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A Risk Score Derived from Preoperative Data Analysis Predicts the Need for Biventricular Mechanical Circulatory Support

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Abstract

Background—Right ventricular (RV) failure after left ventricular assist device (LVAD) placement is a serious complication and is difficult to predict. In the era of destination therapy and the total artificial heart, predicting post-LVAD RV failure requiring mechanical support is extremely important.

Methods—We reviewed patient characteristics, laboratory values, and hemodynamic data from 266 patients who underwent LVAD placement at the University of Pennsylvania from April 1995 to June 2007.

Results—Of 266 LVAD recipients, 99 required RV assist device (BiVAD) placement (37%). We compared 36 parameters between LVAD (n=167) and BiVAD patients (n=99) to determine preoperative risk factors for RV assist device (RVAD) need. By univariate analysis, 23 variables showed statistically significant differences between the two groups ($P \leq 0.05$). By multivariate logistic regression, cardiac index ≤ 2.2 L/min·m^2 (odds ratio [OR] 5.7), RV stroke work index ≤ 0.25 mmHg·mL/m^2 (OR 5.1), severe preoperative RV dysfunction (OR 5.0), preoperative creatinine ≥ 1.9 mg/dL (OR 4.8), previous cardiac surgery (OR 4.5), and systolic blood pressure ≤ 96 mmHg (OR 2.9) were the best predictors of RVAD need.

Conclusions—The most significant predictors for RVAD need were cardiac index, RV stroke work index, severe preoperative RV dysfunction, creatinine, previous cardiac surgery, and systolic blood pressure. Using these, we constructed an algorithm which can predict which LVAD patients will require RVAD with greater than 80% sensitivity and specificity.

Background

Left ventricular assist device (LVAD) support is well-established as a bridge to heart transplantation or an alternative to transplantation.[1-10] Despite increasing experience, right ventricular (RV) failure occurs in 20-30% of LVAD recipients.[1,11-15] It is difficult to predict which patients will develop RV failure after LVAD implantation, and those who do have a poor prognosis.[16-20]

Currently, implantable VADs are only utilized to support the LV. Consequently, outpatient and destination therapy are only available to patients tolerating isolated LVAD support.

Additionally, increased morbidity and mortality among patients who require biventricular assist devices (BiVAD) may preclude some patients from consideration for VAD therapy.[16,17] However, Tsukui demonstrated that pre-planned BiVAD implantation for morbid heart failure yields acceptable mortality and survival to transplantation,[21] and Klotz proved that RVAD implantation yields reverse structural and functional remodeling of the RV.[22] Optimal patient and device selection therefore depend on the ability to predict which patients will tolerate isolated LVAD support.

Despite the frequency and significance of RV failure in LVAD recipients, relatively few studies identify predictors of post-LVAD RV failure. More concerning is the lack of consensus among these.[16,19,20,23-26] For example, Dang reported that elevated central venous pressure (CVP) predicts post-LVAD RV failure, however no study corroborates this finding.[16] Similarly, Kormos identified pulmonary edema, fever without infection, and preoperative mental impairment as predictors of RVAD use, but no subsequent study provides confirmation.[20] In total, the literature identifies at least 25 different predictors of post-LVAD RV dysfunction, yet few are supported by multiple authors.[16,18-21, 23-26] Accordingly, we attempted to identify preoperative differences in demographic, clinical, hemodynamic, and laboratory parameters in 266 LVAD recipients in order to identify predictors of LVAD support failure. This represents the largest reported series of mechanical assist patients to address this question.

Hypothesis

We hypothesized that the need for biventricular mechanical support can be anticipated based on critical analysis of preoperative data. We further hypothesized that a risk score based on these data accurately predicts the need for univentricular or biventricular mechanical support.

Methods

Patients

All 266 patients who underwent LVAD implantation at the Hospital of the University of Pennsylvania from April 1995 to June 2007 were retrospectively reviewed. Of these, 99 (37%) required RVAD support. The remaining 167 (63%) received isolated LVAD support. These formed the study groups.

Devices

Multiple devices were used throughout the study period (Table 1, Table 2). These include the BioMedicus Perfusion System (Medtronic, Inc., Littleton, MA), TCI IP (Thermo Cardiosystems, Inc., Woburn, MA), TCI VE (Thermo Cardiosystems), HeartMate XVE (Thoratec Corp., Pleasonton, CA), Abiomed BVS-5000 (Abiomed, Inc., Danvers, MA), Thoratec PVAD (Thoratec), and HeartMate II (Thoratec). We did not differentiate between the TCI VE and the HeartMate XVE as they are essentially equivalent.

All patients and device types were included in the study. The wide range of devices and the varying characteristics of the study population make this analysis challenging, and may explain the paucity of studies on this topic. However, our patient population is representative of real world practice, and therefore allows the greatest potential applicability to clinical practice. Patients who received BiVADs as a preoperative intention-to-treat were included in the study. These patients are invaluable to this study because their preoperative characteristics, though undefined at the time of implantation, classified them as a population requiring biventricular support. It was the purpose of this study to define those characteristics.

The decision to implant an RVAD was made by the individual cardiac surgeon in consultation with the heart failure cardiologist, solely based on the clinical situation. There was no protocol which influenced the decision to place univentricular versus biventricular devices.

Data

The study protocol was approved by the institutional review board (IRB) of the University of Pennsylvania. Data were collected retrospectively. Following data accrual, identifying information was removed from the database and a unique code number was assigned.

Because the study was designed to identify patients who required biventricular support on the basis of *preoperative* status, the clinical, hemodynamic, and laboratory data collected were those recorded immediately prior to device implantation.

Preoperative RV dysfunction was graded as none, mild, moderate, or severe, as determined from the echocardiogram performed prior to LVAD insertion.

Preoperative mechanical circulatory support was defined as clinical requirement for extracorporeal membrane oxygenation (ECMO) or the BioMedicus System as a bridge to VAD placement. When the BioMedicus was used as the only support device (or as part of a combination), it was defined as a VAD.

Non-separation from cardiopulmonary bypass (CPB) was defined as the intraoperative need for VAD implantation to successfully separate from CPB.

Right ventricular stroke work index (RVSWI) was calculated by the equation:

$$\text{RVSWI} = (\text{mean} \quad \text{PAP} - \text{CVP}) \times \text{SVI}$$

where stroke volume index (SVI) was calculated by dividing cardiac index (CI) by heart rate (HR).

Statistical Analysis

Data were analyzed using SAS 9.1.3 (SAS Institute, Cary, NC). Categorical variables were compared with X^2 tests. Continuous variables were expressed as means ± standard deviation and were compared using unpaired student t-tests. The level of significance was $p \leq 0.05$. Significant variables by univariate analysis entered into the multivariate logistic regression model. Prior to entry into multivariate logistic regression, continuous variables were converted into dichotomous categorical variables. This was accomplished for each variable by serial X^2 testing with stepwise threshold progression to determine maximal divergence between LVAD and BiVAD groups. This established thresholds for each variable which identified high and low risk categories for LVAD support failure. Patients requiring preoperative mechanical circulatory support were excluded from analysis of hemodynamic parameters and multivariate analysis due to our inability to establish baseline hemodynamics. When there were a large number of missing values for a parameter, that variable was not included in multivariate analysis.

Results

Univariate Analysis

Table 3 shows demographics and patient characteristics. BiVAD support was required more commonly for female patients (P=0.0011) and those with smaller body surface area (BSA,

P=0.0029). Results of clinical factor comparison are shown in table 4. Severe pre-operative RV dysfunction, mechanical ventilation, previous cardiac surgery, use of an intra-aortic balloon pump (IABP), preoperative mechanical circulatory support, and non-separation from cardiopulmonary bypass, were all present in greater proportions in BiVAD patients.

Hemodynamic comparison is shown in table 5. Among hemodynamic variables, systolic blood pressure (SBP), diastolic blood pressure, mean arterial pressure, systolic pulmonary artery pressure (PAP), mean PAP, CI, SvO_2, and RVSWI were significantly lower in the BiVAD group. CVP was significantly higher in BiVAD patients.

Table 6 summarizes comparison of laboratory data. Values for white blood cell count, international normalized ratio (INR), creatinine, and total bilirubin were significantly higher in BiVAD patients. Platelet count and albumin were significantly lower in the BiVAD group.

Multivariate Logistic Regression

Variables with statistical significance by univariate analysis were tested in multivariate logistic regression. Independent predictors of LVAD support failure were: CI ≤ 2.2 L/min·m^2, RVSWI ≤ 0.25 mmHg·L/m^2, severe pre-VAD RV dysfunction, creatinine ≥ 1.9 mg/dL, previous cardiac surgery, and SBP ≤ 96 mmHg (Table 7).

Risk Score

Based on the odds ratios, a weighted coefficient was assigned to each of the six independent predictors to construct a risk score which predicts the success or failure of isolated LVAD support. For each variable, if a patient meets the “high risk” criterion (e.g. creatinine ≥ 1.9 mg/dL), they are assigned a score of one for that variable. Alternatively, if the patient meets the “low risk” criterion for a particular variable (e.g. creatinine < 1.9 mg/dL), they are assigned a score of zero. Those scores are then entered into the final risk score equation:

$$18\bullet(\text{CI}) + 18\bullet(\text{RVSWI}) + 17\bullet(\text{Creatinine}) + 16\bullet(\text{Previous Cardiac Surgery}) + 16\bullet(\text{RV Dysfunction}) + 13\bullet(\text{SBP})$$

with a maximum possible score of 98. Applying the risk score to our cohort, a threshold of 50 points (with a score < 50 predicting successful LVAD support, and a score ≥ 50 predicting need for BiVAD), achieves sensitivity and specificity of 83% and 80%, respectively.

Further analysis showed that 96% of patients with scores <30 underwent successfully LVAD support (50/52 scorable patients). Additionally, 89% of patients with scores ≥65 required BiVAD support (34/38 scorable patients).

Discussion

The most effective treatment for end stage heart failure is cardiac transplantation.[27,28] Discrepancy between the number of donors and those waiting for transplantation causes many potential recipients to die before transplantation, and yields lengthy waiting times for many who ultimately receive transplants. VADs have increased the duration that moribund heart failure patients can survive while waiting for transplants, and are also successfully used for long-term therapy.[1-10] Despite increasing experience with VADs, poorly anticipated RV failure occurs in a significant proportion of LVAD recipients. The literature does not yet support a consensus of which preoperative parameters can be utilized to optimally select patients for univentricular or biventricular support.

Multiple factors influence the decision to utilize univentricular versus biventricular support. In addition to clinical status, preoperative considerations include patient size, transplant eligibility, device availability, and expected duration of support. Traditionally, small patients require extracorporeal LVADs or smaller axial-flow LVADs, while larger patients can receive implantable pulsatile-flow LVADs, though continuous-flow devices can achieve results similar to those of traditional, pulsatile-flow devices.[29] Transplant ineligible patients are inappropriate for long-term RVAD use. Additionally, if a brief period of RV support is anticipated, a temporary RVAD can be inserted expeditiously and with excellent success.[30] Furthermore, the choice of LV device influences the use of an RV device. For example, with a HeartMate XVE LVAD, there is a higher threshold to place an extracorporeal RVAD because 1.) warfarin anticoagulation becomes necessary; 2.) the HeartMate XVE is more tolerant of RV dysfunction than devices such as the HeartMate II; and 3.) patients with extracorporeal VADs are less eligible for outpatient therapy. In contrast, with a Thoratec LVAD, the RVAD threshold is lower because 1.) warfarin anticoagulation is already required; and 2.) outpatient therapy is generally not anticipated. Also, the technical challenges of RVAD insertion in the presence of an implanted LVAD, particularly if cannulating the RV, may bias the surgeon to implant LVAD and RVAD concurrently.

The presence of these and other confounding factors highlights the importance of establishing widely accepted criteria defining the need for biventricular support. These criteria must be valid in variable clinical scenarios and to all available devices to maximize the applicability and potential benefits of mechanical circulatory support.

This review of 266 LVAD patients found that CI ≤ 2.2 L/min·m^2, RVSWI ≤ 0.25 mmHg·L/m^2, severe pre-VAD RV dysfunction, creatinine ≥ 1.9 mg/dL, previous cardiac surgery, and SBP ≤ 96 mmHg, measured preoperatively, are independently associated with the need for biventricular support. Additionally, female gender, elevated INR, low systolic PAP, elevated CVP, non-separation from CPB, and preoperative mechanical circulatory support were strongly associated with BiVAD placement.

Thirty-seven percent of our cohort required biventricular support. Two published series report similar or greater proportions of patients who required BiVADs, [20, 26] though most series have a smaller percentage. The higher proportion in our cohort is explained by the fact that most series report only patients who failed LVAD support and then required RVAD support, thereby excluding patients who received pre-planned BiVADs. Additionally, our BiVAD cohort may represent a population more likely to require RV support than those reported in other studies, evidenced by the high proportion of females (37%), preoperative mechanical ventilation (71%), intra-aortic balloon pump (61%), or ECMO (21%), in our cohort.

The risk score established by this study is at least equivalent, if not superior, to any currently available metric in predicting the need for biventricular support, including the clinical judgment of experienced clinicians in this and other reported series. Furthermore, when the risk score is <30 or ≥65, the predictive value of the algorithm is extraordinarily high. The authors stress that the risk score as presented is preliminary and requires prospective validation. We are currently seeking IRB approval for this study.

Not unexpectedly, severe preoperative RV failure is likely the most significant factor in determining which patients require BIVADs. However, no well-established objective parameter determines to what extent RV failure results from LV failure in each patient. Sophisticated echocardiographic indices of RV dysfunction now exist,[31] but are not yet universally applied to this morbidly ill population. Investigators have therefore attempted to define a parameter which quantifies the amount of RV dysfunction that is independent of

LV dysfunction. RVSWI may be the best surrogate for isolated function of the RV, because it measures the work performed by the RV with each contraction, corrected for heart rate and pressure. Fukamachi used RVSWI as a surrogate for RV function, and found low RVSWI was more common among BiVAD patients.[25] Kormos found RV hypertrophy and low RV ejection fraction to inotropic support ratio to be predictors of BiVAD use.[20] Additionally, multiple parameters which indirectly reflect poor RV performance are supported in the literature. Dang found that elevated CVP independently predicted post-LVAD RV failure.[16] Fukamachi found that low mean PAP was more common in BiVAD patients,[25] a finding corroborated by Santambrogio.[23] Farrar showed that low pulmonary capillary wedge pressure and low CI were more common in BiVAD recipients.[26] Our study found that low RVSWI and severe echocardiographic RV dysfunction were two of the strongest predictors of the need for biventricular support. Additionally, indirect measures of lower CI and SBP among BiVAD patients were also independent predictors in our cohort.

Patients with severe biventricular dysfunction frequently manifest signs of multi-organ dysfunction. Though not an independent predictor in our study, preoperative mechanical ventilation was strongly associated with eventual BiVAD placement, confirming the findings of multiple other investigators.[20,23,26] However, it is unclear if RV failure results in the need for mechanical ventilation in these patients. Alternatively, perhaps pulmonary edema and/or mechanical ventilation increase pulmonary vascular resistance, impairing the function of a susceptible RV.

Dysfunction of the central nervous, renal, and hepatic systems also occurs in BiVAD patients. Kormos found that BiVAD patients exhibit greater preoperative mental impairment than LVAD patients.[20] The finding of elevated creatinine as an independent predictor in our study was also identified by multiple prior studies.[23,26,32] Elevations in bilirubin, AST, and ALT have also been proposed,[19,23] and bilirubin was indeed higher among our BiVAD recipients.

The fact that previous cardiac surgery was independently associated with BiVAD use in our population likely reflects two phenomena. First, patients who have undergone prior cardiac surgery and ultimately require an LVAD may comprise a subgroup with more severe underlying cardiac disease. Second, the nature of reoperative cardiac surgery increases the complexity of the VAD operation, resulting in increased operative time, increased intraoperative bleeding, higher likelihood of aortic cross-clamping, and poorer protection from myocardial ischemia (due to patent grafts from prior CABG).

Limitations

This retrospective study identified LVAD +/- RVAD recipients at our institution and worked backwards to identify preoperative factors associated with BiVAD use. Data collection was not complete in every field and therefore was not as accurate as in a prospective trial. Additionally, all VADs were implanted at a single institution and our results may reflect some institutional bias.

We included all patients and device types, because we believe the physiologic status of the patient, rather than the device, is the primary determinant of the need for biventricular support. However, we do recognize that some devices, such as the HeartMate II, may be more sensitive to RV dysfunction.

There were patients who “failed” LVAD support but never received RVADs; either because they did not survive, or a decision was made not to proceed with RVAD implantation. We could not ensure that these patients were appropriately identified by chart review. Therefore, these patients were classified in our study as LVAD patients, rather than introduce potential

classification bias. Had we been able to appropriately classify these patients as “failure of isolated LVAD support” (i.e. BiVAD group), the results likely would be stronger since these patients would exhibit physiology indicative of a need for biventricular support.

Because our goal was to identify preoperative parameters useful in predicting the need for biventricular support, we included patients who received intention-to-treat BiVADs. This increased the power of the study to identify predictors of BiVAD use. However, because these patients never underwent a trial of LVAD support, it is impossible to determine if any of these patients may have tolerated univentricular support.

Conclusions

Preoperative data are useful in predicting the need for biventricular mechanical circulatory support. This study identified that preoperative CI ≤ 2.2 L/min·m^2, RVSWI ≤ 0.25 mmHg·L/m^2, severe pre-VAD RV dysfunction, creatinine ≥ 1.9 mg/dL, previous cardiac surgery, and SBP ≤ 96 mmHg are independently associated with the need for biventricular support. Odds ratios for these predictors were used to create a risk score predictive of the need for biventricular mechanical support. The risk score will undergo prospective validation. Additional studies are indicated to establish universal selection criteria for the institution of univentricular and biventricular support.

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Table 1

Type of device utilized in the isolated LVAD support group

Device	***N***
TCI IP	34
TCI VE/Heartmate XVE	83
Abiomed BVS-5000	6
Thoratec PVAD	37
Heartmate II	6
Total	167

Table 2

Device combinations utilized in the BiVAD support group

RVAD Device	LVAD Device	*N*
Biomedicus	Biomedicus	1
Biomedicus	Abiomed	1
Biomedicus	TCI IP	1
Abiomed	TCI IP	5
Abiomed	Abiomed	14
Thoratec PVAD	Thoratec PVAD	62
Thoratec PVAD	TCI IP	5
Thoratec PVAD	TCI VE/HeartMate XVE	10
	Total	99

Table 3

Demographics and Patient Characteristics; Univariate Analysis

Variable	LVAD group (n=167)	BiVAD group (n=99)	P-value
Age (years)	52.0 ± 13.9	51.5 ± 11.6	0.7507
Gender (% female)	19	37	0.0011
Body Surface Area (m^2)	2.03 ± 0.24	1.93 ± 0.26	0.0029
Ischemic Cardiomyopathy (vs. Non-Ischemic, %)	62	56	0.509
COPD (%)	11	8	0.4739
Diabetes (%)	21	26	0.3198

Table 4

Clinical Factors; Univariate Analysis

Variable	LVAD group (n=167)	BiVAD group (n=99)	P-value
Mechanical Ventilation (%)	44	71	<0.0001
Acute Myocardial Infarction (%)	29	25	0.4719
Previous Cardiac Surgery (%)	26	42	0.0067
Severe Preoperative RV Dysfunction (%)	29	73	<0.0001
Intra-aortic Balloon Pump (%)	47	61	0.0283
Preoperative Circulatory Support (%)	12	21	0.0437
Non-separation from Cardiopulmonary Bypass (%)	10	22	0.0073

Table 5

Hemodynamic Factors; Univariate Analysis

Variable	LVAD group (n=167)	BiVAD group (n=99)	P-value
Heart Rate (beats/minute)	100.2 ± 21.3	103.7 ± 22.5	0.2862
Systolic Blood Pressure (mmHg)	106.7 ± 18.5	95.7 ± 16.2	<0.0001
Diastolic Blood Pressure (mmHg)	59.9 ± 11.6	55.9 ± 12.2	0.0231
Mean Arterial Blood Pressure (mmHg)	75.6 ± 11.6	69.1 ± 12.5	0.0004
Central Venous Pressure (mmHg)	16.9 ± 6.9	22.3 ± 7.8	<0.0001
Pulmonary Artery Systolic Pressure (mmHg)	51.5 ± 15.1	44.7 ± 11.6	0.0006
Pulmonary Artery Diastolic Pressure (mmHg)	29.0 ± 9.9	26.4 ± 8.4	0.0546
Mean Pulmonary Artery Pressure (mmHg)	36.5 ± 11.0	32.5 ± 8.7	0.0066
Cardiac Index ($L/min/m^2$)	2.10 ± 0.62	1.80 ± 0.41	0.0001
SvO_2 (%)	61.8 ± 13.8	56.2 ± 12.0	0.0077
Right Ventricular Stroke Work Index ($mmHg \cdot L/m^2$)	0.413 ± 0.286	0.199 ± 0.193	<0.0001
LV Ejection Fraction (%)	13.1 ± 7.9	14.7 ± 13.3	0.2724

Table 6

Laboratory Values; Univariate Analysis

Variable	LVAD group (n=167)	BiVAD group (n=99)	P-value
White Blood Cell Count (10^9/L)	11.5 ± 5.5	13.3 ± 6.9	0.0335
Hemoglobin (g/dL)	11.1 ± 1.9	11.3 ± 1.9	0.4139
Platelet Count (10^9/L)	205.3 ± 99.3	178.7 ± 102.3	0.0498
International Normalized Ratio	1.42 ± 0.42	1.79 ± 0.94	0.0005
Partial Thromboplastin Time (seconds)	53.2 ± 22.5	55.5 ± 33.3	0.5562
Creatinine (mg/dL)	1.47 ± 0.64	2.04 ± 1.41	0.0003
Total Bilirubin (mg/dL)	1.15 ± 0.94	1.64 ± 1.53	0.0108
Alanine Aminotransferase (U/L)	271.3 ± 892.3	550.7 ± 1493.4	0.1567
Aspartate Aminotransferase (U/L	296.1 ± 852.4	554.3 ± 1546.5	0.1979
Albumin (g/dL)	3.2 ± 1.8	2.7 ± 0.7	0.0145

Table 7

Results of Multivariate Logistic Regression

Variable	Odds Ratio	95% Confidence Interval	P-value
Cardiac Index ≤ 2.2 L/min·m^2	5.7	1.3–24.4	0.0192
RVSWI ≤ 0.25 mmHg·L/m^2	5.1	2.1–12.2	0.0002
Severe Pre-VAD RV Dysfunction	5.0	2.0–12.5	0.0006
Creatinine ≥ 1.9 mg/dL	4.8	1.9-12.0	0.0010
Previous Cardiac Surgery	4.5	1.7-11.8	0.0023
SBP ≤ 96 mmHg	2.9	1.2-6.9	0.0162