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Ventricular Assist Devices or Inotropic Agents in Status 1A Patients? Survival Analysis of the United Network of Organ Sharing Database

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Abstract

Background—Improved outcomes as well as lack of donor hearts have increased the use of ventricular assist devices (VADs), rather than inotropic support, for bridging to transplantation. Recognizing that organ allocation in the highest status patients remains controversial, we sought to compare outcomes of patients with VADs and those receiving advanced medical therapy.

Methods—The United Network of Organ Sharing (UNOS) database was used to compare survival on the waiting list and posttransplantation survival in status 1A heart transplantation patients receiving VADs or high-dose/dual inotropic therapy or an intraaortic balloon pump (IABP), or both. Adjusted survival was calculated using Cox's proportional hazard model.

Results—Adjusted 1-year posttransplantation mortality was higher among patients with VADs compared with patients receiving inotropic agents alone (hazard ratio [HR], 1.48; $p < 0.05$). Survival remained better for patients receiving inotropic agents alone in the post-2008 era (HR, 1.36; $p = 0.03$) and among those with isolated left-sided support (HR, 1.33; $p = 0.008$). When patients who received IABPs were added and analyzed after 2008, the left ventricular assist device (LVAD) group had similar survival (HR, 1.2; $p = 0.3$). Survival on the waiting list, however, was superior among patients with LVADs (HR, 0.56; $p < 0.05$). In a therapy transition analysis, failure of inotropic agents and the need for LVAD support was a consistent marker for significantly worse mortality (HR, 1.7; $p < 0.05$).

Conclusions—Although posttransplantation survival is better for patients who are bridged to transplantation with inotropic treatment only, the cost of failure of inotropic agents is significant, with a nearly doubled mortality for those who later require VAD support. Survival on the waiting list appears to be improved among patients receiving VAD support. Careful selection of the appropriate bridging strategy continues to be a significant clinical challenge.

Ventricular assist devices (VADs) have been used increasingly as a bridge to heart transplantation. Since 2009, more than 30% of heart transplant recipients have been bridged with a mechanical device [1]. The impact of VAD implantation on posttransplantation survival has had variable results, depending on era, cause of heart failure, and database used [2–4]. As patient management and device technology improve, survival after VAD

implantation continues to improve, and patients with implantable devices are increasingly more stable than their counterparts with first-generation VADs from the 1990s [5]. As such, challenges remain about how best to allocate donor hearts in light of limited donor availability and increased LVAD stability. United Network of Organ Sharing (UNOS) status attempts to balance competing demands and reflect recipient priority. UNOS status 1A designation contains a diverse subgroup of patients (Table 1), including those with potentially stable VADs who are using 30 days of allocated status 1A time, as well as patients requiring intraaortic balloon pumps (IABPs), extracorporeal membrane oxygenation (ECMO), or total artificial hearts. Additional designations include patients with VAD complications [6], those receiving mechanical ventilation, or the more frequent patient who requires both inotropic agents and continuous hemodynamic monitoring. In the earlier era, although VAD support was often lifesaving, it was considered unreliable, and therefore these patients were afforded 1A status to allow expeditious bridging to heart transplantation. In the current era of stable patients with LVADs, some have questioned whether allowance of 30 days at status 1A to a stable patient with an LVAD is equitable [7, 8]. As such, we sought to compare waiting list and post-transplantation survival between patients with VADs using their 30 days at status 1A with the “sickest” medical patients, ie, those patients receiving high-dose/multiple inotropic agents and hemodynamic monitoring or IABPs.

Patients and Methods

Adult patients (≥ 18 years of age) listed as status 1A in the UNOS database who underwent heart transplantation in the United States from 1998 to 2012 were included. The University of Utah Investigational Review Board waived the need for formal approval and individual consent for this study because of its retrospective design and use of deidentified information from a publicly available database. As defined in Table 1, we specifically compared transplant recipient registrants who were listed as status 1A-(a)(i) and 1A-(d). Status 1A-(a)(iii) patients with IABPs were added to the group receiving inotropic agents to create a “combined medical therapy” group in secondary analysis to provide a higher risk comparison group. Excluded groups were patients with total artificial hearts, those undergoing ECMO, those with VAD complications, and those receiving mechanical ventilation, as well as those undergoing combined or redo transplantation. Further analysis was conducted on the initial listing status (transplant candidate registration) for the purpose of calculating waiting list survival.

The primary end point was all-cause mortality. Adjusted survival was performed using Cox proportional hazards analysis. Survival models were adjusted for age; sex; body mass index; cause of heart failure; mean pulmonary artery and pulmonary capillary wedge pressures; cardiac output; ischemic time; bilirubin, creatinine, and panel reactive antibody levels; diabetes; and previous cardiac operations. These variables were selected in an attempt to account for what we perceived as important markers of patient outcomes, organ function, sensitization, and previous operations. We also made an effort to use variables whose data had the fewest missing values. Notably, the incidence of acute rejection was unable to be reliably determined because of marked variations in reporting and numerous missing values in the database. To account for increasing use of implantable continuous-flow devices, additional survival models were constructed both before and after 2008. Because of the known survival disadvantages in patients needing biventricular support, models were also constructed comparing patients with isolated LVADs and patients receiving inotropic agents, and later to patients receiving inotropic agents ± IABPs.

The dynamic nature of listing status also prompted identification of patients who had different support therapy at the time of listing and the time of transplantation. This generated 4 distinct treatment groups: (1) deescalated (inotropic agent/IABP to no support), (2) no

change (inotropic agent/IABP to inotropic agent/IABP), (3) switched (inotropic agent/IABP to VAD), or (4) combined (inotropic agent/IABP to VAD + inotropic agent/IABP). VAD at listing was used as the reference group for Cox's proportional hazards model.

Baseline demographic and clinical data were recorded. Comparison of baseline patient characteristics was performed using analysis of variance for continuous variables and χ^2 contingency table analysis for dichotomous variables. Significance was set to reflect a confidence interval (CI) of 95% for all analyses. Statistical analysis was performed using SAS, version 9.2 (SAS Institute, Cary, NC).

Results

A total of 5,230 status 1A patients were included in the posttransplantation survival analysis. Table 2 summarizes the pretransplantation characteristics of patients in the respective groups. Patients receiving inotropic agents were somewhat older and had slightly higher serum creatinine levels. From a hemodynamic standpoint, they had slightly higher mean pulmonary artery pressures and pulmonary capillary wedge pressures. The VAD cohort had more male patients, a higher incidence of previous cardiac operations, and longer ischemic times. No significant differences in sensitization were observed between the groups.

Sixty-one percent of patients had isolated left ventricular (LV) support, whereas 11% had biventricular support. Unfortunately, 17% were documented as "unspecified." The 5 most frequently used devices were the HeartMate II (Thoratec Corp, Pleasanton, CA) (45%), HeartMate XVE (Thoratec Corp) (17%), an unspecified category of "Thoratec" (12%), "Other" (7%), and Thoratec IVAD (Thoratec Corp) (4%).

Adjusted 1-year posttransplantation mortality was higher among patients with VADs (HR, 1.48; 95% CI, 1.3–1.8; $p < 0.0001$) compared with patients receiving inotropic agents alone. At 10 years of follow-up, the risk of death was not significantly different between the groups (Fig 1). To ascertain whether early VAD technology may have contributed to the inferior survival among patients with VADs, a second survival analysis comparing patients with VADs before and after 2008 to their same-era counterparts receiving inotropic agents was conducted. Although survival improved in the patients with VADs, it also similarly improved in the medical patients. Before 2008, 1-year risk of death was higher among patients with VADs compared with patients receiving inotropic agents alone (HR, 1.49; 95% CI, 1.2–1.84; $p = 0.0003$); after 2008, patients with VADs had worse survival as well (HR, 1.36; 95% CI, 1.02–1.8; $p = 0.03$).

Given the known inferior outcomes in patients requiring biventricular support, a survival analysis of patients requiring isolated LV support was conducted. This analysis also demonstrated worse survival among patients with LVADs compared with those receiving only inotropic agents at 1 year (HR, 1.33; 95% CI, 1.08–1.6; $p = 0.008$), although there was no significant survival difference at 10 years of follow-up (HR, 1.1; 95% CI, 0.9–1.3; $p = 0.21$).

To identify a higher risk medical cohort, analysis was repeated to add IABPs to the group receiving inotropic agents. Although 1-year survival before 2008 remained worse for patients with VADs (HR, 1.4; 95% CI, 1.2–1.8; $p = 0.0001$), in the post-2008 era, there was no difference in survival between the VAD cohort and the combined medical therapy cohort (HR, 1.2; 95% CI, 0.94–1.6; $p = 0.1$).

We next isolated the survival analysis both by era (before and after 2008) and left-sided support only (LVAD). Here we found that patients with an LVAD implanted after 2008 had survival comparable to that of patients who received combined medical therapy (inotropic

agents or IABP, or both) (HR, 1.2; 95% CI, 0.9–1.5; $p = 0.3$). Interestingly, the same was found for patients with LVADs implanted before 2008; they had survival similar to that of patients in the combined medical therapy arm (HR, 1.2; 95% CI, 0.9–1.6; $p = 0.3$) (Fig 2).

At this point, our posttransplantation survival analysis focused on the status of the patient at the *time of transplantation*. We next sought to examine how status 1A patients did from the *time of their listing* as transplantation candidates. First, we determined respective waiting list mortality. Adjusted survival models for patients on the waiting list based on their initial designation of either VAD or inotropic treatment were created. One-year waiting-list mortality showed no significant difference between the VAD group and the group receiving inotropic agents (HR, 2.6; 95% CI, 0.6–10.6; $p = 0.19$). As in our previous analysis, this analysis included what was arguably a heterogeneous group of patients with VADs. When we narrowed the waiting list mortality analysis to patients with an isolated LVAD and expanded the medical group to include IABPs, patients with LVADs were found to have significantly improved survival while on the waiting list (HR, 0.56; 95% CI, 0.42–0.76; $p < 0.0001$) (Fig 3).

Given that not all patients initially listed remained in their initial status at the time of transplantation, we devised another set of posttransplantation survival models in an attempt to understand survival differences within this dynamic process. Table 3 shows the multiple different therapy transition pathways that a patient might take and shows multiple complex interactions. For patients who remain on the same level of support both at listing and at the time of transplantation, results were generally favorable. Patients who were able to be maintained on inotropic agents at the time of listing and at transplantation often had better survival, specifically when the reference group was either patients with VADs (versus those receiving inotropic agents) or patients with LVADs (versus patients receiving inotropic agents/IABPs). In other words, inotropic agents to inotropic agents (VAD as reference group) and inotropic agents/IABPs to inotropic agents/IABPs (LVAD as reference) had superior survival. One final pattern is clear from Table 3—patients requiring escalation of therapy had significantly worse 1- and 10-year survival, with HRs ranging from 1.2 to 1.38 for those requiring mechanical assistance, and 1.7 to 2.2 for those requiring both medical and mechanical support.

Comment

This report provides an extensive set of comparisons ostensibly designed to evaluate relatively stable patients with LVADs and the sickest medical patients, both of whom share similar priority status within UNOS heart allocation system. When we looked strictly at predefined UNOS categories, stage 1A patients receiving inotropic agents had better 1-year posttransplantation survival, but not 10-year survival, than their UNOS status 1A counterparts with VADs, even in the modern (post-2008) era. Interestingly, when excluding patients with right-sided and biventricular mechanical support, these trends remained intact.

Although denoting a distinct UNOS category, most physicians consider IABPs as an extension of “medical” support. We therefore narrowed much of our analysis to patients with isolated left-sided support and to patients requiring inotropic agents or IABPs, or both (ie, the sickest medical patients). Within this cohort, we found that 1-year survival was similar between the groups. Priority scores must balance posttransplantation survival with waiting list mortality. Waiting list survival in patients with LVADs was associated with enhanced survival compared with those receiving inotropic agents. This finding, coupled with equivalent posttransplantation survival, might then lead to the consideration that a strategy of early LVAD implantation may be advantageous. This otherwise reasonable conclusion becomes problematic for 1 reason—survival among patients needing inotropic

agents alone, and *not* balloon pumps, was consistently superior in our initial analyses comparing inotropic agents alone and VADs.

To help clarify these findings, we performed an extensive set of analyses identifying groups of patients by their therapy transition pathway, ie, comparing the respective cohorts based on support status at the time of listing (transplant candidate registration) and at the time of transplantation (transplant recipient registrants). The highlight of these multiple analyses demonstrated that significantly higher mortality was observed if an LVAD was required after failed medical support. If patients went on to require both an LVADs and inotropic agents before transplantation, the mortality was nearly doubled.

Multiple other reports have addressed post-transplantation survival after VAD therapy but have varied on whether posttransplantation survival is superior in patients with VADs or those without VADs [2, 9–13], with only 1 study showing a definitive difference—79% survival with VADs compared with 85% survival without VADs at 1 year [10]. Early reports, however, relied almost exclusively on pulsatile-flow devices. In 2009, Pal and associates [14] published a series that included both pulsatile-flow (n = 73) and continuous-flow (n = 13) devices and found comparable survival among patients who were bridged to transplantation with an LVAD versus inotropic agents. In their analysis of earlier UNOS data, Russo and colleagues [15] also found no survival differences between those bridged with intracorporeal devices and those bridged with inotropic agents, although they did find diminished 90-day adjusted mortality in those bridged with extracorporeal devices. In another database study that examined survival differences between inotropic agents, intracorporeal VADs, and extracorporeal VADs, posttransplantation mortality was higher among the VAD groups at 6 months, was nonsignificant between 6 months and 5 years, and became higher again after 5 years [16]. The authors postulated that infection might have contributed to early mortality, but explanations for the observed late mortality differences remained unclear.

Given the equivalent, and sometimes worse, survival of patients with VADs after transplantation, some investigators have examined the practice of intentional LVAD implantation to facilitate patient placement on the stage 1A transplantation list [8]. These investigators found a much lower pretransplantation adverse event rate among patients with implantable devices when compared with those with either paracorporeal devices or medical support (inotropic agents $\pm$ IABPs). In this analysis of the Scientific Registry of Transplant Recipients, they found posttransplantation survival patterns that were similar to those in the International Society for Heart and Lung Transplantation reports. Survival was similar among status 1A patients with implantable VADs, paracorporeal VADs, VADs with complications, and exceptions. Pretransplantation ventilator dependence was the single significant status 1A justification predicting increased posttransplantation mortality. In light of the lower waiting list event rate and similar posttransplantation survival among patients with implantable LVADs, the authors concluded that allowing elective status 1A time for patients with implanted LVADs is not justified. They recommended reducing the status 1A allowance for stable patients with implantable LVADs and consideration of indefinite status 1A listing for those with paracorporeal devices.

Our findings of improved LVAD survival on the waiting list might also support adoption of a reduction of status 1A time, but our group cautions that this could lead to a higher rate of device complications and with it mortality [17]. In this comprehensive study of pretransplantation mortality and event rates by era (before and after 2008), both mortality and a composite end point of mortality or delisting among status 1A, status 1B, and status 2 patients who were medically supported and patients with VADs who were mechanically supported with continuous- and pulsatile-flow devices were evaluated while on the waiting

list. A significant decrease in overall waiting list mortality was observed in the current era—2.1% per month versus 2.9% per month. More striking was the marked reduction in LVAD waiting list mortality. In the current era, patients with continuous-flow LVADs had a waiting list mortality similar to that of status 2 patients at 1% per month, a notable improvement from the early era when pulsatile-flow LVADs were more commonly used, with significantly higher mortality (4.5% per month). In multivariable Cox regression analysis, mortality risk among patients with continuous-flow LVADs actually trended lower than it did in status 2 patients. The composite outcome of either death or delisting as a result of worsening clinical status was also similar to that of status 2 patients (1.4% per month). Once their 30 days of status 1A time expired, they found that the patients with LVADs in 1B status had no difference in survival. In contrast to Dardas and colleagues, [8] findings, an upgrade to status 1A because of a device complication was associated with significantly higher rates of death and death or delisting.

In contrast to our report, other investigators using the UNOS database found that escalation from inotropic to VAD therapy was not found to be a marker for worse outcomes [18]. These differing observations likely relate to methodology. In addition to their use of unadjusted survival models, their report included patients who were all status 1; our report narrowly examines 3 select status 1A subgroups. Their inclusion of status IB patients probably led to improved survival in their therapy escalation group. A notable similarity is that despite different methodology, survival in patients receiving only inotropic agents (88% at 1 year, 74% at 5 years) was also superior to survival in patients LVADs (85% at 1 year and 72% at 5 years). The narrower difference between the inotropic agent and LVAD cohorts may also be related to inclusion of stage IB patients.

Our findings are limited in several ways. Listing patterns vary among institutions, and the legitimate practice of avoiding listing in a high-risk patient with a VAD until clinical improvement may not be accurately reflected in our database analysis. Prelisting management also varies widely among institutions, and the database has no practical way of capturing relevant prelisting events. Furthermore, patients in whom inotropic agents fail have extremely limited options, and if “rescued” with a VAD, we presume their overall survival would be worse, not because of the VAD itself but because of deteriorating clinical status and underlying disease. Although we attempted to control for these factors in our survival models, we acknowledge this as a limitation of a retrospective review. We also did not conduct survival analysis of discreet device types and instead opted to isolate just left-sided support. Based on previous reports, removing extracorporeal devices may have improved VAD outcomes. Furthermore, we do not have data on the urgency of VAD placement or the duration of support. Finally, we have not included patients with VAD complications; thus our results probably indicate a “best-case scenario” for the LVAD group. As stated previously, our group has reported on the inferior outcomes of this subset of patients in the past [6].

In conclusion, posttransplantation survival among status 1A patients with VADs using their 30-day 1A status time is worse when compared with status 1A patients receiving inotropic agents alone. Survival remained worse for patients with LVADs and for patients in the modern era (after 2008) of devices.

The addition of IABPs to the inotropic agent group changed the dynamic. When compared with patients in the combined medical therapy group (inotropic agents or IABPs, or both), patients with isolated left-sided support had equivalent posttransplantation survival. While on the waiting list, however, patients with LVADs had significantly better survival than did those in the combined medical group. Although an early LVAD strategy may seem appealing, this is tempered by the fact that if patients were successfully bridged while

receiving inotropic agents, posttransplantation survival was improved. This needs to be weighed with the serious consequence of inotropic agent/IABP failure that nearly doubled the posttransplantation mortality risk.

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Fig 1.
Posttransplantation survival at (A) 1 and (B) 10 years for United Network for Organ Sharing (UNOS) status IA patients between 1998 and 2012. IA Inotropic Agent = status IA, subgroup d; IA VAD = status IA, subgroup a(i).

Fig 2.

One-year posttransplantation survival (A) before and (B) after 2008 for United Network for Organ Sharing (UNOS) status 1A patients with left ventricular assist devices (LVADs) versus patients receiving continuous inotropic agents or intraaortic balloon pumps (IABPs), or both.

Fig 3. Waiting list survival at 1 year for United Network for Organ Sharing (UNOS) status 1A patients stratified by left ventricular assist device (LVAD) versus continuous inotropic agents $\pm$ intraaortic balloon pump (IABP).

Table 1**Status 1A Definitions and Subgroups**

Status 1A	
a.	Mechanical circulatory support for acute hemodynamic decompensation that includes at least 1 of the following:
i.	Left or right assist device, may be listed for 30 d after implantation once clinically stable ^a
ii.	Total artificial heart
iii.	Intraaortic balloon pump ^a
iv.	ECMO
b.	Device complication
c.	Mechanical ventilation
d.	Continuous infusion of a single high-dose intravenous inotropic agent or multiple intravenous inotropic agents, in addition to continuous hemodynamic monitoring of left ventricular filling pressures. ^a

^aStudy group patients.

Patients with total artificial hearts, those undergoing extracorporeal membrane oxygenation, those with device complications, and those receiving mechanical ventilation were not included in the study.

Table 2

Characteristics of Status IA Patients With VADs and Status IA Patients Receiving Inotropic Agents at the Time of Transplantation

Variable	Status IA Patients With VADs (n = 2,443)	Status IA Patients Receiving Inotropic Agents (n = 2787)	p Value
Age (y)	50.8 ± 12.6	52.3 ± 12.4	<0.0001
Male sex (%)	81	75.5	<0.0001
White (%)	70.1	69.3	0.5
Creatinine (mg/dL)	1.3 ± 0.8	1.4 ± 0.8	<0.0001
Body mass index (kg/m ²)	26.7 ± 4.8	25.9 ± 4.6	<0.0001
Mean PAP (mm Hg)	28.8 ± 10.7	31.4 ± 10.3	<0.0001
Mean PCWP (mm Hg)	19.2 ± 9.5	21.3 ± 8.6	<0.0001
Cardiac output (L/min)	4.6 ± 1.6	4.3 ± 1.5	<0.0001
Ischemic time (h)	3.38 ± 1.1	3.2 ± 1	<0.0001
PRA class 1 (%)	28.6 ± 29.2	26 ± 27.2	0.21
PRA class 2 (%)	28.9 ± 29.9	34.7 ± 30.5	0.053
Total bilirubin (mg/dL)	1.4 ± 2.6	1.5 ± 3.1	0.16
Diabetes (%)	18.5	17.3	0.26
Previous cardiac operation (%)	32.8	22.2	<0.0001

Values are mean ± standard deviation unless otherwise indicated.

PAP = pulmonary artery pressure; PCWP = pulmonary capillary wedge pressure; PRA = panel of reactive antibodies; VADs = ventricular assist devices.

Summary of Survival Differences Among Patients With VADs and Patients Receiving Inotropic Agents/IABP Based on Therapy Crossover

Table 3

VAD at Listing As Reference Group		1-Year Survival		10-Year Survival	
Support at Listing	Support at Transplantation	HR	95% CI	p Value	p Value
Inotropic agent	No support	0.95	0.8–1.1	0.53	0.99
Inotropic agent	Inotropic agent	0.90	0.8–0.9	0.03	0.98
Inotropic agent	VAD	1.38	1.1–1.8	0.02	1.1
Inotropic agent	Inotropic agent + VAD	1.98	1.4–2.8	<0.001	1.49
VAD at Listing As Reference Group		HR	95% CI	p Value	p Value
Support at Listing	Support at Transplantation				
Inotropic agent/IABP	No support	0.98	0.9–1.1	0.8	1.0
Inotropic agent/IABP	Inotropic agent/IABP	0.92	0.8–1.0	0.09	1.0
Inotropic agent/IABP	VAD	1.35	1.0–1.8	0.04	1.1
Inotropic agent/IABP	Inotropic agent/IABP + VAD	2.2	1.6–3.0	<0.001	1.6
LVAD at Listing as Reference Group		HR	95% CI	p Value	p Value
Support at Listing	Support at Transplantation				
Inotropic agent/IABP	No support	0.89	0.7–1.1	0.27	0.97
Inotropic agent/IABP	Inotropic agents/IABP	0.87	0.8–0.9	0.008	0.98
Inotropic agent/IABP	LVAD	1.2	1.0–1.4	0.048	1.1
Inotropic agent/IABP	Inotropic agent/IABP + LVAD	1.7	1.3–2.1	<0.0001	1.4

CI = confidence interval; HR = hazard ratio; IABP = intraaortic balloon pump; LVAD = left ventricular assist device.