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OPEN External assessment of the EUROMACS right-sided heart failure risk score

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The EUROMACS Right-Sided Heart Failure Risk Score was developed to predict right ventricular failure (RVF) after left ventricular assist device (LVAD) placement. The predictive ability of the EUROMACS score has not been tested in other cohorts. We performed a single center analysis of a continuousflow (CF) LVAD cohort (n = 254) where we calculated EUROMACS risk scores and assessed for right ventricular heart failure after LVAD implantation. Thirty-nine percent of patients (100/254) had postoperative RVF, of which 9% (23/254) required prolonged inotropic support and 5% (12/254) required RVAD placement. For patients who developed RVF after LVAD implantation, there was a 45% increase in the hazards of death on LVAD support (HR 1.45, 95% CI 0.98–2.2, p = 0.066). Two variables in the EUROMACS score (Hemoglobin and Right Atrial Pressure to Pulmonary Capillary Wedge Pressure ratio) were not predictive of RVF in our cohort. Overall, the EUROMACS score had poor external discrimination in our cohort with area under the curve of 58% (95% CI 52–66%). Further work is necessary to enhance our ability to predict RVF after LVAD implantation.

Abbreviations

| BNP | Brain natriuretic peptide |
|-----------|--|
| BMI | Body mass index |
| COPD | Chronic obstructive pulmonary disease |
| EUROMACS | European Registry for Patients with Mechanical Circulatory Support |
| INR | International normalizing ratio |
| INTERMACS | Interagency Registry for Mechanical Circulatory Support |
| LVAD | Left ventricular assist device |
| RVF | Right ventricular failure |

Right ventricular (RV) failure remains common after left ventricular assist device placement (LVAD) even in contemporary continuous flow era¹, and remains a leading cause of morbidity and mortality after LVAD placement^{2,3}. A number of definitions of early right ventricular failure after LVAD exist. All include unplanned right ventricular assist device (RVAD) placement after LVAD implantation, however definitions vary by length and use of pulmonary vasodilators or intravenous inotropes^{1,4,5}. Several prediction tools have been developed to try to capture risk of post-operative RV failure with pre-operative variables, however the performance of these models has been variable to poor on external validation^{3,6}. One of the more recently published risk models was developed from the EUROMACS database⁷. This analysis included 2,988 patients implanted with LVADs in Europe in which 433 patients (21.7%) developed right ventricular failure. After performing logistic regression, a combination of five variables were found to be highly predictive of right sided heart failure. These variables include right atrial/pulmonary capillary wedge pressure >0.54, hemoglobin <10 g/dL, use of multiple intravenous inotropes prior to LVAD implantation, INTERMACS Class 1-3, and severe right ventricular dysfunction on echocardiography. The C-Statistic for this risk score was 0.7, which was higher than other risk scores that have been published. The performance of this score has been less than the development cohort in several small to intermediate sized external validation datasets $(n = 93-194)^{8-10}$. The purpose of this study was to assess the performance of the EUROMACs score in a large, external continuous flow LVAD dataset and assess for other univariate predictors of RV failure.

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Methods

Cohort and inclusion criteria. The institutional review board of the University of Minnesota Medical Center approved this study. The requirement of informed consent for the study is waived by the institutional review board of the University of Minnesota. All methods were carried out in accordance with relevant guide-lines and regulations. At the time of this analysis, the larger continuous-flow LVAD cohort consisted of 451 patients implanted between 2007 and 2017. Of these, 254 patients met the following inclusion criteria 1) first time, continuous-flow LVAD implantation 2) complete pre-operative variables to complete EUORMACS score calculation, and 3) complete post-operative data to determine date of inotrope wean, pulmonary vasodilator wean and RVAD use.

The following demographic and clinical covariate data are available in the University of Minnesota LVAD database, which is updated through data extraction and manual chart review: age, gender, body mass index (BMI), serum creatinine, albumin, Interagency Registry for Mechanical Circulatory Support (INTERMACS) profile, pre-operative hemodynamics, bridge to transplant status, cardiomyopathy type, presence of diabetes, and NT pro b-type natriuretic peptide (NT-proBNP). Vital status was obtained from chart review. The date of the last clinic visit was recorded for patients who were still alive at the end of follow up. For cardiac transplant tation, the date of cardiac transplant was obtained from the electronic medical record and confirmed with an operative report.

Primary predictor and outcome. The primary predictor for this analysis was follow up EUROMACS RV score, which was calculated by totaling points for the following pre-LVAD clinical variables. RA/PCWP>0.54: 2 points, hemoglobin \leq 10 g/dL:1 point, multiple inotropes: 2.5 points, INTERMACS 1–3: 2 points, and severe RV dysfunction: 2 points. The primary outcome was early severe post-operative right ventricular failure defined as need for short/long-term mechanical right-sided circulatory support within 30 days of LVAD implantation, continuous inotropic support greater than or equal to 14 days, or need for pulmonary vasodilators for greater than 48 h.

Statistical methods. All statistical analyses were performed using STATA 16 (College Station, Texas). A *p* value of <0.05 was considered statistically significant. Baseline characteristics between cohort subjects who developed early RVF and those who did not develop early RVF were compared with normally distributed continuous variables were compared with t-tests and Wilcoxon rank sum tests for non-normally distributed continuous variables. Categorical variables were compared with Pearson chi-squared tests or Fishers exact test, where appropriate. In order to determine the relationship between baseline co-variates and follow up pulmonary capillary wedge pressure, multivariable linear regression analyses were performed.

In order to assess EUROMACS model discrimination, a receiver operator curve was generated with EUROMACS score as the predictor and post LVAD RVF as the outcome. This was repeated using the RVF definition of RVAD or prolonged inotropes use only. The EUROMACS score was also assessed as a predictor of RVF using logistic regression. In order to determine the relationship between other pre-operative variables and RVF, logistic regression was performed. The relationship between RVF (or RVAD use alone) and subsequent LVAD mortality was assessed with cox regression.

Results

The mean age of the cohort was 59 years of age. Eighty two percent were male, 80% were Caucasian, and 51% were designated as bridge to transplantation. The majority of patients (52%) were INTERMACS profile 2–3. A total of 100 patients (39%) were diagnosed with early right ventricular failure and 154 patients (61%) did not have post-operative right heart failure. There were no significant differences in age, sex, race, baseline atrial fibrillation, cardiomyopathy type, diabetes, chronic obstructive pulmonary disease, LVAD surgical strategy, INTERMACS profile, pulmonary artery systolic pressure or cardiac index between both groups (Table 1). The 60 day mortality of the cohort was 10.6% (27/254). Of those, 15/27 (56%) were deaths attributable to right heart failure.

Outcomes of right heart failure. Of the 100 patients who met RV failure criteria, 12 patients required RVAD and 23 patients required inotropes > 14 days. Patients who required pulmonary vasodilators > 48 h comprised the vast majority (n = 65) of patients who were defined as having post-operative RVF. Early right-sided heart failure was associated with increased mortality (unadjusted HR 1.45; 95% CI 0.98–2.16, p = 0.066). Use of RVAD after LVAD surgery was the primary driver of increased mortality (HR 4.56; 95% CI 2.28–9.11, p < 0.001, Fig. 1).

Risk factor for early postoperative right heart failure. We tested 66 distinct risk factors for early post-operative right heart failure. An additional nine factors were calculated from these 66 variables (Tables 2, 3, 4). Of the individual variables tested, a higher pulmonary arterial pressure was protective against RV failure as was a higher pulmonary arterial pulse pressure. Higher creatinine, lower albumin, and higher total bilirubin were all associated with increased risk of RV failure after LVAD. Pre-operative ventilator support, multiple inotropes, extra corporal membrane oxygenator support, and non-elective IABP were also associated with higher risk of RVF. Of note, hemodynamic parameters such as right atrial pressure, right atrial/pulmonary capillary wedge pressure, pulmonary artery pulsatility index, pulmonary artery compliance, and pulmonary artery elastance were not associated with increased risk of right sided heart failure in this dataset.

| Variable | Total cohort | No early RHF (N=154) | Early RHF (N = 100) | <i>p</i> value |
|--|------------------|----------------------|----------------------|----------------|
| Age at LVAD implantation | 62 (52–69) | 62 (54-69) [0] | 62 (50-68) [0] | 0.35 |
| Male | 208 (82%) | 127 (83%) [0] | 81 (81%) [0] | 0.87 |
| Race White | 204 (86%) | 121 (85%) | 83 (88%) | 0.56 |
| Race Black | 20(8) | 12 (9%) | 8 (8.5%) | |
| Race other | 12(5) | 9 (6%) | 3 (3.2%) | |
| Race missing | 18 | 12 | 6 | |
| Baseline atrial fibrillation | 115(46%) | 68 (45%) [2] | 47 (48%) [1] | 0.70 |
| Ischemic cardiomyopathy | 134 (53%) | 78 (51%) [0] | 56 (56%) [0] | 0.44 |
| Diabetes | 122 (47%) | 75 (49%) [2] | 47 (48%) [1] | 0.80 |
| Chronic obstructive pulmonary disease | 60 (24%) | 35 (23%) [2] | 25 (25%) [1] | 0.76 |
| Bridge to transplant | 129 (51%) | 79 (51.3%) [0] | 50 (50%) [0] | 0.90 |
| INTERMACS 1 | 30 (12%) | 14 (9%) | 16 (16%) | 0.14 |
| INTERMACS 2–3 | 131 (52%) | 78 (51%) | 53 (53%) | |
| INTERMACS 4–7 | 93 (37%) | 62 (40%) | 31 (31%) | |
| Body Mass Index (kg/m ²) | 28.3 (25.2-33.0) | 28 (25.0-32.4) [6] | 29.3 (26.1-33.3) [6] | 0.48 |
| Creatinine (mg/dL) | 1.2 (0.96–1.7) | 1.1 (0.9–1.6) [2] | 1.3 (1.1–1.8) [1] | 0.015 |
| Albumin (g/dL) | 3.3 (2.5–3.7) | 3.4 (3-3.8) [2] | 3.3 (2.9–3.5) [1] | 0.21 |
| Right atrial pressure (mmHg) | 11.5 (7–17) | 10 (7–15) [19] | 14 (10–18) [19] | 0.03 |
| Pulmonary artery systolic pressure (mmHg) | 50 (40-60) | 50 (40-60) [19] | 50 (43-62) [19] | 0.56 |
| Pulmonary capillary wedge pressure (mmHg) | 22 (17–28) | 22(16-29) [19] | 23 (18–28) [19] | 0.06 |
| Pulmonary artery diastolic pressure(mmHg) | 25 (19-30) | 23 (18–30) [19] | 26 (21–32) [19] | 0.15 |
| Cardiac Index (L/min/m ²) | 1.9 (1.6–2.3) | 1.9 (1.6–2.3) [14] | 1.9 (1.5–2.3) [15] | 0.97 |
| Pulmonary arterial compliance (mL·mmHg ⁻¹) | 1.9 (1.4–2.7) | 1.9 (1.4–2.9) [23] | 1.8 (1.3–2.4) [21] | 0.18 |
| Pulmonary artery pressure index | 2.2 (1.4-3.6) | 2.4 (1.6–4) [19] | 1.9 (1.3–3.1) [19] | 0.02 |
| Right ventricular stroke work index (g/m/beat/m ²) | 13.7 (10–17) | 13.9 (11–17) [23] | 13.4 (10–18) [21] | 0.65 |
| Severe right ventricular dysfunction by echo | 40 (17) | 18 (12%) [13] | 22 (22%) [10] | 0.18 |

Table 1. Baseline characteristics of the cohort by presence or absence of early right heart failure by the. Continuous variables are described with median (IQR) [N missing]. Binary variables are described with N (%) [N missing].



Figure 1. Kaplan Meier survival curves of LVAD recipients by type of right heart failure. RHF: right ventricular heart failure, RVAD: right ventricular assist device within 30 days, Inotropic: Inotrope Use > 14 days after LVAD, PV: pulmonary vasodilator Use > 48 h.

| Predictor | Odds-ratio (95% CI) | <i>p</i> value |
|--|---------------------|----------------|
| Age (years) | 0.53 (0.19, 1.47) | 0.221 |
| Body Mass Index (kg/m ²) | 1.19 (0.38, 3.73) | 0.761 |
| log NT-proBNP (pg/mL) | 1.06 (0.36, 3.12) | 0.910 |
| Glomerular filtration rate (mL/min) | 0.18 (0.05, 0.66) | 0.010* |
| Hemoglobin (g/dL) | 0.51 (0.15, 1.81) | 0.300 |
| International normalized ratio | 2.77 (1.28, 6.00) | 0.010* |
| Platelets | 0.79 (0.24, 2.66) | 0.707 |
| Creatinine (mg/dL) | 3.71 (1.63, 8.46) | 0.002* |
| C-reactive protein | 2.49 (1.09, 5.72) | 0.031* |
| Prealbumin (mg/L) | 0.21 (0.05, 0.85) | 0.029* |
| Sodium | 1.33 (0.41, 4.30) | 0.638 |
| Albumin(mg/dL) | 0.22 (0.07, 0.69) | 0.010* |
| ALT | 1.80 (1.02, 3.17) | 0.041* |
| AST | 2.08 (0.94, 4.58) | 0.070 |
| Total bilirubin (mg/d) | 1.93 (1.03, 3.59) | 0.039* |
| Total cholesterol (mg/dL) | 3.46 (1.27, 9.40) | 0.015* |
| High density lipoprotein (mg/dL) | 1.01 (0.32, 3.23) | 0.981 |
| White blood cell count | 2.31 (1.01, 5.28) | 0.047* |
| Partial thromboplastin time | 1.65 (0.73, 3.75) | 0.228 |
| log NT-proBNP (pg/mL) | 1.06 (0.36, 3.12) | 0.910 |
| Heart rate (beats/min) | 1.22 (0.39, 3.82) | 0.736 |
| Diastolic blood pressure (mmHg) | 0.73 (0.25, 2.19) | 0.578 |
| Ejection fraction (%) | 2.10 (0.74, 5.94) | 0.161 |
| Left ventricular end diastolic dimension (cm) | 0.85 (0.27, 2.69) | 0.776 |
| Left ventricular end systolic dimension (cm) | 0.62 (0.19, 1.97) | 0.417 |
| International normalized ratio | 2.77 (1.28, 6.00) | 0.010* |
| Mean arterial pressure (mmHg) | 0.55 (0.20, 1.54) | 0.256 |
| Systolic blood pressure (mmHg) | 0.51 (0.18, 1.47) | 0.215 |
| Cardiac output (L/min) | 1.34 (0.43, 4.13) | 0.615 |
| Right atrial pressure (mmHg) | 1.04 (0.33, 3.31) | 0.949 |
| Pulmonary artery systolic pressure (mmHg) | 0.21 (0.06, 0.77) | 0.019* |
| Pulmonary capillary wedge pressure (mmHg) | 0.40 (0.12, 1.34) | 0.140 |
| Pulmonary artery diastolic pressure (mmHg) | 0.48 (0.14, 1.63) | 0.239 |
| Pulmonary pulse pressure (mmHg) | 0.22 (0.06, 0.76) | 0.016* |
| Pulmonary artery elastance (mmHg/mL) | 0.49 (0.12, 2.04) | 0.327 |
| Pulmonary artery compliance (mL·mmHg ⁻¹) | 1.66 (0.77, 3.55) | 0.193 |
| Pulmonary artery pulsatility index | 0.21 (0.02, 2.53) | 0.218 |
| Right atrial: wedge pressure ratio | 1.51 (0.56, 4.07) | 0.415 |
| Right ventricular end diastolic pressure (mmHg) | 1.76 (0.57, 5.48) | 0.327 |
| Systolic blood pressure (mmHg) | 0.51 (0.18, 1.47) | 0.215 |
| Stroke volume (mL) | 1.10 (0.36, 3.31) | 0.870 |
| EUROMACS score | 6.88 (2.31, 20.45) | 0.001* |

Table 2. Odds-ratio of each standardized continuous risk factor for early right heart failure based onunivariate logistic regression models. Each odds ratio estimate reflects a 2 standard deviation change in thecorresponding variable.

1 0

Validation of the EUROMACS score. An elevated EUROMACS score was associated with increased risk of RVF (OR 6.88; 95% CI 2.31 to 20.45, p = 0.001). The EUROMACS score had an area under the curve of 59%, (95% CI 52–66%) (Fig. 2). The performance of the EUROMACS score to predict RVF as defined by RVAD use or prolonged inotrope use was 67% (95% CI 54–79).

Discussion

In this external validation of the EUROMACs score to predict right ventricular failure after CF-LVAD, we found we found that the EUROMACS score had relatively poor discrimination in predicting RV failure. Right ventricular failure was significantly associated with mortality after CF-LVAD in this dataset, which was mainly driven by the need for RVAD and/or prolonged inotropes. Many of the variables used in the EUROMACs score were not associated with RV failure in our cohort including hemoglobin and RA/PCWP ratio.

| Predictor | Odds-ratio (95% CI) | <i>p</i> value |
|---|----------------------|----------------|
| Sex | 2.51 (0.32, 19.96) | 0.384 |
| Bridge to transplant LVAD | 0.68 (0.21, 2.2) | 0.520 |
| Diabetes mellitus | 0.51 (0.15, 1.73) | 0.280 |
| Non-ischemic cardiomyopathy type | 0.28 (0.07, 1.07) | 0.063 |
| Coronary artery disease | 0.39 (0.12, 1.29) | 0.123 |
| Atrial fibrillation | 0.83 (0.26, 2.68) | 0.755 |
| History of coronary artery bypass surgery | 0.77 (0.16, 3.62) | 0.739 |
| Chronic obstructive pulmonary disease | 0.62 (0.13, 2.91) | 0.545 |
| Hypercholesterolemia | 1.14 (0.36, 3.64) | 0.823 |
| Hypertension | 0.85 (0.27, 2.7) | 0.779 |
| Implanted cardiac defibrillator | 0.55 (0.16, 1.89) | 0.340 |
| History of smoking | 0.85 (0.18, 4.02) | 0.840 |
| Ventilator use | 4.34 (1.22, 15.45) | 0.023* |
| Continuous renal replacement therapy | 0 (0, Inf) | 0.992 |
| Inotropes | 2.76 (0.73, 10.45) | 0.135 |
| Multiple inotropes | 10.52 (3.12, 35.53) | < 0.001* |
| Extra corporal membrane oxygenation | 5.87 (1.42, 24.32) | 0.015* |
| Impella | 10.91 (0.92, 129.67) | 0.058 |
| Intra-aortic balloon pump (non-elective) | 3.25 (1.01, 10.46) | 0.049* |

Table 3. Odds-ratios of each binary risk factor for early right heart failure based on univariate logistic regression models.

| Predictor | Odds-ratio (95% CI) | <i>p</i> value |
|-------------------------------|---------------------|----------------|
| Race | - | 0.523 |
| INTERMACS profile | - | 0.142 |
| Right ventricle function | - | 0.307 |
| Right ventricle size | - | 0.890 |
| Tricuspid regurgitation grade | - | 0.293 |

Table 4. Likelihood ratio test *p* value corresponding to each categorical risk factor for early right heart based on univariate logistic regression models (omitting odd-ratios as there are multiple per variable). INTERMACS: interagency registry for mechanical circulatory support.



Figure 2. Receiver operator curve for the performance of the EUROMACS right ventricular risk score in an external, validation cohort. AUC: area under the curve, with 95% confidence interval.

Right heart failure is one of the most common causes of early morbidity and mortality after CF-LVAD implantation. Predicting RV failure is important as planned institution of RVAD during LVAD surgery has been associated with improved outcomes compared to delayed RVAD implantation^{11,12}, and a direct to transplant strategy can be employed in eligible patients to avoid this severe complication. The present study again demonstrates the difficulty in predicting RV failure after LVAD, even with the most contemporary risk scores. Our results mirror external validations of the EUROMACS right sided heart failure risk score where ROCs were in the 0.65 range^{8–10}.

There are many reasons why our results may have differed from the original EUROMACs analysis. In our cohort, the incidence of the RV failure occurred in 39% patients undergoing CF-LVAD implantation. The majority of the patients (65%) met this definition due to prolonged pulmonary vasodilator use, while the EUROMACs data only had 1% of patients with prolonged pulmonary vasodilator use. RV failure defined by prolonged vasodilator use was not associated with increased mortality in our cohort, which questions the clinical significance of this part of the RV failure definition. The use of pulmonary vasodilators and time course of weaning these medications appears to be different between the University of Minnesota and EUROMACS derivation cohorts, which reflects significant variability in practice. When restricting the RVF definition to inotropes ≥ 14 days and/or need for RVAD, the performance of the EUROMACS score improved. Another difference between the cohorts was the lower numbers of destination therapy CF-LVAD implantations in the EUROMACs cohort (14% vs. 49%). The larger number of patients with comorbid conditions in the University of Minnesota dataset may have explained some of the lower performance observed in the model, as these populations have real differences.

There have been several previous studies designed to predict those patients at high likelihood of developing RV failure following LVAD implantation. Many of these include hemodynamic variables such as right atrial pressure, pulmonary artery pulsatility index, and right atrial pressure: pulmonary capillary wedge pressure ratio^{13,14}. Other studies have shown that certain echocardiographic features of RV dysfunction such as TAPSE and semi-quantitative RV function are predictive of RV failure after LVAD^{15,16}. In our cohort, none of the previously mentioned hemodynamic variables were predictive of RV failure. Similar to previous analyses, higher creatinine, lower albumin, and higher total bilirubin were all associated with increased risk of RV failure after LVAD. Pre-operative ventilator support, multiple inotropes, extra corporal membrane oxygenation, and non-elective IABP were also associated with higher risk of RVF in this cohort. All of the associated variables are direct or indirect markers of patient acuity, and may suggest longer standing heart failure is a risk factor for post-operative RV failure.

There are many reasons why published risk scores may perform poorly in validation cohorts. First, RV failure after LVAD does not have a universal definition¹⁷. For example, the widely used INTERMACS criteria for RV failure does not include pulmonary vasodilators as definition for RVF. With regard to the hemodynamic variables, these can change dramatically over a 24 h period as patient are managed with diuretics, inotropes and temporary support. Lastly, insults that occur to the RV in the operating room, such as RV ischemia from hypotension, prolonged cardiopulmonary bypass time, surgical positioning of the inflow cannula, fluid resuscitation and blood transfusions are not predictable ahead of time¹⁸. These intraoperative conditions can "unmask" underlying RV failure that might not have been predicted with traditional risk scores using clinical, hemodynamic, and echocardiographic data.

This study has several limitations. First, this was a single-center observational analysis. Second, our sample size is smaller than the EUROMACs cohort, which could limit the power of our study to determine variables that are associated with severe RV failure.

Conclusion

The EUROMACS Right-Sided Heart Failure Risk Score had poor external discrimination on external validation. In the present cohort, variables associated with long-standing heart failure (creatinine, bilirubin, albumin) were more predictive of right ventricular heart failure. As RV failure post LVAD is a complex syndrome influenced by pre-operative, intra-operative, and post-operative factors, it remains difficult to predict. Further work will be required to enhance our understanding of the post-LVAD right ventricular failure syndrome.

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Author contributions

H.S.: developed the concept, performed the chart review, and wrote the first draft of the manuscript. T.M.: helped design the study, and performed all statistical analysis and provided important contributions to the statistical sections of the paper. J.S.: was instrumental in the University of Minnesota data development, contributed to the idea behind the project, helped interpret data, and critically edited the manuscript. R.J.: helped with study design, data interpretation, writing and editing the manuscript. C.M.M.: helped with study design and in writing and editing the manuscript. T.T.: helped with study design, data interpretation, writing and editing the manuscript. R.C.: Was responsible for the idea, helped to clean data and perform statistical analyses, and wrote significant portions of the manuscript.

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Competing interests

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