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The Impact of Insurance and Socioeconomic Status on Outcomes for Patients with Left Ventricular Assist Devices

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Abstract

Background—There has been a steady increase of patients living in the community with Left Ventricular Assist Devices (LVADs). There is a significant gap in our fund of knowledge with respect to the impact that insurance and socioeconomic status has on outcomes for LVAD patients. We thus hypothesize that low neighborhood socioeconomic status and receipt of Medicaid, respectively, lead to earlier readmissions, earlier death, as well as longer time to transplantation among LVAD patients.

Methods—This was a retrospective review of 101 patients utilizing existing data in the medical information warehouse database at The Ohio State University Medical Center. Primary outcomes measured included time to first event (first readmission or death), death, and time to rehospitalization. Our secondary outcome of interest included time from LVAD implantation to cardiac transplantation.

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Results—Recipients of Medicaid did not have an increased risk of adverse events compared to patients without Medicaid coverage. Low Median Household Income (MHI) was associated with an increased risk of readmission (log-rank $p=0.0069$) and time to first event (log-rank $p=0.0088$). Bridge to Transplantation was the only independent predictor of time to death (HR 2.1, [95% CI=1.03–4.37]). Low MHI and a history of atherosclerosis were both significant predictors for readmission and time to first event. Aldosterone antagonist use decreased the risk of readmission or time to first event by 46%.

Conclusion—LVAD recipients with a low MHI were more likely to be readmitted to the hospital after LVAD implantation. Whether these patients are adequately monitored on an outpatient basis remains unclear.

Introduction

Heart Failure (HF) is a national epidemic,¹ and the lifetime risk for the development of HF is 20%.² Cardiac transplantation is the best treatment option for end-stage HF, but a severe shortage of donor organs is a serious issue and many patients are poor candidates for transplantation.^{3,4} Left ventricular assist devices (LVADs) have quickly revolutionized and improved the care of the sickest HF patients. For NYHA class IV patients that require LVAD support, overall quality of life and functional capacity is improved with LVADs.⁵ The Centers for Medicaid and Medicare Services (CMS) mandated that all U.S. hospitals approved for mechanical circulatory support (MCS) as destination therapy (DT) enter patient data into the Interagency Registry for Mechanical Circulatory Support (INTERMACS) database.⁶

Survival with continuous-flow pumps exceeds 80% at 1 year and 70% at 2 years, comparable to patients receiving heart transplants.^{7–9} The cost-effectiveness associated with continuous-flow LVADs for DT and for bridge to transplantation (BTT) has improved significantly over the past several years.¹⁰ There has been a 50% reduction in the hospitalization cost associated with LVAD implantation since 2001. Improvements in operative technique and postoperative management appear to play critical roles in the observed cost reduction.¹¹ In an elegant study using a decision-analytic model, Long and colleagues were able to demonstrate that indeed DT and BTT LVADs improve long-term survival when compared to inotrope dependent therapy, although unlike orthotopic cardiac transplantation they fail to meet conventional cost-effectiveness thresholds. Because of this shortcoming it is reasonable to identify other financial or societal issues associated with outcomes in this complex patient population.¹²

Once these patients are discharged and return to the community, it remains unknown if insurance or socioeconomic status (SES) is associated with increased readmission and mortality, or longer time to transplantation among LVAD patients. HF has been described as a socio-geographic condition, and where a patient lives could be a predictor of adverse outcomes.¹³ Patients with low SES may be less inclined to follow-up with physicians in general, which in turn could lead to longer evaluation times or outright cause them to be denied transplantation altogether due to a history of noncompliance.¹⁴ Thus it is important to understand how neighborhood-level SES impacts HF progression for LVAD patients in the

community. While health insurance is a prerequisite for long-term LVAD support, due to significant costs to maintaining the quality of the device, patients with certain types of insurance may utilize preventive services differently, which may in turn influence outcomes. Little is known about the impact SES and insurance status has on the LVAD population. Recent data demonstrated that short- and long-term mortality after LVAD implantation among Medicare beneficiaries improved overall survival, but information regarding the Medicaid population is lacking.¹⁵ We believe there is a gap in our fund of knowledge with respect to the care of patients post-LVAD implantation once they leave the hospital and return to the community. We thus hypothesized that low neighborhood SES and receipt of Medicaid, respectively, would lead to earlier readmissions and death, as well as a longer time to transplantation among LVAD patients.

Methods

This was a retrospective review which was approved by The Ohio State University Medical Center's (OSUMC) Institutional Review Committee utilizing existing patient data in the medical information warehouse (IW) database. The main inclusion criteria were age over 18 with a history of HeartMate II® (HMII) LVAD (Thoratec Corporation, Pleasanton, CA, USA) placement between January 1, 2006 and December 31, 2010 (as this device is approved in the US for bridge to transplantation [BTT] and DT). Follow-up continued through December 31, 2011. A total of 121 patients underwent implantation with a HMII. Of these, 10 patients did not survive to be discharged and 10 were implanted with LVADs other than a HMII and were excluded (all short-term, non-durable LVADs were excluded), leaving 101 patients for analysis.

Primary outcomes measured included time to first event (first readmission or death), readmission, and death. We obtained readmission data using the IW database, and readmission was recorded as the first inpatient admission after the initial discharge date (which followed LVAD implantation). No readmissions were due to cardiac transplantation. We used mortality data from the IW which arises from the Social Security Death Index. Our secondary outcome of interest was time to cardiac transplantation among patients for whom the LVAD was not DT. We ascertained DT or BTT at the time of LVAD implantation from an internal database maintained by OSUMC LVAD coordinators.

Using patients' zip code of residence as indicated in the medical record, we linked each LVAD patient with year 2010 U.S. Census median household income (MHI) data, which are publicly available from the US Census website (<http://factfinder2.census.gov>). At the time of LVAD placement, eligible patients were living in Ohio and West Virginia. We categorized MHI into tertiles from the representative zip codes as follows: low, <\$38,370; medium, \$38,371 to < \$56,890; and high, >\$56,891. We obtained insurance status from the medical record, and classified patients as either Medicaid or non-Medicaid recipients, according to previous work.¹⁶

We abstracted patient age, date of LVAD placement, gender, race, and co-morbid conditions, and concurrent treatments from the medical record. Specifically, we ascertained the prevalence of common underlying conditions at the time of LVAD implantation using

International Classification of Diseases, Version 9 (ICD-9) discharge codes. We used ICD-9 codes 401.1–401.9, 249.-250.93, 410–412, 440–440.9, 414.0–414.4, 36.11–36.16, and 276.1 to define hypertension, diabetes, myocardial infarction, atherosclerosis, stroke, coronary artery disease, and coronary artery bypass graft (CABG) surgery, respectively. We recorded drug therapy (ACE-inhibitor, angiotensin receptor blocker, diuretic, beta-blocker, aldosterone antagonist, inotrope) as indicated in the medical record, whether the patient had a medication order with order activation as an outpatient or received the medication during the initial admission during which the LVAD was implanted. Hence the medications prescribed are pre-implant variables. We defined hyponatremia as a sodium level < 135 mEq/L¹⁷ and moderate to severe renal failure as a creatinine > 1.5 mg/dL.¹⁸ All covariates were assessed on the date of LVAD implantation. Using ICD-9 procedure code 37.51 we were able to determine which patients were transplanted, and then we reviewed the medical record to verify that the transplant occurred.

Data Analysis

We presented continuous data as means and standard deviations. We assessed continuous variables for normality and compared them using Student's t-tests. Categorical variables were analyzed using contingency tables and the McNemar test statistic with Yates' correction for continuity. We produced survival curves depicting survival free of readmission or death. For the primary outcomes, multivariable Cox regression was used to estimate the hazard of readmission or death and receipt of Medicaid and SES based on MHI. Multivariable predictors were selected using backwards selection with a p-value threshold of 0.10 to be included in the model. We assessed the proportional hazards assumption for time-dependent covariates (age and MHI) visually and graphically. We ran separate models to estimate the hazard of death, readmission or death, and readmission alone. All participants were censored at the end of 2011. Time to transplant was defined as the interval from the day of LVAD implantation to the day of cardiac transplantation. Our study was not powered to assess for covariates associated with time to transplantation.

Insurance status (Medicaid versus non-Medicaid) and MHI-readmission/mortality relationship analyses were conducted, the influence of covariates in a full model were tested, and effect modification (interaction $p < 0.05$) of the insurance status/MHI-readmission/mortality relationship was assessed by age, race, sex, hypertension, diabetes, history of co-morbid illness (myocardial infarction, atherosclerosis, stroke, coronary artery disease, coronary artery bypass graft surgery, hyponatremia, and renal failure) and HF medication use (ACE-inhibitor, angiotensinogen receptor blocker, aldosterone antagonist, beta-blocker, and inotrope use). In the full models, hazard ratios and 95% confidence intervals were estimated adjusting for all significant covariates. All tests were 2 sided, and p-values < 0.05 were considered to indicate statistical significance. All statistical analyses were performed using STATA 12 (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP).

Results

When comparing participants based on insurance status (Medicaid versus non-Medicaid), the MHI was very similar (\$46,786 versus \$44,928 respectively). As shown in Table 1, a greater proportion of non-Medicaid recipients were older (mean age of 57), and had a greater proportion of comorbid illnesses such as diabetes, coronary artery disease, a history of stroke, CABG surgery, hyponatremia, renal disease, and these patients experienced higher mortality. With respect to MHI, as shown in Table 1, the mean age was very similar in all groups, but participants with high MHI had the lowest percentage of overall mortality and participants with low MHI had the highest proportion of hypertension. Irrespective of MHI or insurance status, the majority of the participants were Caucasian males (Table 1). Forty-one of the patients were BTT candidates, and 46% of these individuals were transplanted within the study timeframe.

Time-to-Event Analyses

Median time to event—Recipients of Medicaid experienced earlier median times to death, readmission, and time to first event (Table 2) despite being 15 years younger on average (Table 1). A similar trend towards earlier events was seen with participants in the low MHI tertile, where the median time to death occurred nearly 100 days earlier for low MHI participants versus high MHI participants, and the median time to readmission occurred 59 days earlier for low MHI participants and 26 days earlier for medium MHI participants compared to high MHI participants (Table 2). With respect to time to transplantation, the median time for recipients of Medicaid was 187 days versus 332 days for participants without Medicaid, and the median time to transplantation was also shorter for participants in the lowest versus the highest tertile of MHI (Table 2).

Insurance Status—As shown in Figure 1, there was also no significant difference in time to first event (death or readmission) based on insurance status. In comparing survival curves, recipients of Medicaid did not have an increased risk of death (log-rank $p=0.4995$) or readmission (log-rank $p=0.8224$) compared to patients without Medicaid coverage. Further, there was no significant difference between insurance groups in time to cardiac transplantation (log-rank $p=0.128$).

Median Household Income—Similar to insurance status findings, patients living in low MHI areas did not have an increased risk of death (log-rank $p=0.2687$), but low MHI was associated with an increased risk of readmission (log-rank $p=0.0069$) compared to high MHI. As shown in Figure 2, there was a significant difference in the time to first event between participants with low MHI versus those living in middle and high MHI areas. Similar to insurance status, there was no significant difference between the MHI groups in terms of time to cardiac transplantation (log-rank $p=0.77$).

Multivariable analysis—Using multivariable analysis, we were able to identify several significant risk factors for death, readmission, and time to first event (Table 3). Medium, but not high, MHI was associated with a lower hazard of first event (0.4, 0.25–0.65) and readmission (0.4, 0.24–0.65), compared to low MHI. No differences by MHI were observed

for the outcome of death. In addition, a history of atherosclerosis increased the hazard of first event or readmission, and aldosterone antagonist use decreased the hazard of first event or readmission by nearly 50%. History of atherosclerosis was also a significant predictor for readmission and time to first event (2.86, 1.34–6.08). BTT was the only independent predictor of time to death identified (HR 2.1, [95% CI=1.03–4.37]). Aldosterone antagonist use decreased the risk of readmission or time to first event by 46% (Table 3). We could not assess predictors of time to transplantation for LVAD patients in the multivariable analysis due to the small number of events (transplants, n=22). The effect of insurance status and MHI in multivariable models was not modified by age, race, sex, hypertension, diabetes, history of co-morbid illness, or HF medication use.

Discussion

These data were the first of their kind to provide insight into the role of insurance coverage and SES in outcomes for LVAD recipients. Our data strongly suggest that patients with medium MHI are significantly less likely to be readmitted to the hospital compared to patients with low MHI after receiving a LVAD. In the present study, recipients of Medicaid did experience shorter median times to death, readmission, and first event, but this did not result in a higher hazard of readmission or death in multivariable models. There are two possible explanations for this unexpected finding. First, Medicaid recipients were much younger than recipients of non-Medicaid insurance (mean age of 42 versus 57) and would be expected to have better overall survival and fewer events, and secondly there were only a total of 21 Medicaid patients in our cohort, thus we may not have had sufficient numbers to detect a difference between the groups.

Meanwhile, higher MHI was associated with a decreased hazard of readmission and longer time to first event, but this relationship did not hold when considering time to cardiac transplantation. These findings are consistent with a review of SES in HF patients that concluded that hospital admission rates increase with increased social deprivation,¹⁹ and a study in which HF patients had an increased hazard of readmission, death, and readmission or death if they lived in a lower MHI area.¹⁶ Previous data suggests that persons living in economically deprived areas may be less likely to follow-up with care providers as regularly and, thus, may seek care in the hospital for device-related conditions that can be managed outside the hospital.²⁰ Additionally it has been reported that follow-up rates with physicians were lowest among patients with high neighborhood socioeconomic deprivation.¹⁴

For patients that return to the community with LVADs, frequent physician and clinic follow-up is imperative to monitor the status of the patient and to assess for potential device complications. Prior to receiving mechanical support with a LVAD, patients typically are assessed for candidacy and future compliance by a multidisciplinary team consisting of social workers, case managers, psychiatrists/psychologists, LVAD coordinators/nurses, cardiac surgeons, and HF cardiologists. As a result, these patients, irrespective of SES, should be more likely to follow-up with physicians and to make routine clinic visits due to the rigorous screening process.

While previous studies have shed light on the critical importance of place of residence and comorbidity, the same studies were critiqued for their lack of clinical details about disease severity and type and class of HF.¹³ In the present study, we include factors of disease severity and restrict the study to one HF class. LVAD patients must have New York Heart Association (NYHA) Class IV HF with a left ventricular ejection fraction of less than 25% for reimbursement purposes.²¹

What is striking about these data is that insurance status had no impact on readmission rates. Any definitive conclusion about the role of insurance status is limited by the small number of participants in our study that had Medicaid insurance (n=21). There are examples in the literature where insurance status has been used to represent individual SES,^{22–24} and for the most part Medicaid coverage is only provided to patients below the federal poverty level.²⁵ The majority of Medicaid recipients have incomes below the federal poverty line²⁶, thus, in the absence of other SES data, receipt of Medicaid can be interpreted as a surrogate for low SES.

Readmission is an important outcome to assess because of the cost incurred on the health care system as a whole. In a recent single center study, readmission rates after continuous flow LVAD implantation decreased during the first 6 months and then stabilized. The leading causes for readmission were bleeding, cardiac (HF and arrhythmia), infections, and thrombosis.²⁷ We identified several other potential risk factors for readmission, including lower MHI and history of atherosclerosis. We also identified that aldosterone antagonist use decreased time to readmission. This is a typical component of advanced HF therapy, and previous data strongly suggests this class of medications can reduce morbidity and mortality in HF patients.^{28,29} One limitation with this finding is that all medications in the study are pre-implantation variables and were assessed at the time of LVAD implantation, thus we do not know the exact duration of therapy.

Interestingly, BTT was identified as a significant predictor for time to death. This was an unexpected finding, since DT typically portends a slightly worse prognosis.³⁰ Specifically, the difference in predicted 1-year survival between BTT and DT is 5%.³⁰ The increased mortality observed with BTT in our study could be due to our small sample size and any death would have more impact on the final analysis, especially considering that at baseline there is only a 5% difference between the two cohorts with respect to one year survival.³⁰ It is important to note that our study was not powered to answer this particular question.

The present study is not without limitations. It was a retrospective, single-center review of patients from a large tertiary care referral center. Being a single-center study, it may not be representative of what occurs at other institutions. Therefore, in interpreting the results, one should be aware of the patient characteristics described by the authors. It should also be noted that while we characterized SES at the zip-code level, future studies may wish to define MHI in smaller geographic units, such as U.S. Census tracts, which may more closely approximate neighborhood-level exposures in smaller medical center catchment areas.

It is quite possible that LVAD patients were readmitted or died at another institution, and if so that would bias our results toward the null and we underestimated the risk of an adverse

outcome based on insurance status and MHI. But due to the complexity of these devices, these patients are often transferred back to the institution where the LVAD was implanted as many community hospitals are not familiar or comfortable with managing these patients, so in all likelihood loss to follow-up was minimal. Additionally, our LVAD coordinators keep detailed records on all of our LVAD patients with respect to morbidity and mortality as these data are reported to the INTERMACS registry.

Due to our low overall numbers which would minimize power, we decided to avoid performing a cost analysis and cost-comparisons. Future directions should include such analyses to build upon the work by Long. Additionally we have interest in assessing preoperative risk scores to further define this complex cohort of patients and create strategies to minimize adverse events and costs.

Conclusions

In the present study, LVAD recipients with a higher MHI were less likely to be readmitted to the hospital after LVAD implantation. Whether these patients are adequately monitored on an outpatient basis remains unclear. Regardless, more work needs to be done to clarify the socioeconomic context of patients with LVADs in the community as this form of treatment becomes a more viable option for the millions of patients with HF in America.

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Figure 1.
Time to First Event Based on Insurance Status
There was no significant difference in time to first event (death or readmission) between Medicaid Recipients (dashed line) and Medicare Recipients (solid line).

Figure 2.

Time to First Event Based on Median Household Income (MHI) Status

There was a significant difference in the time to first event (death or readmission) between participants with low MHI (<\$38,370, dash-dot line) versus those living in middle (solid line) and high MHI areas (dashed line).

Table 1
Baseline Characteristics of Participants with LVAD Implantation by Medicaid Status and MHI

	Medicaid Recipient		Median Household Income			
	Yes (n=21)	No (n=80)	p-value	Low (n=31)	Medium (n=49)	High (n=21)
Median Household Income, USD *	\$46,786	\$44,928	0.8137	\$35,483	\$45,852	\$65,938
Medicaid (%)	---	---	---	23%	18%	24%
Males (%)	81%	74%	0.5010	71%	69%	95%
Caucasian (%)	67%	86%	0.0372**	71%	88%	86%
Age (years)	42 ± 13.4	57 ± 12.6	<0.0001**	53 ± 14	55 ± 14	55 ± 15
Mortality (%)	24%	31%	0.5115	35%	31%	19%
Hypertension (%)	43%	43%	0.9768	52%	39%	38%
Diabetes (%)	29%	55%	0.0312**	42%	57%	43%
Myocardial Infarction (%)	19%	13%	0.4447	13%	14%	14%
Atherosclerosis (%)	5%	10%	0.4584	10%	8%	10%
Stroke (%)	5%	18%	0.1469	16%	12%	19%
Coronary artery disease (%)	48%	75%	0.0152**	68%	69%	71%
ACE Inhibitors † (%)	57%	45%	0.3262	65%	41%	38%
ARB ‡ (%)	19%	15%	0.6551	10%	16%	24%
Aldosterone antagonist (%)	67%	59%	0.5140	58%	55%	76%
Diuretics (%)	67%	58%	0.4515	58%	55%	71%
Beta Blockers (%)	76%	80%	0.7053	77%	78%	86%
Inotrope (%)	90%	78%	0.1877	77%	82%	81%
CABG § (%)	0	5%	0.3005	6%	0	10%
Orthotopic transplant (%)	24%	21%	0.8027	16%	22%	29%
Hyponatremia (< 135 mEq/L)	33%	50%	0.1764	42%	47%	52%
Moderate to severe renal failure (creatinine > 1.5 mg/dL)	11%	22%	0.5746	7%	30%	17%

* United States Dollars

† Angiotensin-converting-enzyme inhibitor

‡ Aldosterone Receptor Blocker

§ Coronary Artery Bypass Grafting

##

p-value<0.05 considered statistically significant

Median Time to Event

	Medicaid Recipient		Median Household Income				
	Yes (n=21)	No (n=80)	p-value	Low (n=31)	Medium (n=49)	High (n=21)	p-value
Time to Death (Days)	428 (n=7, 33%)	466 (n=23, 29%)	0.7354	362 (n=11, 35%)	566 (n=15, 31%)	457 (n=4, 19%)	0.5918
Time to Readmission (Days)	43 (n=18, 86%)	71 (n=75, 94%)	0.7476	45 (n=31,100%)	78 (n=41, 84%)	104 (n=21,100%)	0.0807
Time to Death or Readmission (Days)	43 (n=18, 86%)	71 (n=75, 94%)	0.7506	45 (n=31,100%)	78 (n=41, 84%)	78 (n=41, 84%)	0.0822
Time to Transplantation (Days)	187 (n=4, 24%)	332 (n=18, 23%)	0.3889	258 (n=6, 19%)	210 (n=11, 22%)	342 (n=5, 24%)	0.5240

Table 3

Significant Risk Factors for Death, Readmission, and Time to First Event (HR, 95% CI, p-value [<0.05 statistically significant])

	Death	Readmission	Death or Readmission
BTT	HR 2.1, [1.03–4.37], $p=0.041$	---	---
MHI (low MHI referent)	---	Medium: HR 0.4, [0.24–0.65], $p<0.001$ High: HR 0.69, [0.39–1.22], $p=0.204$	Medium: HR 0.4, [0.25–0.65], $p<0.001$ High: HR 0.69, [0.39–1.22], $p=0.206$
Atherosclerosis	---	HR 2.9, [1.36–6.12], $p=0.001$	HR 2.86, [1.34–6.08], $p=0.001$
Aldosterone Antagonist	---	HR 0.54, [0.35–0.85], $p=0.008$	HR 0.54, [0.347–0.85], $p=0.008$