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The Impact of Socioeconomic Status on Patients Supported with a Left Ventricular Assist Device: An Analysis of the UNOS Database

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Abstract

Background—Low socioeconomic status (SES) is a known risk factor for heart failure, mortality among those with heart failure, and poor post heart transplant (HT) outcomes. This study sought to determine if SES is associated with decreased waitlist survival while on LVAD support and after HT.

Methods and Results—3,361 adult patients bridged to primary HT with an LVAD between May 2004 and April 2014 were identified in the UNOS database. SES was measured using the AHRQ SES index using data from the 2014 American Community Survey. In the study cohort, SES did not have an association with the combined endpoint of death or delisting on LVAD support (p=0.30). In a cause-specific unadjusted model, those in the top (HR 1.55, 95% CI 1.14–2.11, p=0.005) and second greatest SES quartile (HR 1.50, 95% CI 1.10–2.04, p=0.01) had an increased risk of death on device support compared to the lowest SES quartile. Adjusting for clinical risk factors mitigated the increased risk. There was no association between SES and complications. Post-HT survival, both crude and adjusted, was decreased for patients in the lowest quartile of SES index compared to all other SES quartiles.

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Conclusions—Freedom from waitlist death or delisting was not impacted by SES. Patients with a higher SES had an increased unadjusted risk of waitlist mortality during LVAD support, which was mitigated by adjusting for increased comorbid conditions. Low SES was associated with worse post-HT outcomes. Further study is needed to confirm and understand a differential effect of SES on post-transplant outcomes that was not seen during LVAD support prior to HT.

Keywords

transplantation; heart failure; left ventricular assist device; socioeconomic position

Socioeconomic status (SES) has been identified as a risk factor for heart failure,[1] hospital readmission,[2, 3] and mortality.[1, 2] Among patients who progress to Stage D heart failure, both heart transplantation and left ventricular assist devices (LVAD) provide improved quality of life and survival. Previous studies have identified race[4, 5] and SES[6] as a risk factor for decreased post-transplant survival in adults and children respectively. Similarly, low SES has been shown to be associated with increased risk of rejection and graft loss after transplantation.[7, 8] One single-center study suggested that among patients bridged to transplantation (BTT) with an LVAD, low median household income was the only predictor of death or readmission.[9] A 136 patient single-center study investigated at the impact of psychosocial determinants on LVAD patients found no impact on mortality, but found current drug use, depression, and paradoxically not currently smoking to increase the risk of readmission in destination therapy LVAD patients.[10] This study sought to determine if SES and its determinants are associated with decreased survival while on LVAD support and after HT.

Methods

The United Network for Organ Sharing (UNOS) database was analyzed for patients bridged to transplantation with a continuous-flow LVAD (CF-LVAD) between May 2004 and April 2014. Follow-up data was collected through June 2014. Adult candidates (age ≥18 years) registered for a single organ primary heart transplant who received a Food and Drug Administration (FDA) approved CF-LVAD were included. Devices were limited to the Heartmate II (Thoratec/St. Jude, Pleasanton, CA) and Heartware HVAD (Heartware, Framingham, MA). Patients who required temporary left sided mechanical circulatory support, BiVAD, or total artificial heart were excluded from the analysis. The primary endpoint was freedom from death or delisting while on LVAD support. Secondary endpoints included death while on LVAD support, delisting while on LVAD support, complications (thromboembolism, device infection, device malfunction, or life-threatening ventricular arrhythmia) requiring UNOS listing status upgrade, and post-transplant survival. BTT was the ultimate strategy for all patients.

Socioeconomic status was measured using the Agency for Healthcare Research and Quality (AHRQ) SES index. The AHRQ SES index is a measure of neighborhood SES and was generated using the following Zip-code level Census variables: percentage of people in the labor force who are unemployed, percentage of people living below poverty level, median household income, median value of owner-occupied dwellings, percentage of people ≥25

years of age with less than a 12th-grade education, percentage of people ≥25 years of age completing ≥4 years of college, and percentage of households that average ≥1 people per room. (Supplemental Material)[11]. The SES index for this study was calculated using data from the 2014 American Community Survey and has been previously used.[12–14] The study was submitted to the Institutional Review Board of Columbia University Medical Center and was determined to be exempt from review.

Statistical Analysis

Demographic and clinical variables were summarized with standard descriptive statistics and expressed as median (with interquartile range) for skewed continuous variables and count (with percentage) for categorical variables. Group comparisons were made with the Chi-squared and the Kruskal-Wallis test where appropriate. Kaplan-Meier survival analysis, univariate and multivariable Cox proportional-hazards regression were performed to determine survival statistics with Dunnett's test applied for pairwise comparisons. Cause-specific hazard models were created and cumulative incidence functions were calculated with death and delisting alternating as a competing event. A two-tailed p-value of less than 0.05 was considered significant. Analyses were performed using SAS version 9.4 (SAS Institute, Inc, Cary, North Carolina).

Results

During the study period 3,361 patients met inclusion criteria. The Heartmate II was the predominant LVAD used among the study population (84%). After grouping patients into quartiles based on SES index score, demographic variables differed as anticipated: the top quartile was more educated, had a higher median income, had a greater proportion with private insurance, was more likely to be white or Asian, and was slightly older (Table 1). Clinical characteristics were similar across all quartiles except diabetes was less common and BMI was slightly less among those with a higher SES index score. A greater proportion of those in the highest SES quartile had the lowest functional status at listing. Lastly, patients in the top SES quartile were less likely to have an LVAD in place at the time of transplant listing and had a shorter time on LVAD support.

A total of 681 patients experienced death or delisting while on LVAD support. Between SES quartiles, there was no difference in event-free survival (Figure 1, p=0.30). Analysis of individual determinants of SES (education level, household income, type of insurance, and race) failed to demonstrate that any were significant predictors of the composite endpoint (Figure 2). Competing risks analysis was performed for all patients (Figure 3) and for each SES quartile, demonstrating differences in individual outcomes (Supplemental Figure 1). When accounting for delisting and transplantation as competing events, there was an increased risk of death for the top (HR 1.55, 95% CI 1.14–2.11, p=0.005) and third (HR 1.50, 95% CI 1.10–2.04, p=0.01) SES quartiles compared with the bottom quartile. A multivariable cause-specific hazard model was created for SES quartile, adjusting for clinical acuity at listing (functional status at listing and ventilator use at listing) and clinical comorbidities and factors that increase the difficulty of finding a suitable donor (age, gender, ABO blood group, BMI, pulmonary vascular resistance >3 Wood units, renal function,

presence of an ICD, PRA>10%, complications requiring UNOS listing status upgrade, and waitlist time on LVAD support), which found that the increased risk of death during device support among patients of greater SES was no longer present (Top quartile 95% CI 0.95–2.04; p=0.09; Third Quartile 95% CI 0.84–1.79; p=0.28). The incidence of delisting was similar between SES quartiles.

A complication requiring UNOS listing status upgrade while on LVAD support occurred in 599 (18%) patients during the study period. There was no association between SES and frequency of complications requiring UNOS listing status upgrade (Range 17.1%–18.7%, p=0.86). Similarly, there was neither an increased risk of a composite measure of complications (thromboembolism, device infection, device malfunction, or life-threatening ventricular arrhythmia) across SES index quartiles, nor was there an increased risk of individual complications (Table 2).

Heart transplantation occurred for 2,402 (71.5%) patients during the study period. The incidence of transplantation did not differ by SES, though the median time from LVAD implantation to transplantation was longer for the lowest SES quartile (Table 1). For the entire cohort one and two-year post-transplant survival was 89.9% and 86.2% respectively. When stratified by SES index quartiles, patients in the lowest quartile had a 29–41% increased risk of post-transplant graft loss (87.3% one-year and 82.2% two-year, p<0.03, Figure 4) compared with those in higher SES quartiles. However, no individual SES determinant (education level, income, race, or insurance type) was an independent predictor of post-transplant graft loss (Supplemental Figure 1). Adjusting for age[15], renal dysfunction[15], device infection[16, 17], and duration of LVAD support[18, 19] (previously reported pre-transplant causes of decreased BTT post-transplant survival) in addition to ischemic time, allograft rejection requiring hospitalization, and post-transplant hospitalizations for infection [15] the increased risk of post-transplant mortality among those of in the bottom SES quartile remained (Second Quartile: HR 0.57, 0.39–0.82, p=0.002; Third Quartile: HR 0.67, 0.47–0.94, p=0.02; Top Quartile: HR: 0.68, 0.48–0.95, p=0.02).

Discussion

Socioeconomic disparities exist in healthcare in the United States. These disparities extend to Stage D heart failure with differences in multiple listing prior to heart transplantation[14] and survival & rejection after transplantation[7]. This study examined the impact that SES and its determinants SES had on patients bridged to transplantation with a LVAD and resulted in three notable findings. First, all patients regardless of SES had similar freedom from death or delisting on LVAD support. Second, patients in the top two SES quartiles had an increased risk of death on the waitlist during LVAD support, which was explained by increased clinical acuity and differences in baseline clinical risk factors. Lastly, patients in the lowest SES index quartile had an early and sustained decreased post-transplant survival compared with each greater SES index quartile.

Implantation of a left ventricular assist device leads to improved quality of life, increased exercise tolerance[20], and improved survival.[21] In this study, SES did not impact freedom from death or delisting while on device support. However, higher SES status was associated

with an unadjusted increased risk of death. A plausible explanation is that those of greater SES were clinically different and a higher risk population, which was the case in this study. Those in the top SES quartile had increased odds of being severely debilitated & hospitalized at the time of listing and on a ventilator at the time of listing. While clinical acuity at listing accounted for some of the increased risk of death for those with greater SES, a portion remained unexplained. This analysis attempted to account for alternative etiologies for the increased risk by controlling for clinical characteristics that increase the difficulty of finding a suitable donor (PRA>10%, BMI, gender, ABO blood type) and those that signify additional comorbidities (PVR suggesting pulmonary hypertension, ICD presence for chronicity of heart failure, renal dysfunction, age, waitlist time on LVAD support, and device complications). The increased risk of death on LVAD support was no longer significant for higher SES quartiles when adjusting for those clinical differences, suggesting that the listing characteristics may differ based on SES. Patients of lower SES more often had an upfront strategy with LVAD implantation at the time of listing (potentially bridge to decision) and were not as functionally debilitated when compared to those with the highest SES. Whether this was due to earlier engagement in care by those with higher SES or a bias based on SES remains unclear, but merits further exploration.

In this study SES index was associated with post-transplant outcomes. Patients in the lowest SES quartile had an early and sustained decrease in post-transplant survival, even after controlling for risk factors for post-transplant mortality. This finding is consistent with the impact of SES on pediatric heart transplant recipients[6] and previous analyses of the UNOS database demonstrating an association between public insurance and worse outcomes following kidney[22], liver[23], and lung transplantation[24]. Insurance coverage of immunosuppressive drugs is one possible cause for the difference in post-transplant outcomes, as prescription coverage can vary between different types of insurance. In this study survival was equivalent for all SES during LVAD support when new medications (warfarin, aspirin, and/or dipyridamole) are not prohibitively expensive. However post-transplantation, when more expensive immunosuppressive drugs ($31,209 annually in 2011)[25] are required, those with low SES had an increased risk of death. Post-transplant care requires frequent follow-up for monitoring of immunosuppressive drug levels and rejection surveillance, which is another potential explanation of this difference. In this study, however, there was no evidence of increased odds of hospitalization for rejection or hospitalization for infection following transplantation among those of lower SES.

Limitations of this study include the retrospective nature of the study. The UNOS dataset that was used is high-quality in that for all U.S. transplant centers data submission is mandatory by law, however it is limited to the data collected. As such, a number of covariates of interest including readmission, bleeding, and serum albumin were not available for analysis. Further, there were missing data. Although no variable had more than 1% missing aside from hemodynamic parameters where up to 15% was missing. Nevertheless this introduces the potential for bias into the analysis. Similarly, not all complications were able to be captured given the limitations of the UNOS database. The most serious complications that required UNOS status upgrade were captured however. The study population was also BTT, as the UNOS database does not include destination therapy patients. Lastly, the SES index was calculated using Zip-code level Census data as some

specific SES determinants are not captured by the UNOS database. This has been used as a strategy in many prior analyses of the UNOS database; nonetheless Zip-code level data was used as a proxy for patient level data under the presumption that these factors are homogenous within a Zip-code and a patient's Zip-code did not vary.

In conclusion, SES and its determinants did not impact survival to transplantation on LVAD support. Those of higher SES had an unadjusted increased risk of death during LVAD support, though this was due to clinical differences. Following transplantation, low SES was associated with worse post-transplant survival. Further study is needed to confirm and understand a differential effect of SES on post-transplant outcomes that was not seen during LVAD support prior to HT.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Clinical Perspective

One major criticism of healthcare in the United States is the impact that socioeconomic status (SES) has on individual health outcomes. Previous studies have demonstrated that lower SES is a risk factor for heart failure, hospital readmission, and death. The impact of SES extends to Stage D heart failure as those with lower SES have decreased survival and an increased risk of rejection following transplantation. This study was an analysis of 3,361 adult patients in UNOS database to examine the impact of SES on patients supported with a continuous-flow left ventricular assist device (LVAD). The data demonstrated in an unadjusted analysis that there was increased waitlist mortality for the higher SES quartiles; however this increased risk was due to increased comorbid conditions. There was no difference between SES quartiles for complications requiring UNOS listing status upgrade. Post-transplantation survival was less for the lowest SES quartile, consistent with previous studies. This study demonstrated that SES and its determinants did not impact survival to transplantation on LVAD support and that SES should not be a barrier to use of an LVAD.

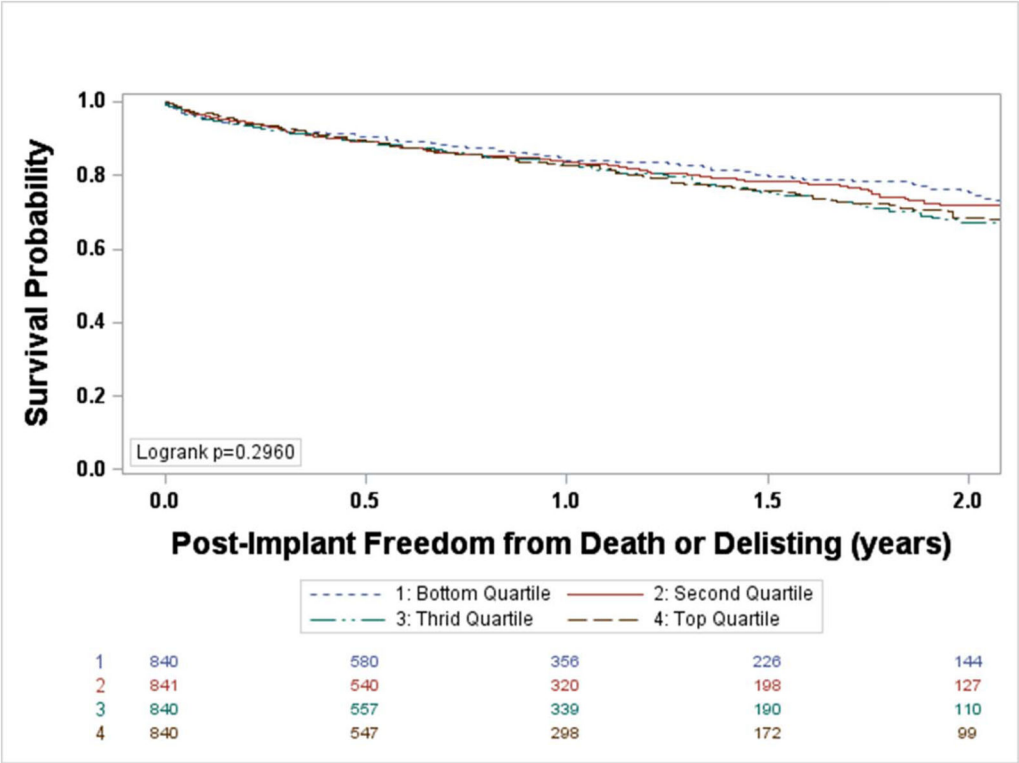

Figure 1.
Freedom from death or delisting while on LVAD support stratified by SES index quartiles

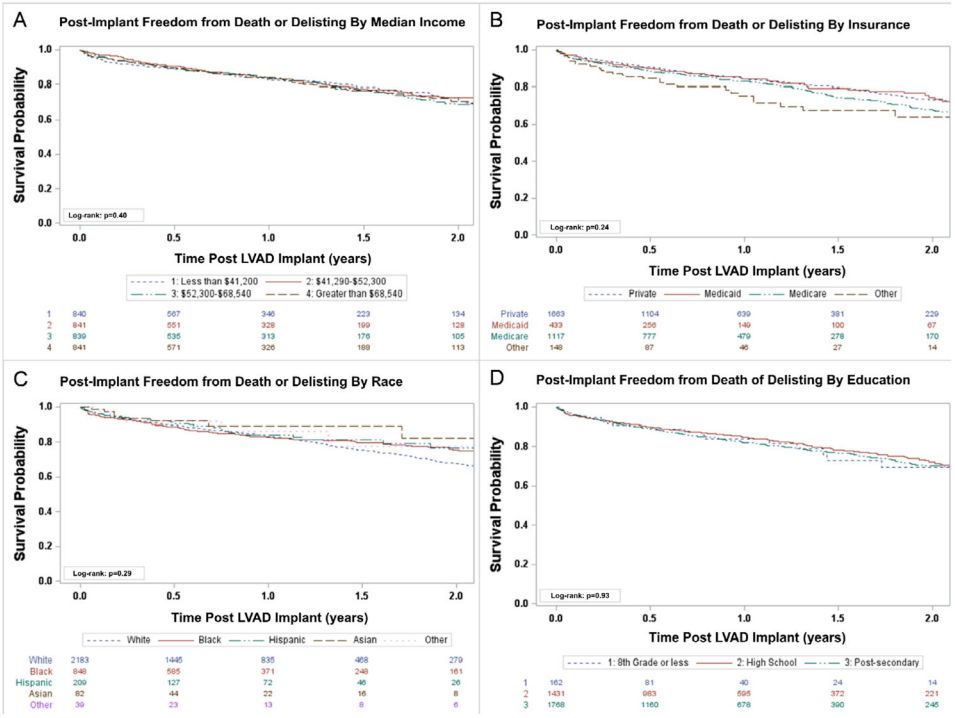

Figure 2.

Freedom from Death or Delisting stratified by income (A), type of payment (B), race (C), and education (D)

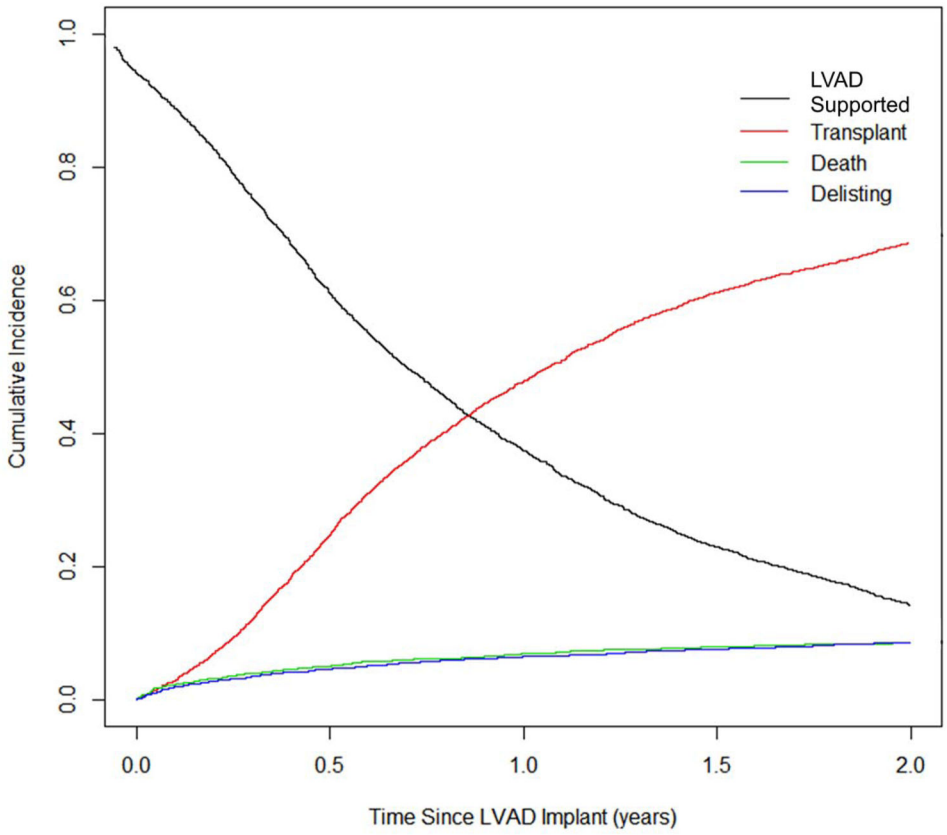

Figure 3.
Competing Risk Plot of Waitlist Events for All Patients

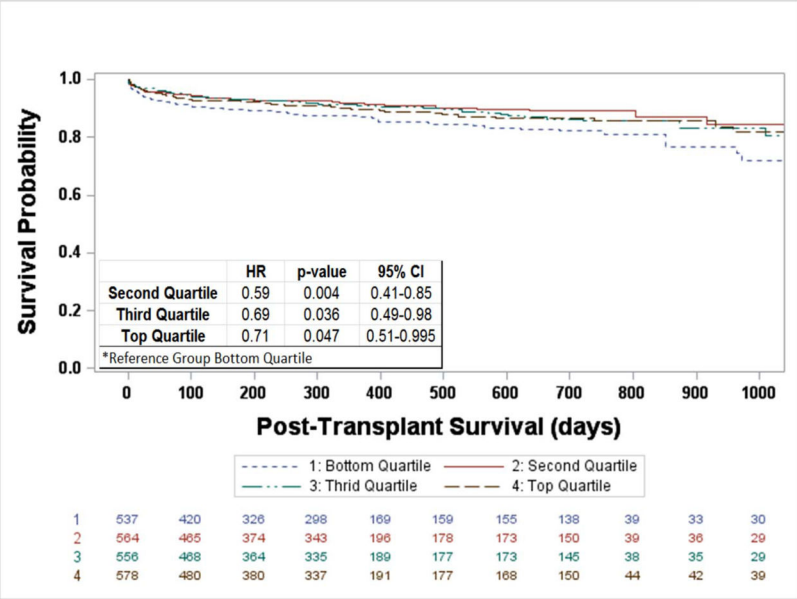

Figure 4.
Post-transplant freedom from graft loss stratified by SES index quartiles

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Table 1

Baseline characteristics of study population

	Bottom Quartile N= 840	Second Quartile N= 841	Third Quartile N= 840	Top Quartile N= 840	p-value
Male	629 (75.5)	642 (76.3)	661 (78.7)	648 (77.1)	0.31
Age	53 (42–61)	55 (45–62)	56 (46.5–62)	57 (47–63)	<0.0001
LVAD Type					0.43
Heartmate II	706 (84.1)	713 (84.8)	713 (84.9)	691 (82.3)	
Heartware HVAD	134 (15.9)	128 (15.2)	127 (15.1)	149 (17.7)	
Etiology of Cardiomyopathy					0.03
Ischemic	310 (36.9)	369 (43.9)	345 (41.1)	332 (39.5)	
Non-ischemic	530 (60.1)	472 (56.1)	495 (58.9)	508 (60.5)	
Insurance Type					<0.0001
Private	306 (36.4)	388 (46.1)	457 (54.4)	512 (61.0)	
Medicaid	152 (18.2)	108 (12.8)	97 (11.6)	75 (8.9)	
Medicare	338 (40.2)	310 (36.9)	245 (29.2)	224 (26.7)	
Education Level					<0.0001
Eighth Grade or Less	69 (8.2)	39 (4.6)	27 (3.2)	27 (3.2)	
High School	428 (51.0)	397 (47.2)	363 (43.2)	243 (28.9)	
Post-Secondary	343 (40.8)	405 (48.2)	450 (53.6)	570 (67.9)	
Income	$35,477 (30,857–40,418)	$46,846 (42,087–51,427)	$57,881 (52,301–64,866)	$83,496 (71,393–97,955)	<0.0001
Functional Status at Listing					0.016
Disabled & Hospitalized	221 (27.8)	224 (27.9)	226 (27.1)	272 (33.9)	
Moderate Disability	317 (39.9)	292 (36.4)	295 (37.1)	266 (33.2)	
Cares for Self	257 (32.3)	287 (35.7)	285 (35.8)	264 (32.9)	
Race (%)					<0.0001
White	376 (44.8)	572 (68.0)	620 (73.8)	615 (73.2)	
African-American	351 (41.8)	196 (23.3)	165 (19.6)	136 (16.2)	
Hispanic	92 (11.0)	44 (5.2)	34 (4.1)	39 (4.6)	
Asian	14 (1.7)	15 (1.8)	12 (1.4)	41 (4.9)	
Diabetes (%)	282 (33.6)	290 (34.5)	257 (30.6)	232 (27.6)	0.01
Renal Function					0.17

	Bottom Quartile N= 840	Second Quartile N= 841	Third Quartile N= 840	Top Quartile N= 840	p-value
GFR>60	519 (61.8)	484 (57.6)	470 (50.6)	460 (54.8)	
CKD Stage III	261 (31.1)	309 (36.7)	317 (37.7)	320 (38.1)	
CKD Stage IV	31 (3.7)	22 (2.6)	23 (2.7)	31 (3.7)	
CKD Stage V, Not on HD	3 (0.4)	1 (0.1)	3 (0.4)	1 (0.1)	
Dialysis	26 (3.1)	25 (3.0)	27 (3.2)	28 (3.3)	
BMI at Listing Hemodynamics	28.3 (24.6–32.3)	28.1 (24.9–32.0)	28.1 (24.7–31.9)	27.7 (24.4–31.0)	0.005
Mean PA Pressure (mmHg)	31 (23–40)	30 (23–38)	30 (22–38)	31 (24–39)	0.07
PCWP (mmHg)	21 (13–28)	20 (13–27)	20 (13–27)	22 (15–28)	0.15
Cardiac Index (L/min/m^2)	2.1 (1.8–2.5)	2.1 (1.8–2.5)	2.1 (1.8–2.6)	2.0 (1.7–2.5)	0.04
PVR (Wood units)	2.27 (1.49–3.37)	2.29 (1.46–3.33)	2.22 (1.40–3.16)	2.29 (1.52–3.48)	0.18
LVAD at Listing (%)	552 (65.7)	540 (64.2)	548 (65.2)	506 (60.2)	0.08
Time from LVAD to Transplant (days)	318 (170–580)	283 (149–517)	294 (152–516)	265 (151–477)	0.03
Former Smoker (%)	437 (52.2)	457 (54.5)	463 (55.1)	421 (50.2)	0.16
ICD (%)	667 (79.4)	671 (79.8)	668 (79.5)	659 (78.5)	0.97
Prior Stroke (%)	54 (6.4)	61 (7.3)	40 (4.8)	44 (5.2)	0.36

Values are summarized as number (%) or median (interquartile range). GFR=Glomerular filtration rate; CKD= Chronic kidney disease; HD=Hemodialysis; BMI=Body mass index; PA=Pulmonary artery; PCWP=Pulmonary capillary wedge pressure; PVR=Pulmonary vascular resistance; ICD=Implantable cardiac defibrillator

Table 2

Complications requiring UNOS listing status upgrade

	Second SES Quartile		Third SES Quartile		Top SES Quartile	
	HR	**p-value**	**HR**	**p-value**	**HR**	**p-value**
Thromboembolism	0.92	0.74	0.94	0.81	0.73	0.25
Device Infection	0.98	0.89	0.89	0.43	0.82	0.19
Device Malfunction	1.18	0.57	1.28	0.38	1.32	0.31
Arrhythmia	2.11	0.22	2.54	0.11	2.99	0.06
Composite	0.98	0.87	0.98	0.78	0.92	0.73

*Reference Group: Bottom SES Quartile