ORIGINAL RESEARCH ARTICLE

Racial disparities and outcomes of left ventricular assist device implantation as a bridge to heart transplantation

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Abstract

Aims   This study investigated outcomes after continuous flow left ventricular assist device (CF-LVAD) implantation as bridge to heart transplantation (BTT) in advanced heart failure patients stratified by race.

Methods and results   De-identified data from the United Network for Organ Sharing database was obtained for all patients who had a CF-LVAD as BTT from 2008 to 2018. Patients were stratified into four groups on the basis of ethnicity [Caucasian, African American (AA), Hispanic, and others (Asian, Pacific Islanders, and American Indian)]. Outcomes investigated were waitlist mortality or delisting and post-transplant 5 year survival. Cox proportional hazards modelling was used to identify independent predictors of waitlist mortality or delisting and post-transplant survival. We used Kaplan–Meier survival curves and the log-rank test to estimate and compare survival among groups. A total of 14 234 patients who had CF-LVADs as BTT were identified. Of these, 64% (n = 9058) were Caucasians, 26% (n = 3677) were AA, 7% (n = 997) were Hispanic, and 3% (n = 502) had a different race. Compared with Caucasian, AA, and Hispanic patients had higher body mass indexes and a lower level of education and are more likely to be public health insurance beneficiaries. There was a significantly lower incidence of transplantation in AAs compared with Caucasians, Hispanics, and others at 12, 24, and 60 months, respectively (Gray's test, $P < 0.001$). The AA race was a significant predictor of waitlist mortality or delisting owing to worsening clinical status [hazard ratio, 95% confidence interval: 1.10 (1.01 to 1.16; $P < 0.001$)]. Among those who were successfully BTT, risk-adjusted post-transplant survival was similar among the four groups (log-rank test: P = 0.589).

Conclusions   Disparities exist among different races that receive a CF-LVAD as a BTT. These disparities translate into increased waitlist morbidity and mortality but not long-term post-transplant survival among those who successfully reach transplant.

Introduction

The use of left ventricular assist devices (LVADs) as a bridge to transplantation (BTT) has expanded the number and diversity of patients receiving a heart transplant (HTx).[1–3] The ramifications of race on post-transplant survival have been previously investigated with an increase in mortality being cited in minorities, specifically African Americans (AAs).[3]

Collective efforts by practitioners aimed at studying and minimizing the adverse outcomes of minorities post-transplant have resulted in an upsurge in the number of non-Caucasians receiving LVADs as a BTT.[4] Additionally, the

nationwide attempt at universal medical insurance through the Affordable Care Act has resulted in more treatment options for minorities with heart failure ranging from increase in number of mechanical circulatory support (MCS) devices implanted to a surge in the prevalence of minorities receiving an HTx.[5,6] For chronic conditions such as heart failure, the long-term costs are expensive and thus warrant careful evaluation of available therapies and their impact on outcomes in order to mitigate any potential racial disparities that may exist.

While previous studies have investigated the effects of race on survival post-transplant, there are scant data on the effect of race on patients receiving a CF-LVAD as a BTT. This present study aimed to investigate the outcomes of CF-LVAD implantation as a BTT stratified specifically by race.

Methods

Data source

This study is a retrospective analysis of de-identified data from the United Network for Organ Sharing (UNOS) registry. Data were provided based on the UNOS data use agreement protocol. In brief, the protocol supports work by health resources and instils responsibility and integrity of the data into the hand of authors alone, without reflecting the views and policies of third parties. The registry was queried for data on patients who were listed for transplant and had a CF-LVAD implanted as a BTT between January 2008 and June 2018. Waitslist data were merged with post-operative follow-up data to determine the impact of race on post-transplant outcomes. The need for institutional review board approval was waived owing to the retrospective nature and use of de-identified data from a multi-institutional registry.

Study design and definitions

Data of all patients who had a CF-LVAD implanted at the time of listing as a BTT were reviewed. Patients were excluded if they (i) were 18 years or younger, (ii) had undergone a multiorgan transplant, and (iii) were supported with total artificial hearts or extracorporeal or percutaneous LVADs. Other exclusion criteria were the use of biventricular assist devices and right ventricular assist devices. Devices implanted were the HeartMate II and HeartMate III (Abbott, Minneapolis MN) and the HeartWare HVAD (HeartWare International, Inc., Framingham, MA). Patients were classified based on race Caucasian, AA, Hispanic, and others (Pacific Islander, Asian, and American Indian). Disparities in access to care over the study period were investigated by comparing

(i) baseline clinical and demographic characteristics among all four groups, (ii) trends in utilization of listing with an LVAD and successful BTT, and (iii) regional differences in LVAD use in the pre-specified 11 UNOS regions. The primary outcome of interest was (i) a composite end-point of waitlist mortality or delisting. Secondary outcomes were (ii) complications while on the waitlist and post-transplant 5 year survival among patients who were successfully bridged to heart transplant. In a subgroup analysis, we investigated the differences in both post-implant survival in AA and CC stratified by sex.

Statistical analysis

Baseline demographics and clinical characteristics are summarized with standard descriptive statistics and expressed as count (with percentage) for categorical variables and mean (with standard deviation) for continuous variables. Group comparisons were made with the χ^2 test for categorical variables, and the t-test was utilized for continuous variables. The univariate odds ratio, obtained using a logistical regression analysis, was adjusted for the presence of measured confounders.

A competing risk analysis with death or delisting for worsening status and transplantation as events was performed. Dependent covariates included in the cause-specific hazards model were age, sex, body mass index (BMI), blood type, CF-LVAD type, aetiology of heart failure, education level (high school graduate and under), insurance status (private versus public), history of diabetes mellitus, history of a cerebrovascular accident (CVA), history of tobacco use, history of automatic implantable cardioverter defibrillator (AICD) implantation, inotrope dependence, serum creatinine, history of dialysis use, and bilirubin levels. Other variables included were haemodynamic parameters like the mean pulmonary artery pressure, pulmonary capillary wedge pressure, and cardiac output. For both models, race was forced into the final model to assess its impact on waitlist mortality or delisting due to worsening clinical status.

Post-transplant 5 year overall survival was examined using Kaplan–Meier survival curves stratified by race classes. Only patients with at least a 5 year follow-up were included in the survival analysis. Differences in race classes were tested using the log-rank test for survival. A Cox proportional hazards model was used to identify independent predictors of 5 year post-transplant survival. Hazards ratio and 95% confidence interval were reported for each of the dependent covariates included in the proportional hazards model. All statistical analyses were performed using the JMP Version 14.0 software (SAS Institute, Inc., Cary, North Carolina). A two-sided P-value of less than 0.05 was considered as statistically significant.

Results

Between January 2008 and September 2018, a total of 14 234 patients received a CF-LVAD as a BTT in the USA. Of these, there were 9058 (64%) Caucasians, 3677 (26%) AAs, 997 (7%) Hispanics, and 502 (3%) patients with races other than those pre-specified. Baseline clinical and demographic characteristics are given in *Table 1*. Compared with other races, Caucasians were older, predominantly male, and more likely to have an ischaemic aetiology for their end-stage heart failure. The incidence of dilated cardiomyopathy was significantly higher in the AA group. AA and Hispanic patients had higher BMIs and lower educational levels and were more likely to be Medicaid or Medicare beneficiaries than were Caucasians. Consequently, these differences resulted in longer waitlist duration to transplantation for AAs and Hispanics than Caucasians.

Similarly, minority racial groups had a higher rate of AICD implantation, worse renal function, and haemodynamic status at the time of listing. At baseline, the incidence of previous history of CVA, inotrope dependence, and serum bilirubin levels were comparable among all four race groups.

Demonstrated in *Figure 1A, B* are the trends in utilization of CF-LVADs as BTT and successful BTT over the study period. Overall, about one of five BTT patients was AA, while Caucasians consisted about 65% of the population. The trends in listing for BTT were similar to those observed among the transplanted population. Shown in *Figure 2A, B* is a schematic geographical representation of the 11 UNOS regions. The regional differences among UNOS regions are shown in *Figure 2B*, with the highest percentages of AA located in regions 2, 3, and 11, while Hispanics were more predominant in UNOS regions 5 and 9.

Table 2 describes waitlist morbidity among listed patients. The rates of device-related infections were significantly higher in AA (8.2%) compared with Caucasians, Hispanic, and other group (5.8%, 5.1%, and 5.2%, respectively; $P < 0.001$). Device-related thrombosis (2.9%) and malfunction (2.3%) were more common among Caucasians than other races (AA, Hispanic, and others; 2.4% and 2.1%, 0.8% and 1.3%, and 2.2% and 0.8%, respectively; $P < 0.05$).

Among the 14 234 patients implanted with a CF-LVAD, 9283 (65%) went on to receive an HTx. Of these, there were 5983 (65%) Caucasians, 2269 (24%) AAs, 677 (7%) Hispanics,

Table 1 Baseline demographic and clinical characteristics of patients stratified by race at the time of listing
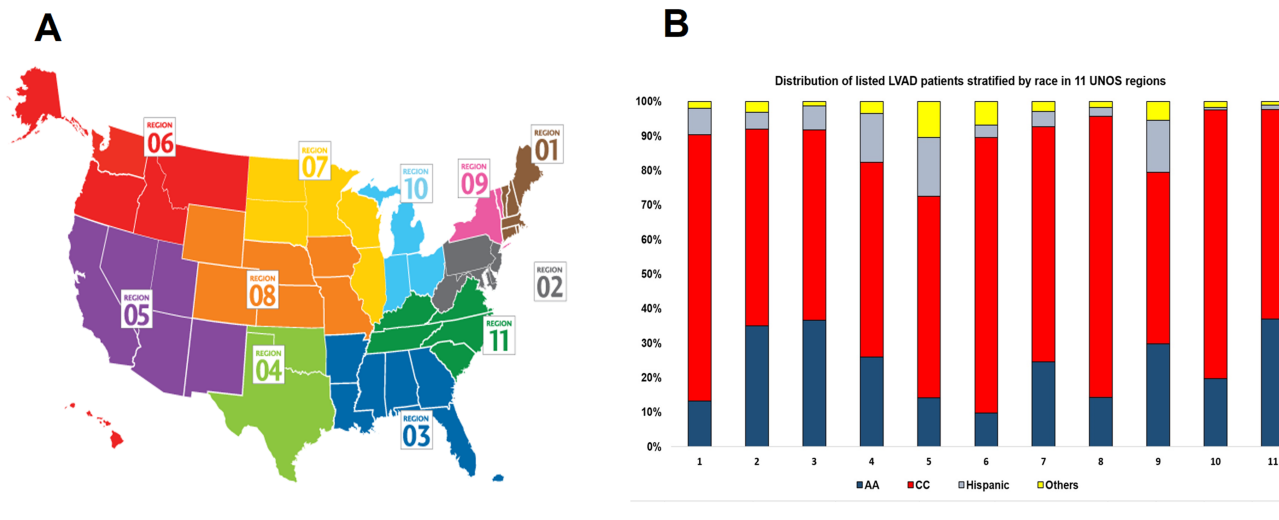
Variable	African Americans ($n = 3677$)	Caucasians ($n = 9058$)	Hispanics ($n = 997$)	Others ($n = 502$)	*P*-value
Age (years)	50 ± 12	55 ± 12	51 ± 13	50 ± 13	<0.0001
Sex (male)	2698 (74)	7403 (82)	781 (78)	400 (80)	<0.0001
BMI (kg/m^2)	28.9 ± 5.4	28.4 ± 4.9	27.9 ± 5.2	26.3 ± 5.3	<0.0001
Blood type O	1931 (52.5)	4209 (48.8)	589 (59)	200 (39.8)	<0.0001
CF-LVAD type					
HeartMate II	2448 (67.1)	5925 (65.4)	650 (65.2)	305 (60.7)	0.002
HeartWare HVAD	1118 (30.4)	2781 (30.7)	319 (32.2)	187 (37.2)	
HeartMate 3	111 (3.2)	352 (3.9)	28 (2.8)	10 (1.9)	
Aetiology of heart failure					
Ischaemic	722 (19.6)	4080 (45.1)	352 (35.2)	187 (37.2)	
Dilated	2801 (76.2)	4452 (49.1)	600 (60.2)	284 (56.6)	<0.0001
Other	117 (3.2)	452 (4.9)	36 (3.6)	27 (5.4)	
Restrictive	36 (0.9)	71 (0.8)	9 (0.9)	4 (0.8)	
Level of education					
≤High school	1766 (48.1)	3638 (40.2)	595 (59.7)	187 (37.3)	<0.001
Insurance status					
Private	1420 (38.6)	4844 (53.5)	376 (37.7)	272 (54.2)	<0.0001
Public	2229 (60.6)	4157 (45.9)	612 (61.4)	224 (44.6)	
History of					
Diabetes mellitus	1137 (30.9)	2940 (33.1)	395 (39.7)	2289 (42.7)	<0.001
CVA	240 (6.5)	537 (5.9)	53 (5.3)	312 (5.8)	0.130
Tobacco use	1705 (46.3)	5044 (55.7)	434 (43.5)	2826 (52.7)	<0.001
AICD	3018 (82.1)	7094 (78.1)	791 (82.4)	4413 (82.4)	<0.001
Inotrope dependent	170 (7.7)	440 (7.5)	53 (8.0)	22 (6.3)	0.767
Serum creatinine (mg/dL)	1.4 ± 0.9	1.3 ± 0.7	1.2 ± 0.7	1.2 ± 0.6	<0.001
History of dialysis	87 (2.4)	116 (1.3)	20 (2.1)	17 (3.4)	<0.001
Total bilirubin (mg/dL)	0.9 ± 1.4	0.9 ± 1.2	0.9 ± 1.9	0.8 ± 0.6	0.179
Time since LVAD insertion (months)	15 ± 16	13 ± 14	14 ± 14	11 ± 13	<0.001
Haemodynamic parameters					
Mean PAP (mmHg)	30.7 ± 10.7	29.2 ± 10.6	29.3 ± 10.8	30.6 ± 11.4	<0.001
Pulmonary CWP (mmHg)	19.9 ± 9.7	19.5 ± 9.3	20.6 ± 9.7	19.6 ± 9.6	0.004
Cardiac output (L/min)	4.4 ± 1.5	4.5 ± 1.4	4.1 ± 1.3	4.1 ± 1.4	<0.001

AICD, automatic implantable cardioverter defibrillator; BMI, body mass index, BSA, body surface area; CF-LVAD, continuous flow ventricular assist device; CVA, cerebrovascular accident; CWP, capillary wedge pressure; PAP, pulmonary artery pressure; PVR, pulmonary vascular resistance.

Figure 1 Percentage of patients listed with a continuous flow left ventricular assist device (CF-LVAD) between 2008 and 2018 sub-stratified by race (A) and those who were successfully bridge to heart transplantation (BTT) during the same time period (B).
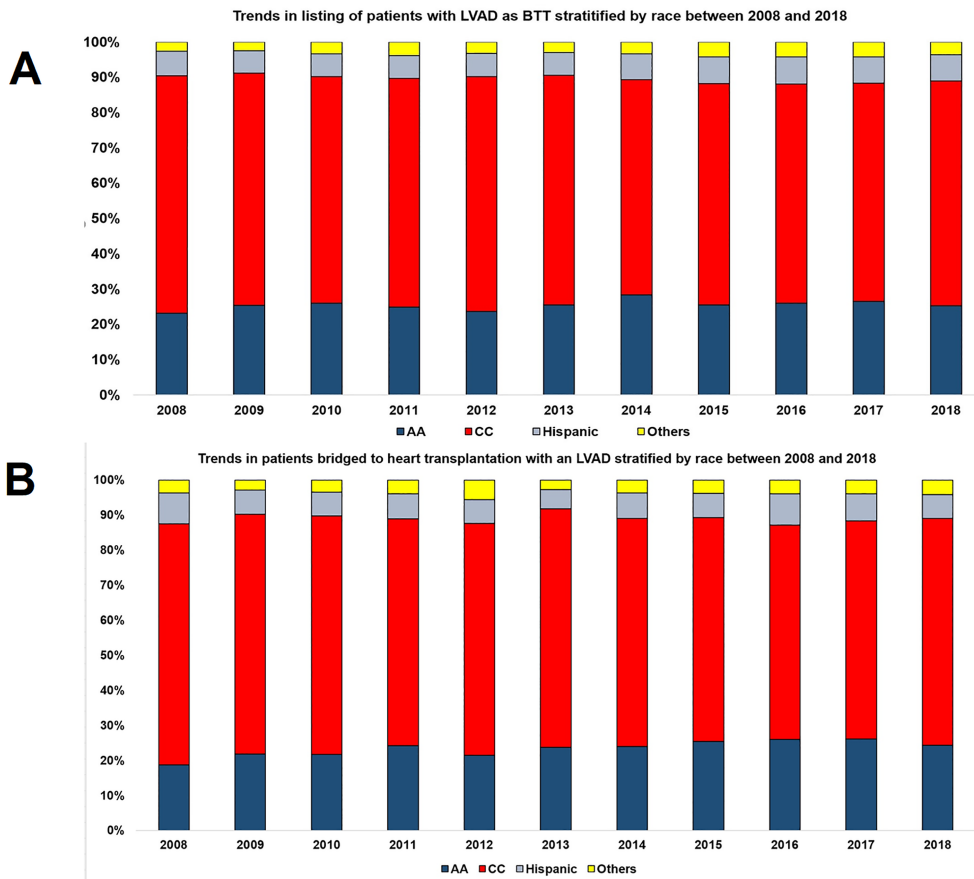
Figure 2 A map of the USA showing all 11 United Network for Organ Sharing (UNOS) regions (A) with the percentage of listed patients with a continuous flow left ventricular assist device (CF-LVAD) as a bridge to heart transplantation (BTT) subdivided by UNOS regions (B).

Table 2 Waitlist and post-transplant outcomes of patients stratified by race

| Variable	African American (n = 3677)	Caucasian (n = 9058)	Hispanic (n = 997)	Others (n = 502)	P-value
Device related					
Infection	303 (8.2)	522 (5.8)	51 (5.1)	26 (5.2)	<0.001
Thrombosis	88 (2.4)	266 (2.9)	8 (0.8)	11 (2.2)	<0.001
Malfunction	78 (2.1)	207 (2.3)	13 (1.3)	4 (0.8)	0.015
Life threatening arrhythmia	24 (0.7)	91 (1.0)	5 (0.5)	5 (1.0)	0.114
Transplanted (n = 9283)	2269 (61.7)	5983 (66.1)	677 (67.9)	354 (70.5)	<0.001
Post-transplant					
Dialysis	297 (13.5)	677 (11.6)	84 (12.8)	41 (11.8)	0.233
Stroke	68 (3.1)	203 (3.5)	21 (3.2)	18 (5.2)	0.349
PPM	62 (2.8)	196 (3.4)	16 (2.4)	6 (1.7)	0.149
Length of stay (days)	24 ± 24	22 ± 23	23 ± 28	25 ± 42	0.002

and 354 (4%) others. Except for post-operative length of stay (AA vs. Caucasian vs. Hispanic vs. others: 24 vs. 22 vs. 23 vs. 25; $P < 0.002$), post-transplant outcomes including dialysis, stroke, and permanent pacemaker implantation were similar in all race groups. A competing risk analysis demonstrated a significantly lower incidence of transplantation in AAs compared with Caucasians, Hispanics, and others at 12, 24, and 60 months, respectively (Gray's test, $P < 0.001$). In a parallel fashion, the incidence of death or delisting due to worsening clinical status among Caucasians was lower at defined time points with that of AAs, Hispanics, and others (Gray's test, $P < 0.001$). (*Figure 3A, B*). After potential confounders were adjusted for, the AA race was still a significant predictor of waitlist mortality or delisting due to worsening clinical status [hazard ratio, 95% confidence interval: 1.10 (1.01 to 1.16; $P < 0.001$)].

Illustrated in *Figure 4* is Kaplan–Meier survival (A) and Cox proportional hazards adjusted estimates (B) comparing 5 year

Figure 3 A competing risk model of waitlist outcomes [death or delisting due to worsening clinical status (A)] and transplantation (B) by race categories.
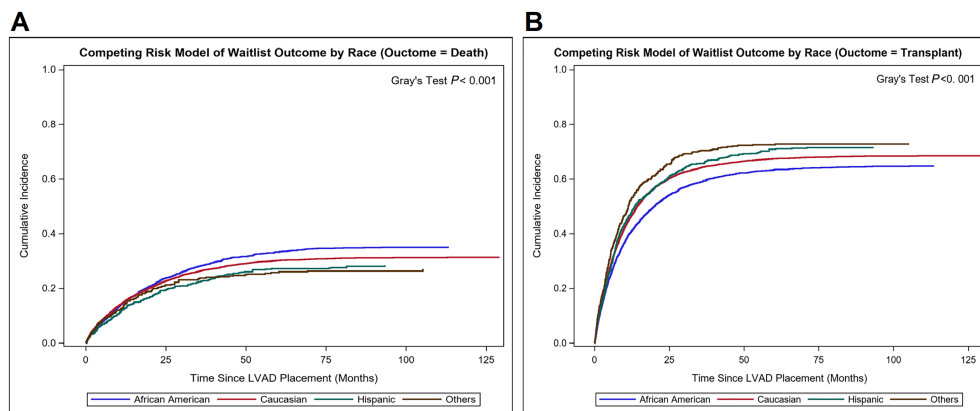
Figure 4 Kaplan–Meier survival estimates of (A) unadjusted and (B) risk-adjusted post-transplant survival in the four race classes.
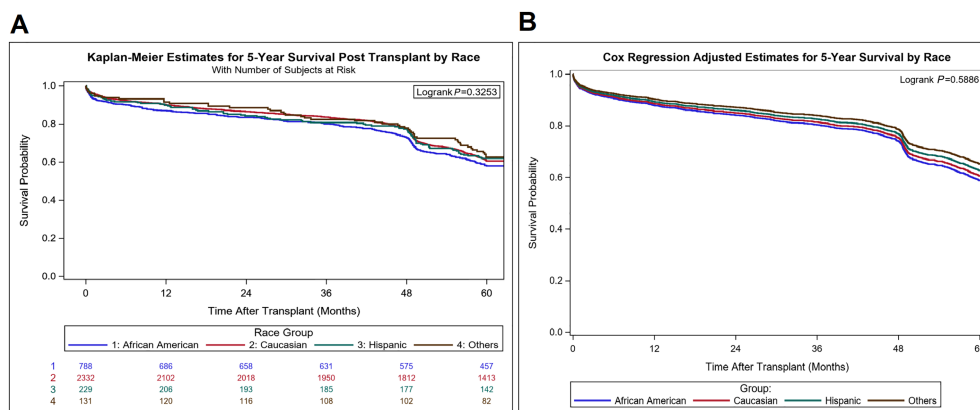
survival among BTT-LVAD patients stratified by all races. Out of the 9283 who met the study criteria, 3480 patients had at least a 5 year follow-up. Post-transplant survival was comparable among all races in both unadjusted ($P = 0.325$) and adjusted analyses ($P = 0.589$). In a separate analysis comparing AAs with Caucasians only, the similarity in survival persisted even after adjusting for independent risk factors associated with graft survival and post-transplant mortality (*Figure 5A, B*). In another subgroup analysis of post-implant survival in AAs or Caucasians stratified by sex, we noted significant differences in outcomes. Among the AA cohort, men were more likely to die or be delisted owing to worsening clinical status than were women (log-rank test: $P = 0.019$). On the contrary, the scenario was different for Caucasians, who were reported have a higher risk of mortality or delisting in women than men (log-rank test: $P = 0.007$) (*Figure S1*).

Discussion

The findings from this large multicentre registry of end-stage heart failure patients listed for HTx showed that demographic and socio-economic differences exist among race groups who received a CF-LVAD as a BTT. The AA race had a higher hazard of waitlist mortality or delisting owing to deteriorating clinical status. However, among those who were successfully BTT, long-term post-transplant survival was similar for all race groups.

The influence of race on morbidity and mortality after HTx and other cardiac surgeries has been studied extensively,[3] and several reasons have been postulated for the worse outcomes. Lower socio-economic status and poverty are seen more frequently in minority ethnic groups, and these factors have been associated with unhealthy lifestyle habits (diet, smoking, and illicit drug use), unemployment, and lower educational levels. Moreover, the unequal distribution of medical

insurance by race reflects the disparities in access to care, which have been reported as an independent risk factor for worse outcomes after cardiac surgery.[7] Our study results demonstrated a similar trend with a significantly higher BMI and a lower level of education in minority groups who were more likely to be Medicaid or Medicare beneficiaries than in Caucasians. Consequently, these differences resulted in longer waitlist duration to transplantation for minority populations than Caucasians. In an attempt to bridge the gap in disparities, some remarkable policies have included the expansion of access to care in 2014 and the rapid adoption of ventricular assist device (VAD) technology. This is reflected in the our regional analysis of transplant listing according to various UNOS regions, as minority patients were frequently listed in regions of higher populations. On the contrary, the proportion of patients successfully bridged to heart transplantation has remained relatively unchanged over the past decade and can be explained by the demographic and socio-economic differences at baseline.

We found that AAs and Hispanics are at a higher risk of delisting owing to deterioration in their clinical status or death while on the waitlist. Hispanics have been identified to have a higher risk of waitlist death for transplant,[8] and AAs are known to have lower survival after orthotopic HTx.[3] Expectedly, the aim of the rigorous pre-LVAD workup, which includes evaluating patients' compliance and access to post-operative care, is to improve post-LVAD and waitlist outcomes in patients listed as BTT. Tsiouris *et al.*,[9] in their analysis of 88 LVAD patients reported on similar 30 day, 6 month, and 1 year post-LVAD survival in all patients irrespective of race. Although their study was limited by a smaller sample size and clinical management by a hospital with a higher proportion of AA patients, the lack of preventive care, counselling about therapeutic options, and delays in referrals for transplant may explain the clinical profile of patients at the time of listing. A worse baseline clinical status inadvertently places the patient at a higher risk for operative

Figure 5 Kaplan–Meier survival estimates of (A) unadjusted and (B) risk-adjusted post-transplant survival among African American (AA) vs. Caucasians only.
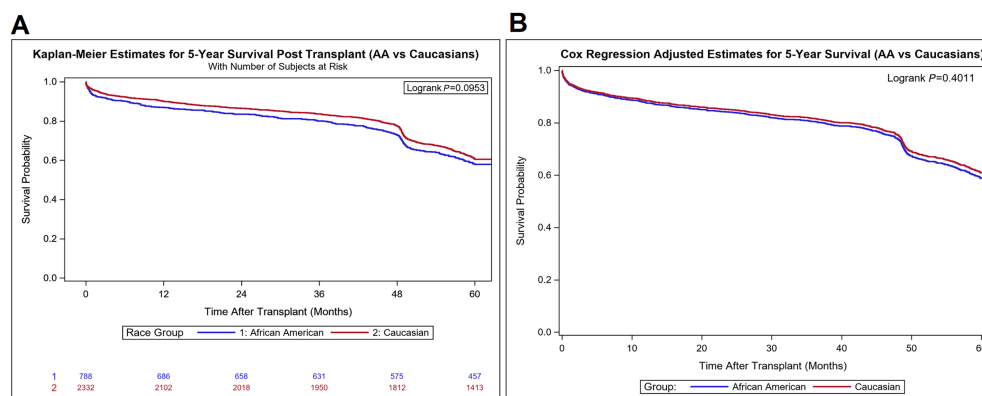
mortality and morbidity. In addition, other biological factors can play a role on the unfavourable outcomes in the minority ethnic groups. For example, left ventricular hypertrophy secondary to long-standing uncontrolled hypertension is common in AAs. Left ventricular hypertrophy can compromise myocardial protection during cardiopulmonary bypass and is associated with post-operative arrythmias.[10] Other immunologic mechanisms such as genotypes associated with reduced immune function and pro-inflammatory states put AAs at higher surgical risk.[10]

Among the patients who were successfully bridged to an HTx, unadjusted and risk-adjusted 5 year survival was comparable irrespective of race. While AAs are known to have lower survival after orthotopic HTx,[3] BTT with an LVAD was found to result in similar outcomes. These findings are in contrast to what was described by Lui *et al.*,[11] who reported on 6478 patients who were BTT between 2005 and 2018. The authors found that the AA race is associated with an increased rate of post-transplant graft failure and 5 year mortality when compared with Caucasians. Interestingly, the timing of their study included a period where both pulsatile and CF-LVAD were in use and access to VADs was limited. In the present study, we investigated a cohort that included only CF-LVADs, which better represent current clinical practice patterns. Of the 9283 patients who met the study criteria, a 5 year follow-up was available in 3480. In both the unadjusted and risk-adjusted survival analyses, there was no difference in survival among the respective races. The difference in outcomes can be explained by the difference in device selection and timing. The issue of sex-related differences in outcomes has been previously investigated by DeFillipis *et al.*[12] In their analysis of the UNOS dataset, the authors concluded that, when matched with similar male control subjects, women experienced higher mortality and lower rates of HTx. In our cohort, there was a significantly lower number of women who underwent BTT therapy with LVAD overall. Besides, we found a similar trend with sex-related differences among the AA cohort, and men were more likely to die or be delisted owing to worsening clinical status than were women (log-rank test: $P = 0.019$), while the scenario was different for Caucasians who reported a higher risk of mortality or delisting in women than men (log-rank test: $P = 0.007$). These findings may reflect underutilization of advanced therapies for heart failure in some sex groups and represent a later presentation of disease course for others.

This present study is limited by its retrospective nature and, as such, is subject to confounding and bias. Additionally, the data analysis is subject to the variables that are collected by UNOS and leaves no room for other factors that could have influenced post-transplant survival and waitlist morbidity. For instance, a better understanding of how long patients had been diagnosed with end-stage heart failure and their level of compliance with therapeutic options may help explain the high waitlist mortality risk in minority populations. In addition, variables such as those evaluating baseline right ventricular (RV) function on LVAD or at least the number of hospitalizations for RV failure on LVADs would have been necessary because RV function is a major determinant of prognosis after LVAD implantation. The huge limitation of the UNOS database as every national registry is that it does not provide these details on RV haemodynamics at multiple times and makes this challenging to include.

In conclusion, we demonstrated that health and health care disparities exist among different races that receive a CF-LVAD as a BTT. These disparities translate into increased waitlist morbidity and mortality for AAs, but not long-term post-transplant survival among those who successfully reach transplant.

Conflict of interest

None declared.

Funding

No funding source to be declared.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. Kaplan Meier Survival curves showing post–LVAD implantation in African Americans and Caucasians stratified by Sex.

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