospital mortality difference was statistically not significant between the diabetes vs. the non-diabetes group (adjusted odds ratio [aOR] 0.79, 95% CI 0.57 to 1.10, p = 0.166). Also, diabetes was not associated with any statistical difference regarding most of post-LVAD complications, including, cardiac, vascular, neurological events and kidney injury. Also, there was no statistical difference between the two groups regarding cost of hospitalization and rates of non-routine hospital discharges, which is a ICD code includes rate of discharges to a rehabilitation facilities. Table 2 shows clinical outcomes and short-term in-hospital complications of cardiac mechanical support with LVAD implantation, according to presence or absence of diabetes mellitus.

4. Discussion

Our study compares in-hospital mortality; post-procedural short-term complications, and costs for cardiac support with left ventricular assist device (LVAD) in patients with versus without diabetes mellitus (DM), using a national database. Patients with DM have no increased risk of in-hospital death, short-term complications or cost of hospitalization than those without DM. Diabetes mellitus is a risk factor for developing congestive heart failure, and the combination of DM and CHF is one of the most common associations encountered in clinical practice [11]. A vulnerable subset of heart failure patients will end up eventually requiring ventricular assist devices, either as a bridge to transplantation or as final destination therapy, yet the available evidence regarding the impact of DM on the short-term outcomes of mechanical support with LVAD remains somehow conflicted. Topkara et al. in 2005 [12], was the first to publish a retrospective analysis study, including patients (N = 201) who underwent LVAD insertion at their institution from 1996 to 2004, and they compared the diabetic group (24.4%) to non-diabetic group in term of post LVAD mortality and complication. They concluded that diabetic group had a higher mean body mass index (30.1 ± 6.0 versus 26.1 ± 4.8, p < 0.001) and a higher proportion of hypertension (57.4% versus 19.7%, p < 0.001). Although post-LVAD survival was similar, post-transplant survival in DM group was significantly lower compared with non-DM patients.

Butler et al. also evaluated DM impact on LVAD recipients and [13] concluded, after controlling for other variables, patients with diabetes were at a higher risk of mortality (OR 1.76, 95% CI 1.05–2.94). This report agrees with Topkara et al. study in term of overall long-term mortality [12]. However, subsequently, Uriel et al. evaluated diabetic LVAD recipients with average hemoglobin A1c of 7.7 [6]. Their study showed a beneficial outcome in the diabetic group in term of glycemic control after support with LVAD, which could be explained by improved tissue metabolism ensued from improved cardiac function while in support and likely decreased insulin resistance. Vest AR et al. conducted a single-center retrograde study in 2016 [14], including 300 LVAD patients (43% of them were diabetic) to evaluate the impact of DM on LVADs implantation, and concluded a similar finding to Topkara et al. study [12], that DM does not increase the immediate post-LVAD mortality or rate of major adverse events during LVAD support, including stroke/TIA, pump thrombosis, and device-related infection. Asleh R. et al. in a retrospective cohort study, included 341 patients who had LVADs between 2007 and 2016 at their center [15]. However, 38% of the Asleh R. et al. study candidates had diabetes and were compared to non-diabetics in term of mortality and adverse events after LVAD implantation. They concluded that diabetic group is associated with increased rates of all-cause mortality and adverse events, although this group showed better glycemic control after LVAD implantation. However, the contradicting outcomes between Vest et al. and Asleh et al. studies could be explained by that most of LVAD patients included in the Vest et al. study were having LVAD implanted as a bridge to transplantation (62%), hinting for a possibly healthier study population that was selected for transplantation, with possible shorter duration of support with LVAD.

The International Society for Heart and Lung Transplantation recommended that DM with poor glycemic control or end-organs damage to be considered as a relative contraindication (Class IIb; Level of Evidence C) for LVAD implantation [16]. This recommendation is based on previous single-center studies, which yielded conflicting results [6,12,13]. These results could be explained by small study populations, glycemic control differences, operator experience, institutional differences in post-implantation care, possible underlying study population co-morbidities and other potential confounders. Arnold SV et al. published a study at 2016, evaluating the frequency of poor outcome after LVAD implantation as a destination therapy using the INTERMACS Registry. Poor outcome was defined as death or an average Kansas City Cardiomyopathy Questionnaire (KCCQ) <45 during the year after LVAD. Quality of life was measured using KCCQ questionnaire. Their study showed that patients with severe diabetes were more likely to have a poor outcome (15.6% vs. 11.5%, p = 0.038) [17]. However, KCCQ didn't capture variables related to quality of life that may be affected by the LVAD like device care difficulties and possible bleeding. Also, follow-up KCCQ scores were reported to be missing on 15% of surviving patients. Finally, There were reported concerns regarding patients' responses accuracy and reliability, since it is likely that there are patients who reported KCCQ scores of more or <45 based on their perception and level of expectations, hence under- or overestimated the proportion of patients who have poor quality of life after LVAD.

Our study, using NIS database, includes a large number of LVAD-supported patients to assess the impact of DM on the in-hospital mortality and immediate post-LVAD adverse events. Our statistical analysis used regression analysis to treat for possible confounders. Our results showed no statistical difference in in-hospital mortality between the diabetic and non-diabetic group. This result comes in agreement with Vest AR et al. study, in term of mortality and post LVAD procedure complications like stroke, thrombosis, and device-related infections [14]. Our study also showed that no increased risk of other short-term post LVAD complications like cardiac complications, bleeding requiring transfusion, acute kidney injury, sepsis and respiratory complications. Although our study showed no statistically significant results, the p values and confidence intervals show a trend towards significance, that hints towards a possibility of detecting a significant difference with a larger sample and more adjustment of comorbidities. From a fiscal perspective, we did not observe an increase in hospitalization cost in the DM group in compare to non-DM group. However, these results need to be evaluated by further studies and trials.

Our study has several limitations that need to be acknowledged. First, our study includes 2596 LVAD patients from the NIS registry from 2011 to 2014. However, >9000 patient received an LVAD between 2011 and 2014 according to INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) database [18]. However, since NIS is only a 20% stratified sampling of hospital discharges, there is a chance that our sample might not be fully representative of all the LVAD centers. For this current analysis, while we extracted 2596 LVAD cases from the NIS dataset, the provided trend/discharge weights were then used to generate a national estimate of 12,754 LVADs (weighted sample) implanted during the study period as highlighted in Table 1. However, this weighted sample is still very limited to represent all centers, also it's limited considering that implanting centers have very variable LVAD patients risk profiles and outcomes, and that depend on many factors like the center size, experience and equipment (e.g. ECMO). Hence, we strongly acknowledging this limitation and our results should be interpreted with caution, since NIS might not be fully representative of the entire US population undergoing support with LVAD. Secondly, NIS database does not capture variables like hemoglobin A1c and severity of retinopathy and nephropathy, insulin-use, type 1 and type 2 DM differentiation, diabetes duration, NYHA class, inotrope dependence, LVAD thrombosis, driveline infection, emergency versus non-emergency LVAD insertion, INTERMACS scores, hemodynamic and imaging data, operative conduct data and ICU data. Based on that, the impact of such poorly captured variables on the outcome is unpredictable. Some of these limitations are shared with most of the previous studies in the literature. However, the above mentioned unavailable diabetes severity variables like HbA1c, retinopathy, nephropathy, vasculopathy, and neuropathy are clinically relevant and important during LVAD candidates selection meetings, so the lack of these variables in our analysis calls for a certain caution in interpreting our results, and should be always reviewed with previously published literature. Thirdly, our cost of hospitalization analysis does not count any cardiac rehabilitation expenses, which is a possible common pathway for many advanced heart failure patients after such interventions. This cost analysis leads to underestimation of the real total medical expenditure and cost. Fourthly, the lack of data on longer-term outcomes, which is not available on our database, is a worth mentioning limitation. Finally, as with many projects that use the national database, the use of a registry database to calculate the impact of DM on mechanical support with LVADs is at risk of coding errors [19]. Various previous studies have shown that disparities in coding practice can affect the observed events and outcomes of any condition in the NIS database. However, the NIS database has been a valid tool and was used in many studies.

In conclusion, we observed no significant statistical difference in immediate in-hospital mortality and short-term post LVAD complications between diabetic and non-diabetics patients after cardiac mechanical support with LVAD implantation. Thus when needed, mechanical support with LVAD is a feasible and relatively safe in patients with diabetes and stage D congestive heart failure as a bridge to heart transplantation or as destination therapy for patients who are not candidates for transplantation. However, the selection process of LVAD candidacy among diabetics is a complex clinical decision based on multiple factors including overall comorbidities, prognostication factors and diabetic severity parameters. Readers must consider our study database limitations and that it might not be fully representative of the entire US population undergoing support with LVAD. Further studies and trials using larger sample number and more comprehensive and representative databases (e.g. INTERMACS) are needed to better evaluate LVAD potential benefits, survival and procedure-related outcomes among diabetic patients, aiming to reach a stronger evidence that might change our practice and enhance patient's outcomes.

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