Continuous flow left ventricular assist device technology has influenced wait times and affected donor allocation in cardiac transplantation

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Objective: Bridge to transplantation patients with continuous flow left ventricular assist devices (cLVADs) are assigned United Network for Organ Sharing status 1A or 1B priority while awaiting orthotopic heart transplantation. We investigated the influence of cLVAD on the waitlist times and organ allocation.

Methods: The United Network for Organ Sharing database was examined from 2005 to 2012 for patients with cLVAD and pulsatile flow LVAD (pLVAD). These 2 cohorts were compared with patients who did not receive LVAD.

Results: Of 16,476 total orthotopic heart transplantations, 3270 (19.8%) were performed on patients with an LVAD as a bridge to transplantation. The cLVAD group had the longest total waitlist time (259.6 days) compared with the pLVAD (134.6 days) and non-LVAD (121.7 days) groups ($P < .001$). The cLVAD group spent more time in status 1A (44.7 days) than did the pLVAD (32.1 days) and non-LVAD (16.4 days) cohorts ($P < .001$). The median waitlist survival was better for the cLVAD group (1234.0 days) than in the pLVAD (441.0 days) and non-LVAD (471.0 days) groups ($P < .001$). The cLVAD recipients were older, had a greater body mass index, and more often had diabetes than did pLVAD and non-LVAD patients. The cLVAD cohort received hearts from older, more often male donors, with a greater body mass index. Post-transplant survival was not significantly different among the 3 groups on Kaplan-Meier analysis ($P = .12$).

Conclusions: Despite being older, less favorable recipients, the cLVAD patients spent more time in status 1A and had greater waitlist survival. This might allow cLVAD patients to receive preferred donor hearts, which might allow for better post-transplant survival. (J Thorac Cardiovasc Surg 2014;147:1966-71)

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Left ventricular assist devices (LVADs) have increasingly been used to bridge patients to orthotopic heart transplantation (OHT).¹⁻³ Currently, patients implanted with an LVAD await OHT as United Network Organ Sharing (UNOS) status 1B with a 30-day upgrade to status 1A at the discretion of the transplant center. In addition, patients with an

LVAD can be upgraded to status 1A in the event of a device complication or malfunction.⁴⁻⁷ This organ allocation protocol was designed in the era in which pulsatile flow devices (pLVADs) predominated. Since 2007, continuous flow devices (cLVADs) have been approved by the Food and Drug Administration for bridge to transplantation (BTT), primarily by documentation of improved survival and decreased complications.^{1,3,8,9} The goal of the present study was to determine the effect of cLVAD use on the waitlist times and organ allocation.

METHODS

Data Source

After approval from the local institutional review board, the public-use Standard Transplant Analysis and Research data files were obtained from the UNOS registry. Because information on mechanical circulatory support was poorly documented before 2005, we analyzed the data from January 2005 to December 2012. Patients requiring temporary right ventricular assist devices, biventricular assist devices, or a total artificial heart were excluded from the present analysis.

The type of LVAD used was not available for patients placed on the waitlist after LVAD implantation but who did not undergo transplantation. Thus, to analyze waitlist survival, we designated implantations with LVAD from 2005 to 2008 as the pLVAD era and implantations from 2009 to 2012 as the cLVAD era. Previous studies have corroborated that most LVADs implanted before 2009 were pLVAD, and the vast majority of those implanted in 2009 and beyond were cLVAD.¹⁰

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Abbreviations and Acronyms

BMI	= body mass index
BTT	= bridge to transplantation
cfLVAD	= continuous flow left ventricular assist device
LVAD	= left ventricular assist device
OHT	= orthotopic heart transplantation
pLVAD	= pulsatile left ventricular assist device
UNOS	= United Network Organ Sharing

For patients who underwent OHT, the type of LVAD implanted was available. Patients receiving the following long-term, continuous flow devices were placed in the cfLVAD cohort: HeartMate-II, Jarvik 2000, Micromed DeBakey VAD, Heartware HVAD, Terumo DuraHeart LVAD, Ventracor VentrAssist LVAD, and Worldheart Levacor LVAD. Patients who were bridged to OHT with a pulsatile device were placed in the pLVAD cohort. The cfLVAD and pLVAD cohorts were compared with the recipients who had not received any type of mechanical circulatory support before OHT.

Statistical Analysis

Analysis of variance and the chi-square test were used to examine the continuous and categorical variables. Continuous variables are presented as the mean $\pm$ standard deviation and categorical variables as the percentage of the total number of data points available for that field. Survival curves were generated using the Kaplan-Meier method and compared using the log-rank test. Cox proportional regression analysis for waitlist mortality was developed in 2 steps. First, the covariates were run in a univariate analysis as predictors of mortality. Next, the covariates with $P < .20$ were entered simultaneously as a multivariate Cox model. Covariates missing $>15\%$ of data in the registry were excluded. All covariates evaluated in the study are listed in [Tables 1 through 3](#). Survival was determined using all-cause mortality. Data were analyzed using Statistical Analysis Systems statistical software, version 9.2 (SAS Institute, Cary, NC).

RESULTS

Use of LVAD by Era

Of 16,476 total OHTs, 3270 (19.8%) were performed on patients with an implanted LVAD as BTT. From 2005 to 2008, 1389 (16.3%) of OHTs were performed on patients with an implanted LVAD as BTT. This number increased from 2009 to 2012, with 1881 OHTs (23.7%) performed on patients with an implanted LVAD as BTT ($P < .001$).

Comparison of Regional Time Spent Waiting to Transplantation

The total waitlist time by region is shown in [Figure 1, A](#). The cfLVAD cohort had the longest total waitlist time in every 1 of all 11 UNOS regions ($P < .001$). The average time spent in status 1A by UNOS region is shown in [Figure E1](#). The cfLVAD group spent the greatest amount of time in status 1A in 10 of 11 UNOS regions ($P < .001$). In UNOS region 8, the pLVAD group spent the longest time in status 1A ($P < .001$). In region 8, cfLVAD spent more time in status 1A than did the non-LVAD group.

Comparison of National Time Spent Waiting for Transplantation

A comparison of the total waitlist time is shown in [Figure 1, B](#). Patients in the cfLVAD group had the longest total waitlist time (259.6 days) compared with the pLVAD (134.6 days) and non-LVAD (121.7 days) groups ($P < .001$). The cfLVAD group spent more time in status 1A (44.7 days) than did the pLVAD (32.1 days) and non-LVAD (16.4 days) cohorts ($P < .001$; [Figure E2](#)). The cfLVAD cohort also spent the greatest amount of time in status 1B compared with the pLVAD and non-LVAD cohorts.

Waitlist Survival

Kaplan-Meier survival curves for patients on the waitlist awaiting OHT are shown in [Figure 2, A](#). Median survival was significantly better in the cfLVAD group (1234.0 days) than in the pLVAD (441.0 days) and non-LVAD (471.0 days) groups ($P < .001$).

The results of the Cox proportional regression analysis for waitlist mortality are listed in [Table 1](#). Patients undergoing OHT were considered survivors for this analysis. Compared with the non-LVAD patients, the pLVAD group was associated with waitlist mortality (hazard ratio [HR], 2.96; 95% confidence interval [CI], 1.14-7.73; $P = .03$). The cfLVAD group was not associated with mortality (HR, 1.88; 95% CI, 0.69-5.16; $P = .22$). The other factors associated with mortality included a primary diagnosis of congenital heart disease (HR, 8.24; 95% CI, 2.47-27.49; $P < .001$) and repeat transplant or graft failure (HR, 9.30; 95% CI, 3.15-27.41; $P < .001$).

UNOS Status at Transplantation

Of the 2132 cfLVAD patients who underwent OHT, 1728 (81.1%) were status 1A at OHT. In contrast, in the pLVAD cohort, 656 (84.8%) were status 1A at OHT. The cfLVAD cohort ($n = 999$, 46.9%) was less likely to receive OHT during the 30-day grace period compared with the pLVAD cohort ($n = 461$, 59.6%; $P < .001$). The cfLVAD group was more likely to undergo OHT in status 1A because of device complications ($n = 729$, 34.2%) compared with the pLVAD group ($n = 195$, 25.2%; $P < .001$). Of the patients in status 1A because of device complications, the cfLVAD group was more likely to have had device infection (59.3% vs 48.7%), less likely to have had device malfunction (8.5% vs 22.1%), less likely to have had thromboembolism (9.7% vs 16.4%), more likely to have had life-threatening ventricular arrhythmia (3.7% vs 0.5%), and more likely to have had another or unknown reason (15.1% vs 8.7; $P < .001$).

Primary Diagnoses in BTT-LVAD Patients Undergoing OHT

The results of a comparison of the primary diagnoses in the BTT-LVAD patients who underwent OHT are listed in

TABLE 1. Multiple variable model for waitlist mortality

Variable	HR	95% CI	P value
pLVAD era	2.96	1.14-7.73	.03
cfLVAD era	1.88	0.69-5.16	.22
Age (y)			
19-39	Reference	Reference	Reference
≤18	0.52	0.15-2.48	.49
40-49	0.60	0.15-2.48	.49
50-59	1.38	0.45-3.91	.61
≥60	1.33	0.43-4.09	.62
Female gender	0.79	0.36-1.73	.56
Congenital heart disease	8.24	2.47-27.49	<.001
Coronary artery disease	1.51	0.62-3.69	.36
Hypertrophic cardiomyopathy	<0.001	<0.001->99.99	.99
Restrictive cardiomyopathy	<0.001	<0.001->99.99	.99
Valvular heart disease	<0.001	<0.001->99.99	.99
Retransplantation or graft failure	9.30	3.15-27.41	<.001
Race			
White	Reference	Reference	Reference
Asian	2.20	0.52-9.40	.29
Black	1.46	0.48-4.13	.53
Hispanic	1.41	0.48-4.13	.53
Mechanical ventilation before transplantation	0.80	0.23-2.78	.72
ECMO before transplantation	0.25	0.06-1.02	.06

HR, Hazard ratio; CI, confidence interval; pLVAD, pulsatile flow left ventricular assist device; cfLVAD, continuous flow LVAD; ECMO, extracorporeal membrane oxygenation.

Table E1. The recipients bridged to OHT with cfLVAD were most likely to have a primary diagnosis of dilated cardiomyopathy (54.4%) compared with the pLVAD cohort (50.1%) and those not requiring LVAD (44.6%; $P < .001$). Patients bridged with pLVAD were more likely to have ischemic cardiomyopathy (45.3%) than were the cfLVAD (42.3%) and non-LVAD (31.7%) cohorts ($P < .001$). The non-LVAD cohort were most likely to have a primary diagnosis of congenital disease, restrictive cardiomyopathy,

hypertrophic cardiomyopathy, valvular heart disease, repeat transplant and/or graft failure, or some other diagnosis (Table 2).

Baseline Characteristics of BTT-LVAD Patients Undergoing OHT

The results of a comparison of baseline recipient characteristics for the BTT-LVAD patients who underwent OHT are listed in Table 2. The cfLVAD cohort was older (52.6 years) than the pLVAD (50.1 years) and non-LVAD (43.1 years) cohorts ($P < .001$). The cfLVAD cohort had the greatest body mass index (BMI) (28.2 kg/m²) compared with the pLVAD (BMI, 27.5 kg/m²) and non-LVAD (BMI, 24.9 kg/m²) cohorts ($P < .001$). The recipient creatinine level was greater in the pLVAD (1.29 mg/dL) and cfLVAD (1.28 mg/dL) groups than in the non-LVAD (1.23 mg/dL) group ($P < .001$). The cfLVAD group (29.6%) was also more likely to have diabetes than the pLVAD (27.7%) and non-LVAD (19.9%) groups ($P < .001$).

The class I plasma reactive antigen panel results were greater in the pLVAD (10.0%) and cfLVAD (8.6%) cohorts than in the non-LVAD (6.2%) cohort ($P < .001$). The class II plasma reactive antigen panel results and the requirement for inhaled nitric oxide at OHT were not significantly different among the 3 groups.

Donor Characteristics for All BTT-LVAD Patients Undergoing OHT

The cardiac donor hearts used in the BTT-LVAD patients who underwent OHT were compared (Table 3). The donor hearts used for the cfLVAD cohort were slightly older (31.2 years) than those for the pLVAD (30.6 years) and non-LVAD (27.0 years) cohort ($P < .001$). The donor hearts used for the pLVAD cohort (78.8%) and cfLVAD cohort (78.2%) were more likely to be from males than were those for the non-LVAD cohort (67.3%; $P < .001$). Donor BMI

TABLE 2. Baseline recipient characteristics

Recipient characteristic	pLVAD (n = 774)	cfLVAD (n = 2188)	Non-LVAD (n = 13,206)	P value
Age (y)	50.1 ± 12.2 (n = 774)	52.6 ± 12.4 (n = 2188)	43.1 ± 21.9 (n = 13,206)	<.001
Male gender	662 (85.5) (n = 774)	1786 (81.6) (n = 2188)	9085 (68.8) (n = 13,206)	<.001
BMI (kg/m ²)	27.5 ± 4.9 (n = 774)	28.2 ± 5.1 (n = 2188)	24.9 ± 6.1 (n = 13,135)	<.001
Race				
White	514 (66.4) (n = 774)	1491 (68.1) (n = 2188)	8777 (66.5) (n = 13,206)	<.001
Black	171 (22.1) (n = 774)	480 (21.9) (n = 2188)	2541 (19.2) (n = 13,206)	<.001
Hispanic	59 (7.6) (n = 774)	138 (6.3) (n = 2188)	1275 (9.7) (n = 13,206)	<.001
Asian	21 (2.7) (n = 774)	61 (2.8) (n = 2188)	430 (3.3) (n = 13,206)	<.001
PVR	2.14 ± 1.48 (n = 540)	2.31 ± 1.97 (n = 1809)	2.63 ± 2.83 (n = 9411)	<.001
Diabetes	208 (27.7) (n = 751)	632 (29.6) (n = 2137)	2587 (19.9) (n = 12,997)	<.001
Creatinine (mg/dL)	1.29 ± 0.87 (n = 769)	1.28 ± 0.72 (n = 2183)	1.23 ± 1.05 (n = 13,090)	.03
Class I PRA panel	10.0 ± 22.0 (n = 719)	8.6 ± 20.2 (n = 2052)	6.2 ± 17.5 (n = 12,158)	<.001
Class II PRA panel	5.3 ± 18.5 (n = 624)	5.0 ± 15.5 (n = 1946)	5.6 ± 17.5 (n = 11,343)	.41

Data presented as mean ± standard deviation or n (%), followed by number of patients. pLVAD, Pulsatile flow left ventricular assist device; cfLVAD, continuous flow LVAD; BMI, body mass index; PVR, pulmonary vascular resistance; PRA, plasma reactive antigen.

TABLE 3. Baseline donor characteristics

Donor characteristic	pLVAD (n = 774)	cfLVAD (n = 2188)	Non-LVAD (n = 13,206)	P value
Age (y)	30.6 ± 11.3 (n = 774)	31.2 ± 10.9 (n = 2188)	27.0 ± 14.8 (n = 13,206)	<.001
Male gender	610 (78.8) (n = 774)	1710 (78.2) (n = 2188)	8883 (67.3) (n = 13,206)	<.001
BMI (kg/m ²)	27.5 ± 5.4 (n = 774)	27.5 ± 5.5 (n = 2188)	25.2 ± 6.2 (n = 13,205)	<.001
Diabetes	16 (2.1) (n = 770)	62 (3.7) (n = 2181)	355 (2.7) (n = 13,167)	.52
Ischemic time (h)	3.44 ± 1.13 (n = 753)	3.32 ± 1.06 (n = 2152)	3.29 ± 1.09 (n = 12,848)	.001
Total HLA mismatches	4.68 ± 1.06 (n = 649)	4.63 ± 1.11 (n = 1905)	4.64 ± 1.08 (n = 11,547)	.54
ABO-compatible donor	122 (15.8) (n = 774)	275 (12.6) (n = 2188)	2253 (17.1) (n = 13,205)	<.001
Race mismatch	377 (48.7) (n = 774)	1168 (53.4) (n = 2188)	6719 (50.9) (n = 13,206)	.04
Clinical signs of infection	318 (42.2) (n = 753)	1236 (57.7) (n = 2143)	6721 (52.1) (n = 12,897)	<.001
History of cocaine use	105 (13.9) (n = 756)	338 (15.8) (n = 2137)	1519 (11.7) (n = 12,991)	<.001
History of cancer	12 (0.02) (n = 770)	35 (1.6) (n = 2183)	188 (1.4) (n = 13,163)	.79

Data presented as mean ± standard deviation or n (%), followed by number of patients. pLVAD, Pulsatile flow left ventricular assist device; cfLVAD, continuous flow LVAD; BMI, body mass index; HLA, human leukocyte antigen.

was greatest in the cfLVAD (27.5 kg/m²) and pLVAD (27.5 kg/m²) cohorts as compared with the non-LVAD cohort (25.2 kg/m²; *P* < .001). The ischemic time was lowest in the non-LVAD group (3.29 hours) compared with the cfLVAD (3.32 hours) and pLVAD (3.44 hours) groups. A history of diabetes and total human leukocyte antigen mismatches was not significantly different among the 3 groups. The number of ABO compatible donors was lowest in the cfLVAD group (12.6%) compared with the pLVAD (15.8%) and non-LVAD (17.1%) groups (*P* < .001).

Morbidity and Mortality for BTT-LVAD Patients After OHT

The length of stay was shorter for the cfLVAD group (20.0 days) than for the non-LVAD group (20.8 days; *P* = .01). The length of stay was longest in the pLVAD cohort (23.0 days; *P* = .01). The number of acute rejection episodes at the index hospitalization was greatest in the cfLVAD group (19.3%), followed by the pLVAD (16.2%) and non-LVAD (14.9%) cohorts (*P* < .001).

The Kaplan-Meier survival curves for the patients who underwent OHT are shown in Figure 2, B. Survival was not significantly different among the 3 groups (*P* = .12). The median follow-up time was 1448.0 days for the pLVAD

cohort, 422.0 days for the cfLVAD cohort, and 954.0 days for the non-LVAD cohort.

The Kaplan-Meier survival curves for the cfLVAD-BTT patients who underwent OHT as status 1A during their 30-day grace period, status 1A by exception, or status 1B are shown in Figure 2, C. Survival was not significantly different among these 3 groups (*P* = .14).

A comparison of survival by era in the non-LVAD cohort is shown in Figure E3. Survival by Kaplan-Meier analysis was significantly better in the non-LVAD recipients in the more recent cfLVAD era (*P* = .01).

DISCUSSION

The current UNOS allocation protocol was designed during the era of older generation pLVADs.⁷ The newer generation of cfLVADs has proved to be durable, with significantly fewer reported device malfunctions, and have simultaneously produced significant improvements in morbidity and mortality as BTT patients await transplantation.^{1,3,7,8} These 2 metrics have reshaped how donor hearts are allocated. The goal of the present study was to determine how the advent of the cfLVAD has influenced the waiting times and organ allocation using a national database.

FIGURE 1. Total waitlist time stratified by (A) all 11 United Network Organ Sharing (UNOS) regions and (B) nationally. LVAD, Left ventricular assist device; pLVAD, pulsatile flow left ventricular assist device; cfLVAD, continuous flow left ventricular assist device.

FIGURE 2. Survival for patients (A) on the waitlist, (B) after orthotopic heart transplantation, and (C) continuous flow left ventricular assist device (cLVAD) patients after orthotopic heart transplantation. LVAD, Left ventricular assist device; pLVAD, pulsatile flow LVAD.

Our analysis suggested that cLVAD patients who survived to OHT had less favorable profiles compared with the pLVAD and non-LVAD cohorts. They were older, had a greater BMI, were more likely have diabetes, and had worse renal function. Despite these findings, these patients were able to compete for high-quality donors. The donors to the cLVAD recipients were more likely to be men, have a greater BMI, and to be ABO identical.

The ability to compete for high-quality donors in the cLVAD cohort was likely multifactorial. Our analysis has suggested that the cLVAD cohort experienced enhanced waitlist survival compared with the pLVAD and non-LVAD cohorts. cLVAD was not associated with waitlist mortality. The excellent outcomes with cLVAD in patients with end-stage heart failure and decreased device failure compared with pLVAD have also been well documented in previous studies.^{1,8-10} The improved survival seen for BTT patients with cLVAD was observed across all 11 UNOS regions, and when the US waitlist activity was viewed as a composite, and appeared to translate into longer time spent alive on the waitlist. This, in turn, might allow transplant centers to wait for a preferable donor. In addition, sophisticated transplant centers with knowledge of the local and regional waitlist population could legitimately choose to use the 30-day status 1A grace period at any point during a patient's post-LVAD life, thus optimizing chances of a transplant with a high-quality donor. Thus, 999 (45.7%) of the 2188 cLVAD patients underwent OHT during the 30-day status 1A grace period. This trend has been observed nationwide, because the cLVAD patients in 10 of the 11 UNOS regions spent the longest time in status 1A. Dardas and colleagues¹¹ also observed that cLVAD patients were far more likely to be status 1A, despite their more favorable adverse event profile, compared with the patients awaiting OHT without an LVAD. Even among the cLVAD patients who were listed for, and underwent, OHT as status 1A because of a device complication ($n = 729$, 34.2% of all cLVAD patients)—because the complication types were more likely to be infectious or arrhythmogenic, in contrast to those in

the pLVAD era—the patients were more likely to survive to transplantation and to have post-transplant survival similar to that of their peers undergoing OHT as status 1A by the 30-day grace period and those in status 1B. All these factors undoubtedly affect the ability to obtain preferred donor hearts for cLVAD patients.

The selection of more favorable donors for cLVAD patients might allow better outcomes after OHT. In the present study, the BTT patients with cLVAD had a shorter length of stay than did the non-LVAD group, despite having a greater incidence of acute rejection episodes at the index hospitalization. BTT patients are known to have a greater rejection risk owing to sensitization¹²; however, this does not necessarily result in worse outcomes owing to effective immunosuppressive regimens.¹³ We observed no difference in survival between the cLVAD and non-LVAD cohorts. However, the follow-up time was relatively short, because information on LVADs was only reliably available in UNOS starting in 2005. Previous studies have shown that BTT patients with a cLVAD had survival at least equivalent to that of non-LVAD patients.¹⁴⁻¹⁶ However, these studies were again limited by the short-term follow-up period because the cLVAD technology is relatively new. Additional studies are needed to determine whether patients bridged to OHT with cLVAD will experience better long-term post-OHT outcomes.

To determine whether the survival of OHT recipients in the non-LVAD cohort was a result of receiving less favorable donor hearts, we compared the non-LVAD recipients from 2005 to 2008 with those in the non-LVAD cohort from 2009 to 2012. We found that non-LVAD patients in the more recent era actually had slightly better survival (Figure E3). However, this improved survival in the more recent era could have resulted from a number of factors that could not be accounted for in the present study, such as improved medical therapy and immunosuppressive regimens. The International Society for Heart and Lung Transplantation annual report verified that survival after OHT has continued to improve in more recent years.³ Additional studies are warranted to determine whether

outcomes in non-LVAD patients have worsened in the era of the cLVAD.

As the outcomes with cLVAD-BTT patients have continued to improve, many investigators have called for a re-evaluation of the current UNOS organ allocation protocol.^{7,11,17} The current protocol was designed for the pLVAD era,⁷ in which device complications were more numerous and survival was not as good. The goal of the present protocol was to maximize the allocation of donor hearts to patients with the greatest likelihood of dying while waiting for a donor organ. However, because cLVAD patients have continued to have unprecedented outcomes, patients receiving donor hearts are no longer the ones at greatest risk of mortality. Our study has indicated that more and more patients have been bridged to OHT with LVAD. In the pLVAD era, 17% of patients were BTT, and this increased to 23% in the cLVAD era. Some institutions have reported an even greater acceptance of device technology, with up to 64% of OHT patients being BTT with a cLVAD.⁷ With more and more cLVAD patients added to the waitlist, it might not be unreasonable to re-assess the current donor heart allocation policy to facilitate an equitable distribution of donor hearts.

The present study was not without limitations, including those inherent to retrospective registry analysis. The database did not include all relevant confounders, such as the immunosuppressive regimen type or socioeconomic factors. In addition, the study was limited by the relatively short follow-up time, because information on LVADs did not become available in the UNOS database until 2005. Finally, the type of device implanted was not available for patients who were on the waitlist but had not undergone transplantation. Thus, when analyzing waitlist mortality, we considered all patients implanted with an LVAD from 2005-2008 as pLVAD and those implanted from 2009 to 2012 as cLVAD.

In conclusion, despite being older and less favorable recipients, the patients bridged to OHT with cLVAD spent more time as status 1A and had greater waitlist survival. This might allow cLVAD patients to receive preferred donor hearts, which might allow them to have greater post-OHT survival. Because of these findings, it might be time to revisit the current UNOS donor allocation system.

References

1. John R, Kamdar F, Liao K, Colvin-Adams M, Boyle A, Joyce L. Improved survival and decreasing incidence of adverse events with the HeartMate II left ventricular assist device as bridge-to-transplant therapy. *Ann Thorac Surg*. 2008;86:1227-34.
2. Rogers JG, Aaronson KD, Boyle AJ, Russell SD, Milano CA, Pagani FD, et al. Continuous flow left ventricular assist device improves functional capacity and quality of life of advanced heart failure patients. *J Am Coll Cardiol*. 2010;55:1826-34.
3. Kirklin JK, Naftel DC, Kormos RL, Stevenson LW, Pagani FD, Miller MA, et al. The Fourth INTERMACS Annual Report: 4,000 implants and counting. *J Heart Lung Transplant*. 2012;31:117-26.
4. OPTN Allocation of Thoracic Organs, 2013. Available at: http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_9.pdf. Accessed October 17, 2013.
5. Lietz K, Long JW, Kfoury AG, Slaughter MS, Silver MA, Milano CA, et al. Outcomes of left ventricular assist device implantation as destination therapy in the post-rematch era implications for patient selection. *Circulation*. 2007;116:497-505.
6. Rose EA, Gelijns AC, Moskowitz AJ, Heitjan DF, Stevenson LW, Dembitsky W, et al. Long-term use of a left ventricular assist device for end-stage heart failure. *N Engl J Med*. 2001;345:1435-43.
7. Uriel N, Jorde UP, Woo Pak S, Jiang J, Clerkin K, Takayama H, et al. Impact of long term left ventricular assist device therapy on donor allocation in cardiac transplantation. *J Heart Lung Transplant*. 2013;32:188-95.
8. Miller LW, Pagani FD, Russell SD, John R, Boyle AJ, Aaronson KD, et al. Use of a continuous-flow device in patients awaiting heart transplantation. *N Engl J Med*. 2007;357:885-96.
9. Boyle AJ, Russell SD, Teuteberg JJ, Slaughter MS, Moazami N, Pagani FD, et al. Low thromboembolism and pump thrombosis with the HeartMate II left ventricular assist device: analysis of outpatient anti-coagulation. *J Heart Lung Transplant*. 2009;28:881-7.
10. Kirklin JK, Naftel DC, Kormos RL, Stevenson LW, Pagani FD, Miller MA, et al. Fifth INTERMACS annual report: risk factor analysis from more than 6,000 mechanical circulatory support patients. *J Heart Lung Transplant*. 2013;32:141-56.
11. Dardas T, Mokadam NA, Pagani F, Aaronson K, Levy WC. Transplant registrants with implanted left ventricular assist devices have insufficient risk to justify elective organ procurement and transplantation network status 1A time. *J Am Coll Cardiol*. 2012;60:36-43.
12. John R, Lietz K, Schuster M, Naka Y, Rao V, Mancini DM, et al. Immunologic sensitization in recipients of left ventricular assist devices. *J Thorac Cardiovasc Surg*. 2003;125:578-91.
13. Joyce DL, Southard RE, Torre-Amione G, Noon GP, Land GA, Loebe M. Impact of left ventricular assist device (LVAD)-mediated humoral sensitization on post-transplant outcomes. *J Heart Lung Transplant*. 2005;24:2054-9.
14. John R, Pagani FD, Naka Y, Boyle A, Conte JV, Russell SD, et al. Post-cardiac transplant survival after support with a continuous-flow left ventricular assist device: impact of duration of left ventricular assist device support and other variables. *J Thorac Cardiovasc Surg*. 2010;140:174-81.
15. John R, Eckman P, Colvin-Adams M, Shumway SJ, Liao K. Postcardiac transplant survival in the current era in patients receiving continuous-flow left ventricular assist devices. *J Thorac Cardiovasc Surg*. 2013;145:575-81.
16. Smedira NG, Hoercher KJ, Yoon DY, Rajeswaran J, Klingman L, Starling RC, et al. Bridge to transplant experience: factors influencing survival to and after cardiac transplant. *J Thorac Cardiovasc Surg*. 2010;139:1295-305.
17. Pinney SP. Timing isn't everything: donor heart allocation in the present LVAD era. *J Am Coll Cardiol*. 2012;60:52-3.

FIGURE E1. Average time as status 1A stratified by all 11 United Network Organ Sharing (UNOS) regions. LVAD, Left ventricular assist device; pLVAD, pulsatile flow left ventricular assist device; cfLVAD, continuous flow left ventricular assist device.

FIGURE E2. Time patients spent as status 1A, status 1B, and status 2 nationally. LVAD, Left ventricular assist device; pLVAD, pulsatile flow left ventricular assist device; cfLVAD, continuous flow left ventricular assist device.

FIGURE E3. Comparison of survival for non-left ventricular assist device (LVAD) transplant recipients in the pulsatile flow (2005-2008) and continuous flow (2009-2012) eras.

TABLE E1. Primary diagnoses of transplant recipients

Diagnosis	pLVAD (n = 749)	cfLVAD (n = 2132)	Non-LVAD (n = 12,747)	P value
Dilated cardiomyopathy	375 (50.1)	1159 (54.4)	5682 (44.6)	<.001
Coronary artery disease	339 (45.3)	902 (42.3)	4036 (31.7)	<.001
Congenital disease	7 (0.9)	11 (0.5)	1382 (10.8)	<.001
Restrictive cardiomyopathy	8 (1.1)	13 (0.6)	479 (3.8)	<.001
Hypertrophic cardiomyopathy	5 (0.7)	23 (1.1)	323 (2.5)	<.001
Valvular heart disease	10 (1.3)	18 (0.8)	222 (1.7)	<.001
Retransplantation/graft failure	5 (0.7)	6 (0.3)	618 (4.9)	<.001
Other	0 (0.0)	0 (0.0)	5 (0.04)	<.001

Data presented as n (%). pLVAD, Pulsatile flow left ventricular assist device; cfLVAD, continuous flow LVAD.