

Preoperative and Perioperative Predictors of Right Ventricular Failure after Left Ventricular Assist Device Implantation

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Abstract

Background: Right ventricular (RV) failure is a serious adverse event for patients with left ventricular assist devices (LVADs). Here, we seek to identify the risk factors which may predict the development of RV failure (RVF). **Methods and Results:** Forty-two patients were implanted with LVADs (32 HeartWare[®] ventricular assist device and 10 Thoratec[®] HeartMate II) between March 2013 and April 2014 at the Ege University Medical School, Izmir, Turkey. Baseline clinical, demographic, and laboratory information were measured and patients prospectively followed after surgery. Endpoint was defined RVF development for patients. Before surgery, hemodynamic parameters, electrocardiographic findings, standard echocardiographic measurements, and medications were recorded. Multivariate regression analysis showed that the presence of ascites, prealbumin <14 mg/dl, bilirubin >1.5 mg/dl, RV diameter >3.2 cm, RV-fractional area change (FAC) <24%, right atrial area (RAA) >28 cm² and RV-myocardial performance index >0.35 were the strongest predictors of RVF after LVAD implantation. **Conclusions:** RAA and RV-FAC are easily obtained and should be evaluated in potential LVAD patients. Risk assessment systems should also take into account the presence of ascites and low prealbumin levels which are not currently incorporated into any risk models. Validation of the relative importance of all of these parameters requires further investigation.

Keywords: Left ventricular assist device, patient outcomes, right ventricular failure, risk factors

INTRODUCTION

Right ventricular failure (RVF) is an important cause of the morbidity and mortality that develops in patients with left ventricular assist devices (LVADs). RVF prolongs stay in the intensive care unit, increases 30-day mortality, and decreases the transplantation bridging rates.^[1,2] INTERMACS has defined RVF as a condition leading to low cardiac output, high central venous pressure (CVP), low left ventricle filling pressure, and requires inotrope infusions for longer than 14 days or ECMO or right ventricular assist devices (RVAD).^[3]

The incidence of RVF after LVAD implantation varies from 6 to 44% according to recent studies. This large variability is due to differences in definitions of RVF and the patient populations of the studies.^[4] Some authors defined RVF only as a condition of need RVAD,^[5-7] and some others especially INTERMACS defined RVF as a condition leading to low cardiac output, high CVP, low left ventricle filling pressure,

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and requires inotrope infusions or need for RVAD. Based on requirement of inotrope time, RVF has been classified by INTERMACS as mild (within 7 days), moderate (7-14 days) and severe (>14 days or need for RVAD). The complex pathophysiology of RVF makes it difficult to predict the patients who are susceptible to developing this condition. The structure of the right ventricular (RV) myocardium and pathologies of the pulmonary vascular bed may contribute to the formation of RVF. Perioperative factors such as myocardial stunning, ischemia, infarction, and arrhythmias can also lead to RVF. Finally, with mechanical circulatory support, the sudden septal displacement which occurs during the emptying of the left ventricle as well as the increase in preload may contribute to the deterioration of right ventricle.^[1,8] The purpose of this study was to identify the clinical, laboratory, hemodynamic, and echocardiographic risk factors that may predict the development of RVF in end-stage heart failure patients requiring LVADs.

MATERIALS AND METHODS

Patient population

Fifty patients were initially enrolled in this prospective study. Bleeding is a known risk factor for RVF and so patients who underwent revision due to bleeding after LVAD implantation were excluded. The forty-two remaining patients were implanted with LVADs between March 2013 and April 2014. The HeartWare[®] ventricular assist device (HVAD, HeartWare Inc., Framingham, MA) was implanted in 32 (76%) of the patients, while the HeartMate II (HM2, Thoratec Corp., Pleasanton, CA) was implanted in 10 (24%) patients.

In this study, RVF was defined as the need for inotropes for more than 14 days and/or need for RVAD implantation. To identify the risk factors for RVF after LVAD implantation, baseline values were collected for the patients' clinical, demographic, and laboratory information. Immediately before surgery, patient hemodynamic parameters, electrocardiographic findings, and medications were also recorded. Finally, the Michigan RV risk score (vasopressor need: 4 points, aspartate aminotransferase [AST] >80:2 points, total bilirubin >2:2.5 points, creatinine >2.3:3 points) and Lietz-Miller risk score (thrombocyte <148000:7 points, albumin <3.3:5 points, INR >1.1:4 points, vasodilator treatment: 4 points, mean pulmonary artery pressure [PAP] <25 mmHg: 3 points, AST >45:2 points, Htc <34%:2 points, BUN >51:2 points, no need for IV inotropes: 2 points) were calculated for all patients. For the analysis, patients were divided into ischemic and nonischemic groups according to the etiology of their heart failure and also were categorized into INTERMACS groups (1/2, 3/4, and 5-7).

Echocardiographic measurements

Before surgery, all patients underwent transthoracic echocardiography to obtain standard echocardiographic measurements (VIVID 7 PRO, GE, M4S probe, 1.5–4.3 MHz). The RV fractional area change (RV-FAC), the right atrial

area (RAA), RV outflow tract (RVOT), the proximal (RVOT1, diastole and systole) and distal (RVOT2) diameters, the RVOT fractional shortening (RVOT-FS), the RV diameters (RVD1, RVD2, RVD3), the tricuspid regurgitation velocity, and the systolic PAP values were calculated according to the guidelines of the American Society of Electrophysiology. The ratio of the RV diameter to the left ventricular diameter (LV diameter) was measured with two-dimensional measurements in apical and parasternal slices separately (RV/LV ratio apical, RV/LV ratio parasternal). The RV myocardial performance index (MPI) was calculated in all cases using the pulsed wave Doppler technique.^[9] The parasternal short-axis slice was measured at the aortic valve level and the anterior wall of the RVOT. The systolic displacement of the RVOT was measured using the M-mod technique (RVOT-SE).^[10]

Statistical analysis

All variables were expressed as percentages or mean \pm standard deviation. All continuous variables were compared with the Mann-Whitney U test and categorical variables were compared with the Chi-square or Fisher's exact test. Logistic regression analyses were performed for the variables that were significantly associated with RVF. ROC curve analyses were performed to identify the cutoff values, diagnostic sensitivity, and specificity of the variables significantly associated with the development of RVF. $P < 0.05$ was considered statistically significant and all analyses were performed using SPSS version 18.0 (SPSS Inc., Chicago, USA).

Ethical statement

This scientific research was initiated with the decision of Ege University Faculty of Medicine Clinical Research Board dated 19/03/2013 and numbered 13-2.2/1.

RESULTS

RVF occurred in 7 (16.7%) patients during follow-up. One patient required an RVAD and the six others required more than 14 days of inotropes. The preoperative baseline characteristics and comorbidity conditions of the patients in both the groups are shown in Table 1 with no significant differences observed between RVF and non-RVF patients. Ischemic etiology was noted in 57% ($n = 24$) of the patients and 43% ($n = 18$) were nonischemic, with no significant association between etiology and RVF. There was, however, a significant association between a low INTERMACS class (class 1 and 2) and the development of RVF ($P = 0.017$).

The hemodynamic parameters in Table 2 show patients who developed RVF had significantly lower systolic and diastolic blood pressures. Although RVF occurred more often in patients who required inotropes the difference was not statistically significant ($P = 0.063$). In addition, ascites was identified in seven patients before surgery and 4 (57%) of those patients developed RVF. Despite the small sample size, there was a significant association between the presence of ascites and RVF ($P = 0.009$). The analysis of the preoperative medication data showed that there were no significant differences in the

Table 1: Basal characteristics and comorbidity conditions

Baseline characteristics	All patients (N _{total} =42), n (%)	RVF (N _{total} =7), n (%)	Non-RVF (N _{total} =35), n (%)	P
Age (years)	50.2 ± 12.4	50.1 ± 15.4	50.2 ± 11.9	0.774
Male	39 (93)	7 (100)	32 (91)	1.000
BMI (m ²)	1.7 ± 0.1	1.8±0.1	1.7 ± 0.1	0.223
BSA (kg/m ²)	24.5 ± 3.3	24.1 ± 2.7	24.6 ± 3.4	0.698
Etiology				
Ischemic	24 (57)	3 (43)	21 (60)	0.438
Non-ischemic	18 (43)	4 (57)	14 (40)	
Diabetes	13 (31)	3 (43)	10 (29)	0.657
Hypertension	18 (43)	2 (29)	16 (46)	0.679
Hyperlipidemia	16 (38)	2 (29)	14 (40)	0.690
COPD	5 (12)	0 (0)	5 (14)	0.569
Liver disease	2 (5)	1 (14)	1 (3)	0.309
Prior sternotomy	7 (17)	0 (0)	7 (20)	0.326
Cerebrovascular disease	5 (12)	0 (0)	5 (14)	0.569
Peripheral artery disease	2 (5)	0 (0)	2 (6)	1.000
Device type				
HVAD	32 (76)	5 (71)	27 (77)	1.000
HMI	10 (24)	2 (29)	8 (23)	
Intermacs				
1/2	8 (19)	4 (57)	4 (11)	0.017*
3/4	34 (81)	3 (43)	31 (89)	

*p value<0,05, RVF: Right ventricular failure, BMI: Body mass index, BSA: Body surface area, COPD: Chronic obstructive pulmonary disease, HVAD: HeartWare® ventricular assist device, HMI: HeartMate II

Table 2: The association of blood pressure, heart rate, need for inotropes and presence of ascites with right ventricular failure

Hemodynamic parameters	All patients (N _{total} =42)	RVF (N _{total} =7)	Non-RVF (N _{total} =35)	P
Systolic blood pressure (mmHg)	94 ± 10	85 ± 5	96 ± 10	0.002*
Diastolic blood pressure (mmHg)	59 ± 7	52 ± 8	60 ± 7	0.032*
Heart rate (beat/min)	81 ± 13	85 ± 17	81 ± 13	0.685
Intravenous inotropes, n (%)				
+	11 (26)	4 (57)	7 (20)	0.063
-	31 (74)	3 (43)	28 (80)	
Ascites, n (%)				
+	7 (17)	4 (57)	3 (9)	0.009*
-	35 (83)	3 (43)	32 (91)	

*p value<0,05, RVF: Right ventricular failure

patients with and without RVF for all medications except for angiotensin-converting enzyme inhibitors (ACE-I). All 15 patients using ACE-I did not develop RVF which was significantly different from the 7 of 27 (25.9%) of patients not using ACE-I who later developed RVF ($P = 0.038$).

Preoperative right heart catheterization (RHC) showed no significant differences between the patients with and without RVF except in the case of mean right atrial pressure (RAP). Patients who developed RVF had significantly higher RAP (15 ± 6 vs. 9 ± 4 mmHg, $P = 0.039$). There were generally no differences in the biochemical laboratory results [Table 3]. Patients with RVF tended to have lower leukocytes and albumin levels but the differences were not statistically significant. The mean prealbumin levels were significantly lower for the patients with RVF ($P = 0.003$). RVF patients

also had significantly higher bilirubin and NT-proBNP levels ($P = 0.008$ and $P = 0.041$, respectively).

The results of current RV risk assessment methods are in Table 4. The Michigan RV Risk score showed a significant association between a high-risk assessment and eventual development of RVF ($P = 0.02$). However for this cohort, the Lietz–Miller Risk Assessment was not successful in identifying which patients were at high risk and eventually developed RVF ($P = 0.203$). Echocardiographic measurements [Table 5] showed that RVF was associated with an overall larger right ventricle as RV diameter, RAA, tricuspid annular diameter, and the ratio of the right to left ventricle were all significantly higher for patients with RVF. As expected, patients with RVF also showed many signs of deteriorated heart condition as they had significantly worse ejection fraction, tricuspid

Table 3: Association between biochemical laboratory results and right ventricular failure

Biochemical laboratory results	All patients (n=42)	RVF (n=7)	Non-RVF (n=35)	P
Hb (g/dl)	12.6 ± 1.7	12.2 ± 1.8	12.7 ± 1.7	0.380
Htc (%)	38.2 ± 4	37.1 ± 4.3	38.4 ± 4	0.353
Leukocyte (K/mm ³)	7 ± 2	6 ± 1	8 ± 2	0.052
Platelet (K/mm ³)	240 ± 84	250 ± 105	239 ± 80	0.566
INR	1.2 ± 0.2	1.2 ± 0.1	1.2 ± 0.2	0.313
BUN (mg/dl)	55 ± 34	66 ± 58	53 ± 28	0.457
Creatinine (mg/dl)	1.07 ± 0.2	1.02 ± 0.4	1.08 ± 0.2	0.589
Uric acid (mg/dl)	6.4 ± 1.9	5.8 ± 1.3	6.5 ± 2	0.489
Sodium (mEq/l)	134 ± 5	133 ± 4	134 ± 5	0.624
Albumin (g/dl)	4 ± 0.5	3.6 ± 0.4	4.1 ± 0.5	0.063
Prealbumin (mg/dl)	18 ± 7	11 ± 3	19 ± 7	0.003*
AST (IU/l)	31 ± 22	50 ± 43	27 ± 12	0.146
ALT (IU/l)	36 ± 41	57 ± 78	32 ± 30	0.468
LDH (IU/l)	245 ± 77	250 ± 70	244 ± 80	0.826
Bilirubin (mg/dl)	1.8 ± 2.1	3.5 ± 3.2	1.5 ± 1.7	0.008*
NT-proBNP (pg/ml)	6045 ± 6660	9237 ± 6882	5406 ± 6527	0.041*

*p value < 0.05 is significant, RVF: Right ventricular failure, Hb: Hemoglobin, Htc: Hematocrit, INR: International normalized ratio, BUN: Blood urea nitrogen, AST: Aspartate transaminase, ALT: Alanine transaminase, LDH: Lactate dehydrogenase, NT-proBNP: N-terminal prohormone brain natriuretic peptide

Table 4: Association between clinical risk scores and right ventricular failure

RV risk scores	All patients (n=42), n (%)	RVF (n=7), n (%)	Non-RVF (n=35), n (%)	P
Michigan RV risk score				
Low/medium	33 (79)	3 (43)	30 (86)	0.02*
High	9 (21)	4 (57)	5 (14)	
Lietz-Miller risk score				
Low	33 (79)	4 (57)	29 (83)	0.203
Medium	8 (19)	3 (43)	5 (14)	
High/very high	1 (2)	0 (0)	1 (3)	

*p value < 0.05, RV: Right ventricle

regurgitation, RV-FAC, tricuspid annular plane systolic excursion (TAPSE), and RV-MRI. Despite the changes in the RV, often patients with and without RVF did not show any significant differences in their left ventricle echocardiographic measurements.

Results of the multiple logistic regression analyses of risk factors for RVF are in Table 6. The presence of ascites, prealbumin < 14 mg/dl, total bilirubin > 1.5 mg/dl, RV diameter > 3.2 cm, RV-FAC < 24%, RAA > 28 cm², and RV-MPI > 0.35 were the strongest predictors of RVF. The ROC curves in Figure 1 show the specificity and sensitivity of pre-albumin, RV-FAC, RAA, and RV-MPI for predicting the development of RVF.

DISCUSSION

The results of our study show that baseline characteristics or comorbidity conditions were not significantly associated with the development of RVF in patients undergoing LVAD placement. Previous studies have suggested that RVF develops more frequently in female patients and those with nonischemic etiology, smaller BSAs, or advanced age.^[11-13] However, in a study of 197 patients, Matthews *et al.*^[14] reported that there

were no significant differences in those baseline characteristics similar to the results of this analysis. Furthermore, a large meta-analysis published in last years reported that female gender is an independent predictor of early RVF.^[15] A low INTERMACS class has been previously reported as a risk factor for RVF,^[16] which is understandable since a lower classification indicates the patient has poor cardiac reserves and systemic circulation. In this cohort, there was also a significant association between low (1/2) INTERMACS class and RVF. In contrast, patients with INTERMACS class 3/4 had a relatively low risk of developing RVF. There was also no significant difference in RVF between groups with and without inotrope use. This may suggest earlier LVAD implantation, before the patient status deteriorates to INTERMACS class 1/2, has the potential to improve morbidity and mortality.

The association between ascites and RVF has not been analyzed previously and the presence of ascites is not considered in any current RVF risk score system. As there was a significant association between the presence of ascites and RVF, it is recommended to include this condition, which should be simple to evaluate in a new risk score system. Univariate analysis showed RVF developed significantly less often

Table 5: Association of echocardiographic measurements and right ventricular failure

Echocardiographic measurements	All patients (n=42)	RVF (n=7)	Non-RVF (n=35)	P
LA diameter (cm)	4.7 ± 0.5	4.6 ± 0.3	4.7 ± 0.6	0.932
LVESD (cm)	6.2 ± 0.7	6.2 ± 0.9	6.2 ± 0.7	0.933
LVEDD (cm)	6.7 ± 0.7	6.6 ± 0.9	6.7 ± 0.7	0.543
RV diameter (cm)	2.7 ± 0.6	3.4 ± 0.6	2.6 ± 0.5	0.004*
LVEDV (ml)	258 ± 83	232 ± 81	263 ± 83	0.447
LVESV (ml)	212 ± 67	198 ± 61	215 ± 68	0.698
EF (% modified Simpson)	17 ± 5	13 ± 4	18 ± 5	0.032*
Mitral regurgitation (mild to severe), n (%)	19 (45)	3 (43)	16 (46)	1.000
Tricuspid regurgitation (mild to severe), n (%)	18 (43)	6 (86)	12 (34)	0.031*
Pulmonary regurgitation (mild to severe), n (%)	3 (7)	1 (14)	2 (6)	0.430
RV-FAC	29 ± 7	20 ± 3	31 ± 6	<0.001*
RAA (cm ²)	24.2 ± 5.8	29.8 ± 3.3	23.1 ± 5.5	0.004*
RVOT-FS	18 ± 8	12 ± 7	19 ± 7	0.018*
Tricuspid annular diameter (cm)	4.7 ± 0.6	5.4 ± 0.2	4.6 ± 0.6	0.005*
TRV (m/sn)	2.9 ± 0.6	2.9 ± 0.7	2.9 ± 0.6	0.986
SPAP (mmHg)	50 ± 16	50 ± 15	50 ± 16	0.879
TAPSE (mm)	15.3 ± 3.2	12.8 ± 1.8	15.8 ± 3.2	0.019*
RVSm (cm/sn)	8.4 ± 2.3	6.5 ± 1.6	8.8 ± 2.2	0.021*
RVOT-SE (mm)	7.3 ± 2.1	4.1 ± 0.6	7.9 ± 1.7	<0.001*
RV-MPI	0.31 ± 0.14	0.51 ± 0.21	0.27 ± 0.09	0.007*
RV/LV ratio (apical)	0.55 ± 0.13	0.66 ± 0.14	0.53 ± 0.12	0.036*
RV/LV ratio (parasternal)	0.41 ± 0.11	0.52 ± 0.15	0.39 ± 0.09	0.049*

*p value<0,05, LV: Left ventricle, RVF: Right ventricular failure, LA: Left atrium, LVESD: LV end systolic diameter, LVEDD: LV end diastolic diameter, RV: Right ventricle, LVEDV: LV end diastolic volume, LVESV: LV end systolic volume, EF: Ejection fraction, RV-FAC: RV fractional area change, RAA: Right atrial area, RVOT-FS: Right ventricular outflow tract fractional shortening, TRV: Tricuspid regurgitation velocity, SPAP: Systolic pulmonary artery pressure, TAPSE: Tricuspid annular plane systolic excursion, RVSm: RV peak systolic velocity, RVOT-SE: Right ventricular outflow tract systolic displacement, RV-MPI: RV myocardial performance index

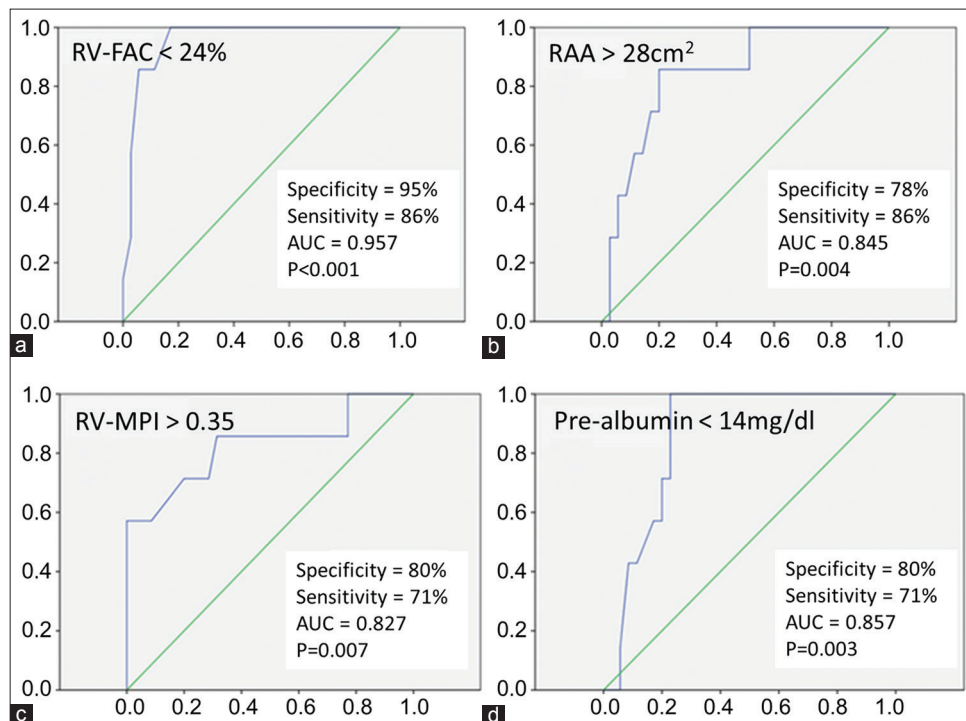


Figure 1: ROC Curves of (a) RV-FAC, (b) RAA, (c) RV-MPI, and (d) prealbumin. Sensitivity is plotted on the vertical axis while 1-Specificity is plotted on the horizontal axis. ROC = Receiver operating characteristic; AUC = Area under the curve; RV-FAC = Right ventricle fractional area change; RAA = Right atrial area; RV-MPI = Right ventricle myocardial performance index

Table 6: Multivariate regression analysis of right ventricular failure risk factors

Risk factors for RVF	P	OR	95% CI
Ascites	0.006	14.2	2.1-95.8
Prealbumin <14 mg/dl	0.014	10	1.5-62.7
Bilirubin >1.5 mg/dl	0.018	15	1.5-140.9
RV >3.2 cm	0.003	19.3	2.7-135.1
RV-FAC <24%	<0.001	99	7.7-1271.9
RAA >28 cm ²	0.009	20.2	2.1-193.9
RV-MPI >0.35	0.014	10	1.5-62.7

RVF: Right ventricular failure, RV: Right ventricle, RV-FAC: RV fractional area change, RAA: Right atrial area, RV-MPI: RV myocardial performance index, OR: Odds ratio, CI: Confidence interval

in patients using ACE-I. However, in the multiple logistic regression analysis, it was determined that the difference was due to the patients' INTERMACS class and ACE-I use was not an independent significant risk factor of RVF.

Postoperative right heart catheterization revealed a statistically significant association between high RAP and RVF, which has similarly been reported in previous studies.^[14,16,17] In this cohort, the other catheter measurements were not associated with the development of RVF as pulmonary artery pressures were not significantly different between the two groups. However, Fukamachi *et al.*^[12] previously reported that a low mean PAP values can be a risk factor for RVF. Alnsasra *et al.*^[18] reported that elevated diastolic pulmonary gradient is associated with RVF. Dandel *et al.* reported in their study including 475 patients that elevated CVP is an independent predictor of postoperative RVF.^[19] Wang *et al.*^[5] also reported that elevated CVP/pulmonary capillary wedge pressure ratio levels have a relation between postoperative RVF. Because of the many underlying mechanisms of RVF development, differences in the patients could lead to these conflicting results.

Although laboratory measurements such as AST, bilirubin, and creatinine can indicate end organ damage, changes in these markers are not specific to RVF. In this study, there was no correlation between most of the laboratory measurements and the development of RVF [Table 3]. However, prealbumin was significantly lower in patients with RVF and prealbumin values of <14 mg/dl predicted RVF with 80% specificity and 71% sensitivity. Prealbumin could serve as a sensitive and early indicator for RV dysfunction since it is a negative acute phase reactant and has a short half-life as previously described.^[20] RVF patients also had significantly higher levels of bilirubin which concurs with other reports.^[21,22] Previous studies have identified associations between RVF and increased AST, creatinine, and NT-proBNP levels.^[12,13,23]

As expected, preoperative echocardiographic data revealed that there was a significant increase in size and decrease in function of the RV in patients who later developed RVF. This is consistent with previous literature where there was increased right heart size based on RV/LV ratio and tricuspid

annulus diameter in patients with RVF.^[23-26] Similarly, right heart function was diminished for those patients as measured by tricuspid regurgitation, TAPSE, RV-FAC, and RVOT-SE.^[10,16,27,28] While previous work has shown that RVOT-SE is predictive of decreased RV function, this study revealed a correlation between RVOT-SE and RVF development after LVAD implantation.

Study limitations

Limitation of this study are that patient data were collected from a single center and site-specific practices may have had an effect on the results. For example, at this institution, patients are often implanted with an LVAD earlier to prevent development of end organ damage. This is supported by the much lower percentage of INTERMACS class 1 and 2 patients receiving the device (19% of cohort) compared to other studies. Because of this earlier implantation practice, it is possible our results did not show significant associations between RVF and certain laboratory measures of end organ damage. In addition, the smaller sample size may have limited our statistical analysis. While the univariate analysis revealed a significant association between RVOT-SE and RVF, this significance was not shown with multiple logistic regression analyses. To better determine if variables such as RVOT-SE are risk factors, larger patient groups should be considered.

CONCLUSIONS

Several hemodynamic, biochemical laboratory, and echocardiographic measurements were significantly associated with the development of RVF in this prospective single-center study. Multivariate regression analysis showed that the presence of ascites, pre-albumin <14 mg/dl, bilirubin >1.5 mg/dl, RV diameter >3.2 cm, RV-FAC <24%, RAA >28 cm², and RV-MPI >0.35 were the strongest predictors of RVF after LVAD implantation. These findings suggest that RAA and RV-FAC, which are easily measured with standard transthoracic echocardiography, should be evaluated in patients with plans for LVAD implantation. Similarly, risk assessment systems should take into account the presence of ascites and low prealbumin levels. Validation of the relative importance of all of these parameters requires further investigation. In this study, the risk for developing RVF was also significantly lower in INTERMACS class 3/4 patients compared to the class 1/2 cohort. This has influenced this institution's LVAD implantation strategies as we believe that earlier LVAD implantation might provide significant morbidity and mortality benefits.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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