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Assessing Risk For Right Heart Failure After Left Ventricular Assist Device Implantation

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Assessing Risk for Right Heart Failure After Left Ventricular Assist Device Implantation

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Abstract

The lives of more than six million people in the United States are negatively impacted by the diagnosis of Advanced Heart Failure. Financial burden, repeated hospitalizations, and declining quality of life account for poor outcomes. Implantation of a left ventricular assist device (LVAD) has offered the promise of improved financial, clinical, and functional outcomes for those awaiting or ineligible for heart transplantation. Right Heart Failure (RHF), however, threatens positive outcomes as it remains the leading cause of mortality and morbidity following LVAD placement. Despite extensive research, there is no comprehensive tool for RHF risk assessment and stratification for this population. The D.N.P. project aimed to adapt and implement a scoring tool for such assessment. Providers rated the assessment tool to be feasible and useful in practice. Though limited by a small number of LVAD patients, RHF risk was found to fluctuate for each patient throughout the phases of care, and no single parameter consistently trended in the same direction as the combined score. This pilot project should inspire future projects aimed at identifying risk for RHF which can offer opportunities for preventative care and realization of all positive outcomes for LVAD recipients.

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Abbreviations

RHF - Right Heart failure

HF - Heart Failure

LVAD - Left Ventricular Assist Device

RVAD - Right Ventricular Assist Device

RV - Right Ventricle

LV - Left Ventricle

PH - Pulmonary Hypertension

PACi - Pulmonary Arterial Compliance Index

PAPi - Pulmonary Arterial Pulsatile Index

Ea - Pulmonary Elastance

CVP - Central Venous Pressure

RAP - Right Atrial Pressure

RVEDVI - Right Ventricular End Diastolic Volume Index

LVEDVI - Left Ventricular End Diastolic Volume Index

RVEDAI - Right Ventricular End Diastolic Area Index

LVEDAI - Left Ventricular End Diastolic Area Index

RVEF - Right Ventricular Ejection Fraction

REF - Right Ejection Fraction

RVLS - Right Ventricular Longitudinal Strain

PAS - Pulmonary Artery Systolic Pressure

PAD - Pulmonary Artery Diastolic Pressure

PCWP - Pulmonary Capillary Wedge Pressure

TAPSE - Tricuspid Annular Plane Systolic Excursion

ECMO - Extracorporeal Membrane Oxygenation

IABP - Intra-aortic Balloon Pump

2D - Two Dimensional

3D - Three Dimensional

NYHA - New York Heart Association

ACCF - American College of Cardiology Foundation

AHA - American Heart Association

EUROMACS - European Registry for Patients with Mechanical Circulatory Support

INTERMACS - Interagency Registry of Mechanically Assisted Circulatory Support

ICU - Intensive Care Unit

ARC - Academic Research Consortium

KTA - Knowledge to Action Model

SWOT - Strengths, Weaknesses, Opportunities and Threats Analysis

I-CVI - Item Content Validity Index

RN - Registered Nurse

APRN - Advanced Practice Registered Nurse

D.N.P. - Doctor of Nursing Practice

Chapter 1

Introduction, Significance, and Problem Statement

Introduction

Right heart failure (RHF) is the most common postoperative complication following implantation of a left ventricular assist device (LVAD) for advanced left heart failure. Advanced heart failure negatively impacts the lives of over six million people in the United States today, accounts for approximately one million hospitalizations, and is mentioned on over 300,000 death certificates annually (Centers for Disease Control and Prevention [CDC], 2020). For this population, resistance to medical treatment and repeated hospitalizations are associated with worsening prognosis, poor quality of life, and a projected rise in healthcare cost from $39 billion currently to $53 billion by 2030 (Gohar et al., 2018, p. 35). Though heart transplantation remains the gold standard treatment for end-stage heart failure, the LVAD has become an accepted alternative treatment for this disease. It offers an effective solution for a population of patients otherwise facing an unmatched and unpredictable availability of compatible donor organs (Harshvardhan & Satsangi, 2020).

The durable LVAD was introduced in 2001 and became a life-saving option for bridging patients to heart transplantation. The one-year survival rate of candidates waiting with an LVAD reportedly increased from 10.2% during 1996-2000 to 70% during 2011–2017 (Bakhtiyar et al., 2020). Since then, the indication for use has been expanded to include destination therapy for a growing number of LVAD recipients who are not candidates for transplantation. Once implanted, the LVAD restores organ perfusion, preserves physical strength, and improves overall survival rate by 27% (Bowen et al., 2020). Significantly improved survival and quality of life

outcomes are consistently reported, independent of the indication for LVAD placement (Emani et al., 2016).

Despite successes with advanced heart failure treatment, RHF remains the primary cause of morbidity and mortality following LVAD implantation, reducing the 80% one-year survival rate to 59% (Ali et al., 2020). Morbidities associated with the development of RHF include prolonged hospital length of stay, coagulopathy, altered drug metabolism, cardiac cachexia, diuretic resistance, gastrointestinal bleeding, and decreased quality of life (Lambert & Tueteberg, 2015).

The Problem Statement

Concomitant implantation of a durable RVAD would be the ideal solution to the problem of RHF after LVAD. However, there is no such FDA-approved device currently available. Treatments aimed at preventing or minimizing RHF have proven effective, though are dependent on the accurate identification of risk for impending RHF associated with LVAD placement.

Numerous studies have aimed to identify the best preoperative predictors of right heart failure after LVAD (Bellavia et al., 2017; Hayek et al., 2014 & Lampert & Tueteberg, 2015). The majority have been conducted in single centers with retrospective data collection, using small sample populations. Inclusion and exclusion criteria, the specific parameters evaluated, and the definitions of RHF have differed between studies, therefore offering minimal opportunity for comparison or conclusion. A recent meta-analysis reported conflicting evidence with several of the proposed risk assessment instruments and parameters reaching statistical significance yet having small effect sizes (Bellavia et al., 2017). Though the evidence offers minimal consensus for accurate assessment of risk for RHF after LVAD, there is clear agreement that the need to do

so is essential to producing the positive outcomes this technology offers patients with advanced heart failure.

The lack of a comprehensive instrument for reliably predicting RHF has resulted in the inaccurate and inconsistent assessment of risk and a failure to recognize worsening right ventricular dysfunction before progression toward irreversible, debilitating RHF. This D.N.P. project assessed the use of an adapted, evidence-based RHF risk assessment instrument for LVAD candidates and recipients at a large medical center.

Significance of the Problem

Advanced heart failure is a progressive condition associated with several cardiovascular disease processes. The prevalence of advanced heart failure continues to rise steadily with the aging population and improved survival from acute cardiovascular disease. It is the most common diagnosis in hospitalized patients over 65 years of age and the most frequently associated with 30-day readmission (Nair et al., 2020).

Despite significant advances in medical therapies, the diagnosis of advanced heart failure carries a 30-40% mortality rate, varying with severity (Nair, 2020). Though heart transplantation significantly improves survival, less than 20% of eligible candidates will receive a compatible donor heart (Bakhtiyar et al., 2020). Forty-five percent of patients on the waiting list may lose eligibility or will not survive to transplantation (McLarty, 2015).

The life expectancy for patients with advanced heart failure is less than 12 months. Over the past decade, the LVAD has increased one-year survival to 80%, and two-year survival to 70% for patients with advanced heart failure, either as a bridge to transplantation or as destination therapy (Wagner et al., 2020). Placement of an LVAD has the potential to increase life expectancy to over ten years (Gustaffson & Rogers, 2017). Despite these successes, as many

as 50% of recipients may develop postoperative right heart failure, threatening loss of the survival, clinical, and quality of life improvements this technology promises (Baxter et al., 2019). These patients will have a sixfold increase in mortality (Farag et al., 2021). Nair (2020) found a reduction in one-year survival to 71%, and two-year survival down to 54%. Along with the loss of promised longevity, patients with RHF after LVAD will experience a higher incidence of coagulopathy and hemorrhage, respiratory and renal failure, postoperative length of stay, hospital readmissions, failure to bridge to transplantation, loss of independence, and an overall poorer quality of life (Baxter et al., 2019 & Kurihara et al., 2017).

The severity of sequelae is associated with the severity of right heart failure following LVAD implantation (Baxter et al., 2019). Failure to identify risk for impending RHF can result in a missed opportunity for the timely employment of alternate treatments proven to protect and support the struggling right heart. Therefore, the focus must remain on the urgent need to reliably assess RHF risk if this devastating complication is to be prevented or its severity minimized (Raina & Patarroyo-Aponte, 2018). Fulfillment of this need is critical to mitigating poor financial, clinical, and functional outcomes for the rapidly growing population of LVAD recipients.

Chapter 2

Review of Literature, Project Models, Organizational Assessment, SWOT, and Aims

Review of the Literature

A search was performed to review evidence for the prediction of RHF following LVAD implantation. Databases searched included Ovid Medline, Scopus, and Google Scholar. Search terms included: RHF, LVAD, RHF after LVAD, prediction of RHF after LVAD, risk for RHF after LVAD, right ventricular function and left heart failure, cardiac reserve function, Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS), and European Registry for Mechanically Assisted Circulatory Support (EUROMACS). The articles were limited to English language, humans, and adults. Articles before 2011 were eliminated, except for three review articles. All articles without the primary focus on right heart failure after LVAD and those evaluating pulsatile flow LVADs were eliminated. 23 articles of the remaining 54 articles, were eliminated for poor study quality rendering each non-contributory. 27 articles published in 2011 or later, and one classic review article from 2010 were evaluated for inclusion and exclusion criteria, specific endpoints, and parameters and risk scores proposed for prediction of RHF after LVAD (see Appendix A). A total of 29 articles published were included in this review (Appendix B).

Implantation of an LVAD has become an accepted alternative to heart transplantation for patients with end-stage left heart failure. It offers an effective solution for a population of patients who otherwise face unmatched and unpredictable availability of compatible donor organs (Harshvardhan & Satsangi, 2020). Most patients with severe left heart failure are classified as American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Stage D Heart Failure (HF) and have New York Heart Association Class IV HF

symptoms. Approximately 80% of patients will improve to class I-II symptoms six months after LVAD implantation (Kiernan et al., 2016). Significantly improved survival and quality of life outcomes are consistently reported (Emani et al., 2016).

Despite efficient left ventricular function, LVAD recipients may manifest symptoms of worsening HF attributed solely to RHF (Kanwar et al., 2020). RHF is the primary complication after LVAD placement for 3.9-53% of recipients (Ali et al., 2020). The critical need for reliably predicting and preventing RHF has been the motivation for this extensive research.

Most research studies have been conducted in single centers using retrospective data collected from small sample populations. Inclusion and exclusion criteria, the specific parameters evaluated and definitions of RHF endpoints have lacked consistency and may contribute to the broad range of documented incidence and mortality associated with RHF after LVAD. Initial analysis of the evidence finds little consensus regarding parameters predictive of RHF and offers minimal opportunity for comparison (Bellavia et al., 2017; Hayek et al., 2014).

A synthesis of the collective evidence, however, does support the following:

1). Right Ventricle (RV) dysfunction coexists with severe left heart failure.

2). Parameters that measure RV reserve function determine risk.

3). LVAD placement acutely reduces RV reserve function, driving the need to identify early risk.

4). RHF is the endpoint of a continuum beginning with subclinical RV dysfunction.

5). Critical events alter risk for RHF by reducing, restoring, or maintaining RV reserve, allowing movement in either direction along the continuum.

RV dysfunction coexists with severe left heart failure

The right and left ventricles are dependent on each other for producing cardiac output adequate for perfusing all organs. Functional interdependence is achieved through a shared septum and pericardium. Approximately 30% of right ventricular output is reliant on this relationship (Kanwar et al., 2020). Changes in diameter, geometry, or contractility in one ventricle directly affect function of the other (Kukucka et al., 2011). A unique embryonic origin lends the RV the ability to dilate to accommodate increased volume imposed by a failing left ventricle (LV). However, the RV is far less tolerant of pulmonary hypertension (PH) imposed by LV failure (Meineri et al., 2012).

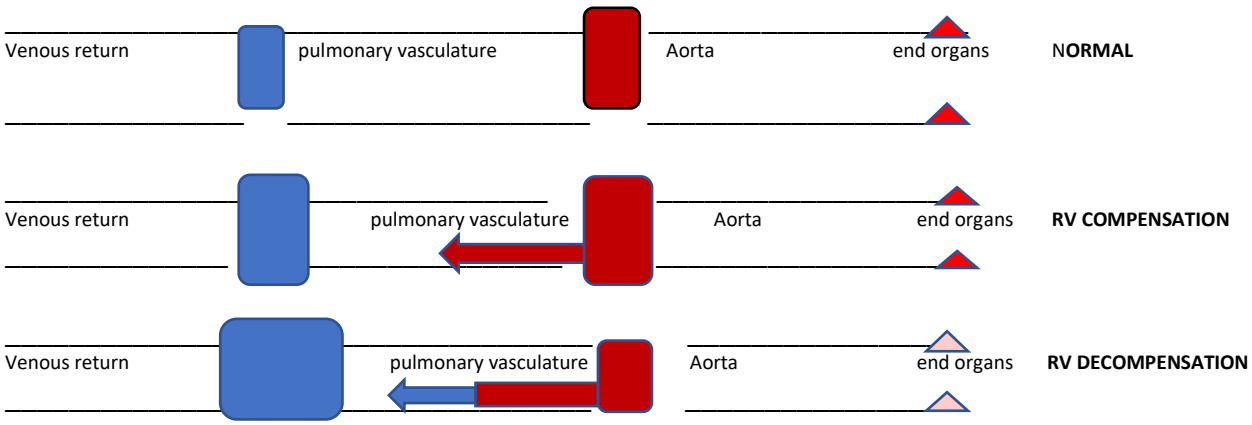
Eighty percent of patients with LV failure develop secondary PH (Rao et al., 2020). Secondary PH also persists for a time following LVAD placement (Houston et al., 2016). Attempting to maintain LV filling in the face of PH, the RV uses alternative, less efficient contractility which eventually leads to RV muscle hypertrophy and dilation. These structural changes are indicative of myocyte loss and diminishing contractility. Prolonged exposure to PH or acute spikes in PH exhaust compensatory mechanisms ultimately leading to RV decompensation (Ali et al., 2020). Decompensation is marked by evidence of end-organ hypoperfusion and dysfunction (see Figure 1).

In a meta-analysis, Bellavia et al. (2017) concluded that nearly all LVAD recipients had some level of preoperative RV dysfunction on echocardiogram. Newer three-dimensional (3D) echocardiograms capable of detecting even subclinical RV dysfunction have added support for this point of agreement (Aymami et al., 2018). In a comparison of parameters obtained on two-dimensional (2D) and three-dimensional (3D) echocardiograms, Magunia (2018) reports that the American Society of Echocardiography recommends combining parameters from either

technology with clinical signs to estimate preoperative RV dysfunction, allowing a more accurate determination of risk for RHF following LVAD insertion. Wagner et al. (2020) studied 112 LVAD recipients retrospectively to find the majority with preoperative RV dysfunction. Stratifying recipients on a spectrum of compensated to decompensated RV function showed a relationship between the severity of RV dysfunction preoperatively and the development of early postoperative RHF. Though there is substantial agreement regarding the existence and significance of preoperative RV dysfunction in response to PH, there is little consensus concerning parameters that best assess risk for RHF following LVAD placement (Grant et al., 2021).

Figure 1

Sequelae of Left Heart Failure



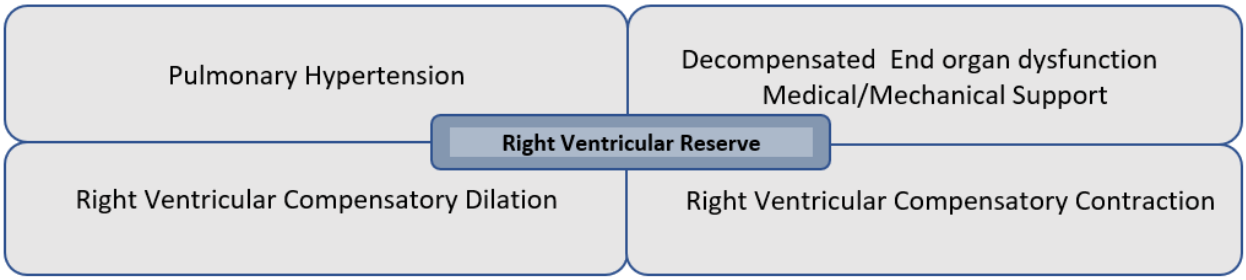
Parameters Measuring RV Reserve Function Determine Risk

RV reserve is the difference between maximal compensatory capacity and basal function. It is the safety margin that allows RV resilience to maintain its output despite progressive PH or additional insult (Grunig et al., 2020). Once compensatory mechanisms such as altered contractility and RV dilation are exhausted, decompensated RV dysfunction is marked by a comparably smaller, underfilled LV and subsequent end-organ hypoperfusion.

Though RV dysfunction exists, it is the ability to maintain function or the remaining reserve function that determines risk for the development of RHF after LVAD. RV dysfunction as a risk factor becomes relative to reserve function, the more accurate measure of risk. The less RV reserve function at any level of RV dysfunction, the greater the risk of decompensation and progression to postoperative RHF. Inconclusive findings and lack of consensus has likely resulted from failure to assess RHF risk with consideration for compensatory expenditure and evidence of decompensation (see Figure 2).

Figure 2

Components of Right Ventricular Reserve Function



Parameters representing each of the components of RV reserve: PH, RV compensation, and RV decompensation, studied independently have been inconsistent in their ability to accurately predict RHF. Additionally, the use of individual parameters has been outperformed by combinations of parameters representing two or more components (see Figure 3). Combined parameters offer evidence of the strong inverse relationship between diminishing RV reserve and increasing risk for RHF after LVAD insertion (Del Rio et al., 2019).

Pulmonary Hypertension. PH has been recognized as the greatest culprit of structural and functional RV changes in the setting of LV failure (Rao et al., 2020). Parameters measuring pulsatile resistance as opposed to those measuring static resistance were found to represent PH

Figure 3

Parameters Constituting RV Functional Reserve

ABBREVIATION	NAME	FORMULA	INTERPRETATION
Pulmonary Hypertension Parameters			
PVR	Pulmonary Vascular Resistance	Pulmonary arterial pressure -pulmonary capillary wedge pressure/CO	Resistance to mean flow
TPG	Transpulmonary Gradient	Alveolar pressure – intrapleural pressure	Net pressure applied to the lungs with inspiration or positive pressure ventilation
DPG	Diastolic Pulmonary Gradient	Diastolic pulmonary artery pressure – pulmonary capillary wedge pressure	Marker of pulmonary remodeling
PAS	Pulmonary Artery Systolic Pressure	Obtained by direct measurement	Pressure in pulmonary artery during right ventricular ejection
PACi	Pulmonary Arterial Compliance Index	Right ventricular stroke volume – pulmonary artery systolic – pulmonary diastolic pressure/BSA	Index of pulmonary vascular elasticity
Ea	Pulmonary Elastance	Pulmonary artery systolic pressure/right ventricular stroke volume	Reciprocal of compliance. Total right ventricular overload including resistive and pulsatile components.
PAPi	Pulmonary Artery Pulsatility Index	Pulmonary artery systolic – pulmonary diastolic pressure/right atrial pressure	Indirect measure of contractility at a given right ventricular preload and afterload
Dilation Parameters			
RAP	Right Atrial Pressure	Obtained by direct measurement	Right heart preload
CVP	Central Venous Pressure	Obtained by direct measurement	Right heart preload
PCWP	Pulmonary Capillary Wedge Pressure	Obtained by direct measurement	Left heart preload
RVEDVi	Right Ventricular End Diastolic Volume index	Derived from echocardiographic right atrial diameter measurement/BSA	Right ventricular size
RVEDAi	Right Ventricular End Diastolic Area Index	Derived from echocardiographic right atrial diameter measurement	Right ventricular size
LAVi	Left Atrial Volume Index	Derived from echocardiographic left atrial diameter measurement/BSA	Left heart afterload
Contractility Parameters			
RV FAC	Right Ventricular Fractional Area of Change	Obtained by echocardiographic measurement	Estimate of the % of change within the right ventricle between systole and diastole
TAPSE	Tricuspid Annular Plane Systolic Excursion	Obtained by echocardiographic measurement	Estimate of the displacement of the tricuspid valve from end diastole to end systole
TrV	Tricuspid Regurgitation Velocity	Obtained by echocardiographic measurement	Estimate of right ventricular systolic pressure
RVEF	Right Ventricular Ejection Fraction	Obtained by echocardiographic or hemodynamic measurement	Estimate of % end diastolic volume ejected during RV systole
RVLS	Right Ventricular Longitudinal Strain	Obtained by echocardiographic measurement	Measure of right ventricular free wall deformation during peak systole
RVSWI	Right Ventricular Stroke Work Index	0.0136 x right ventricular stroke volume x (mean pulmonary artery pressure – right atrial pressure)	Estimation of RV workload and contractility. Implies work capacitance
Decompensation Parameters			
BUN	Blood Urea Nitrogen	Obtained from blood sample analysis	Nitrogen waste remaining in blood/Measure of kidney function
Cr	Creatinine	Obtained from blood sample analysis	Creatinine waste from muscle breakdown in blood/ Measure of kidney function
GFR	Glomerular Filtration Rate	Obtained from blood sample analysis	Rate of filtration of waste by kidney's glomerulus/Measure of kidney function
T bili	Total Bilirubin	Obtained from blood sample analysis	Bilirubin waste product of red blood cell breakdown in blood/Measure of liver function
ALT	Aspartate Transaminase	Obtained from blood sample analysis	Enzyme released from damaged liver cells/Measure of liver function
AST	Alanine Transaminase	Obtained from blood sample analysis	Enzyme released from damaged liver cells/Measure of liver function
MELD	Model for End Stage Liver Disease	Score based on renal replacement therapy, creatinine, total bilirubin, INR and sodium	Predictor of survival n setting of liver disease

more accurately. Neither, however, reached significance as individual predictors of RHF (Bellavia et al., 2017; Grandin et al., 2015; Kimmalardjuk & Ruej, 2017; LoForte et al., 2018; Loghmanpour et al., 2016; Marshall et al., 2020; Muslem et al., 2019 & Scott et al., 2020).

The best performing measures of pulsatile resistance were pulmonary arterial compliance index (PACi), pulmonary elastance (Ea), and pulmonary arterial pulsatile index (PAPi). Though similar, calculation of PAPi uniquely combines pulsatile resistance with a measure of RV dilation. PAPi proved to be the most consistent independent predictor of RHF when compared to all other calculations of PH (Kang et al., 2016 & Marshall et al., 2019). Grandin et al. (2015) and Muslem et al. (2019) found that Ea and PACi performed comparably only when combined with a measure of RV dilation. They also found LVAD recipients at the least risk for RHF when PH and RV dilation were minimal. The greatest risk was associated with greater PH and greater RV dilation. Those with greater PH and minimal RV dilation were found to have moderate risk for postoperative RHF. Evaluation of PH relative to compensatory RV dilation did not reach significance though did consistently improve discrimination for RHF. Relating PH to an RV dilation supported the associations between increasing compensation, diminishing reserve function, and increasing risk for RHF after LVAD.

Right Ventricular Compensatory Dilation. Parameters representing compensatory RV dilation include qualitative descriptions of RV size and direct measurements of RV diameter obtained by echocardiography as well as by hemodynamic pressure measurements. Central venous pressure (CVP) and right atrial pressure (RAP) have been used interchangeably and are cited in nearly every inquiry.

Compensatory dilation is a response to a backup of volume which occurs as compensatory RV contractility becomes overwhelmed by increased or prolonged PH. Parameters

of RV dilation have shown a relationship to declining RV reserve and increased risk for RHF after LVAD. Elevations in RAP immediately preceding LVAD implantation, whether persistent or increased from baseline, were associated with a three-fold risk of progression to RHF after LVAD placement (Grandin et al., 2015).

Evidence suggests that RV dilatation approaching, or exceeding LV size is an indication of diminishing reserve function with the loss of capacity to adequately fill the LV. Increased preoperative ratios of RV:LV dilation outperformed isolated measures of RV dilation as an independent predictor of RHF following LVAD (Kukucka et al., 2011). RV:LV dilation was the only dilation parameter to significantly improve discrimination for RHF when combined with the most cited risk scores, which at best, had performed modestly (Vivo e al., 2013).

Right Ventricular Compensatory Contractility. Traditionally RV contractility has been equated with RV function, long believed to be the greatest determinant of RHF following LVAD implantation. However, qualitative descriptions, semi-quantitative measurements, and hemodynamic calculations representing RV contractility have repeatedly failed to show a consistent association with postoperative RHF (Aymami et al., 2018; Bellavia et al., 2017; Grant et al., 2012; Gumus et al., 2019; Imamura et al., 2015; Kiernan et al., 2015; Magunia et al., 2018; & Scott et al., 2020). Similarly, surrogate parameters such as CVP have not been reliable predictors of RHF and have instead led to delayed recognition of failing RV contractility, diminishing RV reserve, and therefore risk for RHF after LVAD.

2D and 3D echocardiographs have allowed for quantitative estimations of right ventricular ejection fraction (RVEF) and right ventricular longitudinal muscle strain (RVLS). Both parameters are sensitive to early decreases in normal contractility, preceding evidence of RV dilation. RVEF and RVLS were strongly associated with progression to RHF following

LVAD when compared to traditional and surrogate parameters. Like all other parameters of RV contractility, RVEF and RVLS demonstrated significantly augmented discrimination for RHF when combined with parameters of PH, RV dilation, or both (Aymami et al., 2018; Kiernan et al., 2015 & Scott et al., 2020). The combination of parameters representing PH with those of early compensatory RV contractility and later compensatory RV dilation, have repeatedly shown greater implications for diminishing RV reserve function and the threat of progression to RHF than any single measure of RV contractility.

Right Ventricular Decompensation. Right ventricular decompensation is defined by failure of compensatory mechanisms to maintain LV filling, sufficient for end-organ perfusion. Measures of renal and liver function have been the most frequently reported and reliable laboratory predictors of RHF after LVAD placement (Bellavia et al., 2017; Benjamin et al., 2020 & Hayek et al., 2014). These laboratory parameters may be maintained within normal ranges when medical and mechanical support have been added to preserve, restore, or replace RV and/or end-organ function. Quantification of support then also becomes an indicator for RV decompensation and a predictor of postoperative RHF. Worsening organ function despite escalating support indicates loss of reserve function and risk for rapid progression to RHF.

Assigned INTERMACS profiles depicting the progression from compensated RV function to decompensated RV function have been included in several studies (see Figure 4). Though not specific, lower profiles have been strongly associated with a worse prognosis for RHF across all studies (Aymami et al., 2018). Significantly improved discrimination was demonstrated when profiles were combined with parameters representing compensatory RV contractility and dilation (Grant et al., 2012 & Loghmanpour et al., 2016).

The ALMA score uniquely combined parameters representing PH, RV compensation,

Figure 4

INTERMACS Profiles

Profile 1	**Critical cardiogenic shock**	Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels. "*Crash and burn*."	Definitive intervention needed within hours.
Profile 2	**Progressive decline**	Patient with declining function despite intravenous inotropic support, may be manifest by worsening renal function, nutritional depletion, inability to restore volume balance "*Sliding on inotropes.*" Also describes declining status in patients unable to tolerate inotropic therapy.	Definitive intervention needed within few days.
Profile 3	**Stable but inotrope dependent**	Patient with stable blood pressure, organ function, nutrition, and symptoms on continuous intravenous inotropic support (or a temporary circulatory support device or both), but demonstrating repeated failure to wean from support due to recurrent symptomatic hypotension or renal dysfunction "*Dependent stability*."	Definitive intervention elective over a period of weeks to few months.
Profile 4	**Resting symptoms**	Patient can be stabilized close to normal volume status but experiences daily symptoms of congestion at rest or during ADL. Doses of diuretics generally fluctuate at very high levels. More intensive management and surveillance strategies should be considered, which may in some cases reveal poor compliance that would compromise outcomes with any therapy. Some patients may shuttle between 4 and 5.	Elective over weeks to months as long as treatment of episodes restores stable baseline, including nutrition
Profile 5	**Exertion intolerant**	Comfortable at rest and with ADL but unable to engage in any other activity, living predominantly within the house. Patients are comfortable at rest without congestive symptoms, but may have underlying refractory elevated volume status, often with renal dysfunction. If underlying nutritional status and organ function are marginal, patient may be more at risk than INTERMACS 4,and require definitive intervention.	Variable urgency, depends upon maintenance of nutrition, organ function, and activity.
Profile 6	**Exertion limited**	Patient without evidence of fluid overload is comfortable at rest, and with activities of daily living and minor activities outside the home but fatigues after the first few minutes of any meaningful activity. Attribution to cardiac limitation requires careful measurement of peak oxygen consumption, in some cases with hemodynamic monitoring to confirm severity of cardiac impairment. "*Walking wounded*."	Variable, depends upon maintenance of nutrition, organ function, and activity level.
Profile 7	**Advanced NYHA III**	A placeholder for more precise specification in future, this level includes patients who are without current or recent episodes of unstable fluid balance, living comfortably with meaningful activity limited to mild physical exertion. Transplantation or circulatory support may not currently be indicated. Modifiers for Profiles Possible Profiles to Modify TCS-Temporary Circulatory Support can modify only patients in hospital (other devices would be INTERMACS devices) Includes IABP, ECMO, Tandem Heart, Levitronix, BVS 5000 or AB5000, Impella. 1,2,3 in hospital. A-Arrhythmia –can modify any profile. Recurrent ventricular tachyarrhythmias that have recently contributed substantially to clinical compromise. This includes frequent ICD shock or requirement for external defibrillator, usually more than twice weekly. Any profile. FF-Frequent Flyer – can modify only outpatients, designating a patient requiring frequent emergency visits or hospitalizations for diuretics, ultrafiltration, or temporary intravenous vasoactive therapy. 3 if at home, 4,5,6. A frequent flyer would rarely be profile 7.	Variable urgency, depends upon maintenance of nutrition, organ function, and activity.

Adapted from "Right Atrial Pressure Predicts Mortality Among LVAD Recipients: Analysis of the INTERMACS Database", by Guglin, M., & Omar, H.R., Heart and Lung Circulation, p. 595, 10(4), with permission from Elsevier

The ALMA score uniquely combined parameters representing PH, RV compensation, and RV decompensation to stratify patients by the need for insertion of a temporary RVAD at the time of LVAD implantation. The score implies a relationship between minimal RV reserve and the highest risk for early postoperative RHF (see Figure 5). The score demonstrated 82.90% sensitivity and 87.80% specificity for RHF after LVAD. ROC curve comparison to several other parameters previously determined to be independent predictors showed a high ACU0.77(95% CI 0.06-0.88) (LoForte et al., 2018). Though promising, this tool has not been validated. The EUROMACS RHF risk score which also incorporates components of RV reserve has been the only score to demonstrate external validity (see Figure 6), (Silverton et al., 2020).

Though rarely studied, combining parameters of RV compensation with parameters of decompensation appears to afford the greatest insight into the expenditure of RV reserve and associated severity of risk for progression RHF.

LVAD placement acutely reduces right ventricular reserve function, driving the need to identify early risk

Acute physiologic changes inherent in LVAD implantation highlight the significance of tracking reserve throughout the perioperative period. LV unloading, the desired effect, correlates with acute leftward shift of the intraventricular septum. This shift is devastating to a dilated RV which has become heavily dependent on septal contraction (Gudejko et al., 2019). The RV is further challenged by an abrupt increase in venous return as the LVAD increases left-sided output (Gudejko et al 2019).

Parameters of PH were measured individually and in combination with parameters of RV dilation and RV contractility at predetermined intervals following LVAD placement. The relationship between PH, RV dilation, and RV contractility worsened in the immediate

Figure 5

The ALMA Risk Score

Parameter	**Score = 1**
Destination Therapy	Yes
PAPi	< 2.0
RV/LV end diastolic diameter ratio	> 0.75
RVSWi	> 300 mm/Hg/ml/m^2 = 1
MELD score	> 17 = 1

Total score

4-5 *indicates highest risk for requiring right ventricular assist device (RVAD) at time of LVAD*

3 *indicates high risk for requiring RVAD at time of LVAD unless temporary RVAD/pharmacologic support sufficient.*

2 *is a gray area in which isolated LVAD placement will be tolerated with appropriate pharmacologic/ temporary RVAD*

0-1 *Isolated LVAD placement will likely be tolerated*

Developed from Loforte et al., 2018.

postoperative period and declined in a steep parallel manner during later postoperative intervals. LV unloading should acutely relieve PH however, evidence suggests a more gradual reversal of pulmonary hypertension. Persistent PH further challenges RV reserve in the early postoperative phase (Houston et al., 2017). Gudejko et al. (2019) identified the combination of elevated parameters of PH and persistently elevated measures of RV dilation most discriminatory for severe postoperative RHF. Comparably, postoperative RHF requiring emergent temporary

RVAD placement was associated with a combination of elevated PH and worse RV contractility (Imamura et al., 2016). All inquiries reported failure of independent PH, RV contractility, and RV dilation parameters to correlate with postoperative RHF.

Figure 6

The EUROMACS Right Heart Failure

Parameter	Points awarded
• Severe RV dysfunction on echocardiogram	2.0
• RAP: PCWP ≥ 0.54	2.0
• INTERMACS profile 1-3	2.0
• Need for ≥ 3 inotropic medications	2.5
• Hgb < 10 g/dl	1.0

Score	Interpretation
0-2	Low risk
2.5-4	Intermediate risk
> 4	High risk

Developed from Soliman et al., 2018

RHF is the endpoint on a continuum beginning with undetectable Right Ventricular Dysfunction

Proposed predictors and variations of INTERMACS RHF criteria have been unique to each study (see Figure 7). Despite differences, the premise of all research has been a dichotomous relationship between preoperative RV function and the development of RHF following LVAD. This premise is brought into question by studies extending data collection into the intraoperative and early postoperative phases. Findings from these studies support the more dynamic nature of risk for RHF after LVAD (Gudejko et al., 2019; Kumar et al., 2020; LoForte et al., 2018; Loghmanpour et al., 2016).

A score of maximal dependence on inotropic and vasoconstrictor medications during the

Figure 7

INTERMACS Criteria for Right Heart Failure after LVAD Placement

- Physical signs and symptoms of right heart congestion
- Central venous pressure or right atrial pressure > 18 mm Hg
- Pulmonary capillary wedge pressure < 18 mm Hg
- Cardiac index > 2 L/minute
- No tamponade or alternate diagnosis explaining clinical condition
- Required inhaled pulmonary vasodilator
- Required unplanned right ventricular device
- Required inotropes > 7-14 days

Developed from Aymami et al., 2018

initial postoperative 48-hours combined with elevated measures of RV dilation was strongly associated with RHF, independent of preoperative parameters (Kumar et al., 2020). Similarly, increased RV dilation immediately before LVAD insertion was associated with postoperative RHF regardless of earlier preoperative measures (Grandin et al., 2015). Intraoperative factors associated with increased PH, reduced RV contractility, or increased dilation also independently increased risk for postoperative RHF (Houston et al., 2017). A continuum of disease progression from compensated RV function to RHF is supported by studies that collectively demonstrated variable risk for development of RHF throughout the perioperative period, independent of isolated preoperative risk factors.

Critical events alter risk by reducing, restoring, or preserving RV reserve, allowing movement along a continuum

Several critical events, including LVAD insertion, accelerate the movement from subclinical preoperative RV dysfunction with adequate reserve function, toward clinically significant RHF. Progression toward RHF occurs as incremental increases in compensatory

changes with corresponding decreases in RV reserve, render the RV less and less capable of maintaining adequate output in the face of added insult. Large intraoperative volume or blood product resuscitation showed a strong association with RHF post LVAD. Limitless RV dilation observed upon opening the pericardium, and acute worsening of RV contractility immediately following pericardium closure were also strongly associated with progression to postoperative RHF, independent of all prior parameters (Gudejka et al., 2019). Like events resulting in increased dilation or reduced contractility, any event causing a sudden spike in PH such as acidosis and hypoxemia severely challenges RV reserve function and acutely increases risk for postoperative RHF, regardless of timing (Houston et al., 2013).

Identification of critical events that may potentiate risk of progression to RHF offer the opportunity to prevent their occurrence or minimize their impact. Interventions that preserve or restore RV reserve mitigate risk for progression to irreversible RHF; A progression that parallels a continuum from reversible end-organ ischemia to multisystem organ failure and inevitable death.

Summary

Points of agreement derived from seemingly noncomparable study findings collectively suggest abandoning the notion of predicting RHF using parameters defined by distinct points in time. Rather the evidence advises the development of a comprehensive model for evaluating the dynamic interaction between components of RV reserve throughout the perioperative period. Preoperative pulmonary hypertension, RV dilation, compensatory RV contractility, and evidence of decompensation agreeably place candidates at increased risk for progression to RHF. However, the evidence also suggests flexibility in the parameters used to measure these

components of RV reserve as it is the relationship amongst them that is most significant in the determination of risk for RHF after LVAD insertion.

Project Management Model

Graham et al. (2006) identified knowledge creation and action as the two interactive and essential components of the Knowledge to Action framework (KTA) which steered the successful implementation of the D.N.P. project (see Figure 8).

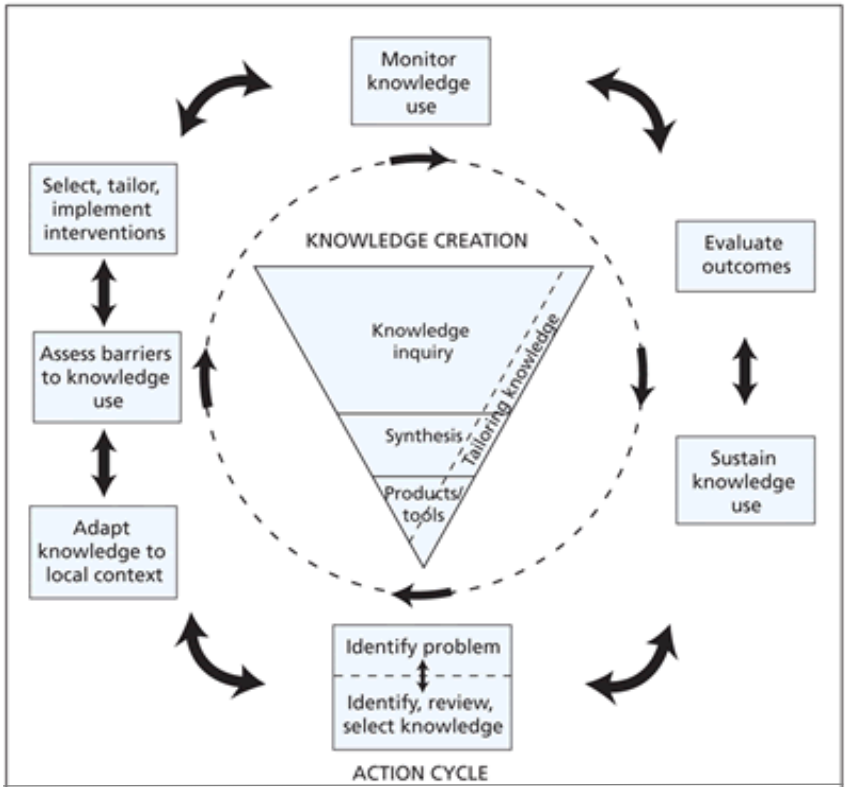
Knowledge creation is depicted as a funnel through which information is gathered during *Inquiry,* filtered during *Synthesis,* and then refined to meet the needs of intended users during *Tool Development* (Graham et al., 2006). For the D.N.P. project, a comprehensive RHF risk assessment instrument for LVAD patients was adapted from the ALMA risk assessment score. Synthesis of evidence guided the extraction of relevance and relatedness amongst the myriad of predictive parameters and definitions of RHF, unique to nearly every study. It also guided the timing and frequency of assessment.

Phases of action encircling the knowledge funnel often begin with *Problem Identification.* Gaps between clinical practice and evidence were realized during this project by repeated movement between this phase and re-entry into the knowledge funnel. The preliminary adapted instrument was tailored to the clinical setting and stakeholders during the *Adaptation of Knowledge*. A*ssessment of Barriers and Facilitators* was used to create an implementation plan maximizing strengths and mitigating risks inherent within the system. Rotation of the knowledge funnel was required upon entry into the *Implementation of Tailored Interventions* to assist with selection of evidence-based, yet accessible risk parameters at the institution of implementation. *Monitoring Use of Tailored Knowledge* proved integral as this project was

dependent on consistent use of the risk assessment instrument. Continuous *Evaluation of Outcomes* and fluid movement between all phases was intended to produce *Sustained Use of Knowledge* for improved clinical and quality of life outcomes for both LVAD patients and care providers (Graham et al., 2006).

Figure 8

Project Management Model: Knowledge to Action



From "Lost in the Knowledge Translation: Time for a Map", by Graham,I ., Logan,T ., Harrison n, M., Strauss, S., Tetro, J., Caswell,W . & Robinson, N., Journal of Continuing Education in the Health professions,20 06,P. 19, 26, with permission from Wolters Kluwer Health, Inc.

Theoretical Model

The MAC Risk Assessment Decision Support Model was adapted from the work of Synderman and Yoediono (2006) to guide RHF risk assessment instrument adaptation, methods of implementation, and evaluation (see Figure 9). The model was originally intended to track

individual risk for developing disease over time. The model was easily adapted for tracking progression from preclinical RV dysfunction associated with LV failure, to irreversible RHF. Directly comparable to progression toward RHF, according to this model, critical events accelerate disease progression. The original model was used to identify biomarkers to detect progression from baseline to irreversible disease. This same concept was applied to identifying parameters that reliably predict progression toward RHF. Synderman and Yoediono (2006), also included risk and monetary cost, both of which increased as the disease progressed. Placing the continuum from subclinical RV dysfunction to RHF on the same graph allowed identification of parameter values associated with increasing risk for progression. For the D.N.P. project, monetary cost was replaced with expenditure of RV reserve to determine parameter values that marked the progression from compensated, preclinical disease to decompensated, less reversible disease.

Prospectively tracking risk and disease development affords the opportunity to provide preventative and therapeutic interventions which mitigate risk for progression (Ginsburg, 2009). The effect of these interventions can also be tracked as positive critical events. The adapted model was applied to better understand the continuum of disease progression and expenditure of functional RV reserve as they relate to positive and negative critical events, ultimately enabling an appropriately dynamic assessment of risk for RHF throughout the perioperative course for LVAD patients.

Organizational Assessment

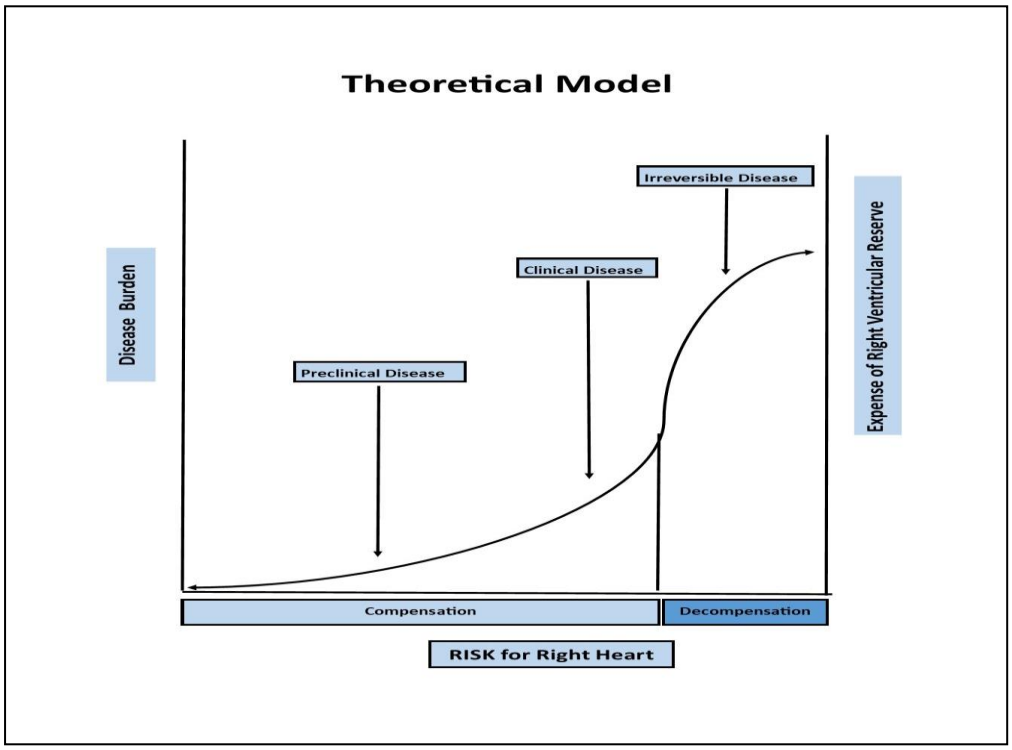
System Description

The institution of implementation is a healthcare delivery system incorporating seven

hospitals, a behavioral health network, a clinical care organization, a regional home care

Figure 9

Theoretical Model: MAC Risk Assessment Decision Support Model



Adapted from "Prospective Care: a personalized, preventative approach to medicine", by Synderman,R., & Yoediono Z. , 2006, *Parmacogenomics*, p. 7, 7(1), with permission from Future Medicine Ltd.

system, senior care service, and a large rehabilitation and physical therapy network with over 350 locations throughout Connecticut and Rhode Island. The system employs a model of Institutes, each sharing the mission of improving the health and healing of targeted populations within the community they serve. Value is placed on offering advanced technology, innovation, and a multidisciplinary approach to care delivery. Strategic planning and large investment led to

the establishment of a *Heart and Vascular Institute*, intended to improve the timeliness of preventative and restorative care for a community with highly prevalent heart disease and associated mortality.

Setting.

The Heart Failure Center within the Heart and Vascular Institute employs and connects an alliance of caregivers to meet the complex needs of patients with heart failure from the time of diagnosis through death. The physician team is comprised of physicians with a specialty certification in heart failure, medical cardiologists, cardiology interventionalist, and cardiac surgeons. Advanced practice registered nurses (APRN), registered nurses (RN) and coordinators are central to the integration of care for each subpopulation of patients receiving various advanced treatments including mechanical circulatory support. Forums of communication that foster a comprehensive, multidisciplinary approach to care are well established. Mechanical circulatory support is offered on the main hospital's campus. LVAD candidates and recipients have a dedicated APRN team leader and Analytics Administrator. The multidisciplinary team involved in the care of patients undergoing LVAD implantation also includes echocardiographers, cardiac anesthesiologists, critical care intensivists, advanced critical care providers, nurse managers, social workers, rehabilitation therapists, and RNs, most of who are represented at weekly team meetings. This integrated setting supported the adaptation, implementation, and evaluation of a comprehensive risk assessment for LVAD patients.

Need for the Project.

Patients referred to the center for LVAD implementation commonly have severe LV failure despite maximal medical therapy. LVAD implantation as either a bridge to

transplantation or as destination therapy has the potential to dramatically improve survival, functional capacity, and quality of life. Development of RHF following LVAD will minimize or eliminate these benefits often leading to a poorer quality of life, increased hospital readmissions, failure to thrive, multisystem organ failure, and often death. Common to most programs, though the opportunity for prevention of this complication exists, there was no standard RHF risk assessment performed before, during, or following LVAD placement at the hospital of implementation. A comprehensive RHF risk assessment for patients undergoing LVAD placement was intended to contribute to the mitigation of potentially poor outcomes and the realization of the many benefits of LVAD therapy.

Organizational Strengths, Weaknesses, Opportunities, and Threats (SWOT).

The primary strength of the healthcare system of implementation was its commitment to providing all necessary resources for advanced mechanical circulatory support to patients with advanced heart failure. State-of-the-art technology, maintenance of staff competency, and established multidisciplinary networks provided the integration needed to implement changes in practice.

Investment in state-of-the-art technology and maintenance of caregivers' competence in using technology allowed ready access to most recent and well-supported measures of RV reserve for RHF risk assessment. Implementation of a comprehensive RHF risk assessment tool for patients undergoing LVAD placement was supported by the nationally recognized team of caregivers and by replication of previously successful processes used for implementation of similar assessment tools within the system. Additionally, a resolute analytics administrator, participation in a national registry, and well-developed local databases enabled project evaluation.

System weaknesses centered around the lack of a standard RHF risk assessment for care planning. Though minimal, a lack of motivation to use the tool may have been attributed to an underestimation of RHF prevalence before implementation with nonspecific data collection, missing data, and limited RHF outcomes reported by the national registry. Communication and implementation were challenged by the large number of providers across the perioperative phases of care needing to improve documentation of risk parameters and to calculate RHF risk scores during the COVID pandemic. These challenges compounded the anticipated weakness in the system related to varying levels of knowledge and skills amongst these providers.

External threats to successful implementation and evaluation of the tool included rapidly changing technology which may render data incomparable. This also means higher costs of equipment as well as costs incurred by extensive and continuous staff education. The lack of externally validated RHF assessment parameters or scores may also challenge the adoption of the proposed risk assessment instrument. Overall, organizational strengths appear capable of overcoming these barriers. (see Appendix C).

Aims

1). Adapt a model for assessing risk for RHF associated with LVAD implantation.

2). Implement and evaluate the RHF risk assessment model for LVAD candidates.

3). Make recommendations for sustainability and scalability of the model's use for added groups of patients.

Chapter 3

Methods, Project Timeline, Human Subjects Consideration, Leadership and Stakeholder Engagement, and Business and Financial Considerations

Overview of Methods

Right heart failure RHF is the primary cause of morbidity and mortality after placement of a durable LVAD. Lack of a comprehensive tool to reliably assess RHF has resulted in failure to recognize risk and progression to irreversible and debilitating heart failure for a substantial number of LVAD recipients. The goal of this D.N.P. project was to adapt, implement and evaluate an evidence-based RHF assessment instrument for patients undergoing LVAD implantation.

The D.N.P. project was a quality improvement project conducted at a large medical center. Providers caring for LVAD patients in and across the preoperative intensive care unit (ICU), operating room, and postoperative ICU, received education and encouragement to use the adapted RHF risk assessment instrument for patient presentations and care planning. Evaluation of the project included a prospective analysis of providers' ratings of the assessment instrument. A retrospective descriptive analysis of parameters and scores was also used to glean information regarding RHF associated with LVAD implantation.

Aim 1: Adapt a model for assessing risk for RHF associated with LVAD implantation.

Adaptation/Development Plan

The evidence addressing risk factors for RHF after LVAD implementation was reviewed resulting in the one model for assessing RHF risk, the ALMA RHF Risk Score, supported by

several other studies identifying comparable parameters for risk of developing RHF after LVAD implantation.

The LVAD RHF risk assessment instrument was adapted from the ALMA Right Heart Failure Risk Score developed by LoForte et al., 2018, intended to predict early postoperative RHF as an indication for implantation of a temporary right ventricular assist device (see Figure 6). The adapted model (see Figure 10) for this project included parameters that are supported by the evidence as comparable and are currently obtained for all LVAD candidates and recipients within the hospital diagnostic testing suites, cardiovascular ICUs, and operating room. Internal and external heart failure experts were invited to rate parameters under consideration for the tool. (see Appendix E).

Figure 10

LVAD Right Heart Failure Risk Assessment Instrument

LVAD Right Heart Failure Risk Score Calculation: Add 1 Point for Each Category if at Least One Parameter Applies	0-1 Point
Category 1: Pulmonary Resistance: ○ PAPI (PAS-PAD/CVP) ≤ 2.0	
Category 2: Right Ventricular Dilation: ○ CVP ≥16 ○ CVP/PCWP ≥ 0.5	
Category 3: Right Ventricular Function: ○ REF ≤ 25 ○ RVSWI ≥300 ○ ≥ Mild RV dysfunction on echo ○ TAPSE ≤ 1.6	
Category 4: Renal /Liver Function ○ Creatinine ≥2 ○ New CVVH, HD ○ MELD Score ≥17	
Category 5: Support ○ ≥ 1 Inotropic or vasopressor medication ○ Mechanical ventilator dependence ○ IABP ○ RVAD ○ ECMO	
Total Points	
RHF Risk Score Interpretation: 4-5 Highest risk 2-3 Intermediate risk 0-1 Lowest risk	

Expert reviewers were sent instructions for reviewing the adapted tool (see Appendix F). They also received a reference table of parameter definitions and measurements (see Figure 11). Experts were asked to rate parameters within the domains defined by RV reserve components. The parameters were rated for relevance to RHF and for their accuracy in measuring each parameter under consideration for inclusion in the adapted risk assessment instrument.

Figure 11

Definition and Measurement of Parameters for Expert Review

ABBREVIATION	NAME	FORMULA	INTERPRETATION
Pulmonary Hypertension Parameters			
PACi	Pulmonary Arterial Compliance Index	Right ventricular stroke volume – pulmonary artery systolic – pulmonary diastolic pressure/BSA	Index of pulmonary vascular elasticity
Ea	Pulmonary Elastance	Pulmonary artery systolic pressure/right ventricular stroke volume	Reciprocal of compliance. Total right ventricular overload including resistive and pulsatile components.
PAPi	Pulmonary Artery Pulsatility Index	Pulmonary artery systolic – pulmonary diastolic pressure/right atrial pressure	Indirect measure of contractility at a given right ventricular preload and afterload
Compensation Parameters			
RV Dilation Parameters			
RAP	Right Atrial Pressure	Obtained by direct measurement	Right heart preload
CVP	Central Venous Pressure	Obtained by direct measurement	Right heart preload
PCWP	Pulmonary Capillary Wedge Pressure	Obtained by direct measurement	Left heart preload
RVEDVi	Right Ventricular End Diastolic Volume index	Derived from echocardiographic or hemodynamic pressure measurement/BSA	Right ventricular diameter
LVEDVI	Left Ventricular End Diastolic Volume index	Derived from echocardiographic or hemodynamic pressure measurement/BSA	Left ventricular diameter
RVEDAI	Right Ventricular End Diastolic Area Index	Derived from echocardiographic diameter at end diastole measurements/BSA	Right ventricular diameter
LVAEDI	Left Ventricular End Diastolic Area Index	Derived from echocardiographic diameter at end diastole measurements/BSA	Left ventricular diameter
Contractility Parameters			
RVEF	Right Ventricular Ejection Fraction	Obtained by echocardiographic or hemodynamic measurement	Estimate of % end diastolic volume ejected during RV systole

A slide presentation was developed for educating providers who were asked to document parameters in the electronic record, calculate, and use the score in practice (see Appendix J). A one- page fact sheet was also developed, distributed by email and posted in ICUs. The fact sheet content included information regarding the purpose of the RHF risk score, an explanation of

parameters included in the score, instructions for calculation, and recommendations for its use (see Appendix K). A laminated pocket reference card for score calculation was developed, distributed to providers, and made available in ICUs. (see Appendix L).

An RHF risk score entry option was added to the critical care provider hand-off for LVAD candidates and recipients. This hand-off existed in the electronic record however was not part of the permanent record. It is an optional worksheet under the ownership of providers and can be edited by any provider who has access to it (see Appendix M).

***Evaluation Plan*.**

The expert responses for relevance and accuracy of parameters required the use of a rating scale from one to four, ranging from not relevant or accurate to highly relevant or accurate (see Appendix G &H). Calculation of an Item Content of Validity Index (I-CVI) was performed for each item to derive the proportion of experts who judged the item relevant and/or accurate (Polit et al., 2007). An I-CVI of $\geq$ 0.79 for a parameter was initially determined to be favorable for retaining the parameter for the final instrument. This was later lowered to a threshold of $\geq$ 0.67 based on the number of expert respondents (see Appendix I).

Aim 2: Implement and evaluate the RHF risk assessment model for LVAD candidates.

Implementation Plan

The adapted RHF risk assessment instrument was introduced during a pre-established, weekly multidisciplinary team meeting in which 15 to 20 LVAD candidates and recipients are discussed. The project leader, who is the critical care representative, delivered a PowerPoint presentation to the team's preoperative, intraoperative, and postoperative provider representatives. (see Appendix J). Providers were asked to reorganize routinely

collected parameters to calculate and incorporate into discussion, RHF risk scores during weekly meetings from September through December 2021.

The one-page fact sheet and laminated pocket reference RHF scoring cards were distributed by email and made available in the ICUs. The team representatives were also asked to encourage implementation of the instrument in their respective departments. Initially, provider education was to be delivered by representatives in each phase of care. Representatives were to voluntarily assume the following responsibilities; however, the process was altered given the limitations imposed by the COVID 19 pandemic.

1. Share a Zoom recording of the PowerPoint presentation or arrange for a live presentation by the project leader.
2. Distribute the one-page fact sheet and pocket reference to providers involved in the care of LVAD patients.
3. Post the one-page fact sheet and reference card in the charting and sign-off locations within their respective departments. The use of a simple fact sheet and scoring reference, particularly posted in these locations, had been a common and effective method for disseminating similar information to providers.
4. Facilitate documentation of tool parameters on the provider handoff.
5. Facilitate calculation and incorporation of the adapted RHF risk score into presentations and care planning for LVAD patients.
6. Collect and provide prospective feedback during weekly email communication with

the project leader.

With unforeseen limitations, the project leader assumed these responsibilities.

The Analytics Administrator of the Center for Advanced Heart Failure continued to collect parameters during the baseline, preoperative, intraoperative, and postoperative phases of care for LVAD patients, as this was the routine practice. The Analytics Administrator agreed to create a password-protected file of coded, deidentified demographic, and parameter data. The project leader was granted access to this separate, coded, and encrypted file.

Evaluation Plan

A combination of formative and summative evaluation was employed to determine usefulness of the RHF risk assessment tool in practice. A post-implementation survey consisting of six items and requiring ratings using a five-point Likert scale ranging from strongly agree to strongly disagree was distributed to providers. Items addressed the providers' perception of the instrument's feasibility, usefulness, and impact on clinical decision-making (see Appendix O). Providers were sent an email including a link to the REDCap application used by the hospital. They were invited to read an information sheet and consent to participate (see Appendix N). Those who clicked a "yes" were sent to the survey in the REDCap application where coded responses were stored for analysis. The scores from all respondents were evaluated for normality of distribution and were presented as mean scores (see Table 1).

The project leader organized the de-identified data collected into the adapted RHF risk assessment tool to arrive at RHF risk scores. RHF risk scores were calculated using parameters at baseline, immediately preoperatively, intraoperatively and within one week postoperatively(see Tables 4,5,6,&7). Based on previous activity, it was anticipated that six patients would be

implanted with an LVAD during the project duration however, a total of four patients were implanted during that period. A descriptive analysis of demographic data, parameters, and scores was performed to inform RHF following LVAD implantation. Incidence of RHF in LVAD recipients during the three-month implementation phase could not be compared to incidence of RHF in LVAD recipients during the six months prior to implementation as the diagnostic criteria had been revised, delaying INTERMACS outcomes reports. Also, outcomes beyond the postoperative data collection point were not included in this project.

Aim 3: Make recommendations for sustainability and scalability of the instrument's use for added groups of patients.

Sustainability

The D.N.P. project will be presented to the leadership of the Heart Failure Center and the Heart and Vascular Institute. Recommendations will be made regarding further implementation of the risk assessment instrument over an extended time for additional LVAD candidates and recipients. A request will be made to INTERMACS for reporting RHF outcomes with analysis of the parameters included in the risk assessment score. INTERMACS encourages such requests and has standardized RHF diagnostic criteria for registries and future trials which will facilitate comparison between studies.

Scalability

Recommendations will be made for collaborating with information technology to construct an algorithm for electronic record population of RHF risk assessment parameters and automatic risk score calculation. This scoring will be embedded into provider documentation by use of a smart phrase, mirroring a similar algorithm for risk of readmission currently in use.

Providers can then be alerted when patients' risk for RHF increases during any phase of care. This would allow providers the opportunity to employ preventative interventions and would also satisfy the need for dynamic risk assessment which is supported by the evidence.

Following repeated and extended use for assessment of LVAD patients; risk for postoperative RHF, adaptation, and use of the assessment instrument for other patient populations with similar risk for RHF, will also be proposed to the administration of the Heart and Vascular Institute.

Dissemination Plan

The D.N.P. project will be submitted for presentation at the National Teaching Institute & Critical Care Exposition and the Annual Right Heart Symposium, 2023-2024. It will be presented in the institution of implementation as well. The project will also be submitted to one of the following for publication to Circulation: Heart Failure Journal, Journal of Heart and Lung Transplantation, Heart and Lung Journal, Nurse Practitioner, and the Critical Care Nurse Journal.

Project Timeline

A draft of the adapted tool for review was completed in July 2021. Expert panel review was conducted during August 2021. The adapted instrument was finalized by September 1, 2021. The PowerPoint presentation was used to introduce the project and background information during a pre-established multidisciplinary meeting on September 8, 2021. Representatives from the departments involved in the care of LVAD candidates and recipients and the project leader shared information with providers from September 9 through October 9, 2021. Implementation of the tool by providers began during September 2021 and continued through December 17, 2021. Providers received email and in-person communications weekly, during the implementation period. They also received a final email containing a link to the post-

implementation survey on December 17, 2021 and were asked to complete the survey by January 17, 2022 (see Appendix D).

Human Subjects Consideration.

This D.N.P. Project was determined a quality improvement project by the Institutional Review Board at Yale. The Nursing Research Council and the Institutional Review Board at the institution of implementation also reviewed and approved this D.N.P. project, as was required for all projects with anticipated future publication.

Leadership and Stakeholder Engagement

As the project leader of this quality improvement project, the D.N.P. candidate adapted the RHF risk assessment instrument, with the support of an expert panel, the APRN Project Manager, and the physician Project Sponsor. The project leader developed and presented an educational program for all providers. The leader also conducted all data analysis and reported findings to all provider stakeholders at the conclusion of the project. The patients were the primary stakeholders whose outcomes may have been positively impacted by the implementation of the RHF risk assessment. The Heart Failure multidisciplinary team and the providers interacting with patients and their families were also primary stakeholders. These stakeholders were supportive of the project. Their knowledge base may have been increased and knowledge variability among providers reduced. The ICU providers were instrumental in facilitating implementation of the instrument in practice and provided a post-implementation rating of the risk score. The Project Manager facilitated communication with, and amongst members of the multidisciplinary team. The Analytics Administrator made possible the analysis of patient data and provided the project leader with necessary education regarding INTERMACS. Other key stakeholders were the members of the expert panel who found value in the project and expressed

interest in future multicenter participation. A stakeholder analysis has been included (see Figure 12).

Figure 12

Stakeholder Analysis

Name	Title/Role	Characteristics/ Interest	Project Engagement	Estimated Priority	Potential Management Strategies
Heart Failure Physician Project Sponsor	Project Sponsor, Heart Failure Certified Cardiologist	Special interest in right heart Failure	High	1	Weekly updates on project planning & Progress
Heart failure APRN Project Manager	Project Manager, LVAD APRN Coordinator	Self - motivated, initiates several quality improvements projects central to all patients, families & caregivers	High	1	Weekly updates and participation in project planning & progression
APRN Project Leader	Operational Leader, APRN CTICU, DNP candidate	Postoperative RHF	High	1	
LVAD Candidates & Recipients, Families/significant others	Care recipients	Varied/Individual, consented to LVAD work up	High	1	Keep informed of risk for RHF & related work-up/tailored interventions
Heart Failure Physician	Medical Director Mechanical Circulatory Support	Leadership, well-connected nationally	High	1	Monthly updates on project development & progress
Heart failure Physician	Chief of Cardiology & Director of Heart Failure Center	Leadership	High	2	Monthly updates on project development & progress
Heart Failure Physician	Heart Failure Certified Cardiologist	Supportive	Intermediate	2	Monthly updates on project development & progress
Heart failure Physician	Heart Failure Certified Cardiologist	Supportive	Intermediate	2	Monthly updates on project development & progress
Echocardiographers	Perform preoperative & postoperative echocardiograms	Skilled	Intermediate	2	Include in planning and tool development/parameter selection
Cardiac Interventionalist	Perform preoperative cardiac catheterization	Skilled/expertise in hemodynamic parameter interpretation	Intermediate	1	Include in planning and tool development/parameter selection, multidisciplinary meetings and INTERMACS report analysis
Cardiothoracic Surgeons	Perform LVAD insertion & participate in preoperative and postoperative management	Skilled in invasive procedures/interventions	Intermediate	1	Include in planning and tool development/parameter selection, multidisciplinary meetings and INTERMACS report analysis
Cardiothoracic Anesthesiologist	Perform Intraoperative echocardiogram & medical management	Skilled in echocardiogram and perfusion management	Intermediate	1	Include in planning and tool development/parameter selection, multidisciplinary meetings and INTERMACS report analysis
Cardiology & Cardiothoracic ICU intensivist, attendings, Advanced practice providers & RNs	Provide immediate preoperative & postoperative management	Expert in hemodynamic monitoring & critical care	High	1	Include in planning and tool development/parameter selection, multidisciplinary meetings, daily care rounds.
Data Manager	Data collection & INTERMACS submission	Supportive, Expert in data retrieval & INTERMACS reporting	High	1	Include in planning and tool development/parameter selection & INTERMACS report requisition & analysis
Cardiology Residents & Fellows	Provide immediate preoperative & postoperative management	Supportive	High	1	Provide education during orientation & include in daily patient care rounds
Outpatient Care Providers	Provide preoperative and late postoperative management, source of referral for Heart failure care	Supportive, established relationship with patients, expert in diagnosis of worsening heart failure assessment	Intermediate	2	Provide education & report of individual patient course/outcomes

Business and Financial Considerations

The cost of standard care for the six LVAD admissions anticipated for this project would have been $1,695,000 or $282,500 per admission. The project adds an estimated $5600 to each admission. After initial one-time costs, the cost of continued use of the RHF risk assessment tool would be reduced to $2500 per admission (see Figure 13). The benefits of its use would include avoidance of the direct, indirect, and intangible costs associated with RHF after LVAD as well as increased access to LVAD implantation.

Figure 13

Project Budget

Program Expense	Estimated Cost	Actual Cost
Staffing (Expert panel, providers)	**$24,789.00**	**$18,956.00**
Services (Scientist assistance/ design & data analysist)	**$ 2,970.86**	**$ 2,970.86**
Equipment & Supplies (paper, copies, lamination)	**$ 100.00**	**$ 473.28**
Total Expense	**$27,859.86**	**$22,400.14**

Actual costs included that of the four LVAD admissions

Up to 50%, or two of the four patients included in this project, will likely develop RHF following LVAD implantation. Increased ICU and hospital length of stay, additional diagnostic procedures, and treatments would contribute to increased direct and indirect medical costs of over $166,000 per implant admission, far surpassing the $5600 spent to prevent or mitigate the impact of RHF. Cost avoidance for 50% of the average 15 admissions per year, beyond the project, would increase to over $1,222,500 annually with the prevention of RHF.

Direct and indirect medical costs related to RHF after discharge primarily include increasingly frequent readmissions within 30 days of discharge and throughout the remaining months of life. Each RHF readmission after LVAD costs approximately $19,000 compared to

$12,000 for similar admissions prior to LVAD placement (Shreibati et al., 2017). These more costly readmissions could be completely avoided with the use of the risk assessment tool and prevention of RHF.

Prevention of RHF would also result in additional avoidance of approximately $12,000-$15,000 each year related to increased outpatient visits, diagnostic testing, increased need for medications, treatments, rehabilitative, home, and long-term care (Urbich et al., 2020). Like readmissions, these avoidable costs escalate as RHF inevitably progresses.

Societal and personal costs account for the remainder of indirect and intangible costs which could be avoided with prevention of RHF after LVAD. Loss of income impacts LVAD recipients, their families, informal caregivers, and employers. Such losses directly associated with advanced heart failure contributed to over $12.4 billion of lost income in the U.S. during the year 2020 (Urbich et al., 2021). Though actual dollars can be attached to medical care and to loss of income, there is no dollar amount capable of placing value on the loss of promised productivity, independence, and longevity. These losses result in worsening pain, suffering, depression, and overall quality of life for LVAD recipients with RHF.

Use of the risk assessment instrument and prevention of RHF after LVAD would improve the financial, clinical, and quality of life outcomes for LVAD recipients. Improved outcomes would then drive improved access to LVAD implantation. Recently, Medicare and Medicaid coverage expanded to include all indications for LVAD because of evidence demonstrating comparable outcomes for bridge to transplant and destination therapy (Urbati et al., 2021). Prior to the 2020 revision, there was limited access to LVAD as a destination therapy based on presumed worse outcomes. Though indication for LVAD no longer inhibits access, poor outcomes associated with the development of RHF continue to limit it.

RHF after LVAD raises mortality rate six-fold with remaining months of life consisting of multiple hospital readmissions, need for additional, costly care as well as a quality of life often worse than that prior to implantation. In a healthcare reimbursement system moving toward value-based care, the prevalence of RHF and its associated poorer outcomes will invariably contribute to declining reimbursement and limited access to LVAD implantation for many living with advanced heart failure.

The cost-benefit of this project was achieved by enhancing knowledge of providers and equipping them with an instrument for reliably assessing risk for RHF after LVAD. Identification of risk affords providers the opportunity to prevent RHF or minimize its severity. Any dollar amount attached to this benefit would be an underestimation of its positive impact on the healthcare system, society, and most importantly, those living with advanced heart failure.

Chapter 4

Results

Results

Parameter Selection

The need for a comprehensive assessment of risk for RHF following LVAD implantation served as the motivation for the quality improvement project. The project aimed to address this care gap by adapting and implementing a RHF risk assessment instrument. Adaptation of the instrument began with identification of 22 evidence-based parameters measuring the factors contributing to right heart reserve.

Parameters under consideration for inclusion in the adapted RHF risk score assessment instrument and content validity evaluation forms were emailed to ten experts. Initial written communication was sent during July 2021. A second communication was sent during August 2021. The response rate was 30%. Three of the ten invited experts provided an evaluation of all parameters' relevance to risk of RHF after LVAD. Parameters of pulmonary hypertension, right ventricular dilation, right ventricular function, and end-organ perfusion were additionally evaluated for accuracy of measurement. The I-CVI for each parameter was calculated based on responses from the three content experts (see Table 1). Proportion relevance and accuracy ratings were consistent among the three experts.

Pulmonary Hypertension. This section included three items. For relevance and accuracy, the I-CVI ranged from 0.00-1.00. The PAPi I-CVI was 1.00 for both relevance (*M=3.67)* and accuracy *(M=3.67)*. None of the experts rated PACi or Ea as relevant or accurate. Item PAPi was retained in the final version of the RHF risk assessment instrument. Items PACi or Ea were not retained based on content validity findings.

Right Ventricular Dilation. This section included five items. For relevancy as well as accuracy, the I-CVI ranged from 0.00-1.00. The CVP I-CVI was 1.00 for both relevance (*M=4.00)* and accuracy *(M=4.00).* The CVP:PCWP I-CVI for relevancy was 0.67 (*M=3.00).* The CVP:PCWP I-CVI for accuracy was 1.00 *(M=4.00).* RV:LV diameter I-CVI was 1.00 for both relevance (*M=3.33)* and accuracy (*M=3.33).* None of the experts rated RVEDVI:LVEDVI or RVEDAI:LVEDAI as relevant or accurate. Items CVP and CVP:PCWP were retained in the final version of the RHF risk assessment instrument. Item RV:LV diameter was not retained in the final version of the instrument as it was not a measure reported for LVAD recipients at the institution of project implementation. Items RVEDVI:LVEDVI and RVEDAI:LVEDAI were not retained in the final version of the RHF risk assessment instrument based on content validity.

Right Ventricular Function. This section included three items. The I-CVI for both relevance and accuracy ranged from 0.00-1.00. RVLS I-CVI was 0.33 for relevance (*M=2.00)* and 0.00 for accuracy. This item was not retained in the final instrument based on content validity. The RVEF I-CVI was 0.33 for both relevance (*M=2.00)* and accuracy (*M=2.00).* Though this item did not meet inclusion criteria, it was retained based on evidence, consistent measurement at the institution of project implementation, and consensus among the project leader, project manager, and project sponsor. RVSWI I-CVI was 1.00 for both relevance (*M=4.00)* and accuracy *(M=4.00).* This item was retained in the final version of the RHF risk assessment instrument.

End Organ Perfusion. This section included three items. The I-CVI range was consistently 0.67 for relevance and ranged from 0.67-1.00 for accuracy. Item MELD I-CVI was 0.67 for both relevance (*M=3.00)* and accuracy (*M=3.33).* Creatinine I-CVI was 0.67 for relevance (*M=3.00)* and 1.00 for accuracy *(M=4.00).* Lactate I-CVI was 0.67 for relevancy

(*M=2.67)* and 1.00 for accuracy *(M=4.00).* Items MELD and creatinine were retained in the final version of the RHF risk assessment instrument. Though lactate did meet inclusion criteria, it was not retained as it is not a measure routinely reported for LVAD recipients at the institution of project implementation.

Medical Support. This section included two items rated for relevance to right ventricular decompensation. The I-CVI ranged from 0.33-0.67. Inotropic requirement I-CVI was 0.33 (*M=2.33).* Vasopressor requirement I-CVI was 0.67 (*M=2.67).* Both items were retained in the final version of the RHF risk assessment instrument. Though inotropic support did not meet inclusion criteria, it was retained based on evidence and consensus among the project leader, mentor, and sponsor.

Mechanical Support. This section included six items rated for relevance to right ventricular decompensation. The I-CVI ranged from 0.00-0.67. None of the experts rated IABP requirement as relevant. Temporary RVAD I-CVI was 0.67 (*M=2.67).* Temporary LVAD I-CVI was 0.33 (*M=2.00).* Mechanical ventilation I-CVI was 0.67 (*M=2.67).* Renal replacement I-CVI was 0.33 (*M=2.00).* ECMO requirement I-CVI was 0.33 *(M=1.67).* Mechanical ventilation and temporary RVAD were retained for the final RHF risk assessment instrument. Temporary LVAD was not retained in the final instrument based on content validity findings. Though IABP, renal replacement, and ECMO requirements did not meet inclusion criteria, these items were retained in the final instrument based on evidence.

Of those parameters scored, most parameters retained for the final instrument had an I-CVI $\geq$ 0.67 for both relevance and accuracy. The I-CVI expectation was lowered from $\geq$ 0.79 as a score of 0.67 was achieved when at least two of the three respondents scored the parameter favorably. Though meeting I-CVI criteria, lactate and RV:LV diameter were excluded as neither

was routinely obtained at the institution of implementation. RVEF, a measure of right ventricular function did not meet I-CVI criteria yet was retained. This parameter was well supported by evidence and the two experts rating the parameter unfavorably provided comments indicating an unfamiliarity with the parameter (Aymami et al., 2018; Kiernan et al., 2015 & Scott et al., 2020).

Parameters of medical and mechanical support were rated for relevance to RHF. Though these parameters generally scored lower than all other parameters, they were retained. Evidence suggests that right heart reserve and correspondingly, risk for RHF, are underestimated when these parameters are excluded. Despite achieving low RHF risk scores, patients requiring support are considered at greater risk than those who achieve the same scores without support (Kumar et al., 2020).

Even with an I-CVI <0.67, requirements of inotropic support, renal replacement, and IABP, were also retained for the final instrument. Expert comments indicated these parameters were scored down because of their low specificity for risk of RHF. Inotropic support is a primary criterion and renal replacement, is a secondary criterion for the diagnosis of postoperative RHF according to the most recent consensus statement of the Mechanical Circulatory Support Academic Research Consortium (ARC) (Kormos et al., 2020). IABP was also included as it serves to increase coronary artery perfusion. Research presented at the 2021 annual Right Heart Symposium identified right ventricular ischemia as a culprit of myocardial cell pathophysiology associated with right heart compensation and decompensation (DiCarli, 2021).

The final instrument included fifteen parameters (see Figure 10). In addition to the thirteen retained parameters based on expert panel and evidence evaluation, subjective right ventricular echocardiographic function and TAPSE were also included based on discussion with

the project manager and project sponsor as well as on the consistent availability of these parameters observed during preliminary field observation and project planning.

Table 1

Expert Panel Parameter Rating

	Relevance			Mean	I-CVI	Accuracy			Mean	I-CVI	Comments	Retain
Expert Parameter	A	B	C			A	B	C				
Pulmonary Hypertension												
PAPi	3	4	4	3.67	1.00	3	4	4	3.67	1.00		Y
PACi	1	2	2	1.67	0.00	1	1	2	1.33	0.00		N
Ea	1	2	2	1.67	0.00	1	1	2	1.33	0.00		N
RV Dilation												
CVPCVP:PCWP	4	4	4	4.00	1.00	4	4	4	4.00	1.00		Y
CVP:PCWP	3	2	4	3.00	0.67	3	3	4	3.33	1.00		Y
RV:LV Diameter	3	3	4	3.33	1.00	3	3	4	3.33	1.00		N
RVEDVI:LVEDVI	1	2	2	1.67	0.00	1	2	2	1.67	0.00	Not Used	N
RVEDAI:LVEDVAI	1	2	2	1.67	0.00	1	2	2	1.67	0.00	Not Used	N
RV Function												
RVLS	1	3	2	2.00	0.33	1	2	2	1.67	0.00	Not Used	N
RVEF/REF	1	1	4	2.00	0.33	1	1	4	2.00	0.33	Not Used	Y
RVSWI	4	4	4	4.00	1.00	4	4	4	4.00	1.00		Y
End Organ Function												
MELD	2	4	3	3.00	0.67	2	4	4	3.33	0.67		Y
Creatinine	4	1	4	3.00	0.67	4	4	4	4.00	1.00		Y
Lactate	3	1	4	2.67	0.67	4	4	4	4.00	1.00		N
Medical Support												
Inotropic Infusion	4	1	4	2.33	0.33						All on it	Y
Vasopressor Infusion	3	1	4	2.67	0.67						All on it	Y
Mechanical Support												
IABP	2	1	2	1.67	0.00							Y
Temporary RVAD	4	0	4	1.67	0.67							Y
Temporary LVAD	3	1	2	2.00	0.33							N
Mechanical Ventilatic	3	3	2	2.67	0.33							Y
Renal Replacement	3	1	2	2.00	0.33							Y
ECMO	3	2	0	1.67	0.33							Y

Y=Yes, N=No, I-CVI= Item Content Validity Index

Implementation

Implementation began with a presentation of the project during a weekly LVAD multidisciplinary team meeting. A follow-up email containing project information and the RHF risk assessment instrument reference card was attached to distributed meeting minutes. Though provider use was not specifically evaluated, calculation of the score was requested with the intent of obtaining providers' evaluation of the feasibility and usefulness of the RHF risk score. There was no evidence of score calculation or discussion during meetings following the presentation. This may have been partially attributed to the departure of the project manager who had been a liaison between the project leader and the multidisciplinary group, conversion to zoom meeting forums, and time constraints placed on presenting providers amidst the COVID pandemic.

The initial project design proposed the identification of representatives who would share information with providers in the preoperative, intraoperative, and postoperative phases of care respectively. Given the many providers spanning 24 hours of care, seven days a week, and the increased workload experienced during the pandemic, the implementation plan was revised. The project leader presented repeated-in-person education sessions and weekly follow-up visits to providers working in the preoperative and postoperative intensive care units. As a result, these providers received consistent information regarding the background, risk assessment scoring process, and application to clinical practice. The project leader posted the one-page reference sheet and placed laminated reference cards in the units as planned. Providers in these units did document calculated risk scores on provider hand-outs in both units for each of the four LAVD patients included in the pilot project.

The intraoperative anesthesiology leadership was provided with the same verbal and written information to share with providers. A follow-up email containing the provider

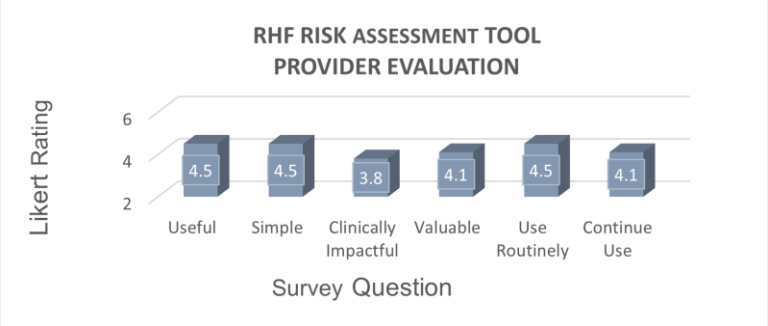
information sheet, risk assessment instrument, and an offer to provide in-person education, was sent. There was no reply and no evidence of intraoperative calculation of the risk score. Verbal follow-up revealed the preferred use of the intraoperative echocardiogram to assess right heart function yet interest in what the project informed at its completion.

Provider Evaluation

All providers working in the preoperative and postoperative ICUs received an invitation to complete a 6-item survey for evaluation of the RHF risk assessment instrument, following implementation. Twelve providers responded. Using a Likert scale, providers consistently agreed the instrument was simple to use (*M=4.50*), valuable (*M=4.10*), and useful in practice (*M=4.50*). All providers agreed with continued (*M=4.10*), routine use, (*M=4.10*) of the instrument for LVAD recipients. Three of the twelve providers responded "do not agree or disagree" with the instrument's impact on clinical decision-making (*M=3.80*) (see Table 1).

Table 2

Provider Survey Responses



Responses: 1=Strongly Disagree, 2=Disagree, 3=Do not Agree or Disagree, 4=Agree, 5=Strongly Agree

Disease Characteristics

A total of four patients underwent LVAD implantation during the implementation period. All patients were diagnosed with either idiopathic or ischemic cardiomyopathy at least two years

prior to admission. Prehospital NYHA classes ranged from III- IV. INERMAC profile at the time of admission ranged from 1-3. All patients were implanted with a heartmate 3 device for destination therapy.

Prehospital Parameters of Right Heart Reserve and Right Heart Failure Risk Scores

Pulmonary hypertension was evaluated for 75% of patients with a mean PAPi of 4.33, when PAS (*M=33.00*), PAD (*M=16.20*), and CVP (*M=7.50*) values were recorded. *Right ventricular dilation was* evaluated for all patients by a mean CVP of 7.50. Documentation of a PCWP (*M=12.00*) for 75% of patients allowed the calculation of a CVP:PCWP (*M=0.37*).

Echocardiographic *right ventricular function* was evaluated by documented normal function for 50% of patients, mildly reduced function for one, and moderately reduced function for the fourth patient. One patient had a recorded TASPE of 1.40. No information was available for evaluation of end-organ *perfusion however,* none of the patients were receiving renal replacement therapy. Seventy-five percent of patients were receiving *medical support* before admission with a continuous home milrinone infusion. One patient was not on medical support before hospital admission. None of the patients were receiving *mechanical support* before admission. No patient had complete data available for *right heart risk score* calculation. Considering missing data, two patients had a minimal risk score $\geq$2.00 (intermediate risk), one had a minimal risk score $\geq$1.00 (lowest risk), and a fourth had a risk score $\geq$0.00 (lowest risk).

Preoperative Parameters of Right Heart Reserve and Right Heart Failure Risk Scores

Pulmonary hypertension was evaluated for 75% of patients by a mean PAPi of 2.11, when PAS (*M=35.67),* PAD (*M=18.70*), and CVP (*M=5.00)* values were recorded. *Right ventricular dilation was* evaluated for 75% of patients by a mean CVP of 5.00. Documentation of a PCWP (*M=23.10)* for 75% of patients allowed the calculation of a CVP:PCWP (*M=0.30*).

R*ight ventricular function* was evaluated for 75% of patients by a recorded mean REF of 14.67. End organ perfusion for 100% of patients was evaluated by a mean creatinine of 1.45 and a mean MELD score of 9.40 using recorded creatinine, (*M=1.45*), total bilirubin (*M=0.70*), Sodium (*M=132.80*), and INR (*M=1.30*) values. None of the patients were receiving renal replacement therapy preoperatively. Seventy-five percent of patients were receiving *medical support.* Two patients received continuous milrinone infusions, while one received both milrinone and dobutamine infusions. One patient was not on medical support preoperatively. Seventy-five percent of patients required preoperative *mechanical support*. Two patients underwent IABP insertion with one of those patients undergoing IABP removal before LVAD implantation. A third patient required both IABP and mechanical ventilation. Incomplete data on one patient did not allow a right heart risk score calculation. The remaining three patients had a mean risk score of 4.00 (highest risk) with one patient scoring a 3.00 (intermediate risk), one scoring a 4.00 (highest risk), and a fourth scoring a 5.00 (highest risk).

Intraoperative Parameters of Right Heart Reserve and Right Heart Failure Risk Scores

There were no recorded parameters allowing intraoperative evaluation of *pulmonary hypertension, right heart dilation,* or *end-organ perfusion*. Available data was also insufficient for calculation of *right heart failure risk score*s. Echocardiographic *right ventricular function* was evaluated by documented normal function for one patient, mildly reduced for a second patient, and moderately reduced for the remaining two patients. All recipients required intraoperative *medical support* with a continuous milrinone infusion. One patient additionally required dobutamine and epinephrine infusions. All patients required *mechanical support* with routine intraoperative mechanical ventilation. Two patients had an IABP in place with one undergoing removal intraoperatively.

Postoperative Parameters of Right Heart Reserve and Right Heart Failure Risk Score

Postoperative evaluation was performed between two and six days *(M= 4.00*) following LVAD implantation. *Pulmonary hypertension* was evaluated for 75% of patients by a mean PAPi of 1.42 using recorded PAS (*M=33.00*), PAD (*M=20.00*), and CVP (*M=9.25*) values. *Right ventricular dilation was* evaluated by a mean CVP of 9.25. There were no recorded PCWP values for CVP:PCWP calculation. R*ight ventricular function* was evaluated for 100% of patients by a mean RVEF of 19.50. *End organ perfusion* was evaluated for 100% of patients by a mean creatinine of 1.33 and for 75% of patients, by a mean MELD score of 15.10 using documented creatinine (*M=1.33*), total bilirubin (*M=0.20*), sodium (*M=133.80),* and INR (*M=3.30*) values. One patient was missing a documented total bilirubin value. None of the patients were receiving renal replacement therapy. Seventy-five percent of patients were receiving *medical support.* Two patients received continuous milrinone infusions while another received a continuous dobutamine infusion. No patient required postoperative *mechanical support*. Patients had a mean postoperative right heart risk score of 2.75 (intermediate risk). Two patients scored a 4.00 (highest risk), one scored a 3.00 (intermediate risk) and the fourth patient scored a 1.00 (lowest risk).

The small sample size and missing data points did not allow statistical analysis or generalization of findings. A descriptive analysis of each patient's data did render further insight into the phenomenon of right heart failure after LVAD implantation (see Appendix P). It was this analysis that offered significant implications for improvement and expansion of the project.

Chapter 5

Discussion and Conclusions

Discussion

Expert Panel

Unfamiliarity with a number of RHF risk parameters amongst the small number of responding experts led to lack of support for parameters otherwise, well supported in the literature. In a repeat cycle of the quality improvement project, evaluation of parameters by a larger and more diverse expert panel should be elicited. This may be achieved by increasing the number of invitations distributed as well as by providing frequent follow-up communication during an extended response time.

Implementation

Implementation was altered for the ICU providers included in the quality improvement project. This revision was associated with successfully eliciting these providers' use of the RHF risk assessment instrument in practice. A second cycle of the pilot project should include repeated, in-person education sessions for intraoperative and multidisciplinary team providers as this may have contributed to the ICU providers' participation. Though both the multidisciplinary group members and intraoperative providers were verbally supportive, email fatigue and increased workload during the pandemic may have contributed to the comparably lower participation rate. One-on-one and frequent communication with physicians and anesthesiologists, outside of the multidisciplinary meetings may also foster participation in the next cycle of the quality improvement project. The same education process should again be repeated for ICU providers. The addition of voluntary representatives from both day and night shifts for each of the care units would reinforce providers' level of knowledge, their collection of

appropriate parameters, and their use of the RHF risk score. Finally, emphasis on the alignment of information garnered from the pilot project with the new INTERMACS guideline for improved data collection and a refined definition of postoperative RHF may motivate increased participation in future project cycles.

Provider Evaluation of Instrument

The preoperative, intraoperative, and postoperative ICU providers were asked to calculate RHF risk scores while caring for LVAD patients, with the intent of evaluating the instrument at the end of the implementation period. They consistently agreed that the instrument was useful, simple to use, and should be routinely incorporated into LVAD patients' assessments. The instrument's clinical impact was more frequently rated with a "Do not agree nor disagree" response when compared to other survey questions. Because provider use was not the focus of the project, lack of consistent use and documentation of the score by all providers likely contributed to this response. Future projects focusing on providers' use of the score and designating a location for documentation common to all providers would allow for a more accurate evaluation of the score's impact on clinical care and outcomes for providers and patients. Ultimately, an algorithm should be built into the electronic record to allow consistent calculation of risk scores, automatic documentation at set intervals, and communication amongst all providers.

Risk of RHF Following LAVD Implantation

A descriptive analysis of patent data did trend toward supporting conclusions derived from the evidence. All patients diagnosed with left ventricular failure for > 2 years had evidence of right heart dysfunction with variable degrees of compensation and decompensation before LVAD placement. Most parameters failed to consistently trend with risk for right heart failure

scores. Reliance on any one of these parameters could have led to an overestimation or underestimation of risk. More consistently, an RVEF/REF $\geq$ 25 did contribute to increased RHF risk scores however, data for this parameter was limited.

Consistent with the literature, pulmonary hypertension worsened throughout the perioperative course for all patients. This worsening, however, was most often independent of increasing, decreasing, or persistent risk for RHF across the phases of care.

The one parameter most widely used for determining risk for right heart failure, CVP, was the least likely to contribute to right heart failure risk scores. Though the CVP trends were inconsistent with those of RHF risk scores, the criteria for a CVP of 16 should be modified for future projects. A CVP of 16 is now the ARC criteria for diagnosing RHF. To recognize risk toward this endpoint, the tool should be revised to award a point for a CVP > 10.

Most patients were admitted on a single inotropic medication. The risk assessment tool did not account for the requirement of additional support which would indicate increased risk for progression to RHF. Accordingly, the RHF risk score should be revised to award points for requirement of additional therapies to produce a more accurate assessment of risk.

Though missing data limited analysis, the variability of parameters, requirement for support, and RHF risk scores throughout the phases of care were consistent with a continuum of right ventricular dysfunction progressing toward RHF. Critical events either restored, preserved, or reduced right heart reserve thereby increasing or decreasing risk scores. Patient C's data best illustrates this continuum with worsening risk scores after a critical decline in heart function at admission followed by an improving risk score once critical supportive therapy was added (see Appendix P).

Future cycles of this project should be revised to allow retrospective chart review of a larger population of LVAD patients that minimizes missing data points and include RHF outcomes. Statistical analysis would more clearly define the relationship between parameters, scores, and outcomes while also further validating the RHF risk assessment instrument.

Scalability and Sustainability

The D.N.P. project provides a foundation for future projects which aim to validate the RHF risk assessment instrument and the concept of right heart reserve. Instrument validation will begin with repeated review by an expanded and more diverse expert panel. The findings of the pilot project and instrument revisions will be communicated to all stakeholders in the system. Through use of the Knowledge to Practice Model, the implementation process will be improved for continued integration and evaluation at the current organization. The long-term goals involve the integration of a comprehensive RHF risk assessment into care of all patient populations at risk for RHF and future multicenter participation.

Sustained integration of the RHF risk assessment into practice will be facilitated by the development of an algorithm for automatic calculation. The algorithm will facilitate common documentation of RHF risk in a designated electronic record location by all providers, across all phases of care. This will contribute to continuous evaluation and data for progressive improvement in patient outcomes.

The concept of right heart reserve will also be further developed as a theoretical model and validated through the activities described. The framework will be validated as a foundation for clinical assessment, treatment, and physical activity prescriptions associated with RHF as well as for the failure of other organ systems and disease progression. Information regarding the RHF risk assessment instrument, the concept of right heart reserve, and the role of the D.N.P.

will be disseminated in journal, textbook, and newsletter publications, as well as in conference presentations.

Conclusion

The need for assessing risk for RHF after LVAD has been strongly agreed upon since the implantation of the first durable LVAD in 2001. This quality improvement project piloted the use of an adapted RHF risk assessment instrument and the newly defined concept of right heart reserve, based on over thirty years of clinical observation and a thorough synthesis of seemingly unrelated research findings. Though limited by a small number of LVAD patients and providers, the findings suggest that the instrument is feasible, useful, and may inform risk for right heart failure more closely than any single parameter.

Accurate identification of risk is an essential first step in preventing RHF for the realization of the clinical, quality of life, and financial benefits of successful LVAD implantation. Clinical outcomes, driven by the new guidelines for diagnosing and reporting RHF after LVAD, are predicted to reveal an incidence of post-LVAD RHF beyond that previously recognized. The next generation of LVADs will likely be wireless, eliminating clinical and social barriers to implantation yet adding to its expense. Potentially improved access to care will become increasingly dependent on positive patient outcomes which drive reimbursement. Presentation of this quality improvement project both in journal and conference communications should inspire future projects aimed at answering the intensifying need to predict and prevent RHF following LVAD implantation.

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Appendix A

Prisma Flow Chart: Right Heart Failure Following Right Heart Failure

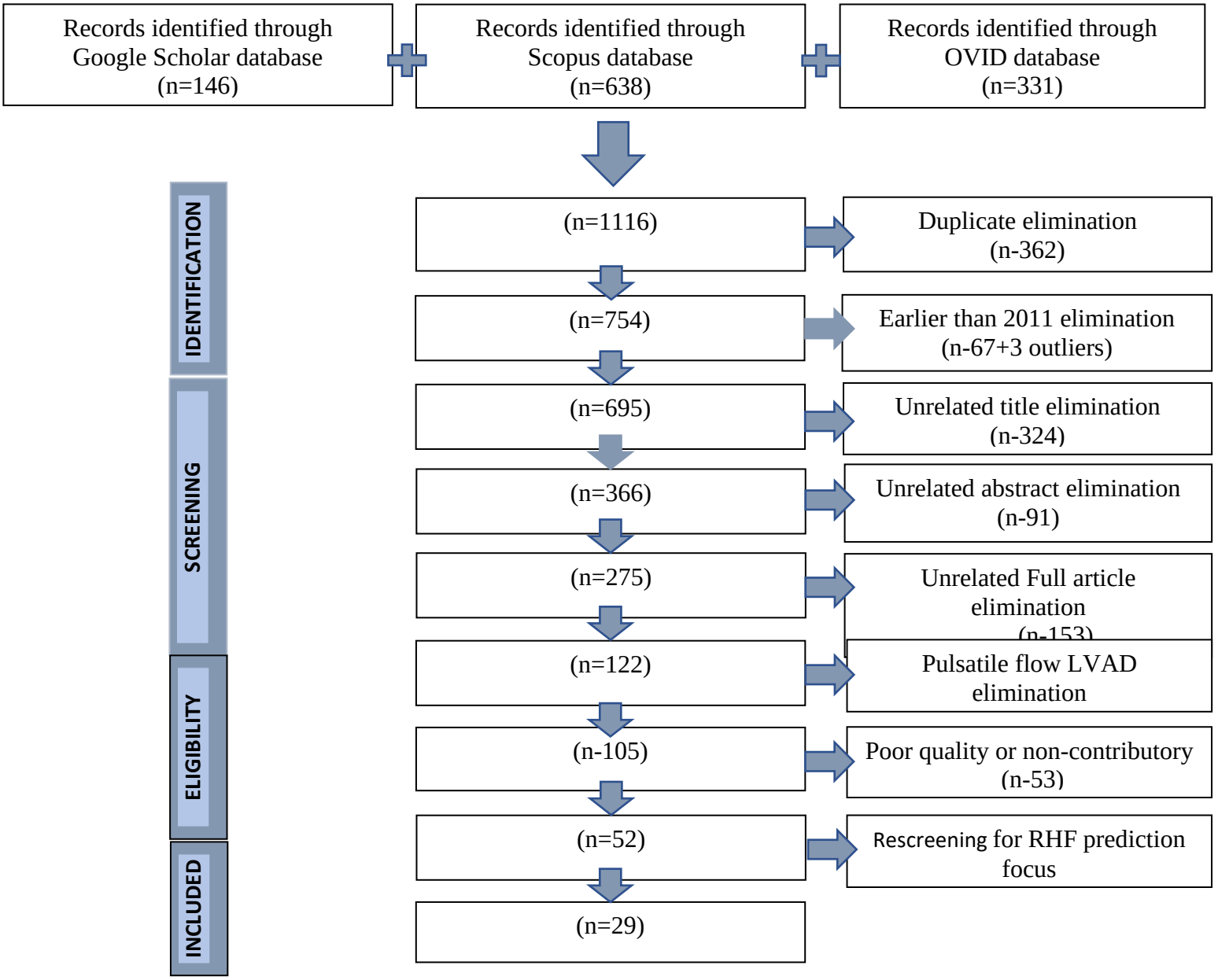


Figure 1 Flow diagram to show number of studies remaining at each stage of literature review. *Source:* From Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & the PRISMA Group. (2009). Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLOS Medicine, 6*(7), e1000097. https://www.doi.org/10.1371/journal.pmed.1000097.

Appendix B

Literature Matrix: Right Heart Failure Following LVAD Implantation

Does use of a RHF risk assessment instrument provide information regarding the development of RHF after LVAD implantation?

Title, Author, Date	Purpose	Sample	Design	Primary Enndpoint	Secodary Endpoint	Additional Endpoints	Results	Limitations	Implications for Practice	Level of Evidence
STUDY 1										
The Incremental Value of Right Ventricular Size and Strain in the Risk Assessment of Right Heart Failure Post - Left Ventricular Assist Device Implantation Aymami, M. Amsallem, M. Adams, J. Sallam, K. Moneghetti, K. Wheeler, M. Hiesinger, W. Teuteberg, J. Weisshaar, D. Verhoye, J. P. Woo, Y. J. Ha, R. Haddad, F. Banerjee, D. 2018	Determine if quantitative measures of RV size & function improve risk stratification for RHF after LVAD beyond validated scores.	•158 of 191 consecutive patients •>18 years old •Mean age 56+ 13 years •79% male •49% •Total bilirubin level within 2 weeks of echo •Complete echo & hemodynamic heart evaluation by echo &cardiac catheterization INTERMACS profile 1-2 •Isolated CF-LVAD under cardiopulmonary bypass on a beating heart •94 Heartmate II •57 Heartware HVAD •7 Jarvis 2000 •4 tricuspid repair •5 undefined concomitant valve surgery •Stanford	•Retrospective consecutive cohort •Prospective registry of patients referred for LVAD •Observational	•RHF<30day -RAP >16 -Inotropes >7 days	•RHF<30days •Unplanned RVAD for -Progressive RVF on echo, -RAP > 16 -Increased inotrope -End organ dysfunction	•Readmission for heart failure ->24 hours in hospitals -lactate, serum creatinine, LFTs •Heart transplant •Death	•RHF (38%) •Unplanned RVAD (12%) within 24 hours •Heart transplant (9%) •No difference among devices •Early morbidity & mortality > with RHF •>Early mortality if RHF & no RVAD •Heart transplant (9%) •Existing scores predictive of RHF performed moderately -CRITT & EUROMAC best •Strong association with RHF: -RV function (RVLS) -RV size (RVEDAI & RVESAI), -RAPRAP/PCWP -total bilirubin and INTERMACS profile strongly associated with RHF •3-fold RHD if RVLS & RVEDAI elevated	•Limited generalizability: -Modified INTERMACS definition with inhaled prophylactic NO routine preventing >RHF	•Limited generalizability: -Modified INTERMACS definition with inhaled prophylactic NO routine preventing >RHF	JBI level 3c

		University Medical Center California •2009-2015.					•RHF predicted 27% using 2005 ASE guideline & 37% using RVLS or TARPSE			
STUDY 2										
Prediction of Right Ventricular Failure after Ventricular Assist Device Implant: Systematic Review and Meta-Analysis of Observational Studies Bellavia, D. Iacovoni, A.Scardulla, C. Moja, L. Pilato,M. Kushwaha, S. Senni,M. Clemenza, F. Agnese, A. Falletta. C. 2017	•Compare patients with early post LVAD RVF with patients who did not develop acute RHF. •Determine prevalence of post LVAD RHF •Determine significant predictors for RHF after LVAD implantation	•36 of 612 studies from a search through OVID, databases of MEDLINE and EMBASE, Scopus, Web of Science and Google Scholar from •January 1, 1995-April 30, 2015. -35% prospective cohort studies -23% case-controlled studies -•995 of a pooled 4428 patients referred for LVAD	•Retrospective meta-analysis •2 individual reviewers -> 18 years old -No preplanned RVAD •Inclusion Criteria: -Overt HF referred for pulsatile or continuous flow LVAD -RHF within 2 weeks post LVAD •Data stratified for -RHF and no RHF	•RHF defined as: -Persistent RVSWI <4g/m2 or -NO > 48hrs or -Emergent RVAD or -Inotropes >2 weeks	•Significant preoperative predictors for RHF after LVAD -Demographic -End organ -Biomarkers -Hemodynamic -Echocardiographic	•Preoperative predictors that are significantly different for RHF post CF LVAD compared to PF LVAD	:•Significant predictors of RVF: -Lower BSA -Female -Preop IABP -Preop mechanical ventilation -Preop RRT -Higher WBC, TB, ALT,AST ,INR,BUN,CR,proBNP -Lower plt ct -Lower cardiac index ,RVSWI,LVEDAI -Higher PVR, PAS, CVP, RVEDAI, RVLS -Preop severe RVD on echo	•Difficult to compare data and generalize from almost exclusively single centered studies Pulsatile flow LVADs no longer used •RVF definition only identify late or severe RHF and may miss mild & moderate RHF between mild and severe •Little explanation for parameter differences between RVH and no RHF •Data collection, RHF diagnosis, protocols for RVAD placement, inotropes and NO subjective among providers, data collectors and centers	•Concluded that parameters currently available reach significance yet have small effect size & are insufficient with to identify RHF after LVAD with acceptable accuracy •Though not significant, parameters consistently trended in expected directions	JBI 3b
STUDY 3										
Right Ventricular Response to Pulsatile Load Is Associated with Early Right Heart Failure and Mortality After Left Ventricular Assist Device Grandin,W. Zamani, P. Mazurek, J. Troutman, G.	•Determine if RV load and RV response to that load are predictive of risk for early RHF and 6 month mortality after CF LVAD implantation -Rv load = pulmonary vascular compliance (PC)i -RV response = CVP/PCWP	151 patients •Inclusion: -Complete preop hemodynamic measurements •Exclusion: -Planned RVAD -Preop mechanical support •Single center, Hospital of the University of Pennsylvania •1/2008 - 6/2014.	•Retrospective cohort •Observational •Longitudinal study •Preoperative data collected without knowledge of the outcome •Patients stratified into subgroups based on PACi and CVP:PCWP -High PACi/low CVP:PCWP	•RHF defined as: -Unplanned RVAD -Inotropes >14 days -Death from RHF within 14 days	•Degree of risk -PACi relationship to CV/PCWP (High,Low)	•Survival at 6 months •Preoperative variables associated with post CF LVAD RHF	•Prevalence: -RHF (40.4%) -Unplanned RVAD (7.9%) -Inotropes 14 days (30.5%) -RHF death <14 days(2.0%) •Preop variables common to postop RHF patients: -Vasopressor requirement	•Single center •Retrospective •Endpoints define severe RVF only	•PACi/CVP:PCWP quantifies risk stratification for RHF & mortality -High PACi/low CVP:PCWP = survival (86%) -Low PACi/high CVP:PCWP= survival (45%) •Implies preop RV reserve related to RVD, critical to determine of postop	JBI level 3c

Birati, E. Vorovich, E. Chirinos,J. Telford, R. Marguilies, K. Atluri, P. and Rame J. 2016			-Low PACi/low CVP:PCWP -High PACi/high CVP:PCWP -Low PACi/high CVP:PCWP •Patients followed until death, heart transplant or LVAD explanation				-↑bilirubin -↓ GFR -↑ echo RV dysfunction (RVD) -↑CVP -↑ CVP:PCWP -↓PACi •Independent predictors of RHF -↓ PACi with strong association to echo RVD •PACi + CVP:PCWP "modestly" improved discrimination for early RHF -Lowest risk = High PACi/low CVP:PCWP -Highest risk = Low PACi/high CVP:PCWP •Death <6 mo. (22.5%) -↓GFR, ↑CVP, ↑CVP:PCWP, ↓PACi, ↓echo RVD -PACi/CVP:PCWP was significantly associated with 6 month mortality		RHF risk.	
STUDY 4										
Validation of Clinical Scores for Right Ventricular Failure Prediction After Implantation of Continuous -Flow Left Ventricular Assist Device Kalogeropoulos, A. Kelkar, A. Weinberer, J. Morris, A. Georgiopoulou, V. Markham,D. Butler,J. Vega D.and Smith, A. 2015	•Evaluate the comparability across pre-existing predictive models using a unified definition of RHF	•116 consecutive patients •Inclusion: -Elective CF LVAD -Heartmate II -Heartware HVAD -Bridge to transplant -Destination therapy •Exclusion: -Unplanned RVAD •Single center, Emory University Hospital •1/2008 – 1/2013	•Retrospective cohort •Observational •RHF risk scores calculated: -Michigan -Penn -Utah -CRITT •Unplanned RVAD risk score -Penn decision tree	•RHF < 90 days defines by: ->48h hours NO/ other pulmonary vasodilators - MSOF with hypotension/ no sepsis -Inotropes >14 days -Inotropes restarted at >14 days -Unplanned RVAD	•RHF < 90 days defined by INTERMACS: -CVP >18 -CI <2.0 -No tamponade -No ventricular arrhythmia -No pneumothorax -Inotrope or inhaled pulmonary vasodilators >14 days -Unplanned RVAD	•RHF< 90 days using the each RHF definition: •Expand sample to include planned RVAD •Preop parameters significantly correlated with postop RHF	•Significant preop predictors of RHF: -Non-white race -↓LV diameter -↑ RAP or CVP -↑ creatinine level •The Michigan score performed best -"modest" discrimination using either RHF definition -Predictive < 60% accuracy	•The models used to calculate RHF risk intended for risk of requiring RVAD •No rationale for Michigan performance •CRITT & Pittsburg decision tree only scores derived exclusively from CF LVADs •Bias toward > destination LVADs	•Inclusion of pre-planned RVAD may have implications for predictors of high risk for early /severe RHF •Unique use of MSOF/hypotension has advantage of no time limit -May capture earlier RHF or missed RHF •Unique use of inotrope restart may capture late RHF -Lead to ID of critical events etiology •Suggest change to using quantitative data since existing scores moderately discriminatory at best •Supports revising a universal RHF definition	JBI level 3c
STUDY 5										

Right Ventricular Failure in Patients with the HeartMate II Continuous-Flow Left Ventricular Assist Device: Incidence, Risk Factors, and Effect on Outcomes Kormos, R. Teuteberg, J. Pagani, F. Russell, S. John, R. Miller, L. Massey, T. Milano, C. Nader Moazami, N. Sundareswaran, K. and Farrar, D. 2010	•Evaluate incidence, risk factors, and effect on outcomes of RHF after Heartmate II, CF LVAD implantation	•484 patients -Heart transplant status 1A or 1B - Heartmate II LVAD •36 centers •3/2005-4/2008.	•Retrospective cohort •Observational •Prospective data collected during multi-center Heartmate II trial	↑RHF risk defined by the Michigan Risk score	•Early RHF after defined by: -Unplanned RVAD -Inotropes >14 days -Inotropes starting > 14 days	•Outcome associated with of RHF at 180 days: -Survival to transplant -Recovery - support -Actuarial Survival	•Met any criteria for RHF (20%) -Unplanned RVAD(6%) -Support >14 days (7%) -Support started > 14 days (7%)support >14 days •Variables significantly correlation to early RHF, with greatest if unplanned RVAD -↑CVP(15 + 7) -↑ CVP/PCWP (0.6+0.2) -↓RVSWI(< 300) -↑WBC (10+4) -↑ BUN -Preoperative ventilator dependence •Survival to transplant, recovery -No RHF (89%) -Early RHF (71%) -Unplanned RVAD (67%) with 77% if RVAD placed within 24 hours & 39% if placed after 24 hours •1 year actuarial Survival: -No RHF (79%) -Unplanned RVAD (59%) -Inotropes >14 days or started after 14 days (56%) •Length of stay for discharged patients: -No RHF 21 days - Unplanned RVAD 32 days for -Inotrope >14 days or started after 14 days 32-35 days	•Exclusive bridge to transplant not representative of larger destination population •Exclusive to Heartmate II device not representative of other device recipients •Increased correlation to unplanned RVAD implies values predict highest risk and predictive of severe/early heart failure -No distinction of values correlated to milder RVD different than no RHF	•Implies variable values may correlated to risk stratification in future studies •Supports concept of preop and declining RV reserve; dynamic risk	JBI level 3c
STUDY 6										

Maximum Vasoactive Inotropic Score in the 48 Hours Post-LVAD Implantation Correlates with Early Severe Right Ventricular Failure Kumar,S. Mustehasan, M. Chinnadurai, T. Gupta, N. Patel, S. Murphy, S. Shin, J. Forest, S. Vukelic, S. Golstein, D. Jorde, U. and Sims,D. 2020	Determine correlation between maximum Vasoactive Inotropic Score (VIS) and early RHF post LVAD	•240 LVAD recipients •Exclusion: - <18 years old -LVAD exchange -Planned RVAD •Single center •1/2006-12/2017	•Retrospective cohort -Stratified maximum VIS within 48 hours postop •Observational	VIS = Dobutamine dose +10 x Milrinone dose +Dopamine dose +100 x Epinephrine dose+100 x Neo synephrine dose+10,000 x Vasopressin dose: -6 hours -24 hours -48 hours	•RHF post CF LVAD stratified by max VIS in 48 hours: -Group 1 (0-10) -Group 2 (11-15) -Group 3 (16-22) -Group 4 (23-87)	Severe RHF defined by: -Inotropic support > 14 days -Unplanned RVAD -RHF Death during admission	Group 4 VIS (23-87): -↑CVP -Advanced INTERMACS profile -Older age -Independently correlated with post LVAD severe RVF	•Single center •Exclusion of planned RVAD may miss highest risk for comparative values & defining mild to moderate RVD that could progress as RV reserve decreases •Minimal correlation with to quantitative measures of RV which would have greatly increased value of study.	•Valuable in capturing early RHF that would not have met accepted or modified INTERMACS definitions previously and more widely used definitions of RHF. •Offers a means of tracking loss of RV reserve and RVD progression to RHF postoperatively	JBI level 3c
STUDY 7										
Calculation of the ALMA Risk of Right Ventricular Failure After Left Ventricular Assist Device Implantation LaForte, A. Montalto, A. Musumeci, F. Amarelli, C. Mariani, C. Polizzi, V. Della, Monica, P. Francesco Grigioni, F. Di Bartolomeo, R.and Marinelli, G. 2018	•Develop "ALMA" simplified risk stratification tool: -To determine tolerance of an isolated LVAD vs. Biventricular support, "ALMA" score	•258 patients •LVAD cohort (n=170) --Derivation cohort (n=135) -Validation cohort (n=35) -unplanned BiVAD(n=88) -Derivation cohort (n=71) -Validation cohort (n=7) •Exclusion: - <18 years old -Artificial heart •Coworker Institutions, South Ursula University Hospital in Bologna and S. Camillo Hospital in Rome	•Retrospective cohort •Observational •Compared demographic, echocardiographic hemodynamic and Laboratory variables	Severe RHF <30 days defined by: -Unplanned RVAD despite maximal doses of inotropic support and NO inhalation	•Unplanned RVAD requirement defined by: -Interop failure to wean off cardiopulmonary bypass pump -Systemic low flow (oliguria, low SVO2, Lactate >2) -CVP>18 -Low flowing LVAD -Escalating NO or inotropes with no improvement	•All-cause mortality	•Mean time from LVAD to RVAD requirement 0-2 days •LVAD & BiVAD preop INTERMACS profiles 2-3 •ALMA 5-point risk score based on parameters predictive of unplanned BiVAD: -Destination therapy -PAPi <2 -RVSWi <300 -RV/LV ratio >0.75 -MELD-XI >17 •ALMA risk score had satisfactory predictive power for RVAD	•May be limited since it only incorporated 5 parameters that had opposing significance in previous and later studies	•Supports significance of RV response measured by size and contractility, to pulmonary vascular load •Supports RV decompensation/ diminished reserve by inclusion of MELD representing end organ function.	JBI level 3c
STUDY 8										
A Bayesian Model to Predict Right Ventricular Failure Following Left Ventricular Assist Device Therapy Loghmanpour, N. Kormos, R. Kanwar, M. Teuteberg, J.	•Investigate the use of a Bayesian statistical risk assessment model for RHF after LVAD -176 preoperative variables considered •Compare the performance of the Bayesian models to previously established and widely used Risk	•10,909 adult patients with CF LVAD placement included in the data of the national INTERMACS registry •December 2006-March 2014	•Retrospective cohorts •Observational	•Acute RHF (<48 hours) defined by INTERMACS before 2014: -33 variables -Most predicted by PAS, WBC, LVEF, CI, Na, % lymphocyte	•Early RHF (48 hours-14 days) -34 variables -most predicted by PAS, pre-albumin, LDH, INTERMACS profile, RVEF, pro-BNP, age, HR, TR and BMI	•Late RHF (>14 day) -33 variables -Mostly predicted by peripheral vascular resistance, MELD score, albumin, %lymphocyte, mean PAP, PAD	•The models for acute, early and late RHF had accuracy levels of 91-97% -out-performed Mathews and Drakos risk scores •Variables most predictive of Acute RHF: - PAS, WBC, LVEF, CI, Na,% lymphocyte •Variables most predictive of Early RHF -PAS, pre-	•Undergoing a current prospective evaluation with no further publication	•Recognizes the continuum of RV dysfunction to failure with dynamic risk & possibly distinct variable or changing values of variables •Supports need to consider relationship between variables of pulmonary vascular load, RV size, RV contractility,	JBI level 3c

Murali,S. and Antaki, J. 2016	scores -Mathews RHF risk score -Drakos score						albumin, LDH, INTERMACS profile, RVEF, pro-BNP, age, HR, TR and BMI •Variables most predictive of Late RHF -PVR, MELD score, albumin, %lymphocyte, mean PAP, PAD		LV filling and end organ perfusion	
STUDY 9										
Postoperative right ventricular failure after left ventricular assist device placement is predicted by preoperative echocardiographic structural, hemodynamic, and functional parameters Raina, A. Seetha Rammohan, H. Gertz, Z. Rame, E., Woo, Y. and Kirkpatrick, J. 2013	•Compare preoperative variables - RHF after LVAD -No RHF •Determine variables with significance for RHF prediction •Compare results to Michigan, Penn, BiVAD & MELD scores	•55 patients •Exclusion: -No preoperative TTE -Poor RV images on TTE -LVAD no RHF (n=26) -LVAD with RHF (n=16) -Unplanned BIVAD (n=13) •Single center •5/2008-6/2011	•Retrospective cohort •Observational •Compared data -LVAD with RHF combined with BIVAD to LVAD no RHF	•Prolonged RHF after LVAD defined by: -Inotropic support >14 days -Planned RVAD -Severe pHTN, -RAP or CVP > 15 -sustained with hemodynamic compromise	Variables significantly predictive of RHF after LVAD		•Significant Predictive preop variables: -↑ BSA -↓albumin -↑with↑ inotropes/ vasopressors -↓ INTERMACS score -↑heart rate -Echocardiographic ↓RV FAC, LA volume index score -Lower left atrial volume index score •↑"echo score" consisting of combination of LA volume index <38%, (2pts),RV FAC <31% (2pts) RAP >8 (2 pts). -Echo score of >5 had 63% sensitivity & 78% specificity for predicting RHF -Favorable in comparison to Michigan, Pennsylvania and MELD scores	•Identified 82% with chronic heart failure but no mention of pre-hospital treatment differences such as continuous, intravenous home inotropic support •No significance difference in RVEDAI between RHF & no RHF which may be explained by variations in definitions & inclusion criteria •Single center •Small sample size	•Though variables differ findings support concepts of pulmonary vascular load, RV response as most significant factors contributing to RHF.	JBI level 3c
STUDY 10										

Risk Factors of early Right Implantation with Intermediate INTERMACS Profile for Advanced Heart Failure Ruiz-Cano, M. Morshuis, M. Koster, A. Lauenroth, V. Prashovikj, E. Gummert, J. and PaluszKiewicz, L. 2020	•Identify predictive parameters for early post LVAD RHF preop with INTERMACS intermediate profile 3-5.	•80 of 214 consecutive •Inclusion: -INTERMAC Profile 3-5 -Bridge to transplant -Destination therapy •Exclusion: ventilation -Preoperative IABP circulatory support -Age <18 -Planned BIVAD -Devices other than CF LVAD •2 centers, Thorax and Cardiovascular Surgery, Heart and Diabetes Center, Ruhr-University Bochum, Bad Oeynhausen, German an LVAD at the between 2016-2018	•Retrospective cohort •Observational	•Early RHF after defined by INTERMACS definition: -CVP>16 -CI<2.3 -Insufficient LVAD flow -Echo evidence of severe RHF despite NO, inotropic and vasopressor support and intravascular volume optimization	•Preoperative parameters significantly correlated with early postoperative RHF	•In hospital death	•Early RHF (32.5%) •All in-hospital mortality organ failure or systemic infection •Preoperative parameters predictive of early RHF -↑ CVP -↑ CVP/PCWP -↑RV dilation -↑ RVEDAI/LV ratio -↑severe TR -↓RV FAC -↑RVLS •Preoperative parameters that were significant independent predictors of early postoperative RHF -CVP/PCWP>0.55 -BUN>44.5 -Combined these values were related to a 6.6-fold increased risk of early RHF	•Small sample and •Single center •Reported but did not include preoperative inotropic support or chronicity of heart failure	•Would be informative to repeat with comparisons made to INTERMACS profile 1-2 •Uniquely identified optimized with INTERMACS score 3-5 using PA catheter parameters 24 hours before surgery and echo parameters within 5 days of surgery which biased results yet a valuable comparison •No time limits included in RHF definition less likely to miss worsening RVD & possibly prevent RHF	
STUDY 11										
Increased Right Ventricular Diameter Ratio is a String Predictor of Right Ventricular failure after Left Ventricular Assist Device Vivo, R. Cordero-Reyes, A. Qamar, U. Garikipati, S. Trevino, A. Aldieiri, M. Loebe, M. Bruckner, B. Torre-Amione, G. Bhimaraj, A. Tractenberg, B. and Estep, J. 2013	•Evaluate pre-LVAD TTE predictors -Early RHF -RHF death •Determine predictive value of TTE variables after adjusting for Mathews RHF risk score and Kormos VIS score	•109 of 142 patients •Exclusion: -Poor TTE images -RVAD placement •Single centers, Methodist DeBakey Heart & Vascular Center •1/2004-7/2011	•Retrospective cohort •Data collected prospectively •Observational •TTEs reviewed by independent readers blinded to study data & outcomes	•RHF within 30 days defined as RHF within 30 days defined as: -Unplanned RVAD -Inotropes >14 consecutive days	• RHF and death within 30 days.	Mathews and Kormos scores	•RHF within 30 days (23%) •↓CI measured across RVOT -↑RV/LV diameter ratio than no RHF •RHF & death within 30 days •↑Mathews or Kormos score = ↑RV/LV ratio -↑Mathews& Kormos combined = significantly >risk of RHF & of RHF death within 30 days • RV/LV more consistent with Mathews than Kormos score • RV/LV combined with either score increased discrimination	•Small sample size •Single center •Exclusion of RVADs eliminated those with greatest risk •RHF defined by time may lead to missed diagnosis or worsening RVD prior to RHF	•Supports concept of preoperative RV compensation and added significance with addition of quantitative RV parameters	JBI level 3c

STUDY 12										
Association of Preoperative Duration of Inotropy on Prevalence of Right Ventricular Failure Following LVAD Implantation Benjamin, M. M. Sundararajan, S. Sulaiman, S. Miles, B. Walker, R. J. Durham, L. Kohmoto, T. Joyce, D. L. Ishizawar, D. Gaglianello, N. Mohammed, A. 2020	•Determine if duration on preop Milrinone is an independent predictor of post LVAD RHF	•104 patients •Inclusion: -ACC/AHA stage D HF -Continuous IV Milrinone preop -Heartmate II -Heartware -Bridge to transplant -Bridge to candidacy -destination therapy •Exclusion: -Preop MSOF -Preop mechanical circulatory support -Emergent LVAD •Single center •2/2012-10/2018	•Retrospective cohort •Observational •Divided patient into 2otherwise similar groups: -Milrinone <30 days (STM) n=55 -Milrinone >30 days (LTM)n=49	•RHF within 30 days defined as RHF within 30 days defined as: -Unplanned RVAD -Inotropes >14 consecutive days	•Survival through follow-up (27±26 months)	•Mortality -RHF -No RHF	•Total RHF (43.3%) •Unplanned RVAD -STM (9.1%) -LTM (18.4%) •Inotropes >14 days -STM (16.4%) -LMTM (44.9%) •RHF significantly >LTM •Survival (74%) -STM (27.3%) -LMT (24.5%) •Mortality: -RHF (40%) -No RHF (22.5%) •Each preop day on Milrinone correlates with a 1% increased risk of RHF postop. •Quantitative RV measures did not reach predictive significance	•Small sample size •Single center •Milrinone may mask degree of RV decompensation which is irreversible without infusion	•Milrinone infusion should be a parameter included in preoperative risk stratification •May have implications for timing of LVAD placement if results are reproduceable in a larger population	JBI level 3c
STUDY 13										
Independent and incremental role of quantitative right ventricular evaluation for the prediction of right ventricular failure after left ventricular assist device implantation Grant, A. D. M. Smedira, N. G. Starling, R. C. Marwick, T. H. 2012	•To determine if quantitative measure of RV function is predictive f RHF after LVAD -Global longitudinal RV strain	•117 of 143 consecutive patients •Inclusion -Heartmate II -Heartware •Exclusion -Planned BiVAD, RVAD, Total artificial heart -LVAD exchange -Preop ECMO -No or Poor TEE •Single center, Cleveland Clinic Foundation •5/2007-4/2011	•Retrospective cohort •Observational •2 groups for comparison -RHF -No RHF •Retrospective calculation - Michigan score -Global longitudinal strain	•RHF defined by -Unplanned RVAD -Inotropic support >14 days	•1 year mortality	•Preoperative predictors of RHF	•RHF prevalence (40%) -Unplanned RVAD (n=10) -Inotrope > 14 days (n=37) •1 year Mortality -RHF (19%) -No RHF (19%) •Preoperative predictors of RHF: -Inotropes -↑bilirubin -↓CI -↑PVR -Moderate RVD on TEE -Severe RVD on echo -RV free wall strain< -9.6% -RV longitudinal strain was an independent predictor •Michigan score + qualitative RV function vs Michigan score+ RV strain -10.4% patients with RHF would be reclassified "at risk" -Alone 67% sensitivity & 76% specificity	•Retrospective calculation of RV strain •Single Center •% patients with insufficient echo windows •Time constrained RHF definition •Only used Michigan score which could have influenced results	•Supports evaluating multiple variables that interact to comprise risk •Supports use of quantitative vs qualitative RV measurements •Supports concept of preop RVD with less reserve or further on the continuum of progression to RHF	JBI level 3c

							•Global longitudinal RV strain outperformed TAPSE & RV:LV diameter			
STUDY 14										
Timing and Trends of Right Heart Ventricular Assist Device Implantation Gulati, G. Sutaria, N. Vest, A. R. Denofrio, D. D. Kawaborl, M. Couper, G. Kiernan, M. S. 2020	•To determine the optimal timing of RAP measurement for prediction of RHF post LVAD •To determine the significance of resolution of right heart congestion prior to LAVD	•134 of 144 consecutives LVAD recipients -INTERMACS profile 2-3 •Exclusion: -Preop ECMO •Inclusion: -Heartmate II (n=86) -Heartware 9n=45) •Single Center, Tufts Medical Center •10/2014-2/2018	•Retrospective cohort •Observational •4 comparative groups -Congested (RAP >14) at admission that improved before LVAD -Congested at admission no improvement before LVAD -No congestion (RAP<14) at admission or before LVAD -No congestion at admission, new congestion before LVAD	•Unplanned RVAD •Death	supports	•Change in RAP from admission to <24 hours prior to LVAD for grouping •Significant other variable differences between groups	•Prevalence of RHF (23%) -Unplanned RVAD (7.5%) -Death (15.7%) • •No difference in RHF between congested & non congested at admit -Admit RAP not associated with RHF -No difference between never congested & resolved •>RVAD & death rate for persistent & newly congested (80%) vs no congestion (31%) pre-LVAD -No significant difference in persistent 7 newly congested -Persistent congestion had worse outcome •prevalence of RHF inclusive of prolonged inotropes (44%) -78% on prolonged inotropes	•Single center •Small sample size -reduced by grouping •Biased in a center that admits and aggressively treats to decongest (RAP<10) before LVAD •Did not account for patients transferred from & possibly treated at outside hospital	•Supports concept of RV reserve vs irreversible or advanced RVD in continuum to RHF •Supports concept of using quantitative vs qualitative RV measurements •supports concept of dynamic vs one pint in timer risk assessment -Registries do not require record of timing for parameters collected -Most studies do not specify timing of parameters collected or change in parameters over time	JBI level 3c
STUDY 15										

Right ventricular free wall longitudinal strain and stroke work index for predicting right heart failure after left ventricular assist device therapy Gumus, F. Durdu, M. S. Cakici, M. Kurklu, T. S. T. Inan, M. B. Dincer, I. Sirlak, M. Akar, A. R. 2019	•To examine new parameters associated with post LVAD RHF •To compare performance of new parameters to existing scoring systems	•57 consecutive LVAD recipients •Inclusion: -Bridge to transplant -Heartmate II (n=17) -Heartware (n=28) -Heartmate III (n=8) •Exclusion: -Planned BiVAD -Planned Total artificial heart •Single center •1/2012-5/2018	•Retrospective cohort •Observational •Comparison groups -RHF -No RHF •Hemodynamic assessment undefined timing, OR and postop •Echo 24-48 hours before	•RHF defined by INTERMACS: -No tamponade -MAP,55 -CVP>16 -CI<2.1 -Prolonged inotropes (Inotrope score 20) -NO or IV vasodilators>14 days -Unplanned RVAD	•Calculated Mathews, Fitzpatrick, Drakes and ARVASE scores compared to calculated scores for heart failure mortality not specific for RHF after LAVD -Seattle Heart Failure Model -MELD score -APACHE II •Quantitative measures of RV -RVEF -RV-FAC -RVEDD -RVSWI -RVFWLS -RVOT systolic excursion	•Death -5 months -10 months -15 months -20 months -25 months	•RHF prevalence (35.1%) -Unplanned RVAD (n=11) -Other criteria (n=9) •Survival significantly > in No RHF group across all intervals •Existing scores performed modestly - Fitzpatrick slightly better than others -HF mortality scores performed > RHF specific scores -SHFM slightly better •Quantitative parameters were predictive of RHF - RVFWLS, RVOT-SE & RVSMI better than others though correlated with like parameters -RVFWLS most discriminatory, 86% sensitivity/845 specificity	•Small sample size •Single center •Did not combine scores with quantitative variables for further comparison though speak to combining a variety of parameters •Biased toward majority of INTERMACS profile I &II •Did not include comparison to qualitative RV parameters most used	•Very supportive of incorporating newer quantitative measures of RV function in risk assessment -Not included in most previously developed scores •Supports concept of measuring RV function/reserve as opposed to size/volume status alone -Would need to be incorporated into a model of other consistently predictive parameters to assess increased performance	JBI level 3c
STUDY 16										
Assessment of right ventricular function in left ventricular assist device candidates Hayek, S. Sims, D. B. Markham, D. W. Butler, J. Kalogeropoulos, A. P. 2014	•To review current evidence for preoperative prediction ocf RHF after LVAD -Focus on imaging & specifically echo	•Reviewed an unspecified number of studies: -RHF prediction models -Quantitative measures of RV functio -INTERMACS data	•Retrospective review	•Identify rationale for inability to predict post LVAD RHF •To evaluate quantitative measures of RV function and how to best obtain data •	•To evaluate quantitative measures of RV function and how to best obtain data	•To make recommendations for future inquiry and practice	•Rationale for no RHF predictive model: -Incidence dependent varied definition -Single centers with no standard for RVAD or Inotrope use -No quantitative RV data included in existing models or INTERMACS -No accounting for contributory interop events -Quickly changing LVAD technology & population -No consensus on how to best measure RV function •Quantitative Measures of RV: -Measures of RV strain & strain rate best -Standardize echo	•Did not speak to other hemodynamic or laboratory parameters consistently predictive based which could be combined	•Recommendations for standardization would improve practice but most significantly value of future research/model development •Supports many important concepts to be incorporated into risk models: -RVD/RV reserve are most predictive -Quantitative RV data reproduceable/less human error -Risk for RHF can increase at any point along a continuum -Newer echo technology negates difficulty with RV imaging especially postoperatively to allow serial evaluation as RVD/risk is dynamic	JBI level 3b

							protocols with possible serial echo -Expand & establish a universal RHF definition -Revise INTERMACS parameters & definitions			
STUDY 17										
Pulmonary artery pulsatility index predicts right ventricular failure after left ventricular assist device implantation Kang, G. Ha, R. Banerjee, D. 2016	•Determine the utility of PAPi in prediction of RHF or unplanned RVAD after LVAD •To determine if PAPi robust as a predictive independent of preoperative Inotrope •To Determine if timing of PAPi measurement changes predictive value.	•83 of 85 LAVD recipients -Heartmat II (n=77) -HeartWare (n-8) •Single center, Stanford university Medical Center	•Retrospective cohort •Observational •Blood work 24 hours prior •PAPi 1-180 days prior	•RHF defined by INTERMACS: -CVP>18 -CI<2.0 -PCWP<18 -Inotropic support or NO >7 days •Unplanned RVAD within 30 days	•PAPi <2 -On inotropes -Off inotropes	•PAPi -> 12 days preop - <12 days preop	•Unplanned RVAD (n=9) significant predictors: -INTERMACS profile 1-2 -↑BUN -↑RAP -↓PAPi <2 -↑CVP/PCWP -No other parameters including PVR •RHF, no RVAD (n=27)) -PAP independently predictive •Effect of inotropes -PAPi more predictive on inotropes -RAP unaffected -CVP/PCWP less predictive on inotropes •Timing of PAPi -No effect on predictive power	•Small sample •Single center •No accounting for amount or duration of inotropes •Minimal explanation of results related to 27 patients with RHF vs. RVAD •Timing may be misleading as >12 days was a span from 13-180 days	•Interesting index which reflects after & RV response more accurately than PVR or CVP/PCWP individually •Would be interesting to track for changes which may correspond to critical events on RVD-RHF continuum	JBI level 3c
STUDY 18										

Preoperative three-dimensional echocardiography to assess risk of right ventricular failure after left ventricular assist device surgery Kiernan, M. S. French, A. L. Denofrio, D. Parmar, Y. J. Pham, D. T. Kapur, N. K. Pandian, N. G. Patel, A. R. 2015	•Determine the association between 3D echo obtained RVEF and RV volumes (RVEDVI RVESVI) with post LVAD RHF •Compare predictive power of2D & 3D echo quantitative RV parameters	•21 of 26 patients •Inclusion: -LVAD & BIVAD recipients with available 2D & 3D echo data -Heartmate II (n=19) -Heart Ware (n=5) •Exclusion: -Poor echo images •Single center, Tufts Medical Center •1/2008-12/2011	•Retrospective cohort •Observational •Grouped for comparison -RHF vs no RHF - 2D vs 3D echo parameters of size & function	•RHF defined by: -Inotrope > 14 days	•Predictive hemodynamic parameters of -RAP -CVP/PCWP -CI -PVR -RVSWI	•Predictive echo parameters -2D RV/LV ratio, RVFAC -3D RVEF, RVESVI, RVEDVI	•Prevalence of Heart failure (46%) -75%INTERMACS profile 1 (75%), -Profile 2-3 (33%) •Predictive Hemodynamics: -↑CVP/PCWP -↓RVSWI -RAP trended ↑ -CO trended ↓ •Predictive 2D echo parameters -↑RV/LV diameters - ↑RV-FAC •Predictive 3D echo parameters: -↓RVEF -↑RVESVI -↑RVEDVI •When influence of RV hemodynamics on RV volumes adjusted, RVESVI & RVEDVI remained significant predictors of RHF -3D echo parameters superior to hemodynamic & 2D echo parameters	•Small size •Single center •No consideration of preoperative support or definition of "medically optimized" •No correlation to end organ perfusion •No comparison to RV strain parameters which have been found predictive -Definition of RHF may have influenced prevalence & results	•Made good case for 3D echo -Greater predictive parameters -No need for contrast -No contraindication with pacemakers or ICDs -Technical ease of obtaining parameters pre & postoperative •Does support RV size and function and central measurements for prediction & suggests opportunities to measure using several different parameters •Interestingly also found PVR insignificant so may be that it isn't he load but the RV's response to the load that is significant	JBI level 3c
STUDY 19										
3D Echo-cardiography Derived Right Ventricular Function is Associated with Right Ventricular Failure and Mid-term Survival after Left Ventricular Assist Device Implantation Magunia, H. Dietrich, C. Langer, H. F. Schibilsky, D. Schlensak, C. Rosenberger, P. Nowak-Machen, M. 2018	•Evaluate association between 3D echo parameters of RV function and RHF post LVAD •Evaluate previously predictive parameters	•26 of 77 LVAD recipients •Inclusion: -Heartmate II -Heartmate 3 -Heartware -Median Sternotomy -"Less invasive" placement -"Few "Valve repair/ replacement •Single Center, University of Hospital Tubingen •10/2013-7/2017	•Retrospective cohort •Observational •Grouped for comparison -RHF vs no RHF •All patients per protocol: -Milrinone started before CPB pump -- Dobutamine before separation from CPB pump -No cardioplegia	•RHF defined by: -Inotrope > 14 days -Unplanned RVAD	•Previous predictive parameters	•Mortality by 3D echo parameters predictive of RHF	•Prevalence RHF (19.2%) -RHF no RVAD (n=3) -Unplanned RVAD (n=3) •3D echo predictive parameters -RV LFWS- 10.1% 100% sensitivity 66.7% specificity -RVEF •Hemodynamic: -CVP >15 40% sensitivity 42.9% specificity -RV/LV diameter >.75 60% sensitivity 47.6% specificity •2D echo: -RVLSFW 100% sensitivity 70% specificity •Mortality: -3D RVEF not significant predictor -3D RVFWLS significant predictor •Reclassification by 3D parameters	•Small sample •Inclusion of full sternotomy & less invasive •Inclusion of valve surgery •No comparison groups who did not follow same protocol •No account of end organ hypoperfusion •No consideration for timing of echo or measurement of other parameters •No consideration of preoperative inotropes/vasopressors	•Study raises many good questions for future research since the low incidence of RHF and RVAD may be explained by: -Inotrope protocol which may also explain inconsistent findings of insignificance of RVEDVI/RVESVI -Minimally invasive LVAD placement -Correction of valvular disease •Significance of RVEF & RVFWLS support importance of RV dysfunction and response to LV dysfunction •All significant parameters imply the importance of RV size and function before further	JBI level 3c

							reclassified patients who would have been classified as low risk by previous parameters		challenge of LVAD & OR events	
STUDY 20										
Pulmonary Artery Pulsatility Index (PAPi) is a Predictor of Right Ventricular Assist Device (RVAD) Use Following HeartMate 3 LVAD Implantation Marshall, D. Malick, A. Truby, L. Butler, C. Griffin, J. Clerkin, K. Fried, J. Raikhelkar, J. Yuzefpolskaya, M. Colombo, P. Sayer, G. Takayama, H. Takeda, K. Naka, Y. Farr, M. Uriel, N. Topkara, V. K. 2020	•Determine if PAPi is a stronger predictor of RHF after Heartmate 3 than CVP/PCWP &RVSWI	•175 Heartmate 3 recipients •Single center •2014-2019	•Retrospective cohort •Observational		•Other parameters associated with RHF		•Unplanned RVAD (31.4%): -Mostly INTERMACS profile 1-2 -↑WBC -↑C reactive protein -RVSWI no significant difference -↑CVP/PCWP significant predictor -PAPi significant and only independent predictor	•Small sample •Single center •No information regarding preoperative treatment •RHF definition limited to RVAD most likely missed all RHF diagnoses -High RVAD incidence may be attributed to a lower-than-average threshold to place, no criteria addressed	•Very limited yet followed trends of many other studies	JBI level 3c
STUDY 21										
Pre-LVAD CT-Derived Measures of RV Size and Function May Be Strong Identifiers of Right Ventricular	•Determine predictive value of ECG-gated contrast enhanced quantitative, volumetric,	•12 of 67 LVAD recipients -GFR >40 -Functional CT •Single center •2016	•Retrospective cohort -Observational	•RHF as defined by INTERMACS criteria -Undefined	•Functional CT parameters -RVEDVI -RVEF	•Other parameters & risk scores previously predictive of RHF	•RHF prevalence (58%) •Significant Predators -REDVI -RVEF	•Small sample •Single center •Ill-defined end points making results difficult to interpret	•Though not generalizable findings follow trend of other studies •Inclusion of GFR	JBI level 3c

Failure Scott, A. Kim, P. Adler, E. Kligerman, S. Tran, H. Pretorius, V. Contijoch, F. 2020	functional measures of RV size and function -RVEDVI -RVEF					-CVP -PAPi -Creatinine -Michigan score -CRITT score	-PAPi •No significant prediction -Michigan score -CRITT score -CVP	•Large bias GFR >40	>40 implies minimally available to a population with a high co-morbidity of chronic kidney disease & often acute kidney injury during states of decompensated HF	
STUDY 22										
Pulmonary Arterial Elastance and INTERMACS-Defined Right Heart Failure Following Left Ventricular Assist Device Muslem, R. Ong, C. S. Tomashitis, B. Schultz, J. Ramu, B. Craig, M. L. Van Bakel, A. B. Gilotra, N. A. Sharma, K. Hsu, S. Whitman, G. J. Leary, P. J. Cogswell, R. Lozonschi, L. Houston, B. A. Zijlstra, F. Caliskan, K. Bogers, Ajjc Tedford, R. J. 2019	•Determine if INTERMACS classification of RHF predicts post LVAD mortality •Identify the preoperative parameters predictive of INTERMACS RHF stages associated with mortality	•375 LVAD recipients •Inclusion: -Heartmate II -Heartmate 3 -HeartWare -Cardiac cath within 30 days before LVAD -Median sternotomy •Multicenter -Medical University of South Carolina (n=91) -University of Minnesota (n=166) -Johns Hopkins University School of Medicine (n=102) -Erasmus Medical center (n=16) •2008-2016	•Retrospective cohort •Observational	•RHF defined by: -Hemodynamic, echo or clinical signs of elevated CVP •Stratification of RHF by severity: -Mild=Inotropes NO <7 days -Moderated= Inotrope/NO 7-14 days -Severe= Inotrope/NO >14 days -Severe Acute= unplanned RVAD or RHF death	•Preop parameters predictive power for of severe-severe Acute RHF -CI -RVEDP -RV systolic pressure -PAS,PAD,Mean PA, -PAPi -PCWP -Ea(PAS/SV) -Creatinine -Total bilirubin -Hgb -Platelet ct -INTERMACS profile	•Survival at 2 years	•Prevalence of RHF (72%): -Mild (34%) -Moderate (16%) -Severe (13%) -Severe Acute (9%) •Parameters significantly & predictive of severe/severe acute RHF -Ea which had increased discrimination if coupled with RAP •Survival at 2 years -No RHF (72%) -Mild-moderate (71%) -Severe-severe acute (55%)	•Retrospective -High quality echo uniformly available •Multicentered -Multiple operators -Varied practices which could influence RV function after LVAD not accounted for -Varied/subjective RAP determination with no accounting for accuracy based on mechanism of assessing	•One of the few multicentered studies with a large population •High prevalence likely related to unique use INTERMACS definition -Broad definition of increased RAP/CVP with multiple mechanisms of confirming -Added time limits which indirectly represented severity to stratify and did correlate to morality however no direct correlation cause of death •Use of Ea as a total RV afterload measure in combination with RV response (RAP/CVP) supports theme of RV reserve as a predictor of post RHF -Though Ea +CVP predictive of severe-severe acute RHF, 2/3 did not progress to RHF which may have been attributed to interventions aimed at preventing progression. Identification of those interventions or the critical events that led to progression would truly support dynamic risk assessment and clinical outcomes.	JBL level 3b

STUDY 23										
Cardiac Passive -Aggressive Behavior? T The Right Ventricle in Patients With a Left Ventricular Assist Device Kimmaliardjuk, D. M. Ruel, M. 2017	•Describe predictive parameters for post LVAD RHF used in most cited prediction models •Identify other independently predictive parameters •Recommend RV remediation interventions	•219 of 526 PubMed references -"RHF after LVAD" -"RV mechanical support" -limited to human & English language	•Expert review: -Literature scoping -Systematic review	•Predictive parameters used in most cited risk assessment scores -Michigan -Penn -Utah -Pittsburgh Decision Tree -CRITT -Kormos Multivariant predictors	•Independently predictive parameters found evidence literature	•Preventive & therapeutic interventions for RHF after LVAD	•No consensus on predictive parameters •Modified definitions •Michigan Score: -↑Vasopressors -↑AST -↑Bilirubin -•Creatinine or dialysis •Penn -↓CI -↓RVSWI -Severe RVD on echo -↑Creatinine -↓SBP -Previous cardiac surgery UTAH: -↑PVR -Preop IABP -Destination therapy -Inotropes -Obesity -ACEi/ARB -Beta-blocker •Pittsburgh: -Age -TPG -↑RAP -↑INR -↑HR -↑ALT -↑WBC -# inotropes •CRITT -CVP > 15 -Severe RVD on echo -Severe TR on echo -Mechanical ventilation -HR > 100 •Kormos: -↑CVP/PCWP -↓CI -Mechanical ventilation -↑BUN •Other parameters: -RV longitudinal strain -RV FAC -PAPi -PACi -Tethered TV •Preventive Interventions:	•Limited discussion of theme /physiology which relates all variables & interventions •Lack of discussion regarding preoperative preventive measures or optimization which could be extracted from review	•Viewing evidence collectively explains the risk factors in related concepts rather than individual parameters or sets of parameters -Degree of RVD/RV compensation & reserve/end organ reversible/irreversible dysfunction assessed by RV size, function and changes in response to pulmonary load, liver & kidney function define RHF risk •Viewing evidence chronologically defines the parameters chosen as they parallel diagnostic technology -Increasing capability of more direct measures of RV parameters are progressively more predictive than less direct •Identification of intraoperative & postoperative preventive measures imply dynamically changing degree of risk and critical events which can change risk throughout course which can	JBI level 3b

							-↓CPB pump time -Minimize transfusions -Full deairing -Lower pump speed/adequate LV volume -Minimize PVR with low PEEP, no hypoxia or acidosis •Medical treatment: -Milrinone - Inhaled NO -IV/PO pulmonary vasodilators •Surgical treatment: -ECMO -RVAD -TV repair			
STUDY 24										
Right Ventricular Afterload Sensitivity Dramatically Increases After Left Ventricular Assis Device Implantation: A Multi-Center Hemodynamic Analysis Houston, B. Kalathiya, R. Hsu, S. Loungani, R. Davis,M. Coffin, S. Haglund, N. Maltais, S. Keebler, M. Leary,P. Judge, P. Steens, G. Shah,A., Russell,S. and Telford, R. 2020	•Compare hemodynamic markers of RV function & afterload before & after LVAD	•60 of 244 patients from 2 large centers between 2005 & 2014 •Inclusion: -LVAD via median sternotomy on cardiopulmonary bypass pump -Cath results at each time interval compete •Exclusion Criteria -On inotropes or mechanical assist preoperatively	•Retrospective cohort •Observational	•Hemodynamic measures of: -PVR -Ea -PACi -PA pressures -RAP -RAP:PCWP -CO at: -within 6 months pre-LVAD -0-6 months post LVAD -7-12 months post LVAD -13-18 months post LVAD -18-36 months post LVAD	•Evidence of ischemia	•Survivorship	•PVR, Ea decreased early postop •PACi increased postop •RAP remained high postop •All parameters improved in later postop intervals •No difference in parameters between ischemic & non-ischemic •Non survivors had higher RAP & RAP at all time intervals	•Strict criteria limited sample size & generalize-ability •Long time interval attributed to high attrition rate	•RV more sensitive to afterload early postop •Decreased RV reserve implied by RAP increases risk of death after LVAD	JB level 3b
STUDY 25										

Right ventricular to Left Ventricular End-Diastolic Diameter ratio and Prediction of Right Heart Failure with Continuous Flow Left Ventricular Assist Devices Kukucka, M. Steponenko, A. Potapore, E. Knobatsch, T. Redlin, M. Mladenow, A. Kuppe, H. Hetzer, R. and Habazetti, H. 2020	•To determine if RHF after LVAD could be predicted by RV/LV ratio	•115 consecutive patients pre-selected for LVAD & 22 for BIVAD between 2007 & 2009 at a single center •Exclusion criteria -Acute CHF -Post cardiotomy heart failure	•Retrospective cohort •Observation	•RHF defined by -MAP <55 -RAP > 16 -CI <2 -SVO2 > 55% -Inotropic support score -Need for RVAD	•RV/LV ratio	•30 day mortality	•↑RV/LV ratio significant predictor of RHF after LVAD •↑RV/LV ratio associated with 30 day mortality	•Definition of RHF and criteria for RVAD center specific •Small sample size	•RV/LV is an easily obtainable parameter which may be capable of demonstrating external validity •Coupling parameters supports the significance of RV reserve in risk for RHF	JB level 3b
STUDY 26										
Intraoperative Transesophageal Echocardiograph and Right Ventricular Assist Device Implantation Silverton, W. Patel, R. Zimmerman, J. Ma J. Stoddard, G. Selzman, C. Morrissey, C. 2021	•To determine whether interop measures of RV function are associated with RHF after LVAD	•100 patients at a single center undergoing elective LVAD	•Retrospective cohort •Observational	•RHF defined by -Inotropes required > 14 days after LVAD	•RV function by TEE -RV FAC -RVLS -RVGS -S' -TAPSE	•Need for unplanned RVAD	•Only RV FAC showed a significant association to RHF after LVAD	•Center specific RVAD RHF and criteria and limited generalizability	•RV function before LVAD is a predictor of RHF as all measures trended toward RHF after LVAD •Supports the lack of consensus for which parameters are best as RV FAC has been an inconsistent predictor of post LVAD RHF	JB level 3b
STUDY 27										
Intraoperative Hemodynamic and Echocardiographic Measures Associated with Severe Right Ventricular Failure after Left Ventricular Assis Device Implantation Gudejko.M. Gebhardtm B.	Evaluate if interop parameters differed between patients with severe RHF and no severe RHF after LVAD •CVP & PAPi •Quantitative TEE measurements	•81 of 100 patients from 2013-2016 •Inclusion criteria: -HM II or HVAD -Prop inotropes •Exclusion criteria: -Missing data -Additional cardiac procedures in OR -Left OR with open chest -RVAD with LVAD	•Retrospective cohort •Chart review •Two comparison groups -Severe postop RHF -Non severe postop RHF	•INTERMACS criteria: - RVAD -Inotropes or pulmonary vasodilator >14 days	•Calculated Mathews, Fitzpatrick, Drakes and ARVASE scores compared to calculated scores for heart failure mortality not specific for RHF after LAVD -Seattle Heart Failure Model -MELD score -APACHE II •Quantitative measures of RV	•Quantitative echo: -TAPSE -RV FAC •Hemodynamic -CVP -PAPi •Clinical factors	•CVP and PAPi showed discrimination for severe RHF •TEE TASPE & RV FAC had some consistency •Michigan score did not differ between severe & nonsevere RHF •Larger volume &	•Small sample size •Single center •No protocol for RVAD placement or inotropic/ pulmonary vasodilator treatment	•Intraoperative events contribute to risk for RHF •Previous risk scores are not reliable for clinical prediction of risk for RHF	JB level 3b

Zahedi, F. Jain, A. Breeze, J. Lawrence,M. Sherman, S. Kapur, N. Kiernan, M. Couper, G. and Cobey, F. 2020					-RVEF -RV-FAC -RVEDD -RVS		blood resuscitation in OR associated with risk for severe RHF			
STUDY 28										
High Pulmonary Vascular Resistance In Addition to Low Right Ventricular Stroke Work Index Effectively Predicts Bi-ventricular Assist Device Requirement., Immamura, T. Kinugawa, K, Kinoshita, O. Nowata, K. andOno, M. 2016	•To assess significance of RVSWI and PVR for BIVAD requirement	•116 patients at a single center between 2003-2015 -All device e types included	•Retrospective cohort •Observational	•RVSWI and PVR •Four groups -RVSWI <5 & PVR <3.7 -RVSWI >5 & PVR <3.7 -RVSWI >5 & PVR >3.7 =RVSWI <5 & PVR >3.7	•Need for RVAD	•INTERMACS profile	•RVSWI <5 coupled with PVR. 3.7 an independent predictor of need for RVAD	•Minimal generalize-ability related to: -Redefined INTERMACS profiles -Center specific RVAD criteria -Many types of devices included	•Decreased RV reserve implied by RVSWI <5 & PVR >3.7 predicts need for RVAD which implies severe RHF	JB level 3b
STUDY 29										
Right Heart Failure Before LVAD Implantation Predicts Right Heart Failure After LVAD Implantation-is it that easy? Wagner, T. ,Bernhardt, A., Magnussen, C., Reichenspurner, H., Balkenberg, S., and Grahn, H. 2020	•To assess predictors of RHF focusing on clinical manifestations	•112 patients of 132 undergoing emergent or elective LVAD at a single center between 2009-2017 •Inclusion criteria -> 18 years old -continuous flow device insertion •Exclusion criteria -Preop hemodialysis -Planned RVAD	•Retrospective cohort - Chart review -Observational	•RHF defined by: -CVP > 16 with no JVD or respiratory variation -> 2+ peripheral edema -Ascites -Hepatomegaly -Total bili >2 -Creatinine >2	•Early RHF -7 days postop -14 days postop	•Late RHF -1 month postop -3 months postop -6 months postop -12months postop	•73 cases (64.3%) with preop RHF ->CVP/PCWP & CVP - < load adaptability index -Lower INTERMACs profile - No difference in echo •Early RHF -Significant association with preop RHF - significantly < survival at 14 days than no RHF or late RHF -preop > CVP/PCWP --<load adaptability index - <Hgb -<INTERMACS profile -Younger	•Retrospective •Small sample size •Single center •Exclusion of preop Hd and planned RVAD -criteria institution specific & may have changed over years reviewed -highest risk exclusion may skew findings & predictive parameters •Very limited definition of RHF may have underestimated pre & postop RH -No accounting for required medical or mechanical support	•Supports concept of decreased RV reserve as a primary risk factor as parameters such as CVP/PCWP combined with load adaptability index define reserve as opposed to function. •Delineation of early, persistent late & new onset late supports the need for early recognition of risk for RHF if worst outcomes are to be prevented.	JB level 3b

							•Late RHF -50% Persistent, 50% new onset -Survival equivalent with early RHF after 30 days -Preop RHF not associated with new onset late RHF •Best predictors of early & persistent late RHF -↑CVP/PCWP -↓load adaptability index -↑BUN/CR -lower INTERMACS profile -younger age•			

Appendix C

SWOT Analysis for Institution of Implementation

Strengths	Weaknesses
▪ Commitment to providing advanced technology, innovation & multidisciplinary care to patients with severe heart failure ▪ Employment of physicians with heart failure specialty certification ▪ Designated heart failure and ICU APRNs who coordinator care across the continuum of care. ▪ Standard preoperative work up for all Hartford Hospital CF LVAD candidates ▪ Employment of a dedicated CF LVAD data manager ▪ Participation of a national registry for outcome measurement & comparison. ▪ Well established forums for multidisciplinary communication regarding CF LVAD candidates & recipients ▪ Availability of state-of-the-art diagnostic and therapeutic technology ▪ Well support for staff education and maintenance of competency	▪ Exclusion of quantitative RV parameters ▪ Exclusion of specific right heart failure (RHF) risk assessment from care planning discussions ▪ Exclusion of RV specific parameters from data collection and analysis ▪ Acceptance of RHF which may underestimated outcomes based on incomplete data input. ▪ Lack of standardized care pathway for patients with increased risk for RHF ▪ Variable knowledge levels of care providers across phases of care regarding RHF ▪ Need for complex coordination of care across providers in several departments and specialties within the heart & vascular institute
Opportunities	**Threats**
▪ Ranked America's top 50 hospitals for cardiac care. ▪ A large referral base from a centrally located main campus and multiple satellite locations across two states ▪ Physicians are nationally connected allowing sharing of data & collaboration across many systems ▪ National recognition of the complex needs of heart failure patients with establishment of a physician specialty education and certification in 2010. ▪ Growing population of heart failure patients managed with CF LVAD implantation with indication expanded to bridge to decision for heart transplant candidacy and destination	▪ A trend toward higher risk and greater number of candidates for CF LVAD: -Expanding indications for use -Availability temporary life-saving technology which serve as bridge to CF LVAD ▪ National registry's exclusion of quantitative, RV specific data for RHF prediction & diagnosis ▪ Rapid advancement of available diagnostic and CF LVAD technology challenging timely and applicable research and caregiver competence ▪ Rising cost of providing diagnostic and mechanical replacement technology ▪ Lack of evidence for parameters proven to reliably predict RHF after CF LVAD

Appendix D

Figure 16

Project Timeline/Gantt Chart

PREDICTING RIGHT HEART FAILURE FOLLOWING IMPLANTATION OF A CONSTINUOUS FLOW LEFT VENTRICULAR ASSIST DEVICE

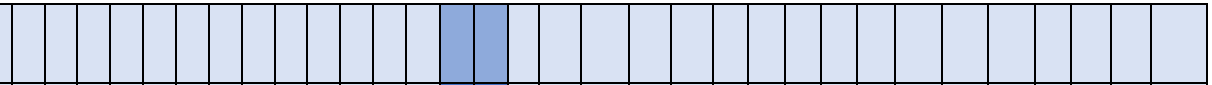
Gantt Chart

Healthcare System: Hartford Healthcare
Operational Leader: Mary-Ann Cyr MSN APRN ACNP
Project Timeline: May – December 2021

Task Sub-task

Adapted from https://www.vertex42.com

Task	Assigned To	Start Date	Finish Date	Progress	May Week 1 2 3 4	June Week 1 2 3 4	July Week 1 2 3 4	August Week 1 2 3 4	September Week 1 2 3 4	October Week 1 2 3 4	November Week 1 2 3 4	December Week 1 2 3 4
Assemble project team	Project leader	5/1	8/20	50%								
Complete proposal & present to nursing research council and IRB portocol	Project leader	8/1	8/19	100%								
Develop preliminary assessment tool	Project leader project manager, project sponsor	6/1	6/14	100%								
Email Expert review form and RHF risk assessment draft	Project leader	8/14	8/14	0%								
Meet with Heart Failure experts	Project leader	8/16	8/26	0%								

Meet with cardiac anesthesiologist/surgeon experts	Project leader	8/16	8/26	0%	
Meet with Internal ICU experts	Project leader	8/16	8/26	0%	
Finalize tool with project manager & project sponsor	Project leader	8/20	8/30	0%	
Complete proposal & present to HHC Nursing Research& IRB	Project leader	7/6	8/15	100%	
Develop data management plan	Project leader, Project manager, Data manager	7/16	8/4	100%	
Team kick off meeting	Project leader, project manager, project sponsor	9/8	9/8	0%	
Weekly communication with representatives to update progress& receive feedback	Project team members	9/9	12/17	0%	
Calculate RHF risk score during each phase of care for each patient undergoing LVAD implantation	Project leader	9/16	12/23		
Attend weekly multidisciplinary patient rounds	Project leader, Project manager	9/16	12/17	0%	
Review monthly registry outcome reports	Project leader, project manager, data manager	10/1	12/17	0%	
closing/distribution of user survey/Analysis of results/planning project's future	Project team members	12/10	12/23	0%	

Appendix E

Expert Panel Invitations

Institution of Implementation

Heart Failure Certified Physician, Critical Care Intensivist, Critical Care APRN

National: Tufts Medical Center, Mayo Clinic, Massachusetts General Hospital, Yale-New Haven Hospital, Cleveland Clinic

Heart Failure Certified Physicians, Critical Care Advanced Practice Registered Nurses, and Physician Assitants

International

Antonio LoForte MD, Developer of ALMA Right Heart Failure Risk Score

Appendix F

Expert Panel's Instructions

Dear Expert,

This review contains parameters related to evaluation of the right heart for patients undergoing LVAD placement. I am seeking your objective expert judgement on the relevance and accuracy of measures which are supported by the evidence for each parameter.

My DNP project aims to adapt, implement and evaluate a right heart failure risk assessment instrument for LVAD candidates and recipients. Your review will be helpful in the final selection of measures to be included in the risk assessment.

I included a reference table with definitions for each measure. It would be helpful if you use this reference to make judgements on parameters you currently use and those which you do not use in practice. You can make any further comments or recommendations concerning measurement of each parameter in the space provided.

Appendix G

Expert Relevance Rating Instrument

Relevance Rating Scale

1 = Measurement ***not*** relevant to parameter

2 = Measurement is ***somewhat*** relevant to parameter

3 = Measurement is ***quite*** relevant to parameter

4 = Measurement is ***highly*** relevant to parameter

Please relevance of measurements to the corresponding parameter using the scale below.

Parameter: PULMONARY HYPERTENSION		
Measurements	**Relevance 1 2 3 4**	**Recommendations/Comments**
PAPi	◯◯◯◯	
PACi	◯◯◯◯	
Ea	◯◯◯◯	
Parameter: RV COMPENSATION FOR PULMONARY HYPERTENSION		
Measurements	**Relevance 1 2 3 4**	**Recommendations/Comments**
CVP or RAP	◯◯◯◯	
CVP : PCWP	◯◯◯◯	
Echocardiographic RV : LV Diameter	◯◯◯◯	
RVEVDI : LVEDVI	◯◯◯◯	
RVEDAI : RVEDVI	◯◯◯◯	
RVLS	◯◯◯◯	
RVEF	◯◯◯◯	
RVSWI	◯◯◯◯	
Parameter: RV DECOMPENSATION		
Measurements	**Relevance 1 2 3 4**	**Recommendations/Comments**
MELD	◯◯◯◯	
Creatinine	◯◯◯◯	
Lactate	◯◯◯◯	
Inotrope Requirement	◯◯◯◯	
Vasopressor Requirement	◯◯◯◯	
IABP Requirement	◯◯◯◯	
RVAD Requirement	◯◯◯◯	
ECMO Requirement	◯◯◯◯	
Mechanical Ventilation Requirement	◯◯◯◯	
Renal Replacement Requirement	◯◯◯◯	

Appendix H

Expert Accuracy Rating Instrument

Please rate the following measurements for their accuracy in measuring the corresponding parameter using the scale below.

Accuracy Rating Scale

1 = ***Not*** an accurate measurement of parameter
2 = ***Somewhat*** accurate measurement of parameter
3 =***Quite*** accurate measurement of parameter
4 = ***Highly*** accurate measurement of parameter

Parameter: PULMONARY HYPERTENSION		
Measurements	**Accuracy** **1 2 3 4**	**Recommendations/Comments**
PAPi	◯◯◯◯	
PACi	◯◯◯◯	
Ea	◯◯◯◯	
Parameter: RV DILATION		
Measurements	**Accuracy** **1 2 3 4**	**Recommendations/Comments**
CVP or RAP	◯◯◯◯	
CVP : PCWP	◯◯◯◯	
Echocardiographic RV : LV Diameter	◯◯◯◯	
RVEVDI : LVEDVI	◯◯◯◯	
RVEDAI : RVEDVI	◯◯◯◯	
Parameter: RV CONTRACTLITY		
Measurements	**Accuracy** **1 2 3 4**	**Recommendations/Comments**
RVLS	◯◯◯◯	
RVEF	◯◯◯◯	
RVSWI	◯◯◯◯	
Parameter: END ORGAN PERFUSION		
Measurements	**Relevance** **1 2 3 4**	**Recommendations/Comments**
MELD	◯◯◯◯	
Creatinine	◯◯◯◯	
Lactate	◯◯◯◯	

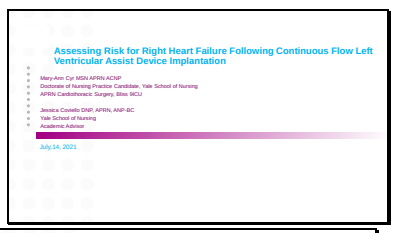
Appendix I

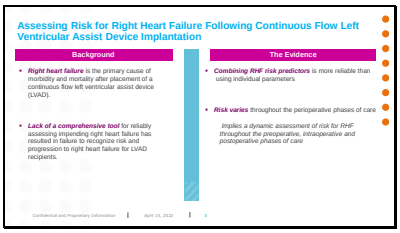
Evaluation of Expert Panel Responses Instrument

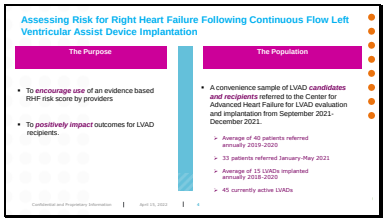
Domain	Relevance Ratings							Accuracy Ratings							Relevance Mean	Accuracy Mean	Relevance CVI	Accuracy CVI	Comments	Include Yes/No
Pulmonary Hypertension																				
PAPi																				
PACi																				
Ea																				
Compensation																				
RV Dilation																				
CVP/RAP																				
CVP/PCWP																				
RVEDVI																				
RVEDAI																				
RVEVDI/LVEDVI																				
RVEDAI/RVEDVI																				
RV Contractility																				
RVLS																				
RVEF																				
RVSWI																				
Decompensation																				
End-organ perfusion																				
MELD																				
Creatinine																				
Lactate																				
Medical support																				
Inotropic Infusion																				
Vasopressor Infusion																				
Mechanical Support																				
IABP																				
Temporary RVAD																				
Temporary LVAD																				
Mechanical Ventilation																				
Renal Replacement																				
ECMO																				

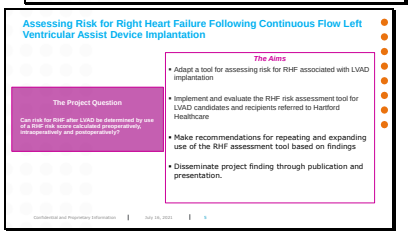
Appendix J

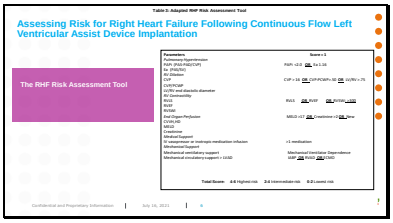
Power Point: Project Introduction

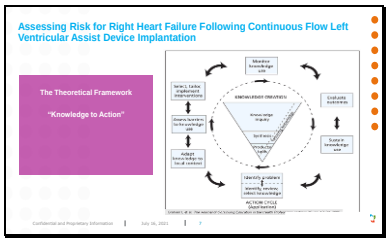


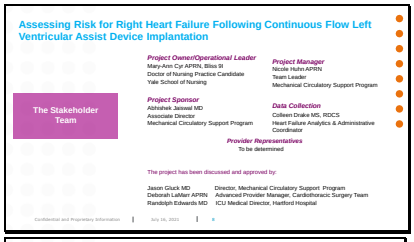


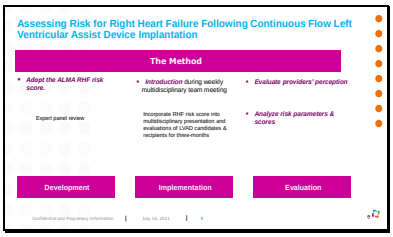


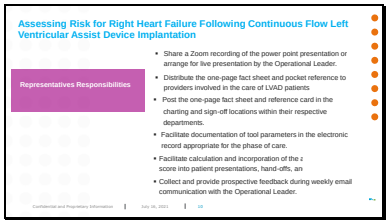


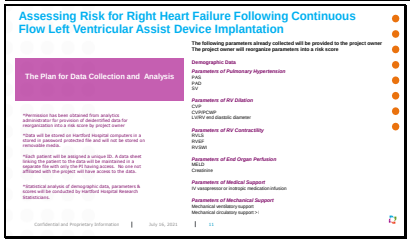


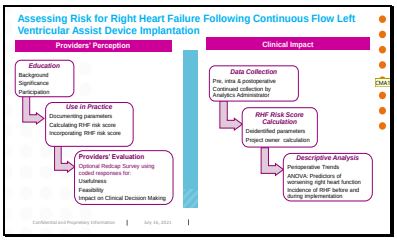


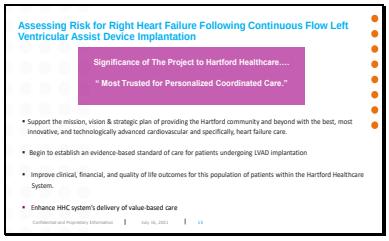


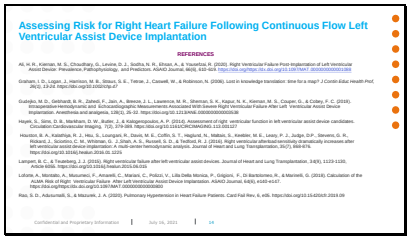












Appendix K

RHF Risk Assessment Provider Information Sheet

Assessing Risk for Right Heart Failure Following Left Ventricle Assist Device (LVAD) Implantation

Problem	Evidence	Plan
• Right heart failure is the primary cause of morbidity and mortality following LVAD placement • Lack of a comprehensive tool for assessing impending right heart failure	• Combining right heart failure risk predictors is more reliable than using individual parameters • Risk is dynamic throughout the perioperative phases of care	• Develop, implement and evaluate a comprehensive right heart failure risk assessment tool for LVAD recipients

What can you do?

- ✓ Assure parameters needed to assess risk are documented
- ✓ Calculate a risk score using the risk assessment tool
- ✓ Include RHF risk assessment in patient presentation, hand-offs, and care planning

Please contact Mary-Ann Cyr APRN

Add 1 Point for Each Category if at Least One Parameter Applies	0-1 Point
Category 1: Pulmonary Resistance: ○ PAPI (PAS-PAD/CVP) ≤ 2.0	
Category 2: Right Ventricular Dilation: ○ CVP ≥16 ○ CVP/PCWP ≥ 0.5	
Category 3: Right Ventricular Function: ○ REF ≤ 25 ○ RVSWI ≥300 ○ ≥ Mild RV dysfunction on echo ○ TAPSE ≤ 1.6	
Category 4: Renal /Liver Function ○ Creatinine ≥2 ○ New CVVH, HD ○ MELD Score ≥17	
Category 5: Support ○ ≥ 1 Inotropic or vasopressor medication ○ Mechanical ventilator dependence ○ IABP ○ RVAD ○ ECMO	
Total Points	
RHF Risk Score Interpretation: 4-5 Highest risk 2-3 Intermediate risk 0-1 Lowest risk	

Instructions

1. **Calculate**: PAPI = $\frac{\text{PA systolic – PA diastolic pressure}}{\text{Central venous pressure}}$
2. **Add 1 point** for each category if at least one parameter applies
3. **Total points** and use RHF risk score interpretation key to assign lowest,
   The intermediate or highest risk

Appendix L

Laminated Reference Card

FRONT

LVAD Right Heart Failure Risk Score Calculation: Add 1 Point for Each Category if at Least One Parameter Applies	0-1 Point
Category 1: Pulmonary Resistance: o PAPI (PAS-PAD/CVP) ≤ 2.0	
Category 2: Right Ventricular Dilation: o CVP ≥16 o CVP/PCWP ≥ 0.5	
Category 3: Right Ventricular Function: o REF ≤ 25 o RVSWI ≥300 o ≥ Mild RV dysfunction on echo o TAPSE ≤ 1.6	
Category 4: Renal /Liver Function o Creatinine ≥2 o New CVVH, HD o MELD Score ≥17	
Category 5: Support o ≥ 1 Inotropic or vasopressor medication o Mechanical ventilator dependence o IABP o RVAD o ECMO	
Total Points	
RHF Risk Score Interpretation: 4-5 Highest risk	2-3 Intermediate risk 0-1 Lowest risk

BACK

Right Heart Failure Risk Score Calculation Instructions

1. **Calculate** PAPI: PAPI = $\frac{\text{PA systolic pressure – PA diastolic pressure}}{\text{Central venous pressure}}$
2. **Add 1 point** for each category if at least one parameter applies
3. **Total points** and use RHF risk score interpretation key to assign lowest, intermediate or highest risk

Appendix M

Sample Hand-off Work Sheet with Addition of RHF Risk Score Entry

<table>
<tr>
<td>Patient
Name
Age
DOB
MRN
Unit/room
Code Status
LOS
Attending
Service

PMH/PSH/SH

Baseline Cr
HGB A1C
Preop Wt.

RHF Risk Score</td>
<td>Summary

Neuro:
CV:
Resp:
GI:
GU:
Heme:
ID:
Endo:
Skin:

<table><tr><th>Lines/Tubes</th><th>Date</th></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td>
<td>Procedures</td>
<td>To do/Pending</td>
<td>Notes</td>
</tr>
</table>

Appendix N

Provider Survey Information Sheet

Principal Investigator: Mary-Ann Cyr APRN Cardiothoracic Surgery

Co-Investigator:

Title of Project: Assessing Risk for Right Heart Failure After LVAD Implantation

You are invited to participate in this survey for providers feedback regarding the RHF risk assessment instrument. I am an APRN in Bliss 9I at Hartford Hospital and a Doctor of Nursing Practice candidate at Yale School of Nursing, and I am interested in finding out how to best assess risk for right heart failure following implantation of a left ventricular assist device as this is the primary cause of postoperative morbidity and mortality.

Your participation in this project will require completion of the linked questionnaire. This should take approximately 10 minutes of your time. Your participation will be anonymous, and you will not be contacted again in the future. Your participation is completely voluntary. You do not have to answer any question that you do not want to answer for any reason. You will not be paid for being in this project. This survey does not involve any risk to you. This project will provide no direct benefit to you today, but the knowledge that we gain may benefit others in the future. Your doctor and other medical providers do not have access to any information that you provide. Your access to and quality of healthcare will not be affected in any way.

Please complete the linked survey. Once you do that, your participation will end.

Thank you.

Who you can call if you have questions about this study:

Questions about:	Contact	Phone #
the project, project-related treatments, or a research related injury	Mary-Ann Cyr	(203) 232-0923
your rights as a project participant	An IRB Representative	(860) 972-2893
the research in general	Vice President, Research	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with project	Patient Advocates	(860) 972-1100

Appendix O

Implementation Provider Survey

Please choose a rate the following with:

5 = Strongly agree

4 = Agree

3 = Neither agree nor disagree

2= Disagree

1 = Strongly disagree

The RHF risk assessment is useful.	1 2 3 4 5
The RHF risk assessment was simple to use.	1 2 3 4 5
The RHF risk assessment impacted clinical decision-making.	1 2 3 4 5
The RHF risk assessment was valuable in discussing LVAD patients' clinical care.	1 2 3 4 5
The RHF risk assessment should be used routinely for all LVAD patients.	1 2 3 4 5
I will continue to use the RHF risk assessment in my evaluation of LVAD patients	1 2 3 4 5

Comments:

_____
_____
_____
_____
_____

Appendix P

Case Reports

Patient A.

Patient A was diagnosed with NYHA class IV heart failure prior to admission. He was admitted with an INTERMACS profile two, consistent with decompensation on inotropic support and an admission diagnosis of cardiogenic shock. Incomplete prehospital data did not allow calculation of a RHF risk score. However, available data revealed a minimal score of two and a maximal possible score of three, indicating an intermediate risk for RHF failure. Fifteen days after admission, the RHF risk score rose to four, indicative of the highest risk for progression to right heart failure. An increased risk score was attributed to worsening pulmonary hypertension and a declining right ventricular ejection fraction. Mechanical support had been added however this did not contribute to the increased score as a point had already been awarded for the continued inotropic medication requirement. On postoperative day six, the right heart failure risk score remained a four. Worsening pulmonary hypertension, declining RV ejection fraction, an elevated creatinine, an elevated MELD score, and continued inotropic support contributed to a persistent score representing highest risk for progression to debilitating right heart failure (see Table 3).

Table 3

Patient A: Right Heart Reserve Parameters and Right Heart Risk Scores

Phase of Care	Prehospital	Preoperative	Intraoperative	Postoperative
Parameter				
Admission to Insertion days)	15			
Insertion to Postoperative (days)	6			
Admission Diagnosis	CS			
NYHA Class	IV			
INTERMACS Profile		2		
Pulmonary Hypertension				
PAPi	**2.0**	**2.0**		**1.2**
RV Dilation				
CVP	10	5		9
CVP:PCWP	0.48	0.23		
RV Function				
RVEF/REF				
RVSWI		**20**		**18**
RV on Echo	**Mild**		**Moderate**	
TAPSE				
Renal/liver Function				
Creatinine		**2.0**		**2.2**
Dialysis		No		No
MELD		**19.6**		**19.6**
Support				
Inotrope	**Milrinone**	**Milrinone**	**Milrinone**	**Dobutamine**
Vasopressor	No	No	No	No
Ventilator	No	No	**Yes**	No
IABP	No	Yes	Yes	No
RVAD	No	No	No	No
ECMO	No	No	No	No
Additional				
PAS	48	25		31
PAD	26	15		20
PCWP	48	22		
Total Bilirubin		0.7		0.2
Sodium		126		2.0
INR		**1.2**		13 0
Risk Score	**≥2**	**4**	**≥3**	**4**
RHF Risk	**Intermediate**	**High**	**≥Intermediate**	**Highest**

CS=Cardiogenic Shock, Highlighted Values Contributed to RHF Risk Score for Each Phase of care

Patient B.

Patient B was diagnosed with NYHA class III heart failure prior to admission. The patient was admitted with an INTERMACS profile three, consistent with stability on inotropic support and elective LVAD implantation. Incomplete prehospital and preoperative data did not allow calculation of a RHF risk score. However, available data revealed a low risk for RHF with a maximal possible score of one. An intermediate intraoperative risk score was attributable to mild RV dysfunction on echocardiogram and the addition of inotropic support. The patient's score of four on postoperative day three, represented highest risk for RHF and was attributable to pulmonary hypertension, decreased right ventricular ejection fraction, elevated creatinine, and continued inotropic support. Despite limited data, the patient was at lowest risk during the prehospital phase of care. Prehospital data and clinical assessment upon admission may have contributed to the foregoing of preoperative hemodynamic assessment. The RHF risk score did increase at one or several points between the prehospital and postoperative phases of care. There was no way to determine if the score increased, decreased, or persisted across the preoperative, intraoperative, and postoperative phases of care (see Table 4).

Table 4

Patient B: Right Heart Reserve Parameters and Right Heart Risk Scores

Phase of Care	Prehospital	Preoperative	Intraoperative	Postoperative
Parameter				
Admission to Insertion (days)	**2**			
Insertion to Postoperative (days)	3			
Admission Diagnosis	PL			
NYHA Class	III			
INTERMACS Profile		3		
Pulmonary Hypertension				
PAPi	5.3			**1.2**
RV Dilation				
CVP	3			10
CVP:PCWP	0.38			
RV Function				
RVEF/REF				**21**
RVSWI				
RV on Echo	Normal		**Mild**	
TAPSE				
Renal/liver Function				
Creatinine		1.1		1.2
Dialysis		No		No
MELD		6.0		**19.6**
Support				
Inotrope	No	No	**Milrinone**	**Milrinone**
Vasopressor	No	No	No	No
Ventilator	No	No	**Yes**	No
IABP	No	No	No	No
RVAD	No	No	No	No
ECMO	No	No	No	No
Additional				
PAS	32			
PAD	16			
PCWP	8			
Total Bilirubin		0.2		0.2
Sodium		136		5.6
INR		**1.8**		135
Risk Score	**≥0**	**≥0**	**≥2**	**4**
RHF Risk	**Lowest**	**≥Lowest**	**≥Intermediate**	**Highest**

PL = Planned LVAD, Highlighted Values Contributed to RHF Risk Score for Each Phase of Care

Patient C.

Patient C was diagnosed with NYHA class III heart failure prior to admission. The patient was admitted with an INTERMACS profile one, consistent with cardiogenic shock despite escalating support. Incomplete prehospital data did not allow a right heart failure risk score calculation. However, available data revealed lowest or possibly intermediate risk for right heart failure with a minimum score of one and a maximal possible score of two. Eleven days after admission, an intermediate risk was defined by a preoperative score of two, attributable to a reduced right ventricular ejection fraction. A point for needed support had been earned for the continuation of a prehospital inotropic medication. The risk score did not reflect the additional support required to maintain intermediate risk during this phase of care. On postoperative day two all support had been successfully discontinued reducing the risk score to one. Though pulmonary hypertension worsened, all other parameters improved leading to a score representing lowest risk for progression to RHF (see Table 5).

Table 5

Patient C: Right Heart Reserve Parameters and Right Heart Risk Scores

Phase of Care	Prehospital	Preoperative	Intraoperative	Postoperative
Parameter				
Admission to Insertion (days)	**10**			
Insertion to Postoperative (days)	2			
Admission Diagnosis	CS			
NYHA Class	III			
INTERMACS Profile		1		
Pulmonary Hypertension				
PAPi	5.5	**1.8**		**1.5**
RV Dilation				
CVP	2	9		10
CVP: PCWP	0.26	0.64		
RV Function				
RVEF/REF		**12**		28
RVSWI				
RV on Echo	Normal		Normal	
TAPSE				
Renal/liver Function				
Creatinine		1.5		0.8
Dialysis		No		No
MELD		6.0		6.0
Support				
Inotrope	**Milrinone**	**Milrinone Dobutamine**	**Milrinone Dobutamine**	No
Vasopressor	No	No	No	No
Ventilator	No	**Yes**	Yes	No
IABP	No	**Yes**	**Yes**/No	No
RVAD	No	No	No	No
ECMO	No	No	No	No
Additional				
PAS	19	47		26
PAD	8	24		11
PCWP	7	14		
Total Bilirubin		0.4		0.3
Sodium		136		2.0
INR		1.0		136
Risk Score	**≥1**	**3**	**≥1**	**1**
RHF Risk	**≥Lowest**	**Intermediate**	**≥Lowest**	**Lowest**

CS = Cardiogenic Shock, Highlighted Values Contributed to RHF Risk Score for Each Phase of Care

Patient D.

Patient D was diagnosed with NYHA class IV heart failure prior to admission. The patient was admitted with an INTERMACS profile two, consistent with decompensation on inotropic support and an admission diagnosis of cardiogenic shock. Incomplete data did not allow calculation of a prehospital risk score. However, available data revealed at least intermediate risk with a minimum score of two and potentially highest risk with a maximal possible score of four. The CVP did not contribute to the score yet was near high enough to increase risk as well. Twenty-four days following admission, the patient's risk score was three, representing intermediate risk for RHF. Despite insufficient data, intraoperatively, the patient continued to have at least intermediate and potentially highest risk for RHF with a minimal score of three. Though two additional inotropic and vasopressor medications were required during this phase of care, they did not contribute to an increased risk score as the patient had earned a point for continuation of the prehospital inotropic infusion. On postoperative day five, the patient remained on one inotropic infusion. Persistent intermediate to potentially highest risk for RHF was represented by a minimum score of three and a maximal possible score of four. The risk score was attributable to worsening pulmonary hypertension, declining RV ejection fraction, and ongoing inotropic medication requirement, though the amount of required support decreased (see Table 6).

Table 6

Patient D: Right Heart Reserve Parameters and Right Heart Risk Scores

Phase of Care	Prehospital	Preoperative	Intraoperative	Postoperative
Parameter				
Admission to Insertion (days)	**24**			
Insertion to Postoperative(days)	5			
Admission Diagnosis	CS			
NYHA Class	4			
INTERMACS Profile		2		
Pulmonary Hypertension				
PAPi		**1.8**		**1.8**
RV Dilation				
CVP	15	1		8
CVP:PCWP				
RV Function				
RVEF/REF		**12**		**11**
RVSWI				
RV on Echo	**Moderate**		**Moderate**	**Severe**
TAPSE	1.4			
Renal/liver Function				
Creatinine		1.2		1.1
Dialysis		No		No
MELD		6.0		1.1
Support				
Inotrope	**Milrinone**	**Milrinone**	**Milrinone Dobutamine**	**Milrinone**
Vasopressor	No	No	**Epinephrine**	No
Ventilator	No	No	**Yes**	No
IABP	No	**Yes**/No	No	No
RVAD	No	No	No	No
ECMO	No	No	No	No
Additional				
PAS		35		
PAD		17		33
PCWP		28		19
Total Bilirubin		1.5		
Sodium		133		3.6
INR		1.1		134
Risk Score	**≥2**	**3**	**≥2**	**≥3**
RHF Risk	**≥Intermediate**	**Intermediate**	**≥Intermediate**	**≥Intermediate**

CS=Cardiogenic Shock, Highlighted Values Contributed to RHF Risk Score for Each Phase of Care