Impact of Center Volume on Outcomes of Left Ventricular Assist Device Implantation as Destination Therapy
Analysis of the Thoratec HeartMate Registry, 1998 to 2005

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Background—More than 400 patients with end-stage heart failure underwent left ventricular assist device (LVAD) implantation of LVAD as destination therapy (DT) after the US Food and Drug Administration approval of DT in 2002. Because most of these patients had surgeries at hospitals that were newly accredited, we sought to examine the impact of LVAD center volume on the outcomes of DT.

Methods and Results—From July 1998 through December 2005, a total of 377 patients underwent implantation of HeartMate I LVAD as DT at 68 centers in the United States. Using data from the Thoratec DT Registry, we examined the association between LVAD center volume at the time of surgery and 1-year survival with DT. Of the studied 377 DT recipients, 53% underwent device implantation at centers that performed ≤4 DT implants at the time of surgery. Center experience with DT seemed to significantly correlate with the 1-year survival (47.8% versus 67.4% in recipients of ≤4th DT versus >9th DT implant; \( P=0.009 \)). However, the DT center volume was not an independent predictor of 1-year survival with DT when adjusted for the preoperative DT Risk Score, suggesting that other factors, such as improved candidate selection, may have accounted for the institutional learning curve.

Conclusions—The institutional experience with DT may have a significant impact on outcomes of this therapy. Better selection of candidates, systemic approach to surgical and postoperative care, as well as the long-term medical management most likely all contribute to these improvements. (Circ Heart Fail. 2009;2:3-10.)

Key Words: center volume ■ destination therapy ■ left ventricular assist devices

Heart failure is a major public health problem affecting >5 million people in the United States. It is estimated that 250 000 of these patients are in the most advanced stage of the disease, refractory to conventional medical treatment.1 Chronic infusion of inotropic agents is associated with a dismal prognosis, whereas only few may be candidates for heart transplantation (HT). Within this large group of patients who are not transplant candidates, it is estimated that 80 000 to 150 000 per year could benefit from implantation of mechanical circulatory support devices.

Editorial see p 1
Clinical Perspective see p 10

The first study to investigate the use of mechanical circulatory support as an alternative to HT, or destination therapy (DT), was the landmark Randomized Evaluation of Mechanical Assistance in the Treatment of Congestive Heart Failure (REMATCH) trial.2 The trial randomized 129 patients with end-stage heart failure (ESHF) ineligible for HT to either left ventricular assist device (LVAD) implantation or medical therapy. The study demonstrated superior survival and quality of life in patients supported with LVAD when compared with those treated medically (52% versus 23% 1-year survival). After completion of the REMATCH trial, the U.S. Food and Drug Administration (FDA) approved use of LVAD as DT in 2002. Since then, the number of U.S. hospitals accredited to perform DT implantations proliferated rapidly. At the end of 2007, there were 63 active accredited DT hospitals.3

Despite the projected enormous national demand for alternatives to cardiac replacement therapy, however, only 451 patients underwent device implantation during the first 5 years after the REMATCH trial (The Interagency Registry for Mechanically Assisted Circulatory Support and Thoratec Corporation, personal communication, 2008), which represents <17% of all implanted mechanical circulatory support.
devices. This large discrepancy between the anticipated demand for DT and the actual number of performed procedures raised several questions regarding the future of this therapy. One of the most important pertains to the safety and outcomes of DT at the many small volume centers, where the majority of these procedures are currently performed.3

The profound impact of procedural volume on surgical outcomes has been demonstrated in many population-based studies.4 In the case of DT implantation, however, the center experience may be of unparalleled importance. Not only is LVAD implantation one of the most complex cardiac surgeries but the care of DT recipient is exceptionally demanding, extending beyond the operative room and lasting throughout the patient’s lifetime. Although many of the LVAD centers have been taking care of patients supported with devices as bridge to transplant (BTT), DT population may present their own set of medical challenges, as these patients are usually older and have many other significant comorbidities.

We analyzed the impact of the center experience with HeartMate I LVAD implantation as DT on the survival of all 377 patients with ESHF who underwent DT implantation in the United States between years 1998 and 2005. The aim of this study was to better understand the DT volume-outcomes relationship, and its implications on the future practices and accreditation of the small volume DT programs.

Methods

Study Population

From May 15, 1998, through December 1, 2005, a total of 377 patients with ESHF underwent HeartMate I LVAD implantation as DT in the United States. Of these, 68 patients received the HeartMate VE LVAD at 19 hospitals as part of the REMATCH trial, and 309 patients underwent implantation of the HeartMate XVE LVAD at 66 hospitals after completion of the REMATCH trial and the U.S. FDA approval of this device for DT in November 2001. All patients were followed until death, HT, reimplantation with pumps other than the HeartMate I LVAD, or day of the last observation on October 1, 2006. Patients were followed for a median time of 9.5 months (range, 1 day to 6.8 years) and a total of 331 patient-years of observation.

Source of Data

Patient data were obtained from the US FDA-mandated DT Registry, maintained by the HeartMate LVAD manufacturer (Thoratec Corporation, Pleasanton, Calif), which collects information from participating U.S. hospitals at the time of LVAD implantation and death. The Thoratec Corporation has also provided the information on BTT hospitals after completion of the REMATCH trial and the U.S. FDA approval. Only implants of the recipients of HeartMate I LVAD (pneumatically and electrically vented VE and XVE models) were counted toward the center LVAD experience.

LVAD Center Volume

To accurately examine the relationship between LVAD center volume and patient survival, the statistical analyses relied on the variation between the number of LVAD implantations and patient survival within hospitals over time, as opposed to the variations between hospitals. Hence, the LVAD center volume is ranked in this analysis according to the total number of implants performed at the given institution on the day of DT implantation. Only implants of HeartMate I LVAD (pneumatically and electrically vented VE and XVE models) were counted toward the center LVAD experience.

Statistical Analysis

The relationship between LVAD center volume and patient survival was examined using the Kaplan–Meier method and compared using log-rank statistics.5 Patient survival on LVAD support was calculated from the day of LVAD implantation until death on mechanical support and was censored at time of HT, reimplantation with pumps other than HeartMate I LVAD, or day of the last observation on October 1, 2006. Because repeat surgery can have substantial impact on survival with DT, all analyses were limited to 1 year owing to the relatively high probability of device exchange at 2 years (72.9%) versus 1 year (17.9%).

Cox proportional hazards survival model was used for multivariate analysis.6 Risk factors that correlated by univariate analysis with the end point at probability value <0.15 were entered using stepwise selection and allowed to stay at probability value of <0.05.7 All continuous variables were treated as such in the multivariate analysis.

To illustrate the relationship between patient survival and the DT center experience using the Kaplan–Meier survival curves, patients were divided into 3 groups according to approximately 50%–25%–25% distribution from small to large DT center experience at the time of surgery. Accordingly, patients were divided into 3 groups of the recipients of ≤4th, 5th to 9th, and >9th DT implant, and referred to as recipients of DT at small, medium, and large DT centers, respectively. Similarly, the studied cohort was divided into 3 groups of the recipients of ≤50th, 51st to 99th, and >99th BTT implant at the time of DT surgery, and these patients were referred to as recipients of DT at small, medium, and large BTT centers, respectively.

Complete preoperative data and local institutional review board approval to use clinical information for this analysis was available in 222 patients who underwent DT implantation in the post-REMATCH era. In this population, we investigated the relationship between DT center volume and candidate preoperative risk, as defined by the previously published DT Risk Score for 90-day in-hospital mortality after LVAD implantation.8 The DT Risk Score is calculated from the following equation: (7 if platelet count ≤148×10^4/μL)+(5 if serum albumin ≤3.3 g/dL)+(4 if international normalizat...Mean pulmonary artery pressures ≤25 mm Hg)+(2 if aspartate aminotransferase >45 U/mL)+(2 if hemocrit ≤34%)+(2 if blood urea nitrogen >51 U/dL)+(2 if no intravenous inotropes). High-risk candidates are defined as patients with a cumulative DT Risk Score ≥16, which correlated in the previously published study with >50% 90-day probability of in-hospital death after LVAD implantation.4 Of note, the DT Risk Score was derived from the same population of patients, and therefore results and outcomes of this subanalysis may be tautological.

Continuous parameters were compared between DT recipients at large centers to those at medium and small centers using the Student t test or nonparametric Wilcoxon rank-sum test, if not normally distributed. Categorical values were compared using χ^2. We did not control for multiple comparisons; therefore, type I errors are inflated above their nominal level of 0.05.

All data were analyzed using the SAS System software version 9.0 (SAS Institute Inc).

Statement of Responsibility

The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.
Results

Study Population

A total of 377 patients underwent DT implantation at 68 centers in the United States. The cumulative number of patients and activated DT programs throughout the studied period is shown in Figure 1. Most DT sites were accredited shortly after the U.S. FDA approval of LVAD use for this indication in November 2002, including 18 sites in the year 2003 and 23 sites in the year 2004. During this time, the total number of DT recipients rose from 119 in 2003 to 259 and

Table 1. Baseline Patient Characteristics by Center Experience on the Day of Surgery With HeartMate I LVAD Implantation as Destination Therapy

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>DT Center Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Small</td>
</tr>
<tr>
<td></td>
<td>1st to 4th DT Implant (n=185)</td>
</tr>
<tr>
<td>Age, y</td>
<td>61±11</td>
</tr>
<tr>
<td>Male, %</td>
<td>84</td>
</tr>
<tr>
<td>Ischemic cause of heart failure, %*</td>
<td>72</td>
</tr>
<tr>
<td>Left ventricular ejection fraction, %</td>
<td>17±6†</td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg</td>
<td>102±18</td>
</tr>
<tr>
<td>Pulmonary-capillary wedge pressure, mm Hg‡</td>
<td>24.1±10§</td>
</tr>
<tr>
<td>Cardiac index, L/min/m²*</td>
<td>2.0±0.7</td>
</tr>
<tr>
<td>Systolic pulmonary artery pressure, mm Hg*</td>
<td>52.3±17</td>
</tr>
<tr>
<td>Serum sodium, mmol/L</td>
<td>134±6§</td>
</tr>
<tr>
<td>Serum creatinine, mg/dL</td>
<td>1.7±0.7</td>
</tr>
<tr>
<td>Estimated glomerular filtration rate, mL/min/1.73 m²</td>
<td>50.6±24</td>
</tr>
<tr>
<td>Total bilirubin, g/dL</td>
<td>1.7±3.7§</td>
</tr>
<tr>
<td>Concomitant medications, %</td>
<td></td>
</tr>
<tr>
<td>Digoxin</td>
<td>67§</td>
</tr>
<tr>
<td>Diuretics</td>
<td>90</td>
</tr>
<tr>
<td>ACE inhibitors or A-II antagonists</td>
<td>64</td>
</tr>
<tr>
<td>β-blockers</td>
<td>43</td>
</tr>
<tr>
<td>Antiarrhythmics</td>
<td>35</td>
</tr>
<tr>
<td>Intravenous inotropic agents</td>
<td>67</td>
</tr>
<tr>
<td>Lung disease, %‡</td>
<td>42†</td>
</tr>
<tr>
<td>Diabetes, %‡</td>
<td>48</td>
</tr>
<tr>
<td>High risk, %</td>
<td>20</td>
</tr>
</tbody>
</table>

Plus–minus are mean±SD. P values represent comparisons of small- and medium-sized DT centers to large volume DT centers. Median was used for the comparison of total bilirubin level. Missing data in *<10% of patients, †10% to 15% of patients, and ‡20% of patients. Analysis does not include 26 patients who did not have local institution review board approval to release preoperative clinical information. †P value <0.005 and §P value <0.05. LVAD indicates left ventricular assist device; ACE, angiotensin-converting enzyme; A-II, angiotensin II receptor.
377 in years 2004 and 2005, respectively. At the time of study closure in November 2005, the majority (69%) of studied centers performed /H11349 DT implants. Only 11 centers performed /H11022 D T implants, including 2 centers that performed /H11022 20.

Characteristics of DT Recipients by DT Center Volume

The baseline characteristics of patients undergoing DT are depicted by the DT center volume on the day of surgery in Table 1. Patients were divided into recipients of DT at centers with low (1st to 4th implant), medium (5th to 9th implant), or high (10th to 40th implant) DT volume on the day of surgery, which represents 53% (n=203), 24% (n=90), and 23% (n=84) of the studied cohort, respectively. There were no major differences between the groups in terms of the baseline demographics, etiology, or severity of heart failure. The Registry did not collect information, which could allow assessment of clinical severity of ESHF using the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) levels.3

Impact of DT Center Volume on Patient Survival

The relationship between DT volume on the day of LVAD implantation and 1-year survival with DT is shown in Figure 2. One-year survival of DT recipients was 47.8%, 57.2%, and 67.4% in low, medium, and high volume DT centers, respectively; P=0.009. The trend reached statistical significance when outcomes were compared between recipients of the first 4 DT implants and >9th DT implant; P=0.006 (Table 2). When treated as a continuous variable, the DT center volume correlated significantly with 1-year survival; P=0.008 (Table 3).

Impact of DT Center Volume on the Causes of Death

Among 166 patients who died during the first year after device implantation, the main causes of death included sepsis (32.5%), multiorgan failure (11.4%), right heart failure (7.2%), and stroke (7.2%). LVAD failure accounted for 8 (5%) deaths in the first year of LVAD support. There were no significant differences in the causes of death among DT recipients who underwent device implantation at centers that performed ≤4 versus >4 DT implants on the day of surgery, as shown in Table 4.
Impact of DT Center Volume on Early Versus Late Survival With DT

The impact of DT center volume on 30-day versus 1-year survival with DT is shown in Table 5. Thirty-day survival increased from 81.3%, 84.4% to 91.7% in low, medium, and high volume DT centers, respectively. Among 317 survivors of the first postoperative month, the 1-year survival after LVAD implantation also increased from 58.8%, 67.8% to 73.5% in low, medium, and high volume DT centers, respectively. These trends were statistically significantly between the low and high volume centers.

Impact of DT Center Volume on Selection of DT Operative Candidates

In a subanalysis of 222 DT recipients with complete preoperative data, we correlated the preoperative DT Risk Score with 1-year survival with DT. Although the mean DT Risk Score tended to be lower in high volume centers, the proportion of high-risk candidates (DT Risk Score >16) was not significantly different among small-, medium-, and large-sized DT centers (Table 6). Low-risk candidates at medium and large volume centers had significantly better 1-year survival than DT recipients at small centers (76% versus 60% 1-year survival, respectively; P=0.03). Outcomes of high-risk candidates, however, were poor regardless of DT center volume (<18% probability of 30-day hospital discharge and <18% 1-year survival).

Impact of BTT Center Volume on Survival of DT Recipients

The relationship between the 1-year survival with DT and the number of HeartMate I LVAD implantations as BTT at the time of surgery is shown in Figure 3. The information on the number of implanted devices as BTT was not available for 16 patients from 8 centers. The remaining 361 patients were divided based on the center BTT volume on the day of DT implantation into 3 groups of recipients of DT at small (1 to 50 implants), medium (51 to 99 implants), and high (100 to 361 implants) volume BTT centers, representing 49% (n=177), 29% (n=106), and 22% (n=78) of the studied cohort, respectively. The 1-year survival after DT was 48.4%, 65.3%, and 58.1% in low, medium, and high volume BTT centers, respectively. The 1-year survival after DT seemed to be significantly better in medium-sized BTT centers when compared with the small volume centers, P=0.03

Table 5. Thirty-Day and 1-Year Survival After LVAD Implantation as Destination Therapy by Center Experience on the Day of Surgery With HeartMate I LVAD Implantation as Destination Therapy

<table>
<thead>
<tr>
<th>Center Volume on the Day of Surgery</th>
<th>No. DT Recipients</th>
<th>% Survival</th>
<th>Odds Ratio (CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thirty-day survival (n=377)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 to 4</td>
<td>203</td>
<td>81.3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>5 to 9</td>
<td>90</td>
<td>84.4</td>
<td>0.8 (0.4–1.6)</td>
<td>0.51</td>
</tr>
<tr>
<td>10 to 40</td>
<td>84</td>
<td>91.7</td>
<td>0.4 (0.2–0.9)</td>
<td>0.04</td>
</tr>
<tr>
<td>Thirty-day to 1-year conditional survival (n=317)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 to 4</td>
<td>165</td>
<td>58.8</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>5 to 9</td>
<td>75</td>
<td>67.8</td>
<td>0.7 (0.4–1.2)</td>
<td>0.19</td>
</tr>
<tr>
<td>10 to 40</td>
<td>77</td>
<td>73.5</td>
<td>0.5 (0.3–0.9)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

*Patient who either died during the first 30 days after LVAD implantation or were followed for <30 days were excluded from this analysis.
Impact of LVAD Center Volume, Era, and Patient Characteristics on Survival of DT Recipients

To further explore the role of center experience in outcomes of DT, we analyzed the following risk factors in a univariate analysis for 1-year mortality after DT implantation, as shown in Table 3: (1) other definitions used to describe the hospital procedural volume, including the center LVAD volume on the day of DT implantation, the center LVAD volume during the calendar year when DT was implanted, and the center LVAD volume on the day of study closure on December 1, 2005; (2) the era of device implantation, including the calendar year of DT implantation and the comparison of the REMATCH versus post-REMATCH era; and (3) the baseline patient characteristics.

When parameters related to DT center volume and era of implantation were entered into a multivariate analysis model, the DT center volume was found to be a significant predictor of 1-year survival (RR = 0.96 per implanted unit; CI, 0.93 to 0.99; P = 0.008). However, when the same analysis was limited to 222 DT recipients with complete preoperative data, and adjusted for patient age, gender, etiology of heart failure, cardiac index, and the DT Risk Score, the DT center experience did not enter the final multivariable model (P = 0.35). The only predictor of 1-year survival was the DT Risk Score (RR = 1.2 per 1 point increase; CI, 1.15 to 1.25; P < 0.001).

Discussion

In this study we show that during the first 3 years after FDA-approved use of LVAD as DT in the United States, only 309 patients underwent device placement. The vast discrepancy between the projected national demand for alternative cardiac replacement therapies and the actual modest application of DT largely reflects the continued use of DT only as the “end-of-life” treatment. The 2008 report of the Interagency Registry for Mechanically Assisted Circulatory Support indicates that 62% of DT recipients underwent DT placement, when they were either in cardiogenic shock or deteriorating on inotropes (INTERMACS profile 1 “crash and burn” and profile 2 “sliding on inotropes”). It is important to realize that these extremely ill heart failure patients constitute only a small fraction of the target DT population.

Unfortunately, most clinicians are reluctant to refer patients with ESHF earlier in the disease course. One of the most important reasons is the overall suboptimal long-term outcomes of the currently approved devices. The survival on the pusher-plate HeartMate LVAD does not exceed 31% at 2 years; the probability of LVAD “end-of-life” requiring device exchange is 73% at 2 years; and the costs involved in each of these surgeries are high. Thus, most cardiologists defer DT referrals until all other options have been exhausted. Late referrals, when patients are too sick to tolerate the LVAD surgery, further perpetuate the vicious cycle of serious operative complications, poor outcomes, and the reluctance to extend such treatment to healthier populations.

Restricted application of DT to the sickest patients resulted in a large number of accredited hospitals that performed only a few DT implantations. Our study shows that since the first LVADs were implanted for this indication in the United States, the majority (53%) of 377 DT recipients underwent device placement at centers that performed ≤4 DT implants. At the time of the study closure in November 2005, more than two-thirds (69%) of the 68 accredited hospitals performed ≤4 LVAD implantations as DT.

We further show that the later in the center’s experience patients underwent DT implantation, the better were the outcomes of this therapy. Patients who received one of the first 4 DT implants at a given institution were able to achieve 47.8% 1-year survival, which is comparable to the REMATCH trial, whereas the survival of those who received DT at centers that performed >9 DT implants improved by nearly 20%, to 67.4% at 1 year. This institutional “learning curve” was most apparent between recipients of the first 4 and >9th DT implant, and correlated with the improved operative 30-day survival and the 1-year survival after LVAD implantation.
Improved outcomes of DT at more experienced centers may have been attributed to better candidate selection. In a subanalysis of 222 patients, we found that patients who underwent DT implantation at centers that performed >9 DT implants tended to have lower preoperative DT Risk Score and achieve higher rates of hospital discharge after LVAD surgery. Moreover, when adjusted for the DT Risk Score, the DT center volume was no more a significant predictor of 1-year survival, suggesting that patient selection was most likely the key determinant of successful DT implantation. Consistent with these findings is the observation that high-risk operative candidates had poor outcomes of device implantation with no benefit of being operated at a larger DT center.

Long-term medical management of patient supported with devices is also of tremendous importance and may account for the improved outcomes of experienced centers. Our study shows that the 1-year survival of low risk DT recipients (DT Risk Score <16) increased from 60% to 76% between ≤4th and >9th DT implant. These improvements may largely pertain to prevention and treatment of infectious complications, the main cause of death with DT. Two previous studies comparing early- to late-enrollment REMATCH trial and outcomes of the 4 largest volume U.S. centers in the post-REMATCH era pointed to infection as the single complication, the rates of which significantly decreased as center experience increased.

Because the distinction between DT and BTT is largely artificial and some BTT patients become noncandidates for transplant with parallel outcomes to DT, the overall center experience with BTT should benefit those undergoing elective DT. Our analysis, however, showed no significant correlation between the outcomes of DT and the BTT volume. Moreover, the study demonstrated slightly poorer outcomes of DT recipients at the largest BTT centers (>100 implants), when compared with the midsize BTT centers (51 to 99 implants). This may be attributable to higher candidate operative risk of DT recipients at large BTT centers, as their 30-day mortality was greater (15% versus 9% in large versus midsize BTT centers).

In conclusion, we show that the institutional experience with DT may have a significant impact on outcomes of this therapy. Although we were not able to elucidate which aspects of center experience were the most critical, better selection of candidates, systemic approach to surgical and postoperative care, as well as the long-term medical management, may have all contributed to the improved outcomes. Multidisciplinary approach that developed in the care of patients with ESHF and cardiac transplantation and future advancements of device design will likely lead to further improvements in the outcomes of the long-term mechanical circulatory support.

**Limitations**

The results of this study should be interpreted with caution as they were based on a retrospective analysis of the voluntary registry. Outcomes of DT in the post-REMATCH era were not independently adjudicated. The described volume-survival relationship did not account for the clustering of patients within centers, because of the relatively small number of patients in each institution, thus the study may be influenced by the possible center-specific risk. The results of this study may not apply to the continuous flow pumps. During the study period, 37 patients underwent axial flow HeartMate II implantation as DT. This number of implantations contributed minimally to the individual centers’ experience with DT and should not impact results of this analysis. Although the HeartMate I LVAD was the most commonly used system for BTT patients during the studied period, other types of devices may have substantially contributed to center experience with BTT. The DT Risk Score was previously derived from a subset of the same patients being analyzed in this study, thus the risk group definitions and outcomes may be tautological. We did not examine VAD-related morbidity and quality of life.

**Acknowledgments**

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**Disclosures**

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**References**


CLINICAL PERSPECTIVE

Between 1998 and 2005, 377 patients underwent implantation of left ventricular assist device as a permanent alternative to heart transplantation or destination therapy (DT) in the United States. The discrepancy between the projected national demand for alternative cardiac replacement therapies, estimated at hundreds of thousands of patients every year, and the actual modest application of this therapy was largely attributable to the continued use of DT as the “end-of-life” treatment. The restricted application of DT to the sickest patients resulted in a large number of accredited hospitals (47 of 68 centers) to perform ≤4 DT implantations. Outcomes of device therapy seemed to substantially improve as centers gained experience. Patients who received >9th DT implant at a given institution had on average 20% better 1-year survival when compared with those who received the first 4 implants (67% versus 47% 1-year survival). Although we were not able to elucidate which aspects of center experience played the most critical role for the institutional learning curve, it is most likely that better selection of candidates, systemic approach to surgical and postoperative care, and the long-term medical management, have all contributed to these improvements. Multidisciplinary approach to care of patients with end-stage heart failure and future advancements of device design will likely lead to further improvements in the outcomes of the long-term mechanical circulatory support.
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