mechanical system. The transition from in vitro to in vivo testing normally reveals unanticipated design problems that require some modification. For example, because the HeartPak’s alarm system is much more sophisticated than that of the HeartMate 1000, it caused a number of false alarms. Subsequent refinement of this feature has resulted in a very reliable alarm system. In response to this phase-I study, the HeartPak was redesigned to address the technical problems encountered. Since that time, the device’s reliability has been excellent. User confidence is higher than ever, and the device appears ready for phase-II studies.

The one case of complete console failure showed that patients and their families can appropriately respond to potentially serious situations involving the HeartPak. It also showed that the device’s emergency back-up system is adequate and is easily used by the average person.

In the current effort to reduce healthcare costs, a primary goal is to shorten the length of hospitalization. This goal, along with prolongation of the waiting times for heart transplantation, has spurred efforts to discharge VAS supported patients from the hospital. These patients are much less costly to maintain in the hospital than in the hospital. In addition, the patients’ quality of life is enhanced in the home environment with their family, and even return to their usual employment. Those who have returned to their jobs have had a profound improvement in emotional well-being, because they have again become contributors to society. With respect to cost, the difference between a hospitalized heart failure patient and a working, VAS-supported patient is extreme. By changing consumers of healthcare resources into contributors to society, mechanical circulatory support technology will become increasingly more affordable.11

There results confirmed that, when used with the HeartPak driver, the HeartMate IP-LVAS can safely support the cardiac output for extended periods, without a need for continuous monitoring by medical personnel. Emergency measures can be carried out by patients and their family members. Moreover, device malfunction does not necessarily lead to injury or death. In short, use of the HeartPak enhances patient mobility while sustaining the patient’s life until a suitable donor heart can be found.

References


Assessment of Timing Right Ventricular Assist Device Withdrawal Using Left Ventricular Assist Device Filling Characteristics

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Right ventricular assist devices (RVAD) are often needed on a short term basis in patients who develop RV failure after left ventricular assist device (LVAD) implantation. The purpose of this study was to use LVAD filling characteristics to help determine the timing for weaning a patient from RVAD support. Eleven patients (age 50 years ± 15) supported with an LVAD (Novacor) and an RVAD (Biomedicus or ABIOMED) were studied. Eight patients (RV recovery group) were studied before RVAD removal and all were successfully weaned from RVAD support. Five patients (RV failure group) were studied at the time of RVAD placement to determine baseline characteristics of RV failure. Simultaneous measures of LVAD volume and routine hemodynamics were recorded during peri-

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The mechanical left ventricular assist device (LVAD) may be a lifesaving therapy for patients with end-stage cardiomyopathy who await cardiac transplantation and in patients with cardiogenic shock after cardiac surgery. Right ventricular (RV) failure develops in about 20–30% of patients supported with an LVAD. This dysfunction may result from increased output to the right side or from abnormal ventricular septal shifts and ventricular interdependence. When this failure is unresponsive to pharmacologic treatment, a mechanical right ventricular assistance device (RVAD) may be needed on a short term basis for circulatory support. It is essential to be able to determine when the right side of the patient’s heart has recovered enough so that the RVAD can be removed. If weaning can be predicted accurately, the RVAD can be removed as soon as possible, which decreases the chances for complications such as thrombosis or infection to occur. Hemodynamics and echocardiography may provide useful information, but are often not sufficient.

The purpose of this study is to investigate LVAD filling characteristics of the Novacor LVAD (Baxter HealthCare Corporation, Oakland CA) as a means to provide additional information to the clinician to help determine whether a patient can be successfully weaned from an RVAD.

Materials and Methods

As a bridge to transplantation, 61 patients with end-stage heart failure received a Novacor LVAD between July 1, 1987 and April 27, 1997, at the University of Pittsburgh Medical Center. Seventeen (28%) of these patients developed RV failure after implantation of the LVAD, which required insertion of an RVAD. This study was carried out on a subset of 11 of these patients (age 50 ± 15 years). The study was approved by the institutional review board of the University of Pittsburgh, and written informed consent was obtained from all patients. Five patients had idiopathic dilated cardiomyopathy and six pa-

![Figure 1. Physiologic waveform data acquired during 4 sec at both high RVAD flow (left panel) and low RVAD flow (right panel) from a patient from the RV failure group.](image1)

![Figure 2. Physiologic waveform data acquired during 4 sec at both high RVAD flow (left panel) and low RVAD flow (right panel) from a patient from the RV recovery group.](image2)
Table 1. Hemodynamics and LVAD Filling Characteristics for the Two Groups

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<th>Patient Number</th>
<th>PR (bpm)</th>
<th>SAP (mmHg)</th>
<th>CVP (mmHg)</th>
<th>LVAD SV (ml)</th>
<th>Output (L/min)</th>
<th>MFR (ml/beat)</th>
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*p < 0.01 versus high RVAD flow. CVP, central venous pressure; High, high RVAD flow; Low, low RVAD flow; MFR, mean filling rate; PR, heart rate; SAP, systolic arterial pressure; SV, stroke volume.

Patients had ischemic cardiomyopathy. The average duration of RVAD support in these patients was 4.3 ± 2.2 days.

Instrumentation

A rapid-response thermodilution pulmonary artery catheter (Edwards Scientific, Santa Ana, CA) was inserted before induction. Fluid-filled femoral arterial catheters (Baxter Summit, Irvine CA) were also used. All patients had a Novacor LVAD implanted initially, and most developed right ventricular failure post LVAD implantation, which required the implantation of an RVAD. The first six patients in the study group received a BioMedicus centrifugal pump (BioMedicus Inc, Eden Prairie, MN) and five patients received the ABIOMED BVS-5000 (ABIOMED Inc, Danvers, MA), which is a two chambered extracorporeal pulsatile assist device. The RVAD was cannulated from the right atrium to the pulmonary artery in all patients.

The Novacor LVAD was operating in the fill rate trigger mode. In this mode, the LVAD synchronizes to the LV by responding to changes in the pump fill rate. The rate at which the LVAD fills varies in response to native heart systole. The filling rate rises at the start of systole, and falls near the end of systole. By detecting this drop in fill rate, pump ejection can be triggered by adjusting the percentage at which the fill rate must fall (from peak fill rate) before pump ejection is triggered.

Data Acquisition and Analysis

Thirteen studies were performed on the 11 patients. Five patients were studied at the time of RVAD insertion (RV failure group), and 8 patients were studied before RVAD removal and were successfully weaned from RVAD support (RV recovery group). Two patients were studied at both time points. Simultaneous electrocardiogram, arterial pressure, pulmonary arterial pressure, central venous pressure, and LVAD volume were digitized and recorded on a computer workstation (Apollo Computer Inc., Model A1421, Hewlett Packard, Chelmsford, MA) during 15 sec intervals at both high RVAD flow (4–5 L/min) and after decreasing to a low RVAD flow (0–1 L/min) for each of the 13 studies. Physiologic waveform data acquired during both the high RVAD flow and low RVAD flow from a patient from the RV failure group is shown in Figure 1. Physiologic waveform data acquired during both high and low RVAD flow from a patient from the RV recovery group is shown in Figure 2.

Data were separated into cardiac cycles by using the R wave of the electrocardiogram. Cycles with ectopic beats were eliminated from subsequent analysis. The following clinical parameters were measured for each cardiac cycle: pump rate (PR), systolic arterial pressure (SAP), and central venous pressure (CVP). The following measurements were obtained from the Novacor LVAD: stroke volume (SV) and pump output (SV * PR). The first derivative of the LVAD volume signal was calculated by using a central difference method, and was used as the flow rate of the LVAD. From this, the average filling rate of the LVAD was calculated. The filling profile was divided into two filling phases for each pump cycle. The initial filling phase was taken from the onset of native heart systole and continued until the end of native heart systole. This filling phase occurred during RV systole. The final phase filling was taken as the filling that occurred during late RV diastole. Although the exact mechanism for this final phase filling is unknown, it may be caused by the leftward shift of the interventricular septum during RV diastole, which may result in some passive filling of the LVAD. The mean filling rate (MFR) that occurred during each phase was then calculated. The parameters for each cardiac cycle were then averaged over 15 sec.
intervals at both high and low RVAD flow. To account for the changes in pump rate that occurred between the two groups, the mean LVAD filling rates were corrected by dividing by the pump rate (MFR-C).

Statistical Analysis

An ANOVA for repeated measures between groups was used to determine the differences between hemodynamics and LVAD filling parameters.

Results

Group mean hemodynamics and LVAD parameters for both groups at both RVAD flows are shown in Table 1. The RV failure group had significantly lower pump rates than the RV recovery group. In both groups, there was a significant decrease in pump rate with decreasing RVAD flow. As RVAD flow decreased, there was a significant decrease in systolic arterial pressure and increase in CVP for the RV failure group, whereas in the RV recovery group, these parameters did not change significantly. As RVAD flow decreased, there was a significant decrease in pump outputs in both groups; however, the magnitude of decrease in pump output was much higher in the RV failure group (38% vs. 12%, \( p < 0.001 \)). The mean filling rate did not change in group I, but significantly decreased in group II (\( p < 0.001 \)). This is depicted graphically in Figure 3. The LVAD mean filling rates for the two patients who were studied serially are shown in Figure 4.

Discussion

Ventricular assist devices, although lifesaving for some patients, may be associated with significant complications with prolonged use. The need exists, therefore, to predict a patient’s ability to be successfully weaned from the assist device that was inserted for potentially reversible disease processes. The LVAD filling characteristics described in this study provide unique parameters that might potentially be used, along with standard hemodynamic measures, to determine the timing of RVAD removal.

We have previously shown that several RV ejection phase indices are closely coupled to LVAD filling.\(^\text{19}\) The LVAD filling was shown to be closely coupled with RV ejection phase indices of RV peak ejection rate and RV stroke work on a beat-to-beat basis. These data support the importance of RV function for proper LVAD filling in patients receiving mechanical circulatory assistance. Because of this close coupling between RV ejection and LVAD filling characteristics, no change in these LVAD filling rates with decreasing RVAD flow might suggest that adequate improvement in RV function has been achieved to allow possible weaning from RVAD. LVAD filling characteristics, therefore, may be used to help determine when weaning from RVAD is possible.

Numerous investigators have attempted to establish criteria to predict the timing for removal of ventricular assistance. Hemodynamics and transesophageal echocardiography can provide information for timing the successful withdrawal of VAD support. Barzilai et al.\(^\text{18}\) used transesophageal echocardiography in 16 patients supported with mechanical assist devices. Changes in ventricular function were made by using semiquantitative wall motion analysis. The wall motion scores improved in the patients who were successfully weaned from ventricular assistance, and did not in patients who remained dependent upon the devices. Termuhlen et al.\(^\text{17}\) used hemodynamic parameters during “on/off” trials to assess recovery in 26 patients supported with Pierce-Donachy VADs. According to these investigators, the most significant predictors of successful weaning were increases in mixed venous oxygen saturation, cardiac index, mean arterial pressure, and ventricular ejection fraction, and decreases in atrial pressures.

Our group recently used online RV pressure—area relationships obtained from a high fidelity catheter and transesophageal echocardiographic automated border detection to assess RV function in a patient with biventricular support during an RVAD weaning protocol.\(^\text{16}\) We demonstrated that increases in RV stroke work, stroke area, and fractional area change with decreasing RVAD flow correlated with successful RVAD removal in a study on one patient.

An obvious limitation of this study is the small number of patients who had serial studies. However, the ease of data acquisition and analysis demonstrated by this quantitative method may potentially be applied to patients in the intensive care unit. The LVAD filling rates can be continually monitored,
as are standard hemodynamics because the volume signal of the Novacor is readily available. In addition, no further instrumentation was needed, such as high fidelity catheters or transesophageal echocardiography. This method could potentially be useful in predicting the proper timing for removal of LVAD following LVAD implantation.

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References


