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INSTITUTIONAL VOLUME OF HEART TRANSPLANTATION WITH LEFT VENTRICULAR ASSIST DEVICE EXPLANTATION INFLUENCES GRAFT SURVIVAL

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Abstract

Objective—We sought to assess the impact of institutional volume of LVAD explant-OHT on post-transplant graft survival.

Background—There are increasing numbers of patients undergoing orthotopic heart transplantation (OHT) with left ventricular assist device (LVAD) explantation. We hypothesized that LVAD explant-OHT is a more challenging surgical procedure compared to OHT without LVAD explantation and that institutional LVAD explant-OHT procedural volume will be associated with post-transplant graft survival.

Methods—This is a retrospective analysis of the Scientific Registry of Transplant Recipients for adult OHTs with long-term LVAD explantation. LVAD explant-OHT volume was characterized on the basis of the center's year-specific total OHT volume (OHTvol) and year-specific LVAD explant-OHT volume quartile (LVADvolQ). The effect of LVADvolQ on graft survival (death or re-transplantation) was analyzed.

Results—From 2004 to 2011, 2681 patients underwent OHT with LVAD explantation (740 HeartMate XVE, 1877 HeartMate II, 64 HeartWare). LVAD explant-OHT at centers falling in the

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lowest LVADvolQ was associated with reduced post-transplant graft survival ($p=0.022$). After adjusting for annualized OHTvol ($HR=0.998$, 95%CI=0.993–1.003, $p=0.515$ and pulsatile XVE ($HR=0.842$, 95%CI=0.688–1.032, $p=0.098$), multivariate analysis confirmed a significantly (approximately 37%) increased risk of post-transplant graft failure among explant-OHT procedures occurring in centers in the lowest volume quartile ($HR=1.371$, 95%CI=1.030–1.825, $p=0.030$).

Conclusion—Graft survival is decreased when performed at centers falling in the lowest quartile of LVAD explant-OHT for a given year. This volume-survival relationship should be considered in the context of limited donor organ availability and rapidly growing LVAD centers.

Keywords

heart transplantation; left ventricular assist device; transplant center volume

INTRODUCTION

Orthotopic heart transplantation (OHT) is the treatment of choice for patients with end-stage heart failure (HF) who have ongoing symptoms despite maximal medical therapy (1). Unfortunately, the number of donor hearts has remained unchanged over the last decades despite an increasing demand, and longer transplant waiting times (1, 2). Long-term mechanical circulatory support with left ventricular assist devices (LVAD) is being increasingly utilized as a bridge to transplantation (BTT) strategy until a suitable donor organ becomes available (3).

Survival outcomes after OHT are dependent upon complex recipient and donor characteristics, and have steadily improved over the past three decades. Most significant advances have occurred during the first year after transplantation, likely related to improvement in surgical technique (4), and immunosuppressive therapy (1). Our understanding of the expertise needed to treat these complex patients has dramatically changed, as a clear association between transplant center volume and graft survival after transplant has been demonstrated, especially among patients with high perioperative risk (5–7). Landmark reports have identified a relationship between LVAD center implantation volume and survival for both pulsatile and continuous flow LVAD populations (8, 9). Although survival outcomes in patients bridged to OHT with long term LVADs is comparable to patients without devices, OHT with LVAD explantation has been generally considered a more challenging surgical intervention (10). Additionally, LVAD device complications commonly lead to UNOS status upgrades, which may further increase perioperative challenges and surgical complexity at time of OHT and LVAD explantation (11). We sought to test the association of institutional volume of LVAD explantation at time of OHT (LVAD explant-OHT) on post-transplant graft survival among adults receiving OHT following LVAD explant.

PATIENTS AND METHODS

This study was a retrospective analysis of the Scientific Registry of Transplant Recipients (SRTR) database. The SRTR data system includes data on all donor, wait-listed candidates,

and transplant recipients in the US submitted by members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors. This research has been approved by the Vanderbilt University Institutional Review Board.

Two thousand six hundred and eighty-one patients underwent long-term LVAD explant-OHT between 2004 and 2011. Explanted LVAD types included in the analysis were HeartMate II, HeartMate XVE, and HeartWare. Patients with temporary extracorporeal mechanical circulatory support devices, right ventricular assist devices, paracorporeal ventricular assist devices, and total artificial heart were excluded from this analysis.

Data Management and Statistical Methods

Among centers performing LVAD explant-OHT, each center's total number of LVAD explant OHT and overall adult OHT procedures within a given calendar year were computed to reflect annualized center-specific volumes for LVAD explants and adult OHT (OHTvol). Then, every center's annualized long-term LVAD explant-OHT volume was characterized based on 25th, 50th, and 75th percentile thresholds for LVAD explant-OHT and OHTvol *among those centers performing these procedures and excluding centers that were not performing these procedures during a given calendar year*. This approach allowed for the establishment of LVAD explant-OHT volume quartile thresholds that were sensitive to changes from year to year in both a) the number of centers performing long-term LVAD explant-OHT, and b) the total number of LVAD explant-OHT procedures performed. These annualized, center-specific procedure volume data were then associated with individual LVAD explant-OHT event data, such that all transplant events within a given center and year were characterized on the basis of the center's LVAD explant-OHT volume quartile for the year and the total number of adult OHT procedures performed at the center during that calendar year. This study also assessed the effect of total annualized OHT volume on post-transplant graft survival, however did not specifically analyze the association of center specific OHT (only) volume quartiles on post-transplant graft survival.

Summary data are expressed as frequencies, proportions, or means $\pm$ SD. Graft survival was analyzed using the Kaplan-Meier method with the log-rank test for comparisons of graft survival on the basis of annualized, center-specific LVAD explant-OHT volume quartiles, with graft failure defined as death or re-transplantation. Multivariate Cox proportional hazards regression analysis was performed to test the effects of annualized, center-specific LVAD volume quartile on graft survival following LVAD explant-OHT after adjusting for center-and year-specific overall adult OHT volume and device type (pulsatile versus continuous flow LVAD).

RESULTS

Center-Level Data for OHT and LVAD Explant-OHT Volume

Figure 1 represents the number of active centers performing adult OHT and LVAD explant-OHT by calendar years 2004 through 2011. We found a temporal decline in the number of

centers performing OHT between 2004 (n=115) and 2011 (n=108) (p=0.061); while the number of centers performing LVAD explant-OHT increased significantly between 2004 (n=48) and 2011 (n=93) (p=0.001). During this period, individual centers performed between 1 and 98 OHT per year, with the median remaining stable at 12 per year in 2004 through 2007, 13 per year in 2008 and 2009 and 14 per year in 2010 and 2011. Figure 2 shows annualized center volume quartiles for LVAD explant-OHT using 25th, 50th and 75th percentile thresholds among those centers performing this procedure in a given calendar year. High volume centers (quartile 4), which numbered between 8 centers (in 2004) and 21 centers (in 2011), performed between 12 and 31 LVAD explant-OHT procedures annually. The lowest volume centers (quartile 1), which numbered between 18 centers (in 2006) and 32 centers (in 2011), performed between 1 and 3 LVAD explant-OHT procedures annually. These summary data for annualized center-level activity for adult OHT and LVAD explant-OHT volumes were used to characterize patient-level data such that each LVAD explant-OHT event was associated with volume data for the center at which the LVAD explant-OHT was performed during a given calendar year.

Patient Characteristics

Summary patient characteristics are presented in Table 1. The sample included 2,681 adult LVAD explant-OHT recipients who were transplanted between January 2004 and December 2011. Average recipient age was 53 ± 12 years (range 18 to 74 years) and 2,227 patients (83%) were male. Average follow-up time at the graft survival endpoint determination was 26 ± 24 months (range <1 to 95 months). As previously reported graft survival after LVAD explant-OHT is equivalent to conventional OHT and does not differ between LVAD type (10, 12). The following long-term LVADs were explanted at time of OHT: HeartMate II (n=1877, 70%), HeartMate XVE (n=740, 28%), and HeartWare (n=64, 2%). By definition, using the approach described above, the majority of transplants were performed at higher volume LVAD explant-OHT centers, with 1307 cases (49%) performed at the highest volume centers and 256 (10%) at lowest volume centers.

Univariate and Multivariate Models of Graft Survival after LVAD Explant-OHT

Overall Kaplan-Meier graft survival among persons having LVAD explant-OHT averaged 74 (95% CI: 72–76) months. Patient status at time of last follow up was 2,206 (82%) were alive, 449 (17%) deceased, 15 (0.6%) were lost to follow-up and 11 (0.4%) had undergone re-transplantation. Initial univariate analysis of the effect of annualized LVAD explant-OHT volume quartile on graft survival demonstrated that there was no difference in survival between patients whose LVAD explant-OHT was performed at centers in the upper three volume quartiles (Figure 3). Reduced graft survival was associated with the lowest volume quartile (Q1 mean=64) in comparison to Q4 (mean=70; p=0.022), and this trend was evident in comparison to Q3 (mean=74; p=0.045), and Q2 (mean=69; p=0.101) (Figure 3). Therefore, subsequent models tested the effect of the lowest LVAD explant-OHT volume quartile in comparison to all other annualized volume quartiles (Q2–Q4). Figure 4 demonstrates that graft survival after LVAD explant-OHT at centers with the lowest annualized volume quartile (Q1) was significantly decreased (64 vs. 74 months, log-rank p=0.022).

Table 2 summarizes the multivariate model of graft survival that considered the effects of three covariates: annualized LVAD explant-OHT volume, pulsatile LVAD (versus continuous flow LVAD), and adult OHT center volume. The negative effect of the lowest LVAD explant-OHT volume quartile on graft survival persisted ($p=0.030$) after adjusting for pulsatile LVAD ($p=0.098$) and a center's annualized total OHT volume ($p=0.515$). Specifically, persons transplanted at centers whose annualized LVAD explant-OHT volume fell in the lowest quartile were, overall, 37% more likely to experience graft failure in comparison to those transplanted at higher volume centers. Whether the explanted device was a pulsatile or continuous flow LVAD was not statistically significant in this multivariate model. Additionally, the independent effect of total annualized OHT volume was not statistically significant, which indicates that graft survival after LVAD explant-OHT is related to a center's annual volume *for this procedure* but not to the total number of adult OHT performed in a given year.

DISCUSSION

This study evaluated the impact of institutional volume of LVAD explant-OHT on post-transplant graft survival. We evaluated the total annualized center and year specific LVAD explant-OHT volume quartiles and total annualized center and year specific OHT volumes on the risk of graft failure. In centers performing LVAD explant-OHT procedures within the lowest annualized volume quartile, we found a 35% increased risk of post-transplant graft failure ($p=0.022$). Interestingly, at centers that performed LVAD explant-OHT, the effect of total annualized OHT procedural volume and pulsatile LVADs, were not independently associated with post-transplant graft survival ($p=0.515$ and $p=0.098$, respectively). These volume survival relationships warrant careful consideration due to limited organ availability and the growing number of LVAD implanting centers.

Increased LVAD utilization

Heart transplantation remains the gold standard treatment for patients with end-stage heart disease; however, scarce donor organ availability limits the number of heart transplant procedures performed, without significant changes in procedural volume over the last decade (1). Increasing experience with LVAD technology and progress in the clinical management of patients with long-term LVADs has led to further utilization of these devices as a bridge to transplantation (3). In fact, LVADs have been shown to reduce heart transplantation wait list mortality while dramatically improving patient quality of life, functional status, and end organ function (14–16). Our data (Figure 1) demonstrated that the number of centers performing LVAD explant-OHT nearly doubled during the past eight years as the number of centers performing only transplants did not significantly change, suggesting ongoing, rapid initiation and development of LVAD programs at centers that perform OHT. Our findings show that Furthermore, Mulloy et al recently reported trends in LVAD and OHT procedures and found that over a 5-year period; the number of LVADs implanted nearly tripled, while the OHT procedures changed only marginally (13). Currently, the proportion of patients awaiting heart transplantation bridged with long-term LVADs is approaching 40% and is projected to continue to rise (3, 14).

Volume-Survival Relationship

The rapid development of LVAD technology and has led to surgical and perioperative care advances which have procedural and general clinical learning curves. Improvements in outcomes with increasing surgical and clinical experience have been demonstrated in LVAD clinical trials when outcomes from early trial cohorts were compared to mid trial and ‘real world’ patient cohorts (15, 16). Lietz et al. analyzed a pulsatile-only LVAD population in the Thoratec HeartMate registry from 1998 to 2005 finding an association between low LVAD center volume and worse 1-year survival outcomes. They concluded that institutional experience likely impacts outcomes of LVAD therapy (8). More recently, in a contemporary continuous flow LVAD population, patients implanted at centers performing < 15 LVADs per year had increased 90-day mortality (9). Arnaoutakis et al. retrospectively evaluated risk factors for early death in a BTT continuous flow LVAD cohort undergoing OHT and found that a higher annual BTT LVAD-OHT procedure volume was associated with a lower risk of death (6). In our study, only centers in the lowest LVAD explant-OHT volume quartile had significantly decreased graft survival, suggesting an institutional LVAD explant-OHT learning curve. However, center volumes in all other LVAD explant-OHT quartiles did not show adverse survival outcomes, implying broad institutional experience had translated into improved outcomes. This association between center volume and graft survival is likely multifactorial in etiology given the complex surgical and perioperative care required to manage LVAD and OHT populations.

Does volume matter?

In an OHT population, Russo et al suggested that higher center volumes may translate into better survival outcomes due to procedural and technical expertise, a greater knowledge base among specialists, and a more developed physical infrastructure (17). We suggest center volume of LVAD explant-OHT may be a surrogate marker of institutional factors that are experience driven such as patient selection and operative and perioperative management expertise. Examination of the survival curves in Figures 3 & 4 support this statement by demonstrating that survival is decreased *early* after LVAD explant-OHT in only the lowest volume quartile (Q1) compared to all other volume survival curves. This needs to be explored further in future volume-survival analyses focusing specifically on LVAD program organization, general operative techniques, and basic perioperative intensive care unit management practices. It is unknown how the effects of ongoing changes in LVAD device types and therefore LVAD surgical procedural changes have on an institutional learning curve in comparison to OHT where there has been little change in OHT implantation technique since the 1990’s where bicaval anastomosis was introduced as an alternative technique to biatrial anastomosis (4). However, when the effect of pulsatile versus continuous flow LVAD was included in our multivariate model, device type was not independently associated with graft survival.

Higher transplant volumes have been associated with improved OHT survival outcomes in studies utilizing the United Organ Sharing Network (UNOS) and SRTR data bases (5, 17–19). Our study did not find a relationship between OHTvol and graft survival outcomes in centers that perform LVAD explant-OHT. This suggests, at centers that perform LVAD explant-OHT, a robust OHTvol is not “protective” against graft failure outcomes for centers

that perform in the lowest volume LVAD explant-OHT quartile. This volume survival relationship reminds us that institutions which perform LVAD-explant-OHT require unique surgical and perioperative management skills which differ from skills utilized for OHT alone.

Limitations

This study has several important limitations that need to be acknowledged. Although the SRTR data collection is rigorous and undergoes periodic audits, some errors in data entry may be present. This study uniquely characterized annualized center level LVAD explant-OHT procedural volumes in relation to annualized OHTvol, however did not specifically examine patient level characteristics such as pre-transplant recipient risk scores, patient or donor selection characteristics, UNOS urgency status at time of transplant, or post-operative management techniques, all of which may contribute to post-transplant graft survival. Additionally, specific LVAD variables such as LVAD-related complications, duration of LVAD support, and LVAD-related operative characteristics may be associated with post-transplant graft survival; however these data are not reliably available in the SRTR database. Uriel et al recently demonstrated that LVAD complications leading to higher priority UNOS listing status was not associated with post-transplant survival (11). Finally, our analyses included patients with pulsatile or continuous flow LVADs, however was adjusted for device type. This approach enhanced the generalizability of our findings in a contemporaneous era during which continuous flow LVAD implantation predominated.

Summary

We demonstrated a decreased graft survival rate at centers that performed LVAD explant-OHT procedures within the lowest volume quartile for a given year. This volume-survival relationship should be considered in the context of limited organ availability and rapidly growing LVAD centers. As the proliferation and dissemination of existing and novel LVADs continue to develop, centers that perform LVAD explant-OHT must develop methods to acquire the surgical and clinical management experience as quickly as possible to minimize adverse impact on post-transplant survival outcomes.

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LIST OF ABBREVIATIONS

OHT	Orthotropic heart transplantation
HF	Heart failure
LVAD	Left ventricular assist device

BTT	Bridge to transplantation
UNOS	United Network for Organ Sharing
LVAD explant-OHT	Left ventricular assist device explantation at time of orthotopic heart transplantation
SRTR	Scientific Registry of Transplant Recipients
OPTN	Organ Procurement and Transplantation Network
HRSA	Health Resources and services administration
OHTvol	Orthotopic heart transplant volume

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Figure 1.

Number of centers performing OHT and VAD explant-OHT by calendar year. The number of centers performing OHT has temporally declined while the number of centers performing VAD explant-OHT has significantly increased during the study period.

Figure 2.
Number of annualized LVAD explant-OHT procedures per center, stratified by 25th, 50th and 75th percentile thresholds.

Figure 3.
Graft survival after LVAD explant-OHT at centers stratified by annualized volume quartile.

Figure 4. Graft survival after LVAD explant-OHT at centers with the lowest annualized volume (Q1) compared to all other annualized volume (Q2-4) was significantly decreased ($p=0.022$).

Table 1

Baseline characteristics

Variable	
Age, yrs	53 ±12 (18,74)
Male (gender)	2,227 (83)
Follow-up duration, months	26 ±24 (<1,95)
LVAD explant-OHT procedure volume quartiles	
Q4	1,307 (49)
Q3	739 (27)
Q2	379 (14)
Q1	256 (10)

Table entries are mean ± SD or n (%). Q=Quartile

Table 2

Multivariate model of graft survival

Effect	B coefficient	p-Value	Hazard Ratio	95% CI
VAD Explant (Q1) (ref: Q2–Q4)	.316	0.030	1.371	1.030 – 1.825
Pulsatile VAD (ref: Continuous Flow)	–.172	0.098	0.842	.688 – 1.032
Total OHT volume (Number of Transplants)	–.002	0.515	0.998	.993 – 1.003