Infections During Left Ventricular Assist Device Support Do Not Affect Posttransplant Outcomes

Prashant Sinha, MEng; Jonathan M. Chen, MD; Margaret Flannery, RN; Brian E. Scully, MD; Mehmet C. Oz, MD; Niloo M. Edwards, MD

Background—Although infections acquired during ventricular assist device support may increase the risk of infection and have an impact on transplant survival, their true posttransplant consequences remain to be determined. This study evaluates the impact of an outpatient program, newer devices, and an updated infection management protocol on infection-related patient outcomes after transplant.

Methods and Results—Eighty-six patients received a left ventricular assist device (LVAD) between June 1996 and June 1999. Fifty patients transplanted during the same period, without prior device support, were used as controls; they were matched to transplanted LVAD recipients by age, sex, diagnosis, and transplant date. The nature of and actuarial freedom from peritransplant and posttransplant infections were compared at 6 months after transplant; actuarial patient survival was compared at 3 years. Infection was defined as leukocytosis or leukopenia, with a positive culture requiring either medical or surgical intervention. Forty-four patients (51%) were successfully discharged home on LVAD support, and 61 (71%) were transplanted. A high incidence of infection during device support did not have an impact on pretransplant or posttransplant mortality, posttransplant infectious rate, or overall patient survival. Active infections at transplant also did not significantly influence 6-month mortality. In comparison, LVAD recipients had a lower freedom from infection than did controls ($P<0.05$); however, 3-year survival did not differ: 79% and 87% for the LVAD and control groups, respectively.

Conclusions—Although LVADs increase the risk of infection in the early posttransplant period, this appears not to have an impact on transplantability or patient survival and likely reflects effective infection control in both inpatient and outpatient settings. (Circulation. 2000;102[suppl III]:III-194-III-199.)

Key Words: heart-assist device ■ survival ■ transplantation ■ heart failure ■ infection

Infections have historically been considered important contributors to morbidity and mortality in patients supported with ventricular assist devices. Furthermore, infections also remain the predominant cause of mortality in the 6-month period after orthotopic heart transplantation. Consequently, infection management and assessment of transplant outcomes are important tasks at all transplant centers.

We undertook the present study to revisit the issue of infection because of a number of important paradigm shifts that have occurred in our 9-year experience with the left ventricular assist device (LVAD) since our last report in 1996. The most important of these changes has been the transfer of patient care into the outpatient setting, facilitated by the development of a portable, vented, electric LVAD. Important changes have also been made in antibiotic use, device and driveline preparation, and additional interventional measures.

Argenziano et al. reported 60 patients evaluated over a 5-year period who underwent predominantly inpatient support with a pneumatic LVAD. Infection in that cohort was not shown to influence transplantability or the incidence of posttransplant infection; however, LVAD endocarditis, a significant cause of mortality, was best managed by device explantation or transplantation. In addition, a small group of 16 patients who were supported by the electric devices demonstrated a trend toward lower infection rates and improved survival.

In light of the programmatic changes at our institution and the potential impact of infections on survival, a reevaluation of infection on pretransplant and posttransplant outcomes is mandated. The present study reports the minimal impact of infections during device support on early posttransplant outcomes and long-term survival.

Methods

Subjects

Eighty-six patients received a Thermo-Cardiosystems Heartmate single-lead, vented, electric LVAD between June 1996 and June 1999, representing all sequential recipients of the device since the time of the prior study. Two of these patients had their devices replaced but were treated in the analysis as if they had received a
single device with the cumulative support time of the 2 devices. 
Explantation with or without transplantation was defined as success-
ful if there was evidence of life-supportive cardiac function after 
device removal.

The control cohort was composed of 50 orthotopic heart transplant 
patients who were not previously supported by an LVAD, reflecting 
a representative portion of all orthotopic heart transplant recipients 
during the 3-year study period. These were matched to the LVAD 
cohort by age, sex, diagnosis, and date of transplant.

Study End Points
All data were collected by retrospective chart review. The nature and 
incidence of infections during device support, pretransplant and 
posttransplant mortality, and the actuarial freedom from posttrans-
plant infection were analyzed for the first 6 months after transplant. 
Actuarial patient survival was also determined beyond the 6-month 
posttransplant period to a maximum of 3 years.

In the analysis, infection was defined as either leukocytosis or 
leukopenia, with a positive culture requiring either medical or 
surgical intervention. Device-related infections were further speci-
fied as infections in which positive cultures were obtained from the 
device inflow, outflow, diaphragm, pocket, or driveline during 
support or at the time of device removal. LVAD endocarditis 
specifically referred to the colonization of blood contacting the 
device surfaces, which led to sepsis.

Data Analysis
Kaplan-Meier survival methods were used for end-point analysis. 
Log-rank and Wilcoxon comparisons were used for patient survival 
and infection-free survival. The Cox proportional hazards model and 
univariate ANOVA were used to test the impact of pretransplant and 
peritransplant infections on posttransplant mortality. All statistical 
comparisons were performed by use of the Stata statistical package.

Results

Pretransplant Demographics: LVAD Cohort
Median age at device implant was 53 (11 to 69) years, and 
mean posttransplant follow-up was 447±300 (1 to 1119) 
days. The mean duration of support was 95±71 (0 to 389) 
days in patients successfully explanted or transplanted. Pre-
transplant diagnoses included 26 (48%) ischemic cardiomy-
opathies, 19 (35%) idiopathic cardiomyopathies, and 9 (17%) 
cardiomyopathies attributable to other causes. Seventy-eight 
percent of the patients were male; 22% were female. Eighty-
five percent were listed as United Network for Organ Sharing 
(UNOS) status 1, and 15% were listed as UNOS status 2.

Forty-four (51%) of the 86 patients were successfully 
discharged home with their devices. Successful explantation 
occurred in 63 patients (73%), of whom 61 (71%) were 
successfully transplanted and 2 (2%) recovered native myo-
cardial function. One patient remained on support at the time 
of this analysis. Twenty-two (26%) patients died before 
transplantation or device reimplantation.

Pretransplant Demographics: Controls
Median age at transplant was 54 (15 to 67) years, and mean 
posttransplant follow-up was 584±321 (5 to 1236) days.

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Log-rank and Wilcoxon comparisons were used for patient survival 
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posttransplant follow-up was 584±321 (5 to 1236) days.

TABLE 1. Nature and Incidence of Infections Acquired During 
LVAD Support

<table>
<thead>
<tr>
<th>Organism</th>
<th>No. of Infectious Episodes</th>
<th>Typical Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>S epidermidis</td>
<td>25</td>
<td>Catheter</td>
</tr>
<tr>
<td>S aureus</td>
<td>8</td>
<td>Blood</td>
</tr>
<tr>
<td>Staphylococcus</td>
<td>6</td>
<td>LVAD surfaces/driveline/pocket</td>
</tr>
<tr>
<td>Candida</td>
<td>15</td>
<td>Sputum</td>
</tr>
<tr>
<td>Pseudomonas</td>
<td>13</td>
<td>Urine</td>
</tr>
<tr>
<td>Klebsiella</td>
<td>12</td>
<td>Sputum</td>
</tr>
<tr>
<td>Enterococcus</td>
<td>10</td>
<td>Blood</td>
</tr>
<tr>
<td>Acinetobacter</td>
<td>10</td>
<td>Bronchi</td>
</tr>
<tr>
<td>E coli</td>
<td>7</td>
<td>Urine</td>
</tr>
<tr>
<td>Propionibacterium</td>
<td>4</td>
<td>LVAD surface/pocket</td>
</tr>
<tr>
<td>Enterobacter</td>
<td>5</td>
<td>Sputum</td>
</tr>
<tr>
<td>Xanthomonas</td>
<td>4</td>
<td>Surgical wound</td>
</tr>
<tr>
<td>Aspergillus</td>
<td>2</td>
<td>Sputum</td>
</tr>
<tr>
<td>Serratia</td>
<td>2</td>
<td>Trachea</td>
</tr>
<tr>
<td>Proteus</td>
<td>2</td>
<td>Trachea</td>
</tr>
</tbody>
</table>

E coli indicates Escherichia coli.

TABLE 2. Primary Causes of Pretransplant Death in 22 
LVAD-Supported Patients

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perioperative hemorrhage</td>
<td>6</td>
</tr>
<tr>
<td>Multisystem organ failure (nonseptic)</td>
<td>5</td>
</tr>
<tr>
<td>Sepsis</td>
<td>5</td>
</tr>
<tr>
<td>CVA</td>
<td>4</td>
</tr>
<tr>
<td>Air embolus</td>
<td>2</td>
</tr>
<tr>
<td>Septic</td>
<td>1</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>1</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>1</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>1</td>
</tr>
</tbody>
</table>

CVA indicates cerebrovascular accident.

TABLE 3. All Complications Occurring in 22 LVAD-Supported 
Patients Who Died Before Transplant

<table>
<thead>
<tr>
<th>Complications</th>
<th>No. of Episodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>13</td>
</tr>
<tr>
<td>Multisystem organ failure</td>
<td>10</td>
</tr>
<tr>
<td>Hemodynamic shock</td>
<td>5</td>
</tr>
<tr>
<td>Septic</td>
<td>5</td>
</tr>
<tr>
<td>CVA</td>
<td>4</td>
</tr>
<tr>
<td>Air embolus</td>
<td>2</td>
</tr>
<tr>
<td>Septic</td>
<td>1</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>1</td>
</tr>
<tr>
<td>Perioperative hemorrhage</td>
<td>9</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>1</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>1</td>
</tr>
</tbody>
</table>
Pretransplant diagnoses included 25 (50%) ischemic cardiomyopathies, 21 (42%) idiopathic cardiomyopathies, and 4 (8%) cardiomyopathies attributable to other causes. Eighty-four percent of the patients were male, and 16% were female. Eighty percent were listed as UNOS status 1, and 20% were listed as UNOS status 2.

Pretransplant Infections: LVAD Cohort
A total of 56 (66%) patients developed one or more infections during device support. Table 1 lists the infecting organisms, their frequency, and sites of colonization. *Staphylococcus* species (in particular, *S. epidermidis*) represented the most frequently cultured organism, followed by *Candida* and *Pseudomonas* species. An estimated 17% of the infectious episodes were device-related, including 7 instances of LVAD endocarditis. Two cases of LVAD endocarditis were fatal.

Pretransplant Mortality: LVAD Cohort
Table 2 lists the primary causes of mortality in the 22 pretransplant deaths; 5 deaths were attributable to infection. When all complications in this subgroup were compiled (Table 3), 13 (59%) patients were found to be infected. However, the presence of pretransplant infection was not significantly associated with pretransplant mortality in the entire LVAD cohort (*P*=0.44).

Posttransplant Outcomes: Impact of Pretransplant Infections
Table 4 stratifies successfully transplanted LVAD patients into 2 groups based on the presence or absence of pretransplant infection. Despite a trend toward a higher infectious rate in those with pretransplant infections, there were no statistical differences in the 6-month posttransplant infection rate, 6-month mortality, or long-term patient survival.

Posttransplant Outcomes: Active Infections During Transplantation
Eleven patients in the LVAD cohort had continuing infections at the time of transplant. Six cases were device-related infections, whereas 5 were non–device-related infections. Four patients in this cohort were initially outpatients. Table 5 lists the nature of these infections, of which 2 were unresolved within the first posttransplant month. Both were fatal at 26 days after surgery, and although both patients died from sepsis, hazard analysis did not demonstrate a significant impact of peritransplant infection on 6-month mortality (*P*=0.39).

Posttransplant Outcomes: Nature and Incidence of Infections
Figure 1 summarizes the course of infections in the posttransplant period. On average, there were 0.53 to 0.83 infections per patient per 6 months. Patients infected typically had 1 or 2 infections within this time period, with the time course of infections usually limited to within 1 month. Table 6 lists the cultured organisms in 20 patients infected both before and after transplant. As shown, the majority of posttransplant cultures were unrelated to the pretransplant cultures.

**TABLE 4. LVAD-Supported Patients Stratified by Presence or Absence of Pretransplant Infection and Their Posttransplant Outcomes**

<table>
<thead>
<tr>
<th>Group</th>
<th>Posttransplant Patients</th>
<th>Posttransplant Survival, d</th>
<th>6-mo Mortality, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVAD cohort (infected before transplant)</td>
<td>29/44 (66%)</td>
<td>508±300 (14 to 1119)</td>
<td>5/44 (11%)</td>
</tr>
<tr>
<td>LVAD cohort (no pretransplant infections)</td>
<td>8/17 (47%)</td>
<td>447±280 (1 to 858)</td>
<td>3/17 (18%)</td>
</tr>
</tbody>
</table>

Values are numbers and percentages of patients or means and ranges.

**TABLE 5. Active Infections at Time of Transplant Occurring in 11 LVAD-Supported Patients**

<table>
<thead>
<tr>
<th>Infection Type</th>
<th>Organism(s)</th>
<th>Site(s)</th>
<th>6-mo Mortality, n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device-related (6)</td>
<td><em>S. epidermidis</em> (4)</td>
<td>Pocket (5)</td>
<td>1/6</td>
</tr>
<tr>
<td></td>
<td><em>Candida</em> (1)</td>
<td>Driveline (1)</td>
<td>(26 d Postop)</td>
</tr>
<tr>
<td></td>
<td><em>Propionibacterium</em> (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-device-related (5)</td>
<td><em>Acinetobacter</em> (3)</td>
<td>Respiratory (2)</td>
<td>1/5</td>
</tr>
<tr>
<td></td>
<td><em>Serratia</em> (1)</td>
<td>Sternum (2)</td>
<td>(26 d Postop)</td>
</tr>
<tr>
<td></td>
<td><em>E. coli</em> (1)</td>
<td>Urosepsis (1)</td>
<td></td>
</tr>
</tbody>
</table>

Values in parentheses indicate number of patients. Postop indicates after surgery.
Infection management has historically been and continues to be of vital importance in the success of an LVAD program. Although the impact of infection has been well studied in the pretransplant period, the true incidence and nature of post-transplant infections after LVAD explant has been lacking. We chose this cohort to update our experience because it represents a novel group in 3 regards: (1) portable electric device use, (2) significant delivery of outpatient care, and (3) changes in infection management. This analysis in conjunction with the previous inpatient study has contributed greatly to the understanding of infection in this patient population, influencing further evolution in our infection management protocol.

Our current approach toward infection includes both preventative and interventional modalities. Preventative strategies are focused on a clean implantation technique with specific attention to infections acquired via the driveline and device pocket, particularly from skin flora. Consequently, implantation of the LVAD is performed under operating-room conditions of limited traffic. Antibiotic prophylaxis (48 hours) at LVAD implantation involves intravenous trimethoprim/sulfamethoxazole, rifampin, and fluconazole; mupirocin ointment is applied to the nares. Additionally, the LVAD surfaces are soaked in vancomycin and gentamycin for 30 minutes, the preperitoneal device pocket is irrigated with povidone iodine, and the subcutaneous driveline tunnel

<table>
<thead>
<tr>
<th>Case</th>
<th>Before Transplant</th>
<th>After Transplant</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Proteus</td>
<td>Candida</td>
</tr>
<tr>
<td>3</td>
<td>Pseudomonas</td>
<td>Klebsiella, S aureus</td>
</tr>
<tr>
<td>5</td>
<td>S epidermidis</td>
<td>CMV</td>
</tr>
<tr>
<td>13</td>
<td>Klebsiella, VREF</td>
<td>Klebsiella, S aureus</td>
</tr>
<tr>
<td>16</td>
<td>Clostridium</td>
<td>Serratia</td>
</tr>
<tr>
<td>18</td>
<td>Acinetobacter</td>
<td>S epidermidis</td>
</tr>
<tr>
<td>21</td>
<td>S epidermidis</td>
<td>S epidermidis</td>
</tr>
<tr>
<td>22</td>
<td>Pseudomonas</td>
<td>Acinetobacter</td>
</tr>
<tr>
<td>30</td>
<td>S epidermidis</td>
<td>MRSA</td>
</tr>
<tr>
<td>31</td>
<td>Escherichia faecalis</td>
<td>Escherichia faecalis</td>
</tr>
<tr>
<td>34</td>
<td>Acinetobacter</td>
<td>Acinetobacter</td>
</tr>
<tr>
<td>35</td>
<td>Propionibacterium</td>
<td>S aureus</td>
</tr>
<tr>
<td>36</td>
<td>Acinetobacter</td>
<td>Acinetobacter, MRSA</td>
</tr>
<tr>
<td>41</td>
<td>S epidermidis</td>
<td>Klebsiella</td>
</tr>
<tr>
<td>44</td>
<td>S epidermidis, candida</td>
<td>Candida</td>
</tr>
<tr>
<td>45</td>
<td>Acinetobacter</td>
<td>Pseudomonas</td>
</tr>
<tr>
<td>50</td>
<td>Acinetobacter</td>
<td>Pseudomonas</td>
</tr>
<tr>
<td>57</td>
<td>Candida</td>
<td>Pseudomonas, E coli</td>
</tr>
<tr>
<td>70</td>
<td>Xanthomonas</td>
<td>S epidermidis</td>
</tr>
<tr>
<td>76</td>
<td>S epidermidis</td>
<td>S epidermidis</td>
</tr>
</tbody>
</table>

CMV indicates cytomegalovirus; E faecalis, Enterococcus faecalis; MRSA, methicillin-resistant Staphylococcus aureus; and VREF, vancomycin-resistant E faecalis.
is extended to cross the abdomen transversely and superiorly to the right upper quadrant. Finally, postoperative care of the driveline includes sterile and semisterile dressing changes.

With respect to our prior experience, an emphasis has been placed on driveline and pocket management. Because driveline and pocket infections have had a significant role in the development of LVAD endocarditis, the use of antibiotic coating for drivelines and longer subcutaneous tunnels may have reduced the incidence of serious driveline infections. Active monitoring for purulence and early signs of infections in the driveline and pocket areas have resulted in a low-tolerance infection management strategy.

These interventional strategies are aggressive and implemented early. Intravenous antibiotics used for most infectious episodes are given for a 3- to 4-week period. For example, vancomycin is typically used against *Staphylococcus*, whereas imipenem has been used against Gram-negative organisms. An effective treatment for fungemia has been the combination of intravenous amphotericin with urgent transplantation. In all cases, infections persisting into the post-transplant period require extended antibiotic treatment, typically 6 weeks, and may include the cautious reduction of immunosuppression in the early posttransplant period. Although there is no established protocol for modulating immunosuppression, the withholding of some or all immunosuppressive medications is common for up to 1 week. Particular care is taken with patients at higher risk of rejection, such as those who have been sensitized or have had mild or moderate acute rejection in their initial heart biopsies.

Although inpatient intervention is preferred, it has been possible to treat some patients either completely or partially on an outpatient basis. Oral agents, such as trimethoprim/sulfamethoxazole and minocycline, have been successfully used in this regard.

The lessons learned early in our experience still hold true regarding unresolved infections; LVAD colonization has proven to be particularly resistant to antibiotic therapy but has been managed by removal of the device and, consequently, the source of infection. An evaluation of cardiac function with the LVAD turned off aids in the subsequent decision to either permanently explant the device or reimplant a new device or a donor heart.

With our present management techniques, there remain relatively few situations in which transplantation is not considered. Two absolute contraindications are evidence of multiple system organ failure or massive cerebrovascular event. Temporary removal from the transplant list and supportive measures are instituted until evidence of organ recovery or stabilization is demonstrated. The most clinically challenging situation occurs when device-related sepsis leads to organ failure. Although this is a relatively uncommon occurrence, the intervention of choice is transplantation or device replacement. The decision to remove the patient from the transplant list and manage versus surgical intervention then becomes a judgment based on hemodynamic stability. The surgical risk becomes greatest when there is little evidence of organ stability or recovery; therefore, urgent intervention at earlier stages and before decompensation can be lifesaving.

**Pretransplant Infections**

Although the incidence of infections during device support remains high, with $\approx 2$ of 3 patients being infected, we have found little impact on survival or posttransplant infection rates. Paradoxically, this incidence is higher than in our inpatient experience; however, this finding may be best explained by our management changes, reflecting both an increased vigilance for infection and a lower treatment threshold. Although we do not preclude an influence of the outpatient environment, our data do not suggest this, and further analysis is necessary. Moreover, a change in the prevalence of infecting organisms may be expected in an ambulatory setting; however, *Staphylococcus*, *Candida*, and *Pseudomonas* represented the 3 most common organisms of the inpatient group.

Despite a higher infection rate, the mortality has not increased but remains low, as reported in the first 16 cases of the vented electric device recipients. Furthermore, as reflected in the analysis, the incidence of infection is not increased in the pretransplant mortality. The patients who expired before transplant represent the sickest group of patients with LVADs, with a majority excluded from transplant. Although infection played a role in pretransplant mortality, hemodynamic decompensation and multiple organ failure were the prominent factors in their ultimate demise. UNOS rules for listing status as of August 16, 1999, reflect some of our management strategies that have been in place for a number of years, notably, the urgency of transplantation with device-related complications.

**Peritransplant Infections**

An area of prior controversy has been the transplantation of device-supported individuals harboring infections. The decision to transplant this particularly sick group is swayed by the hemodynamic status of the patient, with the functional status of other vital organs, particularly the kidney and brain, taken into account. Indicators of decompenation, such as pulmonary artery pressures, and organ function, such as creatinine levels, are used to initiate early interventions. In the presence of infection, life-supportive therapy is augmented by aggressive intervention strategy using antibiotics and explantation. No absolute protocol for the evaluation of organ insufficiency or failure is currently in place; however, clinical judgment and functional status are used to predict the survivability from an operative intervention. The presence of positive blood cultures served as a basis to increase the urgency of transplantation in 4 patients. Resistance to antibiotic therapy in 4 patients with device-related infections was treated similarly.

**Posttransplant Infections**

An increasingly larger percentage of LVADs are currently being transplanted with excellent posttransplant survival. Although LVAD recipients are no more likely to become infected after transplant if they had a pretransplant infection, they are at an increased risk compared with the control group. This reflects the increased risk in LVADs of carrying an infection into the posttransplant period. When active transplant infections are removed from analysis, there is no difference in the posttransplant infection rate compared with
the control rate because most infections are cleared in the first posttransplant month. Table 6 further demonstrates that posttransplant infections are of a different nature than pretransplant infections. Finally, both groups, the LVAD recipients and controls, as shown in Figure 1, have roughly the same frequencies of posttransplant infections; 1 or 2 infections are seen in the majority of patients 6 months after transplant.

The present study has demonstrated that effective infection control allows safe delivery of the LVAD-supported patient from either inpatient or outpatient environments into the posttransplant period. After a short period of increased infectious risk, LVAD recipients can expect a similar survival at 3 years as nonsupported patients.

References


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