Published in final edited form as:

ASAIO J. 2016 ; 62(3): 232–239. doi:10.1097/MAT.0000000000000329.

Assessing Consequences of Intra-Aortic Balloon Counterpulsation vs. Left Ventricular Assist Devices at the Time of Heart Transplantation

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Abstract

The proportion of heart transplant recipients bridged with durable left ventricular assist devices (dLVADs) has dramatically increased; however, concern exists regarding obligate repeat sternotomy, increase bleeding risk due to anticoagulation and acquired von Willebrand disease, and increased rates of allosensitization. Whether dLVAD patients have impaired post-transplant outcomes compared to equivalent patients with less invasive intraaortic balloon counterpulsation (IABP) at the time of transplant is unknown. We therefore analyzed adult, first time, heart-only transplant procedures with dLVAD (n=2,636) compared to IABP (n=571) at the time of transplant based on data from the United Network for Organ Sharing (UNOS) 07/2004 – 12/2011. There was clear geographic variation in IABP and dLVAD at transplant. Multivariable analysis demonstrated equivalent cumulative risk of death (adjusted Cox proportional hazard ratio: 1.08, 95% confidence interval: 0.87 – 1.33, p=0.51). There was no significant difference in adjusted comparison of perioperative mortality, length of stay, postoperative renal failure requiring dialysis, or early acute rejection (p = 0.14 for all). Data from UNOS therefore suggests that the presence of dLVAD at the time of heart transplantation does not have a detrimental effect on postoperative outcomes compared to IABP, which must be considered in the context of pre-transplant mortality and locoregional organ availability.

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Disclaimers: N/A

Conflict of Interest Disclosures:

1. Dr. DeVore has received grant funding from The American Heart Association, Novartis International AG, and Thoratec Corporation.
2. Dr. Milano is a consultant for Thoratec Corporation and HeartWare Inc.
3. Dr. Patel is a consultant for Thoratec Corporation and HeartWare Inc.

Keywords

Heart failure; Heart transplantation; Mechanical circulatory support; Left ventricular assist device; Intra-aortic balloon counterpulsation; Survival

INTRODUCTION

More than 250,000 patients in the United States (US) suffer from end-stage heart failure refractory to maximized medical therapy.[1] Heart transplantation has been established to improve quality and length of life in this population;[2] however, the efficacy of this treatment modality is limited by allograft availability.[3,4] Due to the scarcity of donor organs, the use of mechanical circulatory support (MCS) as a bridge to transplant has been well established.[5,6] The proportion of patients bridged to heart transplantation with MCS has steadily increased over the past 5 years, with over one-third of patients currently utilizing a mechanical support device at the time of transplant.[7] Multiple options exist for the patient requiring MCS as a bridge to transplantation.[6] Left ventricular assist devices (LVAD) are now the most commonly utilized device, currently representing approximately 89% of patients on support at the time of transplant.[7]

The dramatic increase in the proportion of heart transplant recipients bridged with LVAD therapy raises the possibility of a future where the majority of heart transplants will be preceded by placement of a ventricular assist device prior to transplantation.[8] However, this approach results in obligate repeat sternotomy,[9] and may also increase bleeding risk due to anticoagulation and acquired von Willebrand disease[10] as well as increased allosensitization.[11,12] Whether these factors have a negative impact on post-transplant outcomes compared to less invasive circulatory support strategies is unknown. Our objective was to examine the national experience with heart transplantation in the setting of less invasive intra-aortic balloon pump counterpulsation (IABP) vs. durable, intracorporeal left ventricular assist devices (dLVAD) at the time of surgery to determine whether dLVAD has a detrimental effect on post-transplant outcomes when compared to IABP. This must be considered in the context of pre-transplant mortality and locoregional organ availability, which are also addressed.

METHODS

This study was approved by the Institutional Review Board of Duke University Medical Center.

Data Source

The United Network of Organ Sharing (UNOS) database encompassing all US heart transplant procedures performed between 6/30/2004 -12/31/2011 with follow-up through 3/31/2012 was used for this study.

Study Population

Adult (>18 years) heart transplant recipients were included for analysis. Multi-organ and repeat transplants were excluded. The study population was further limited to those treated with IABP or dLVAD at the time of transplantation (transplant recipients without circulatory support were included only for the purposes of calculating the proportion of IABP and dLVAD utilization). Cases where information regarding IABP or dLVAD use was missing or incomplete were also excluded.

Variable Definitions

Primary Predictor Variable—The primary predictor variable for our analysis was the circulatory support modality at the time of transplant (IABP vs. dLVAD). Brands associated with durable, intracorporeal LVADs were included (Table 1).

Baseline Characteristics and Risk Factors—The UNOS database includes donor, recipient, and transplant related characteristics. Please refer to Table 2 to for a listing of characteristics and risk factors extracted from the dataset for analysis.

Outcome Measures and Follow-Up—The primary outcome variable was overall post-transplant survival. Secondary outcome measures included perioperative mortality, postoperative length of stay >25 days, dialysis requirement prior to discharge, and acute rejection within the first postoperative year. Outcome data for each patient were ascertained from the date of transplantation until patient death, date of last follow-up, or the end of study period (3/31/ 2012).

Statistical Analysis

Trends in the use of IABP vs. dLVAD over time as well as geographic usage patterns were reported descriptively. Baseline characteristics were described for the full study population using medians and 25th – 75th percentile (Q1-Q3) for continuous variables and proportions (frequency, percentage) for discrete variables. Comparisons for continuous and ordered categorical variables were made using Kruskal-Wallis tests and unordered categorical variables were compared using the Pearson Chi-square test. Unadjusted patient survival rates were estimated using the product-limit (Kaplan-Meier) method and compared between groups by the log-rank test.

Multivariable Cox's proportional hazards modeling was used to assess the simultaneous effect of circulatory support modality on risk of patient death, while adjusting for potential confounders based on covariates per the Scientific Registry of Transplant Recipients (SRTR) adult 3-year heart transplant risk model.[13] These covariates are listed in the Supplemental Digital Content.

Univariable and multivariable binary logistic regression modeling was used to assess the simultaneous effect of circulatory support modality on risk of perioperative mortality, postoperative length of stay >25 days, dialysis requirement prior to discharge, and acute rejection within the first postoperative year (secondary endpoints), with risk-adjustment

again based on covariates as described above. Odds ratio (OR) and 95% CI were calculated as measures of strength of association and precision, respectively.

Statistical analyses were performed using JMP Version 10.0 (SAS Institute Inc., Cary, NC) and R version 2.15.1 (R Core Team 2012). For all comparisons, p-values ≤ 0.05 were considered statistically significant. All p-values are two-sided.

Secondary Analysis – Pre-transplant Mortality

In evaluating postoperative outcomes of IABP vs. dLVAD at the time of transplant, it is important to put this information in context of pre-transplant mortality. Therefore, a comparison of pre-transplant mortality in patients with dLVAD vs. IABP at the time of listing was performed. Please refer to Supplemental Digital Content.

RESULTS

Primary Study Population

A total of 3,207 patients meeting inclusion criteria having an IABP (n=571, 17.8%) or dLVAD (n=2,636, 82.2%) at transplant were included (see Figure 1 for study inclusion algorithm). The proportion of patients with a dLVAD at the time of transplant remained fairly constant between 2004 – 2008 at 12% - 15%, with more than doubling after 2008 to a peak of 31.1% in 2011 (Figure 2). The proportion of patients with an IABP at the time of transplant remained constant at 3.4 – 6.5% throughout the study period (Figure 2).

Geographic variation in IABP at transplant was observed (Figure 3). The highest proportion of patients supported with an IABP at the time of heart transplant was observed in the southeastern and northeastern states as well as Texas and Oklahoma (approximately 7%) while the lowest proportion of IABP use observed in the northwestern states as well as Michigan, Ohio, and Indiana (2% - 3%) (Figure 3A). Conversely, the highest proportion of dLVAD use was observed in the northwestern states (30% - 35%) with the lowest proportion of dLVAD at the time of transplant in the southwestern states (approximately 10%) (Figure 3B).

Baseline Recipient Characteristics

Compared to the dLVAD group, the IABP group had a higher proportion of females (20.7% vs. 16.7%, $p=0.023$), higher creatinine at the time of transplant [median (Q1-Q3) 1.2 mg/dL (1.0 – 1.5) vs. 1.2 mg/dL (0.9 – 1.4), $p=0.001$], lower BMI [median (Q1-Q3) 25.8 (23.2 – 28.7) vs. 27.7 (24.4 – 31.1), $p<0.001$], lower proportion with blood type O (35.4% vs. 49.7%, $p<0.001$), and more functional impairment represented by a higher proportion requiring full assistance with activities of daily living at the time of listing for transplant (74.6% vs. 56.1%, $p<0.001$) (Table 2).

Baseline Donor and Transplant Characteristics

Baseline donor and transplant characteristics are summarized in Table 2. Donors for the IABP group demonstrated a lower BMI, higher proportion with cigarette use (>20 pack years ever), higher proportion with cocaine use, and a lower proportion requiring

vasopressin administration within 24 hours of procurement ($p = 0.04$ for all). IABP-supported recipients were predictably more likely to require intensive care, ventilator support, or inotropes at the time of transplant ($p < 0.001$ for all). IABP-supported recipients also experienced significantly shorter waitlist times [median (Q1-Q3) 22 (7 – 77) vs. 155 (63 – 314), $p < 0.001$].

Outcome Measures

The IABP group demonstrated significantly shorter unadjusted overall post-transplant survival, with separation in survival curves compared to dLVAD occurring at approximately 1.5 years post-transplant (Figure 4). Upon risk-adjusted multivariable Cox proportional hazard modeling, this relationship did not retain statistical significance (adjusted hazard ratio for IABP vs. dLVAD: 1.08, 95% CI: 0.87 – 1.33, $p=0.51$) (Figure 4).

Upon unadjusted comparison, the IABP group demonstrated a higher proportion with postoperative length of stay > 25 days (23.9% vs. 19.8%, $p = 0.033$) and lower proportion with early acute rejection (20.9% vs. 25.5%, $p=0.048$); however, upon multivariable risk-adjustment there were no significant differences in secondary endpoints ($p = 0.14$ for all) (Table 3).

Secondary Analysis – Pre-transplant Mortality with IABP vs. dLVAD at the time of listing

Please refer to Supplemental Digital Content for results of the Secondary Analysis.

DISCUSSION

The dramatic increase in surgically implanted dLVAD use as a bridge to heart transplant underlines the importance of understanding how dLVAD therapy impacts post-transplant outcomes compared to less invasive circulatory support modalities. Our study is one of the few contemporary analyses examining the use of IABP support as a bridge to heart transplant. Using national registry data, our results suggest that the presence of dLVAD at the time of heart transplantation does not negatively affect postoperative outcomes compared to IABP. This must be considered in the context of other factors impacting bridge-to-transplant management decisions, such as pre-transplant mortality. These are important findings given the lower procedural risks associated with IABP support which must be balanced against effectiveness of circulatory support and device related complications.

Our data shows that the strategy of IABP support is currently utilized for patients who have a smaller body habitus, a lower degree of allosensitization, or a non-O blood type. A greater proportion of transplant recipients who were supported with IABP were inotrope dependent, had ischemic disease as the etiology of heart failure, and had lower cardiac index. These recipient characteristics not only suggest more critically ill recipients but can also result in shorter waitlist times. Conversely, more patients in the dLVAD group were noted to be blood type O and a greater proportion were allosensitized (primarily with class 1 anti-HLA antibodies), which would potentially require a long-term support device while awaiting transplantation. Given these differences we found the median wait time for patients supported with IABP was only 22 days compared with 155 days in the dLVAD group. However this shorter wait time did not translate into improved post-transplant outcomes in

the IABP group which may be due to both donor and recipient factors. Although the choice between percutaneous vs. durable MCS may at times be dictated by circumstances such as anatomic feasibility and expected wait times, there are many clinical circumstances where either modality would be a clinically reasonable approach as well as technically feasible, which in part relates to evolving technology.[14] The data provided in the current study therefore helps guide clinical decisions in this evolving field.

It is important to note that the IABP group demonstrated significantly shorter unadjusted overall post-transplant survival; however, this did not retain statistical significance after adjusting for potential confounders per the SRTR adult 3-year heart transplant risk model (see Figure 4). This may imply that specific risk factors were responsible for the differences in unadjusted outcomes, and that dLVAD therapy either allowed modification of these risk factors (e.g., renal function, respiratory failure requiring ventilator support, and functional status) or dLVAD patients that had these risk factors were transitioned to destination therapy. This may also imply that transplant centers have the ability to be more discerning in the dLVAD population when choosing appropriate candidates for transplantation.

Indeed, the risk of death while awaiting a suitable organ is a fundamental concept when incorporating these data into clinical practice. Our analysis suggests that hemodynamic stability and certain donor characteristics are clinical trade-offs for an anticipated shorter wait time and avoidance of additional cardiac surgery. Donor and transplantation procedure characteristics for both dLVAD and IABP groups showed similar donor age and ischemic time, which are important predictors of primary graft dysfunction (PGD) and early mortality. [15] Despite an overall low incidence of obstructive coronary disease in the donor organs, the proportion of donors with tobacco or cocaine use (known risk factors for coronary disease) was higher in the IABP group than in the dLVAD group. There was also a higher incidence of gender-mismatch transplants performed in the IABP group compared with the dLVAD group (majority female to male). Collectively these data suggest more liberal donor selection in the IABP group but overall a focus in both groups to minimize PGD. Given similar PGD risk factors, the unadjusted survival of the IABP and dLVAD group after OHT was identical until approximately 18 months post-transplant when the survival of IABP patients began to decline. While a variety of post-transplant complications may explain this later attrition, common predictors of late survival including perioperative renal function and rejection episodes are similar between the two groups. Possible reasons include a higher incidence of microvascular dysfunction associated with undersized donor hearts,[16] which may be more likely with greater gender mismatch seen in the IABP group. It is important to re-emphasize; however, that upon risk-adjusted analysis the post-transplant survival between groups was equivalent.

Differences in clinical practice patterns may also be reflected in the decision to utilize IABP, dLVAD or neither as a bridge to transplantation (Figure 3). Geographic variation in IABP or dLVAD use would suggest a degree of equipoise in treatment modality, further highlighting the importance of the current study to guide management of end-stage heart failure. Very few patients in the northwestern states were supported with IABP at the time of transplant but these same states had the highest use of dLVAD, which may demonstrate a regional preference towards use of dLVAD as a bridge strategy. According to the SRTR Annual Data

Report, greater than 60% of patients listed in these same regions were able to be transplanted within a year of listing.[3] The mid-atlantic and northeastern US had the highest use of IABP support as a bridge to transplant. These same states also utilized dLVAD therapy in 20-25% of transplant recipients suggesting selection of device therapy for critically ill patients based on recipient characteristics and the anticipated donor pool. SRTR data for these states suggests less than 50% of listed patients undergo transplantation within a year of listing.[3] Finally, the southwestern US utilized mechanical support devices infrequently as a bridge to transplant, presumably opting for heightened pharmacologic therapy to support patients until a suitable donor organ becomes available. Since classification as UNOS 1A status is possible for dLVAD complication, IABP and increased pharmacological therapy, the data presented in this analysis provides important outcomes data for this patient population. Our data also provides further impetus for continued evaluation of the current UNOS listing process in an era dominated by MCS to appropriately assign priority based on mortality risk while awaiting cardiac transplantation.[17,18]

Given the societal cost of heart failure,[1] management of this disease, including the use of MCS devices as detailed in the current study, necessitates careful cost considerations. The critical questions as articulated by Miller et al include the actual cost of these therapies, associated savings related to fewer readmissions, improved quality of life, and the willingness of society to pay for these interventions.[19] Interestingly, in Britain a cost effectiveness analysis of LVADs compared to medical management as a bridge to transplant demonstrated that based on threshold recommendations posed by the United Kingdom's National Institute for Health and Clinical Excellence, LVAD's are not cost effective; however cost-effectiveness estimates are hampered by the lack of randomized trials.[20] The authors note that this finding is complex for the policy arena and will need to be considered carefully in the light of the burden of disease, available funding, and future supply of donor hearts. Improved cost data in conjunction with clinical information will be crucial in optimizing care of this complex patient population.

Limitations

The results of this study should be interpreted in the context of the study limitations. Given the retrospective nature of this review, unmeasured confounders may exist. Modeling techniques may not entirely account for lack of randomization between cohorts. The date of device placement is not captured in our data source, precluding analysis of duration of support. The type of IABP and the technique for insertion, such as femoral vs. axillary, [21] as well as whether the device permitted ambulation [22], is unknown for our study cohort. Additionally, management strategies using IABP and dLVAD in sequence or in tandem are outside the scope of our analysis. Furthermore, some patients with an IABP or dLVAD placed may have died with the intention to list and transplant; however this information is not available in our dataset and precludes an intention to treat analysis based on the time of device insertion.

Additionally, an important limitation to the current study is lack of information surrounding the circumstances of these therapeutic interventions. Fundamental differences in clinical presentation may exist despite risk-adjusted analysis. This limitation must be considered

when interpreting the results of the current study and should be taken into account in clinical decisions on bridge to transplant strategies.

Conclusions

Data from UNOS suggest that dLVAD at the time of heart transplantation does not have a detrimental effect on postoperative outcomes compared to less invasive IABP therapy. This is despite the presumed risks of repeat sternotomy, anticoagulation, and allosensitization. Anticipated wait time and waitlist mortality are key variables in clinical decision-making in cardiac transplantation as well as preoperative circulatory support, and regional differences in donor availability, philosophy of donor selection at a center, and the number of transplant centers located within the region -- all of which may influence the optimal bridging strategy. Transplant centers may have the ability to be more discerning in the dLVAD population when choosing appropriate candidates for transplantation. Our results provide important information for centers utilizing both dLVAD and IABP support and may help guide in device utilization, donor selection and decisions to escalate to dLVAD support.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGEMENTS

By use of the UNOS database, this work was supported in part by Health Resources and Services Administration contract 234-2005-370011C. The content herein is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

Funding Sources: N/A

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Figure 1.

Study inclusion algorithm.

Abbreviations: UNOS = United Network of Organ Sharing; IABP = intra-aortic balloon pump; dLVAD = durable, intracorporeal left ventricular assist device.

Figure 2.

Trends in use of mechanical circulatory support at the time of heart transplantation.

Abbreviations: IABP = intra-aortic balloon pump; dLVAD = durable, intracorporeal left ventricular assist device.

3A. Percent of heart transplant recipients with IABP at the time of transplant (2004-2011).

3B. Percent of heart transplant recipients with dLVAD at the time of transplant (2004-2011).

Figure 3.
Use of mechanical circulatory support at the time of heart transplantation by geographic region.
IABP = intra-aortic balloon pump; dLVAD = durable, intracorporeal left ventricular assist device.

Unadjusted Kaplan-Meier Survival Analysis **Risk-Adjusted Cox Proportional Hazard Analysis [ref = dLVAD]‡** **Figure 4.**

Survival analysis by circulatory support modality at the time of transplant.

Abbreviations: IABP = intra-aortic balloon pump; dLVAD = durable, intracorporeal left ventricular assist device.

‡ Please refer to "Supplemental Digital Content" for a list of variables used for risk adjustment per the Registry of Transplant Recipients (SRTR) adult 3-year heart transplant risk model.

* indicates statistical significance.

Table 1**Durable LVAD Brands**

Heartmate II
Heartmate IP
Heartmate VE
Heartmate XVE
Heartsaver VAD
Heartware HVAD
Jarvik 2000
MicroMed DeBakey
Novacor PC
Novacor PCq
Terumo DuraHeart
Thoratec IVAD
Ventracor VentrAssist
Worldheart Levacor

Table 2

Baseline characteristics.

Characteristic	Total Sample (n = 3207)	Circulatory Support Modality At the Time of Transplant		p-Value
		IABP (n=571)	dLVAD (n=2636)	
Recipient Characteristics				
Age at transplant	55 (46, 61)	55 (45, 61)	55 (46, 61)	0.442
Age 60	1,002 (31.2%)	183 (32.1%)	819 (31.1%)	0.647
Female Gender	558 (17.4%)	118 (20.7%)	440 (16.7%)	0.023 *
White Ethnicity	2,189 (68.3%)	398 (69.7%)	1,791 (67.9%)	0.413
Etiology of Ischemic heart disease	1,368 (42.7%)	276 (48.3%)	1,092 (41.4%)	0.006 *
History of Diabetes	947 (29.7%)	152 (26.7%)	795 (30.3%)	0.083
Creatinine at Transplant (mg/dL)	1.2 (0.9, 1.4)	1.2 (1.0, 1.5)	1.2 (0.9, 1.4)	0.001 *
BMI (kg/m ²) at Transplant	27.3 (24.1, 30.8)	25.8 (23.2, 28.7)	27.7 (24.4, 31.1)	<0.001 *
Recipient Blood Type O	1,512 (47.2%)	202 (35.4%)	1,310 (49.7%)	<0.001 *
Characteristics at time of listing				
Mean PA Pressure (mm/Hg) (n=2982)	32 (24, 39)	32 (25, 39)	32 (24, 39)	0.398
Medicare or Medicaid Insurance	1,242 (38.7%)	204 (35.7%)	1,038 (39.4%)	0.104
Functional status requiring full assist	1,777/2,994 (59.4%)	391/524 (74.6%)	1,386/2,470 (56.1%)	<0.001 *
Working for income	162/3,017(5.4%)	31 (5.7%)	131/2,472(5.3%)	0.726
Donor Characteristics				
Donor Age	29 (22, 40)	30 (22, 42)	29 (21, 39)	0.083
Donor Diabetes	91 (2.8%)	19 (3.3%)	72 (2.7%)	0.441
Terminal Laboratory Values				
Serum Creatinine (mg/dL)	1.0 (0.8, 1.4)	1.1 (0.8, 1.4)	1.0 (0.8, 1.4)	0.105
BUN/Serum Creatinine ratio	11.8 (8.7, 16.7)	11.4 (8.6, 17.1)	11.9 (8.7, 16.7)	0.693
Aspartate Aminotransferase (u/L)	46 (29, 85)	45 (29, 85)	46 (29, 85)	0.591
Alanine Aminotransferase (u/L)	35 (22, 66)	38 (23, 70)	35 (22, 66)	0.190
Total Bilirubin (mg/dL)	0.8 (0.5, 1.2)	0.8 (0.5, 1.2)	0.8 (0.5, 1.2)	0.876
Donor BMI (kg/m ²)	26.2 (23.5, 30.0)	25.6 (23.1, 29.3)	26.5 (23.6, 30.1)	0.002 *

Characteristic	Total Sample (n = 3207)	Circulatory Support Modality At the Time of Transplant		p-Value
		IABP (n=571)	dLVAD (n=2636)	
Abnormal Coronary Angiogram	55 (1.7%)	14 (2.5%)	41 (1.6%)	0.135
Donor Left Ventricular ejection fraction	60 (55, 65)	60 (55, 65)	60 (55, 65)	0.441
Cigarette Use (>20 pack years ever)	573 (18.0%)	119 (21.0%)	454 (17.4%)	0.043 *
Cocaine Use Ever	456 (14.5%)	100 (17.9%)	356 (13.8%)	0.013 *
Heave Alcohol Use (2+ drinks/day)	482 (15.3%)	94 (16.8%)	388 (14.9%)	0.264
Clinical infection in Donor	1,529 (49.2%)	262 (47.5%)	1,267 (49.6%)	0.374
Vasopressin Within 24 hrs of Procurement	1,951 (61.0%)	323 (57.0%)	1,628 (61.9%)	0.030 *
Inotropic Medications at Procurement	1,730 (54.2%)	307 (54.0%)	1,423 (54.2%)	0.905
Diuretics Within 24 hrs of Procurement	2,081 (65.0%)	373 (65.6%)	1,708 (64.9%)	0.765
High Risk Donor per CDC Guidelines	297 (9.3%)	63 (11.1%)	234 (8.9%)	0.104
Preoperative status and additional support				
Requiring intensive care	805 (25.1%)	486 (85.1%)	319 (12.1%)	<0.001 *
Ventilator dependent	88 (2.7%)	66 (11.6%)	22 (0.8%)	<0.001 *
Inotrope dependent	649 (20.2%)	387 (67.8%)	262 (9.9%)	<0.001 *
Waitlist time (days)	124 (38, 287)	22 (7, 77)	155 (63, 314)	<0.001 *
Transplant Characteristics				
Most Recent Class 1 PRA >25%	351/3,015 (11.6%)	31/538 (5.8%)	320/2,477 (12.9%)	<0.001 *
Most Recent Class 2 PRA >25%	189/2,716 (7.0%)	26/492 (5.3%)	163/2,224 (7.3%)	0.106
Gender Mismatch				
Female Recipient, Male Donor	277 (8.6%)	57 (10.0%)	220 (8.3%)	0.207
Male Recipient, Female Donor	449 (14.0%)	93 (16.3%)	356 (13.5%)	0.082
Race Mismatch	1,511 (47.1%)	279 (48.9%)	1,232 (46.7%)	0.357
Donor/Recipient Size Mismatch [†]	1,047 (33.1%)	178 (31.7%)	869 (33.4%)	0.427
Center Volume (average transplants/y)	19.6 (13.7, 35.6)	26.1 (16.3, 48.8)	19.2 (13.2, 32.1)	<0.001 *
Ischemic Time (hours)	3.3 (2.6, 3.9)	3.2 (2.6, 3.9)	3.3 (2.6, 3.9)	0.194

Median (interquartile range) for non parametric continuous variables. N (%) for categorical variables. If data is missing for > 5% of the study population, the denominator is give for categorical variables and "n" given for continuous variables. Wilcoxon signed-rank test for continuous variables. Pearson Chi-Square test for categorical variables. Abbreviations: IABP = intra-aortic balloon pump; dLVAD = durable, intracorporeal left ventricular assist device; BUN = blood urea nitrogen; BMI = body mass index; PRA = panel reactive antibody.

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Donor/recipient size mismatch is defined as a difference in body mass index of $>20\%$.
* indicates statistical significance.

Table 3

Comparison of early postoperative mortality and complications by circulatory support modality at transplant.

Secondary Outcome Measures [†]	IABP (n=571)	dLVAD [reference] (n=2636)	Unadjusted Comparison		Adjusted Comparison [‡]	
			OR (95% CI)	p-Value	OR (95% CI)	p-Value
30-Day Mortality	33/559 (5.9%)	132/2,498 (5.3%)	1.12 (0.75 - 1.65)	0.562	0.92 (0.59 - 1.44)	0.718
90-Day Mortality	43/546 (7.9%)	186/2,425 (7.7%)	1.03 (0.72 - 1.44)	0.871	0.85 (0.57 - 1.26)	0.427
Postoperative length of stay >25 days	133/556 (23.9%)	514/2,592 (19.8%)	1.27 (1.02 - 1.58)	0.033 *	1.12 (0.88 - 1.42)	0.365
Dialysis prior to discharge	72/566 (12.7%)	267/2,609 (10.2%)	1.28 (0.96 - 1.68)	0.089	1.17 (0.85 - 1.59)	0.337
Early Acute Rejection [‡]	88/421 (20.9%)	453/1,779 (25.5%)	0.77 (0.59 - 0.997)	0.048 *	0.81 (0.62 - 1.07)	0.142

Abbreviations: IABP = intra-aortic balloon pump; dLVAD = durable, intracorporeal left ventricular assist device; Adj. = adjusted.

[†] Adjusted based on covariates per the Scientific Registry of Transplant Recipients (SRTR) adult 3-year heart transplant risk model.

[‡] Defined as drug-treated rejection within the first postoperative year. Patients with less than one year of follow-up are censored.

* indicates statistical significance.