

Predictors of Severe Right Ventricular Failure After Implantable Left Ventricular Assist Device Insertion: Analysis of 245 Patients

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Background—Insertion of an implantable left ventricular assist device (LVAD) complicated by early right ventricular (RV) failure has a poor prognosis and is largely unpredictable. Prediction of RV failure after LVAD placement would lead to more precise patient selection and optimal device selection.

Methods and Results—We reviewed data from 245 patients (mean age, 54 ± 11 years; 85% male) with 189 HeartMate (77%) and 56 Novacor (23%) LVADs. Ischemic cardiomyopathy predominated (65%), and 29% had dilated cardiomyopathy. Overall, RV assist device (RVAD) support was required after LVAD insertion for 23 patients (9%). We compared clinical and hemodynamic parameters before LVAD insertion between RVAD ($n=23$) and No-RVAD patients ($n=222$) to determine preoperative risk factors for severe RV failure. By univariate analysis, female gender, small body surface area, nonischemic etiology, preoperative mechanical ventilation, circulatory support before LVAD insertion, low mean and diastolic pulmonary artery pressures (PAPs), low RV stroke work (RVSW), and low RVSW index (RVSWI) were significantly associated with RVAD use. Elevated PAP and pulmonary vascular resistance were not risk factors. Risk factors by multivariable logistic regression were preoperative circulatory support (odds ratio [OR], 5.3), female gender (OR, 4.5), and nonischemic etiology (OR, 3.3).

Conclusions—The need for circulatory support, female gender, and nonischemic etiology were the most significant predictors for RVAD use after LVAD insertion. Regarding hemodynamics, low PAP and low RVSWI, reflecting low RV contractility, were important parameters. This information may lead to better patient selection for isolated LVAD implantation. (*Circulation*. 2002;106[suppl I]:I-198-I-202.)

Key Words: cardiomyopathy ■ heart-assist device ■ heart failure ■ surgery

The use of implantable left ventricular assist devices (LVADs) as a bridge to heart transplant has become more common but is still sometimes complicated by early perioperative right ventricular (RV) failure, which leads to poor filling of the LVAD, and thus, low pump output. Severe RV failure sometimes necessitates placement of right ventricular assist devices (RVADs) as well; this is the last resort of treatment to sustain LVAD output. Recently, with improved perioperative management and advanced clinical experience, the incidence for requirement of RVAD placement after LVAD insertion has been decreasing.¹⁻³ However, once such severe RV failure occurs, mortality is still quite high.⁴⁻⁸ Even when the RVAD is not required, patients with severe RV failure may require prolonged inotropes, which interferes with their physical rehabilitation, and persistent elevation of the central venous pressure may lead to liver dysfunction and

poor resolution of impeding multiple organ failure. Therefore, prediction of potential RV failure after LVAD replacement is essential for optimal device selection and improved clinical outcome.

Furthermore, with the advent of new circulatory support technologies, such as the artificial heart, prediction of severe RV failure after LVAD insertion is a real clinical problem rather than just a theoretical problem. For implantable LVAD as destination therapy,⁹ it is important to avoid implanting it in a small but meaningful patient population with a risk for significant RV failure. The new implantable rotary blood pumps¹⁰⁻¹² might allow patients to be discharged earlier with the devices if they do not have RV failure. Similarly, a total artificial heart (TAH) might offer the possibility for improved rehabilitation and earlier hospital discharge for patients with biventricular failure.¹³ For the increasing number of patients

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who will receive mechanical circulatory support in the next several years, the surgeon must decide whether to use univentricular or biventricular support if these devices are to be applied successfully. Accordingly, we tried to identify preoperative risk factors for severe RV failure after implantable LVAD by retrospective analysis of data from 245 patients who had received either the HeartMate (Thoratec Laboratories Corp., Pleasanton, CA) or the Novacor (World Heart Corp., Ottawa, ON, Canada) LVAD at the Cleveland Clinic Foundation.

Methods

Devices

The implantable HeartMate LVAD (either the pneumatic air-driven system [1000 IP] or the vented-electric system [VE]) or the Novacor N100 wearable left ventricular assist system was implanted. Patient selection criteria, description of the device, implantation technique, management, and indications for transplantation were published previously.¹⁴ In December 1991 we started to use the HeartMate 1000 IP. In 1993 we began to use the HeartMate VE as well. In 1995 we made a transition from pneumatic implants to VE implants of HeartMate exclusively. From December 1996 to November 1998, we also implanted the Novacor N100 wearable left ventricular assist system.

Patients

From December 1991 to January 2001, 245 patients underwent an initial insertion of an LVAD (64 HeartMate 1000 IP [26%], 125 HeartMate VE [51%], and 56 Novacor N100 [23%]) at the Cleveland Clinic Foundation. We did not include any patients who had undergone device exchange. The LVAD was used as a bridge to heart transplant in 239 patients, as a bridge to recovery in 2 patients, and as a permanent device in 4 patients. There were 208 males (85%) and 37 females (15%), age range from 14 to 74 years (mean, 54 ± 11 years). Indications for LVAD insertion were end-stage heart failure resulting from ischemic cardiomyopathy (65%, 160 patients), dilated cardiomyopathy (29%, 70 patients), myocarditis (2%, 6 patients), valvular disease (3%, 7 patients), idiopathic hypertrophic cardiomyopathy (1 patient), and congenitally corrected transposition (1 patient). We did not exclude any patients from LVAD implantation due to high pulmonary arterial pressure (PAP) or high pulmonary vascular resistance (PVR). Many patients (49%) had previously undergone cardiac surgery. The intra-aortic balloon pump (IABP) was present before the operation in 80%, heparin-coated extracorporeal membrane oxygenation (ECMO) in 19%, and 5 patients had been supported with the Abiomed BVS 5000 (Abiomed, Inc., Danvers, MA) left ventricular (3 patients) or biventricular (2 patients) assist device. Most patients (59%) had been supported with ventilators because of pulmonary edema and recent cardiac arrest. The mean cardiac index was 1.9 ± 0.5 L/min/m² at the time of LVAD insertion.

To determine the preoperative risk factors for RV failure during LVAD support, we compared the group who required additional RVAD support after LVAD insertion (23 patients, RVAD group) to the remaining 222 patients who did not require an RVAD (No-RVAD group). We placed the RVAD because of low LVAD pump flow index (less than 2.0 L/min/m²) even with maximal inotropic support and volume loading. In 2 patients, recurrent ventricular tachyarrhythmia was associated with RV dysfunction and low pump flow. In 1 patient, the LVAD was removed due to infection and replaced with biventricular Abiomed BVS 5000.

Patient demographic information and clinical status were determined before LVAD implantation. We evaluated preoperative laboratory tests for liver and renal function and the incidence of postoperative bleeding. We also evaluated hemodynamics with patients anesthetized for LVAD insertion. A detailed description of hemodynamic measurement was published from our institution previously.⁸ Briefly, using a rapid-response thermistor pulmonary

artery catheter (Swan-Ganz catheter, Baxter Healthcare Corp, Irvine, CA), we measured the right atrial pressure (RAP), systolic, mean, and diastolic PAPs, cardiac output (CO), and cardiac index. The left atrial pressure (LAP) was measured by a fluid-filled catheter inserted into the left atrium. The PVR was calculated by dividing the pressure difference between mean PAP and LAP by the CO. We also calculated the pulmonary vascular resistance index (PVRI). Right ventricular stroke work (RVSW) and RVSW index (RVSWI) were calculated by the following equation:

$$\text{RVSW} = (\text{meanPAP} - \text{meanRAP}) \times \text{SV}$$

$$\text{RVSWI} = (\text{meanPAP} - \text{meanRAP}) \times \text{SVI}$$

where stroke volume (SV) and stroke volume index (SVI) were calculated by the CO and cardiac index divided by heart rate, respectively. In most patients with a circulatory assist device (ECMO or Abiomed) before LVAD implant, we could not measure the actual values of RAP, PAP, SV, or SVI, because the RV had already been unloaded with ECMO. However, in some patients who were supported with ECMO before LVAD, we were able to capture these parameters before ECMO insertion, and therefore calculated RVSW and RVSWI.

Statistical Analysis

Results are reported as percentages or means \pm SD, as appropriate. For all of the continuous variables, the comparisons between the groups were performed either by Mann-Whitney or unpaired Student's *t* test according to the distribution of each variable. Categorical variables were compared by Chi-square or Fisher's exact test. The variables that were significant by univariate analysis were used as potential risk factors for the multivariable model; the contribution of those factors between the groups was estimated by stepwise selection in logistic regression; when 2 factors were highly correlated, only 1 was chosen for final model selection. Because of the large portion of missing value more than 25%, the RVSW and RVSWI were excluded from the multivariable logistic regression. The 4 categorical factors (gender, etiology [ischemic or nonischemic], mechanical ventilation, and circulatory support) and only 2 continuous factors (body surface area [BSA] and mean PAP) entered into the multivariable logistic regression analysis. The significant level in this study was 0.05; all statistical analyses were performed using SAS 8.0 (SAS Institute, Inc., Cary, NC).

Results

RVAD support was required after LVAD insertion for 23 patients (9%). RVAD was required in 13% of HeartMate 1000 IP patients, 4% of Novacor patients, and 10% of HeartMate VE patients ($P = \text{NS}$). Eighteen out of 23 patients received RVADs in the OR just after LVAD implant or on the same day of LVAD implant. Four patients received RVADs on postoperative day (POD) 1 after LVAD implant, POD 2, POD 5, or POD 7. One patient was switched to biventricular Abiomed BVS 5000 more than 4 months after HeartMate implant.

Table 1 shows the patients' preoperative characteristics and laboratory data in each group. Age did not differ between the 2 groups. RVAD use was more common for small BSA ($P = 0.012$) and female gender ($P = 0.003$). When we dichotomized the etiology into ischemic cardiomyopathy or nonischemic (dilated cardiomyopathy, myocarditis, valvular disease, idiopathic hypertrophic cardiomyopathy, and congenital heart disease), a lower proportion of patients in the RVAD group (43%) were categorized with ischemic cardiomyopathy compared with that of the No-RVAD group (68%) ($P = 0.021$). The need for mechanical ventilation ($P = 0.015$) and circulatory support (ECMO or Abiomed BVS 5000

TABLE 1. Patient Characteristics and Laboratory Data

Variables	RVAD (n=23)	No-RVAD (n=222)	P-value univariate
Age (years)	52.0±12.7	54.5±10.5	0.485*
BSA (m ²)	1.85±0.20	1.96±0.21	0.012*
Female (%)	39	13	0.003†
Ischemic cardiomyopathy (%)	43	68	0.021†
Preoperative mechanical ventilation (%)	83	56	0.015‡
Preoperative circulatory support (%)	48	18	0.003†
Preoperative IABP (%)	91	78	0.180†
Total bilirubin (mg/dL)	3.3±3.7	2.2±2.1	0.136*
AST (U/L)	398±1109	142±248	0.137*
BUN (mg/dL)	40±24	41±24	0.819*
Creatinine (mg/dL)	1.9±1.1	1.9±1.7	0.725*

RVAD indicates right ventricular assist device; BSA, body surface area; IABP, intraaortic balloon pump; AST, aspartate aminotransferase; BUN, blood urea nitrogen.

Data are shown as the means±SD or percentage (%).

*P-value from Mann-Whitney test; †P-value from Fisher's exact test; ‡P-value from Chi-square test.

support) ($P=0.003$) before LVAD insertion were more common in the RVAD group. The need for a preoperative IABP was not a risk factor for RVAD use. Among the laboratory tests for liver and renal function, total bilirubin and aspartate aminotransferase (AST) values were higher in the RVAD group, but did not reach statistical significance by the Mann-Whitney test. There was a higher incidence of mechanical ventilation (98% versus 48%, $P<0.001$), IABP (90% versus 77%, $P=0.033$), higher values of total bilirubin (3.6 ± 3.7 mg/dL versus 1.9 ± 1.5 mg/dL, $P=0.002$) and AST (384 ± 808 U/L versus 106 ± 169 U/L, $P=0.02$) in 52 patients who required circulatory support before LVAD as compared with the rest of the 193 patients who had not had circulatory support.

Table 2 summarizes hemodynamic data for the 2 groups. Among these preoperative hemodynamic variables, the mean PAP, diastolic PAP, RVSW, and RVSWI in the RVAD group were significantly lower than those in the No-RVAD group. There were no differences in the cardiac index, LAP, RAP, systolic PAP, heart rate, PVR, or PVRI.

Factors that were univariately significant were tested in a multivariable logistic model, except for the RVSW and RVSWI that had a large portion of missing value. The best predictors for RVAD use after LVAD implantation were found to be the need for preoperative circulatory support, female gender, and nonischemic etiology, as shown in Table 3.

The incidence of re sternotomy for bleeding was more prevalent in the RVAD group (13 of 23 patients, 57%) than in the No-RVAD group (59 of 222 patients, 27%), ($P=0.003$). Survival to transplantation was better in the No-RVAD group (164 of 222 patients, 74%) than that in the RVAD group (4 of 23 patients, 17%), ($P<0.001$). There was a difference in mean duration of LVAD support between the No-RVAD and the RVAD group (94 versus 27 days, $P=0.002$).

The rates of RVAD implant in 1991 to 1995 and 1996 to 2000 were 13% (9 out of 69 patients) and 8% (14 out of 174 patients), respectively. The survival to transplantation in

RVAD patients in 1991 to 1995 and 1996 to 2000 were 22% (2 out of 9 patients) and 14% (2 out of 14 patients), respectively. There were no significant differences in the RVAD implant rates or survival to transplantation between 1991 to 1995 and 1996 to 2000.

Discussion

Implantable LVADs have been successfully used for the treatment of end-stage heart failure, primarily as a bridge to heart transplant.¹⁴ With a portable electric LVAD, permanent use as an alternative to heart transplant has become a realistic ultimate goal of LVAD use.¹⁵ We conducted this retrospective study to identify the best predictors for severe RV failure after implantable LVAD support and to improve patient selection for isolated LVAD implantation. By univariate analysis, female gender, small BSA, nonischemic etiology, preoperative mechanical ventilation, circulatory support before LVAD insertion, low mean and diastolic PAPs, low RVSW, and low RVSWI were significantly associated with RVAD use. Risk factors by multivariable logistic regression were preoperative circulatory support, female gender, and nonischemic etiology.

We have previously reported preoperative risk factors for RV failure after LVAD insertion by analysis of data from 100 patients who received the HeartMate LVAD.⁸ In that small number of patients, the risk factors identified by univariate analysis were female gender, age, BSA, myocarditis, AST level, CO, mean PAP, and RVSWI. The need for preoperative circulatory support was not a risk factor for RVAD use. Multivariable analysis was not performed due to small sample size, especially in the RVAD group ($n=11$). Compared with the results in that report, there are several differences in this study that has a larger sample size of 245 patients. Preoperative circulatory support using ECMO or Abiomed BVS 5000 before LVAD insertion was the most significant predictor for RVAD use in this multivariable logistic regression analysis. Pagani et al¹⁶ reported that there

TABLE 2. Preoperative Hemodynamic Variables

Variables	RVAD (n=23)	No-RVAD (n=222)	P-value univariate
Cardiac output (L/min)	3.4±0.8 (n=17)	3.8±1.2 (n=189)	0.205*
Cardiac index (L/min/m ²)	1.8±0.4 (n=17)	1.9±0.6 (n=189)	0.621*
LAP (mm Hg)	23±5 (n=9)	24±8 (n=125)	0.713†
RAP (mm Hg)	20±7 (n=17)	19±7 (n=188)	0.354*
Systolic PAP (mm Hg)	47±11 (n=17)	53±13 (n=194)	0.118*
Mean PAP (mm Hg)	33±7 (n=17)	37±9 (n=194)	0.041†
Diastolic PAP (mm Hg)	25±7 (n=17)	29±8 (n=194)	0.030*
Heart rate (bpm)	104±18 (n=16)	98±20 (n=178)	0.186*
PVR (dynes · sec · cm ⁻⁵)	271±194 (n=8)	317±200 (n=117)	0.379*
PVRI (dynes · sec · cm ⁻⁵ /m ²)	467±325 (n=8)	614±379 (n=117)	0.230*
RVSW (mm Hg · mL)	543±392 (n=14)	780±437 (n=166)	0.037*
RVSWI (mm Hg · mL/m ²)	285±196 (n=14)	400±221 (n=166)	0.046*

RVAD indicates right ventricular assist device; LAP, left atrial pressure; RAP, right atrial pressure; PAP, pulmonary artery pressure; PVR, pulmonary vascular resistance; PVRI, PVR index; RVSW, right ventricular stroke work; RVSWI, RVSW index.

Data are shown as the means ± SD.

*P-value from Mann-Whitney test; †P-value from unpaired Student *t* test.

was a higher incidence of RV failure after LVAD implantation in patients initially supported with ECMO before LVAD than in patients treated first with LVAD. The authors suggested that this increased incidence could be attributed to a lung injury exacerbated by ECMO or may reflect the overall increased severity of illness and initial degree of hemodynamic instability. The fact that preoperative circulatory support was the most significant factor for RVAD use after LVAD insertion in our study might suggest that patients who are more severely ill in the preoperative period are more likely to require biventricular support. This finding agrees with that of the Pittsburgh group⁵ and the Thoratec experience.¹⁷

TABLE 3. Results of Multivariable Logistic Regression

Factors	Odds Ratio	95% CI	P-value
Preoperative circulatory support	5.3	2.0–14.0	0.001
Female gender	4.5	1.7–12.4	0.003
Nonischemic etiology	3.3	1.3–8.4	0.015

CI indicates confidence interval.

Female gender was also a significant predictor for RVAD use by multivariable logistic regression analysis. BSA was a significant predictor for RVAD by univariate analysis, and there was a significant difference in the BSA between the male and female patients (male: 1.98±0.20 versus female: 1.78±0.16, *P*<0.001). BSA was, however, not a significant factor in the logistic model after adjusting for gender. One female patient with postpartum dilated cardiomyopathy, a specific disease for female, was included in the RVAD group.

Interestingly, patients with an etiology of ischemic cardiomyopathy were less likely to be at risk for severe RV failure after LVAD than patients with nonischemic etiology, suggesting a diseased function of both LV and RV in nonischemic etiology. Of note, Farrar et al¹⁷ reported in their Thoratec experience that a higher proportion of patients receiving an isolated LVAD (54%) had coronary artery disease rather than dilated cardiomyopathy (37%), whereas a higher proportion of the biventricular assistance group appeared to have dilated cardiomyopathy (46%) rather than coronary artery disease (40%). Iskandrian et al¹⁸ reported that RV ejection fraction (EF) was higher and the RV end-diastolic volume/LV end-diastolic volume ratio by multigated radionuclide angiography was lower in 69 patients with ischemic cardiomyopathy than in 21 patients with primary cardiomyopathy, suggesting a preserved RV performance in ischemic cardiomyopathy.

Pulmonary hypertension with elevated PVR has been considered to be a contraindication for LVAD use because of the high risk for RV failure after LVAD insertion.¹⁹ In this study, however, elevated PAP and PVR were not risk factors; in fact low PAP and low RVSWI were significant risk factors by univariate analysis. These findings agree with the results from the Columbia group²⁰ and suggest that in the RVAD group, RV contractility before LVAD insertion was not strong enough to elevate PAP in the presence of high PVR.

We have evolved several strategies to optimize perioperative RV function.²¹ First, we avoid bleeding, which was very common in patients with RV dysfunction. We replace vitamin K (10 mg) the day before the surgery, the morning of the surgery, and for 3 days after the surgery. Also, intraoperative aprotinin and fresh frozen plasma are given to reduce bleeding. No anticoagulants are given for the first 24 hours postoperatively. Second, we are careful not to overfill the RV, especially when transitioning from cardiopulmonary bypass to LVAD support. Third, we decrease RV afterload by dropping left atrial and pulmonary artery pressures with PDE inhibitor, such as milrinone. After LVAD implant, we frequently use milrinone (0.2–0.7 μg/kg/min) with epinephrine to increase RV contractility. We use inhalation of nitric oxide only rarely usually because we don't need it but also it is expensive. Among 245 patients, it was administered in 5 patients. All of these 5 patients were in the No-RVAD group.

There are several limitations in this study. There were only 23 patients who received RVAD, which limits the power to detect associations. This study looked at the most severe RV failure, needing an RVAD, and was not designed to investigate milder but clinically limiting RV dysfunction, ie, prolonged inotropes, elevated central venous pressure, and liver congestion.²¹ Secondly, because of the nature of this retrospective study and the urgent situation at the time of LVAD

implantation, hemodynamic variables, such as RVSW and RVSWI, could not be obtained in more than 25% of the patients. Thirdly, PAP and RVSWI are load-dependent parameters. We need a more sophisticated approach to assess relatively load-independent systolic parameters as well as diastolic RV function using transthoracic²² or transesophageal echocardiography²³ at the patient bedside. Kubota et al²⁴ reported the RV diastolic parameters such as peak filling rate by blood pool scintigraphy were more sensitive indicators for evaluation for RV function in dilated cardiomyopathy.

In conclusion, 3 clinical parameters—the need for circulatory support, female gender, and the non-ischemic etiology—were the most significant predictors for RVAD use after LVAD insertion. Regarding hemodynamic parameters, low PAP and low RVSWI, reflecting the preoperative low RV contractility, were also important parameters. With a combination of patient clinical status and more sophisticated RV systolic and diastolic functional parameters, we might be able to stratify the preimplant overall severity of illness. Patients with risk factors for RV dysfunction might be best treated with biventricular assist devices or a TAH. Patients without risk factors for RV dysfunction would be suitable candidates for long-term use of an LVAD, either as a bridge to recovery or a destination therapy.

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