Improved survival in patients with ventricular assist device therapy: the University of Wisconsin experience

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Abstract

Objective: Ventricular assist devices (VADs) have been implanted since 1990 in our institution, becoming an increasingly common treatment for end-stage heart failure. Beginning in 1997, VAD patients were discharged home when feasible. In August 2003, a dedicated multidisciplinary VAD team (cardiac surgeons, cardiologists, VAD coordinators, nurses, rehabilitation specialists, nutrition experts, psychologists, pharmacists, social workers, and administrators) was created to optimize the management of VAD patients. The purpose of this study is to analyze the impact of these changes in care at our center over the last 17 years. Methods: We retrospectively studied 107 consecutive VAD recipients between June 1990 and August 2006. VADs were implanted as bridge to recovery, bridge to transplant and destination therapy. The cohort was divided by care plans into early (n = 37, June 1990—1996), mid (n = 32, 1997—July 2003), and late groups (n = 38, August 2003—August 2006). Demographic profile, survival and complications were assessed. Results: Patient demographics tended to show an increased severity of illness over time. Post-VAD survival rate significantly improved in the late group (post-VAD 1- and 3-year survival rates; early: 54.1% and 40.5%; mid: 51.6% and 41.9%; late: 86.8% and 82.5%, p < 0.001, respectively). The incidence of complications including re-operation, major bleeding and major infection, significantly decreased in the late group (p < 0.05). Conclusions: Outcomes have improved dramatically in recent VAD patients, despite an increasingly high-risk patient population. These data suggest that advances in device technology and medical therapies, as well as a multidisciplinary approach, have improved survival on VAD therapy.

Keywords: Mechanical circulatory support; Ventricular assist device; Congestive heart failure

1. Introduction

Mechanical circulatory support has become an important therapeutic option for patients with end-stage heart failure refractory to medical and other surgical therapies [1,2]. Over the last 20 years, significant clinical and engineering advances have been achieved in the field of mechanical circulatory support, which led to the first successful cardiac transplant, following bridging with a left ventricular assist device (LVAD), reported in 1984 [3]. In 1994, the United States Food and Drug Administration approved LVADs as a bridge to cardiac transplantation and the first wearable LVADs were used clinically in the same year [4]. Due to technological advances and the increasing need to treat different types of patients, indications for VAD implantation have been broadened to include patients who were once thought to be unsuitable for device insertion. Recently, the REMATCH trial has shown that LVAD therapy for selected patients, who are not candidates for cardiac transplantation, is superior to medical therapy in alleviating symptoms and improving survival rates and quality of life [5].

The care of patients with refractory heart failure who are VAD candidates is also changing as technology advances [6]. Implantable VAD therapy started at our institution in 1990, and has become increasingly common for the treatment of severe decompensated heart failure. Since 1997, our institution allowed VAD patients to be discharged home. In August 2003, a dedicated multidisciplinary VAD team including cardiac surgeons, cardiologists, VAD coordinators, nurses, rehabilitation specialists, nutrition experts, psychologists, pharmacists, social workers, and administrators, was created to optimize the management of VAD patients. The purpose of this study is to evaluate the changing demographic profile of VAD recipients and to analyze the impact of changes in the care approach at our center on survival and VAD-related complications over the last 17 years.
2. Materials and methods

Between June 1990 and August 2006, 107 patients received a VAD as bridge to recovery (BTR), bridge to transplant (BTT) and destination therapy (DT) at our institution (Table 1). The patients were divided, according to the changes in our institutional VAD program, into early (n = 37, 1990–1996), mid (n = 32, 1997–July 2003), and late groups (n = 38, August 2003–August 2006), respectively. Data was collected prospectively and analyzed retrospectively. The institutional review board committee approved this retrospective study.

Preoperative patient demographics, cardiac function, hemodynamics, serum laboratory values, intra-aortic balloon pump (IABP) insertion, ventilatory dependence, and need for continuous veno-venous hemodialysis (CVVH) or intermittent hemodialysis (HD) were recorded for each patient. In addition, in order to evaluate relative preoperative risk factors, we used the existing VAD scoring system published by Rao et al. [7]. This scoring system is derived from five clinical variables, including ventilatory dependence, postcardiotomy shock, previous LVAD, central venous pressure >16 mmHg, and prothrombin time >16 s. The survival during VAD support was assessed and patients were censored at the time of transplant or device explant. Also, post-VAD survival rate was calculated including transplant and device explant due to recovery. Clinical outcomes included survival to hospital discharge and length of hospital stay. Postoperative complications included re-operation within 7 days from VAD insertion, major bleeding, major infection, neurological and renal dysfunction, respiratory failure, right heart failure (RHF), and device malfunction. These definitions, except for re-operation, were based on the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) (http://www.uab.edu/ctsresearch/intermacs/manuals.htm).

2.1. Patient selection

Patient selection criteria have varied slightly over time, reflecting general implantation practices in the United States during each era [2,5,8]. Prior to the availability of evidence-based implantation criteria, patient selection was based on expert opinion. The patient selection criteria in the early and mid groups generally included patients with severe heart failure despite IABP or inotrope support, with unstable hemodynamics, and with early signs of end-organ dysfunction. Fig. 1 shows a typical patient selection process. Clinical judgment is applied to each individual case to evaluate candidacy for VAD implantation. However, patient selection criteria are followed as a guide for decision-making.

The selection criteria in the late group for a BTT intent includes patients listed/deemed candidates for heart transplantation, and having one or more of the following: (1) severe heart failure despite optimal medical therapy (cardiac index (CI) <2, pulmonary capillary wedge pressure (PCWP) >20, or inotrope-dependent), especially if the patient’s body size and blood type suggest that the wait for a donor organ will be prolonged; (2) severe LV dysfunction and intractable arrhythmias; (3) advanced heart failure

### Table 1

<table>
<thead>
<tr>
<th>Intention to treat, device selection, support length and type</th>
<th>Early</th>
<th>Mid</th>
<th>Late*</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bridge to transplant</td>
<td>35 (95%)</td>
<td>27 (84%)</td>
<td>28 (74%)</td>
<td></td>
</tr>
<tr>
<td>Bridge to recovery</td>
<td>2 (5%)</td>
<td>5 (16%)</td>
<td>3 (8%)</td>
<td></td>
</tr>
<tr>
<td>Destination therapy</td>
<td>—</td>
<td>—</td>
<td>7 (18%)</td>
<td></td>
</tr>
<tr>
<td>Devices</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HeartMate IP</td>
<td>24 (65%)</td>
<td>9 (28%)</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>HeartMate VE</td>
<td>2 (5%)</td>
<td>6 (19%)</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>HeartMate XVE</td>
<td>—</td>
<td>3 (9%)</td>
<td>31 (75%)</td>
<td></td>
</tr>
<tr>
<td>HeartMate II</td>
<td>—</td>
<td>—</td>
<td>2 (5%)</td>
<td></td>
</tr>
<tr>
<td>Thoratec</td>
<td>9 (25%)</td>
<td>10 (31%)</td>
<td>4 (10%)</td>
<td></td>
</tr>
<tr>
<td>Thoratec IVAD</td>
<td>—</td>
<td>—</td>
<td>2 (5%)</td>
<td></td>
</tr>
<tr>
<td>DeBakey</td>
<td>—</td>
<td>—</td>
<td>2 (5%)</td>
<td></td>
</tr>
<tr>
<td>Abiomed BVS 5000</td>
<td>—</td>
<td>4 (13%)</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Medtronic Bio-Medicus</td>
<td>2 (5%)</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Device support (days) (range)</td>
<td>45 (0–331)</td>
<td>90 (0–524)</td>
<td>167 (34–860)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Bridge to transplant</td>
<td>52 (0–331)</td>
<td>129 (0–524)</td>
<td>163 (34–503)</td>
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</tr>
<tr>
<td>Bridge to recovery</td>
<td>1 (1)</td>
<td>3 (0–14)</td>
<td>123 (81–185)</td>
<td></td>
</tr>
<tr>
<td>Destination therapy</td>
<td>—</td>
<td>—</td>
<td>451 (253–860)</td>
<td></td>
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<tr>
<td>Device assist type</td>
<td></td>
<td></td>
<td></td>
<td>0.024</td>
</tr>
<tr>
<td>BIVAD</td>
<td>7 (19%)</td>
<td>8 (25%)</td>
<td>3 (7%)</td>
<td></td>
</tr>
<tr>
<td>LVAD</td>
<td>30 (81%)</td>
<td>20 (63%)</td>
<td>34 (91%)</td>
<td></td>
</tr>
<tr>
<td>RVAD</td>
<td>0 (0%)</td>
<td>4 (12%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
</tbody>
</table>

HeartMate and Thoratec, Thoratec Corp, Pleasanton, Calif, USA; DeBakey, MicroMed Technology, Inc., Houston, Tex, USA; Abiomed BVS 5000, Abiomed, Danvers, Mass, USA; Medtronic Bio-Medicus, Medtronic Bio-Medicus, Inc., Eden Prairie, Minn, USA; BIWAD, biventricular assist device; LVAD, left ventricular assist device; RVAD, right ventricular assist device. HeartMate IP, implantable and pneumatic pulsatile; HeartMate VE and HeartMate XVE, implantable and vented electric pulsatile; HeartMate II, implantable and nonpulsatile; Thoratec, paracorporeal and pneumatic pulsatile; Thoratec IVAD, implantable and pulsatile; DeBakey, implantable and nonpulsatile; Abiomed BVS 5000, extracorporeal and pneumatic pulsatile; Medtronic Bio-Medicus, extracorporeal and centrifugal nonpulsatile.

* Including three replacements.
complicated by cardiac cachexia; (4) advanced heart failure complicated by renal or hepatic dysfunction which is felt to be secondary to poor perfusion and/or congestion; (5) severe LV dysfunction complicated by elevated pulmonary pressures not responsive to conventional agents or when these agents cannot be used or optimized due to low cardiac output and systemic hypotension; (6) intractable angina not responsive to medical therapy or revascularization procedures in patients with poor LV function; and (7) post-cardiotomy shock.

The patient selection criteria for DT include: (1) severe heart failure with inability to consistently achieve NYHA FC III status despite aggressive optimization of medical therapy (CI ≤ 2, PCWP > 20, or inotrope-dependent) in a patient who is not felt to be a candidate for heart transplantation; (2) LVEF ≤ 25%; (3) exercise VO₂ ≤ 12 ml/kg/min or need for continuous intravenous inotropes or IABP therapy to prevent symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion.

Contraindications for VAD implantation include: (1) lack of appropriate psychosocial support; (2) inability to comply with the required follow-up regimen; and (3) other life-limiting illnesses or end-organ insufficiencies felt to be secondary to causes other than heart failure.

2.2. Device selection and patient/device matching

Device selection at our institution is shown in Table 1. Strategies of patient/device matching in the eras are summarized in Fig. 2. When we first started using mechanical assist devices, only extra- or paracorporeal devices were available. Since implantable devices became available, we have been able to optimize patient/device matching. Our current strategy to match the device to the patient is: (1) patients whose hearts are most likely to recover within a week receive Abiomed® BVS 5000 as a BTR; and (2) all other patients indicating for BTR, BTT and DT receive intracorporal wearable VADs to allow discharge from the hospital.

2.3. Antibiotics and anticoagulation regimens

The antibiotic and anticoagulation regimens in the early and mid eras were not standardized and were defined by the implanting surgeon. Our current anti-microbial prophylaxis regimen is: vancomycin, 15 mg/kg IV 1 h before surgery then every 12 h for 3 days; ciprofloxacin, 400 mg IV 1 h before surgery then every 12 h for 3 days; rifampin, 600 mg orally before surgery then every 24 h for 3 days; fluconazole, 400 mg orally before surgery then every 24 h for 3 days.

Anticoagulation regimens for each device in the late group are as follows: (1) HeartMate® XVE, aspirin; (2) HeartMate® II, aspirin and coumadin (international normalized ratio [INR], 2.5 top 3.5); (3) Thoratec® IVAD; aspirin and coumadin (INR, 2.5 top 3.5); and (4) Abiomed® BVS 5000, heparin.

2.4. The University of Wisconsin VAD management program

Our VAD management program is multidisciplinary and is in charge of the long-term management of all VAD recipients.
at our institution. The core functions of the program are patient and family education on VAD function and care, outpatient follow-up, inpatient management of complications, coordination of care, psychologic and social support, and financial counseling.

The program includes four cardiothoracic surgeons, six heart failure cardiologists, one heart failure fellow, two nurse practitioners, two VAD nurse coordinators, three heart failure nurse coordinators, three cardiac transplant nurse coordinators, one social worker, one psychologist, one dietician, one financial counselor, physical therapists, pharmacists, and administrative assistants. Additional healthcare providers are available for education and operational support as needed. The organizational structure of the VAD management program is shown in Fig. 3.

As soon as a patient is considered a potential candidate for mechanical circulatory support, program cardiothoracic surgeons and cardiologists verify appropriateness based on patient selection criteria, and rule out surgical or medical contraindications to implantation. The patient's social support and psychological adequacy are assessed by the program social worker and psychologist. If no initial contraindications are found, VAD nurse coordinators begin preoperative VAD education to the patient (if medically possible) and their support persons. Postoperatively, VAD education is resumed, even as early as postoperative day 1, if the VAD recipient is alert and in a disposition to receive teaching.

The VAD education curriculum focuses on device components and operation, recognition and response to device alarms, device care and dressing changes, and recognition of early signs of known device-related complications (device malfunction, infection, thromboembolism, hemolysis, bleeding). In addition to these core elements, the education plan extends to the patient's local community involving the local emergency department and emergency-medical response systems. This allows training in early response to VAD-related emergencies and complications, and increases the patient's and family comfort level upon patient return to the community. Patients cannot be discharged from the hospital until they demonstrate proficiency in all the core areas of the education curriculum. For this purpose, evaluations are administered to the patient and their support persons at different points during the teaching process.

After discharge from the hospital, VAD nurse coordinators are the primary contact for the patient. The VAD nurse coordinators coordinate out-of-hospital care, including local physician visits, medication availability, and home care needs (dressing supplies, physical rehabilitation, durable medical equipment, visiting nurse services, etc.). Close telephone follow-up is used with all patients to maintain open lines of communication. This allows for early detection of complications and increases patient and family comfort. VAD recipients are seen in the heart failure clinic by cardiologists once monthly and as needed during their VAD support period. During these visits, detailed history and physical exams are obtained. Device function is evaluated by physical inspection and periodic echocardiograms, and VAD education is reinforced.

2.5. Statistical analysis

Categorical data were summarized with frequency distributions and percentages. Values of continuous variables were expressed as means ± standard deviations. Length of stay (LOS) in the intensive care unit (ICU) and hospital during VAD support, and VAD support length were expressed as median. Continuous variables were compared by the Kruskal–Wallis test, whereas nominal variables were compared by means of Fisher’s exact test. The Kaplan–Meier survival method was used to assess both survival during VAD support and post-VAD survival. Log-rank tests were used to assess statistical significance in survival differences among the groups. Cox regression test was applied for the univariate analysis of various pre-operative factors (Table 1) with regard to their effect on post-VAD survival. Finally, variables found to be significant in the univariate analyses were entered into a multivariate Cox proportional hazards model. Hazards ratios with corresponding 95% confidence intervals are given for the variables found to be significant in the multivariate analysis. A p value less than 0.05 (two-sided) was considered to be statistically significant. All analyses were performed using the SAS statistical software program (Version 9.1 for Windows; SAS Institute, Cary, NC).

3. Results

3.1. Demographic profiles

Preoperative patient characteristics are shown in Table 2. Mean overall age was 51.0 ± 12.8 years, with 89 (81%) men and 18 (19%) women. Ischemic cardiomyopathy was more frequent in the late group (55%) vs the early (41%) and mid groups (34%), but this difference was not statistically significant (p = 0.39). The population of patients with preoperative ventilation increased in the late group (45%), but was not statistically significant. Preoperative CVVH or HD was most frequent in the mid group (p = 0.035). The mean VAD risk score was significantly different among the groups.
and showed an increased severity of illness in VAD recipients over time.

### 3.2. Survival during VAD Support and post-VAD survival

Kaplan–Meier analysis for survival during VAD support is shown in Fig. 4. Survival rates during VAD support at 1 and 6 months in the late group were significantly higher compared with other groups (early: 85.4% and 48.7%; mid: 70.4% and 66.2%; late: 100% and 87.2%, \( p = 0.007 \), respectively). Post-VAD survival rates at 1 and 3 years in the late group were significantly higher compared with other groups (early: 54.1% and 40.5%; mid: 51.6% and 41.9%; late: 86.8% and 82.5%, \( p < 0.001 \), respectively, Fig. 5). Post-VAD survival was not different between the early and mid groups (\( p = 0.77 \)).

### 3.3. Clinical outcomes

All VAD recipients in the late group successfully discharged from the ICU. The LOS in the ICU and hospital during VAD support significantly decreased in the late group (ICU LOS: early: 12 days; mid: 11; late: 5, \( p = 0.013 \); hospital LOS: early: 55; mid: 30; late: 13, \( p < 0.001 \), respectively). The incidence of LVAD, RVAD or BiVAD and device support length are shown in Table 1. The incidence of BiVAD decreased to 7% in the late group, compared with 19% in the early group and 25% in the mid group. VAD support length significantly increased in the late group (early: 45 days [range: 0—331]; mid: 90 [0—524]; late: 167 [34—860], \( p < 0.001 \), respectively).

### 3.4. Postoperative complications

Postoperative complications data is shown in Table 3. Re-operation within 7 days after VAD insertion and major bleeding were significantly less frequent in the late group (re-operation; early: 11%; mid: 29%; late: 5%, \( p = 0.021 \) and major bleeding; early: 44%; mid: 58%; late: 26%, \( p = 0.025 \), respectively). Major infection was not different among the groups (\( p = 0.093 \)), however the incidence of sepsis significantly decreased over time (early: 44%; mid: 23%; late: 13%, \( p = 0.01 \)) and was the lowest in the late group. Respiratory failure significantly decreased in the late group (\( p = 0.002 \)).
The incidence of RHF among LVAD recipients tended to decrease in the late group (6%), although no statistically significant differences were found ($p = 0.19$).

### 3.5. Predictors of post-VAD survival

Univariate analysis revealed group ($p < 0.001$), age >60 years ($p = 0.045$), etiology ($p < 0.001$), LVEF ($p = 0.009$), and pre-op CVVH or HD ($p = 0.009$) as significant predictors of post-VAD survival. For the etiology, the significance seemed to be due to postcardiotomy and graft failure groups. Multivariate analysis using those factors found to be significant in the univariate analyses, revealed the early group (hazard ratio [HR] 6.3, 95% confidence interval [CI] 2.46—16.12, $p < 0.001$), the mid group (HR 4.7, 95% CI 1.71—12.95, $p < 0.001$), LVEF (HR 1.0, 95% CI 1.01—1.06, $p < 0.004$), and pre-op CVVH or HD (HR 2.6, 95% CI 1.11—5.91, $p < 0.028$) as significant independent predictors of post-VAD survival.

### 4. Discussion

Over the last 25 years, mechanical circulatory support devices have been used for patients with refractory heart failure as a bridge to recovery [9] and a bridge to transplant [2,10]. VAD success in these areas, in addition to recent technological advances, have led to VAD use as destination therapy in patients who are not transplant candidates [5]. A review of data from Mechanical Circulatory Support Device (MCSD) databases shows that the actuarial survival during MCS is 83% at 1 month and 50% at 1 year [1]. Rao et al. reported that while VAD recipients have increasingly high-risk profiles at the time of implantation, VAD-related mortality has remained constant [11]. We observed similar trends in patient clinical profiles in our institutional experience, however survival was dramatically improved in the late group and was better than that reported in MCSD. We are encouraged by our results, which demonstrate a progressive improvement in recent VAD recipient survival over time.

Improvements in VAD patient outcomes are related in part to advances in device design. Recent multicenter trials showed that design enhancements to the HeartMate® XVE significantly reduced the incidence of device malfunctions compared with the HeartMate® VE model [12]. Besides decreasing the risk of device malfunction, HeartMate® XVE enhancements helped decrease the likelihood of device-related infection. Among these enhancements, longer, smaller-diameter, more flexible drive lines, are most likely to be responsible for the reduced rate of infections with the newer HeartMate®. Frazier and colleagues published their experience with the HeartMate® VE device as a bridge to transplant, noting a 40% rate of device-related infections [2]. In the REMATCH trial, where the HeartMate® XVE was used as destination therapy, the observed rate of device-related infection was 28% [5]. Other design improvements in the HeartMate® XVE device contributing to ease of implantation include outflow graft redesigns to prevent kinking and rotating tunneling bullets to ease the passing of the drive line under the skin to the exit site (http://www.thoratec.com/index.htm). The introduction of second and third generation devices with smaller sizes and fewer moving parts, including the HeartMate® II, DeBakey®, and Jarvik 2000, and magnetically levitated centrifugal pumps may further decrease infection and device malfunction rates. Miller and colleagues have shown that the use of the HeartMate® II device as a bridge to transplantation was associated with a 14% rate of device-related infection [8]. Similar findings have been noted with the Jarvik 2000 [13], and DeBakey® [14]. Even though we recognize the impact of developments in device design on meaningful clinical outcomes in VAD recipients, we believe the reasons for our improved outcomes are multifactorial and go beyond improved device design alone. Other important aspects of care will favorably impact outcomes with VAD patients, including patient selection [15,16], perioperative managements [17,18] and a multidisciplinary approach [6].

Patient selection remains the primary determinant of success with VAD therapy. This process involves two major areas of assessment. The first is the evaluation of the appropriateness for device implant based on the patient’s clinical condition, their degree of symptoms, and indications. The second is determining the operative risk of VAD implant to the patient. Many investigators have attempted to develop composite risk scores to predict outcomes after VAD insertion [7,15,16]. There are many risk factors that influence outcomes and no single risk is an absolute predictor of unfavorable results. In our study, we adopted the VAD scoring system proposed by the Columbia University. This score can be expressed numerically, which facilitates comparisons, and was revised in 2003 to adjust to patient-related trends [7]. Our results showed a trend towards higher VAD scores in the late group. However, that group’s VAD score was lower than that published in the Columbia University study [10]. This may be one of the reasons why our survival rates are better than those of other institutions.

Several improvements in perioperative management have played important roles in reducing early mortality and complications. Excessive bleeding was a major complication and limiting factor for successful VAD implantation, increasing the need for blood transfusion, causing fluid overload and RHF, and resulting in prolonged postoperative intubation and ICU stay. Immediate postoperative bleeding occurs in 20—40% of VAD recipients [1,2]. Perioperative requirements for extensive blood product usage can not only be life threatening but also impact secondary outcomes as shown by an increased incidence of RHF caused by a cytokine-mediated increase in pulmonary vascular resistance (PVR). A retrospective multicenter analysis showed that aprotinin was associated with a significant decrease in postoperative blood loss, transfusion requirements, and postoperative requirement for an RVAD, as well as improvement in mortality rates in LVAD patients [19]. We used aprotinin routinely in all patients undergoing VAD implantation in the late group. As a result, re-operation decreased to 5.3%. Additionally, the incidence of RHF was reduced to 5.9%. However, a recent meta-analysis indicated an association between aprotinin use and serious end-organ damage in coronary bypass surgery [20] and we should consider these factors carefully. Since aprotinin is no longer available in the United States,
aminocaproic acid is administered after induction of anesthesia in recent cases.

Infection is one of the most serious common complications after VAD implantation, affecting short- and long-term survival for patients on mechanical circulatory support, with most studies documenting a 30—50% occurrence [21]. In the REMATCH trial, although survival was prolonged for the LVAD group, infection remained a significant cause of morbidity and mortality. Sepsis was the most commonly reported cause of death (31%) and survival of LVAD patients without sepsis was superior to that of patients who experienced sepsis (60% 1-year and 38% 2-year survival in the non-sepsis group vs 39% 1-year and 8% 2-year survival in the sepsis group, respectively). In our experience, the incidence of sepsis was 44.4% in the early group, however it decreased to 13.2% in the late group. It is obvious that the recent increase of implantable device usage and advances in antibiotic therapy led to this improvement [22]. In terms of perioperative management, we start antibiotic prophylaxis preoperatively and continued it for at least 3 days post-implant as shown in the Methods section, compared with the 2 day recommendation of antimicrobial prophylaxis protocol for REMATCH trial [21]. Interestingly, the incidence of infection excluding sepsis did not differ among the groups (localized non-device, \( p = 0.26 \); percutaneous site/pocket, \( p = 0.52 \)). These data suggest that patient education and self-care teaching in our recent VAD program could lead to early recognition of infection, preventing the onset of sepsis by early treatment. In addition, our nutrition experts initiate enteral feeding within two days of VAD implantation if patients will not be weaned from ventilatory support easily, because enteral nutrition supports gut integrity, can be used to modulate the immune system, and carries a lower risk of bloodstream infection than parenteral nutrition [23].

A major determinant of survival after LVAD implantation is the ability of the native right ventricle to provide adequate flow across the pulmonary circuit to sufficiently fill the LVAD. Because of this, RHF after LVAD insertion is a dreaded complication. RHF refractory to maximal pharmacological therapy occurs in 20—40% of patients supported with LVADs, and the mortality in the RHF group is higher than the non-RHF group [24]. In preventing and treating RHF after LVAD insertion, it is particularly important to reduce PVR and volume overload. As most institutions do, we use inhaled nitric oxide (NO) and frequently administer phosphodiesterase inhibitors (PDE-I) such as milrinone to decrease PVR. Additionally, in order to optimize volume balance, CVVH is promptly started when aggressive pharmacologic therapy fails to control volume overload. In the late group, we used peripherally inhaled NO for nine cases (24%) among 37 LVAD implantations, compared with no use in the early and mid groups, and the incidence of RHF after LVAD implant was reduced to 6% from 22.2% in the mid group. Also, the number of BiVAD insertions decreased to only three cases (7%) in the late group, compared with seven (19%) in the early group and nine (25%) in the mid group. The use of NO and PDE-I may have contributed to the decreased incidence of RHF and necessity of BiVAD after LVAD implant.

Neurological dysfunction such as transient ischemic attack (TIA) and stroke have proven problematic with all types of mechanical circulatory support [25]. The reported incidence varies widely from 2.7% to 35% and is undoubtedly influenced by patient variables, pump design, and the different anticoagulant regimens employed. In addition, the degree of thromboembolic neurological events is dependent on the sensitivity of the observer. In the present study, although the incidence of all neurological dysfunction did not differ among the groups, there tended to be a higher incidence of TIA in the late group (Table 3). This could be related to the significantly longer support length in the late group and we also believe that our recent dedicated multidisciplinary approach may have increased the sensitivity of TIA diagnosis.

End-stage heart failure patients in need of a VAD are likely to be critically ill when compared with typical cardiac surgical patients. In addition, these patients have become increasingly high-risk [6]. A commitment to provide the highest quality of care requires a dedicated team focused on the issues that are unique to this patient population. Especially, ongoing communication and co-operation between the cardiac surgeons and heart failure cardiologists taking care of these patients is vital to this effort. Since our recent VAD team was created, cardiologists have asked surgeons to see potential VAD candidates early and had ongoing discussions regarding timing of VAD placement; surgeons have had cardiologists see high-risk cardiac surgical patients (that might need VADs) preoperatively, so the team was already on board if indeed a VAD was required. The contribution of nurses, LVAD coordinators, rehabilitation specialists and nutrition experts are also indispensable. Social workers play an important role in supporting the patient and family. We have found that a weekly meeting attended by the multidisciplinary VAD team facilitates the formulation of a unified treatment plan for patients being supported with VADs, as well as patients under consideration for VAD implantation. By creating a multidisciplinary team, we would argue that we are implanting devices before patients develop profound and/or irreversible multiple systemic organ failure. This institutional multidisciplinary approach is thought to have played an important role in the recent improvements in our outcomes.

Limitations of this study include those related to a retrospectively performed analysis. Clinical data were obtained by chart review, which has inherent limitations, such as access to and accuracy of the recorded data. Additionally, as a retrospective observational study, it is subject to selection bias and incomplete data collection. Finally, extrapolation of the results regarding improved success in post-VAD survival and the incidence of complications is limited because of inter-institutional variability in clinical practice, especially device selection.

In conclusion, the successful use of VADs and remarkable technological advances has led to the increased use of VADs for patients who were once thought to be unsuitable for device insertion. To support and care for these complicated patients, a wide range of areas of expertise and support services are required. In reviewing our institutional experience, outcomes have improved dramatically in recent VAD patients, despite the increasing high risk of the patient population. Recent improvements in our outcomes likely occurred as a result of many major advances in device design, patient selection, and perioperative management, as well as the multidisciplinary approach. Our experience indicates
that an institutional comprehensive patient care program is an important approach to successfully supporting patients with heart failure in need of circulatory support.

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References


