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Impact of thoracotomy approach on right ventricular failure and length of stay in left ventricular assist device implants: an intermacs registry analysis

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mechanical circulatory support;
left ventricular assist device;
right ventricular failure;
congestive heart failure;
minimally invasive

INTRODUCTION: Traditionally, implantation of Left Ventricular Assist Devices (LVADs) is performed via median sternotomy. Recently, less invasive thoracotomy approaches are growing in popularity as they involve less surgical trauma, potentially less bleeding, and may preserve right ventricular function. We hypothesized implantation of LVADs via thoracotomy has less perioperative right ventricular failure (RVF) and shorter postoperative length of stay (LOS).

METHODS: Continuous flow LVAD implants from Intermacs between February 6, 2014 - December 31, 2018 were identified. Patients implanted via thoracotomy were propensity matched in a 1:1 ratio with patients implanted via sternotomy. Outcomes were compared between sternotomy and thoracotomy approach and by device type (axial, centrifugal-flow with hybrid levitation (CF-HL), centrifugal-flow with full magnetic levitation devices (CF-FML)). The primary outcome was time to first moderate or severe RVF. Secondary outcomes included survival and LOS.

RESULTS: Overall 978 thoracotomy patients were matched with 978 sternotomy patients. Over the study period, 242 thoracotomy patients and 219 sternotomy patients developed RVF with no significant difference in time to first moderate to severe RVF by surgical approach overall (p = 0.27) or within CF-HL (p = 0.36) or CF-FML devices (p = 0.25). Survival did not differ by implant technique (150 deaths in thoracotomy group, 154 deaths in sternotomy group; p = 0.58). However, sternotomy approach was associated with a significantly shorter LOS (17 Vs 18 days, p = 0.009).

CONCLUSION: As compared to sternotomy, implantation of continuous flow LVADs via thoracotomy approach does not reduce moderate to severe RVF or improve survival but does reduce post-operative

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LOS. Device type did not influence outcomes and most centers did a small volume of thoracotomy implants.

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While left ventricular assist device (LVAD) therapy has improved survival and quality of life (QOL) for select advanced heart failure patients, it remains burdened by significant perioperative complications.[1,2] Right ventricular failure (RVF), in particular, can occur in up to 40% of implants resulting in increased mortality, poor QOL, and longer length of stay (LOS).[3] Appropriate patient selection is critical to minimize the risk of RVF, but intraoperative approaches and strategies are also important factors.[4]

The traditional surgical approach for LVAD implantation is a full median sternotomy. With decreased device size in newer generation LVADs, there is growing interest in less invasive approaches for implantation.[5-7] Less invasive approaches typically involve bilateral thoracotomies or an upper hemi-sternotomy and left thoracotomy. Smaller series of carefully selected patients demonstrated safety of the thoracotomy approach and suggested that it may prevent RVF and reduce LOS.[8,9] Thoracotomy approach may also be a more cost effective approach, some of which is attributable to length of stay.[10] Consequently, the FDA has approved implantation of the HVAD (Medtronic, Minneapolis, MN) and HeartMate 3 (Abbott Laboratories, Abbott Park, IL) via less invasive thoracotomy approach.

In this study, we aimed to (1) Describe contemporary use of thoracotomy compared to sternotomy LVAD implantation in "real world" patients as reported to Intermacs, (2) evaluate the impact of surgical approach on RVF and LOS, and (3) analyze outcomes by device flow type. We hypothesized that implantation of durable continuous flow LVADs via thoracotomy approach would result in similar survival, but less perioperative RVF and a shorter postoperative LOS, as compared to a median sternotomy.

Methods

We performed a retrospective analysis of the Intermacs Database supported through the Society of Thoracic Surgeons. The study was approved by Intermacs Data Collection and Coordinating Center. The data for this research were provided by The Society of Thoracic Surgeons' National Database Access and Publications Research Program.

Primary durable LVAD implants for patients ≥ 19 years of age from June 2, 2014 through December 31, 2018 were included as data on surgical approach only began being collected in Intermacs on June 2, 2014. Patients with a prior durable LVAD and those receiving total artificial heart support (TAH), durable biventricular support (BIVAD), or pulsatile flow LVAD were excluded. To eliminate any potential influence of outflow location on outcomes, patients where the LVAD outflow cannula was not anastomosed to the ascending aorta were also excluded (Figure 1). Once the cohort of thoracotomy patients was identified, they were propensity matched across all baseline variables in a 1:1 ratio with patients from the sternotomy group.

Outcomes were compared between groups by surgical approach (sternotomy vs thoracotomy) and between axial,

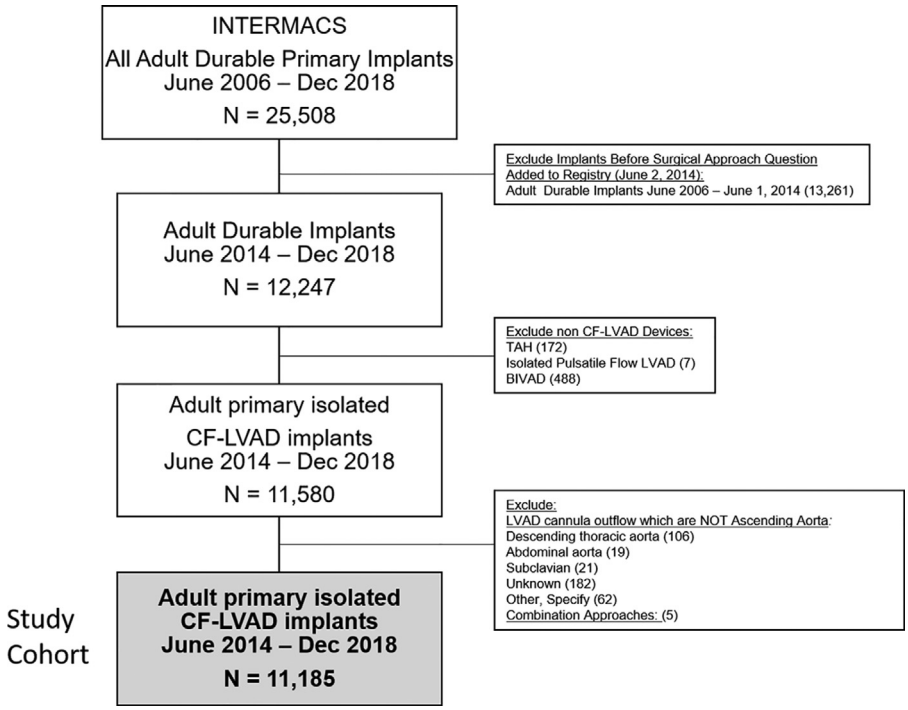

Figure 1 Cohort flow diagram of study population.

centrifugal-flow with hybrid levitation (CF-HL), and centrifugal-flow with full magnetic levitation (CF-FML) devices. The primary outcome was time to first moderate or severe RVF. RVF was defined according to Intermacs Adverse Events classification version 5.0 (Supplementary Table 1). Moderate to severe RVF requires elevated right atrial pressure and post-implant utilization of inotropes for greater than 7 days, inhaled nitric oxide or intravenous vasodilators, or right ventricular assist device support. Secondary outcomes included survival and post-implant LOS. To evaluate center volume of less invasive implants, the number of thoracotomy implants done per center in 2016 (midpoint of the study period) was assessed. The number of temporary or durable right ventricular assist devices (RVADs) used was also analyzed.

Data were analyzed with SAS version 9.4 (SAS, Cary, NC). For all statistical testing, we used a 2-sided significance level of 0.05. Outcomes stratified by surgical approach were evaluated in a propensity score matched cohort with similar pre-implant and implant characteristics. First, a propensity score was assigned to each patient using logistic regression for probability of receiving a thoracotomy based on all variables in supplementary table 2. Then, propensity score matching was conducted using greedy nearest neighbor matching with a 0.1 caliper and a 1:1 match ratio. An appropriate match was found for all 978 thoracotomy patients (Supplementary Figures 1&2). All variables, even those with $p > 0.05$ were included in the logistic model. Missing data was imputed to the group mean and percent missingness was less than 5% in 55 of 75 baseline variables (Supplementary Table 3). For between-group comparisons, we used a chi-square test for categorical variables. The Kaplan-Meier method with the log-rank test was used to compare unadjusted all-cause mortality between patients based on implant approach and pump type.

LOS in the propensity matched cohort was reported using median and interquartile range and compared using the non-parametric Wilcoxon sign-ranked test. For survival analysis, patients were censored at transplant, death, cessation of support, or device exchange.

Results

From an overall available patient cohort of 25,508 implants in the registry, 11,580 durable continuous flow LVAD implants met inclusion criteria. Of these, there were 390 patients where the LVAD outflow cannula was anastomosed to a location other than the ascending aorta and 5 patients where surgical approach was a combination of sternotomy and thoracotomy who were also excluded. In total, 11,185 patients remained (Figure 1). Of these, 10,207 were implanted by traditional sternotomy and 978 implanted with thoracotomy. Matches were found for all 978 thoracotomy patients for a total of 1956 patients analyzed. The propensity matched cohort was well balanced across all covariates as observed in all of the standardized means being substantially <0.1 (Supplementary Table 4). This included 1512 CF-HL, 230 CF-FML, and 214 axial flow devices. Of the CF-HL devices, 749 were implanted by sternotomy and 763 by thoracotomy. For the CF-FML devices, 122 were implanted via sternotomy and 108 via thoracotomy. Finally, for axial flow devices there was an even distribution of sternotomy and thoracotomy approaches with 107 patients in each group.

After propensity matching, pre-implant patient characteristics were compared between sternotomy and thoracotomy groups and mean values are summarized in Table 1. The groups were well matched with the exception of a statistically significant lower pre-albumin in the thoracotomy group.

Over the study period, 242 thoracotomy patients and 219 sternotomy patients developed moderate to severe RVF. This included 29 temporary RVADs, 2 durable RVADs, and 1 total artificial heart used in the matched sternotomy group for a total of 34 patients receiving biventricular mechanical support. In the thoracotomy group, 14 temporary RVADs and 1 durable RVAD were used with 15 total patients requiring biventricular mechanical support. At 24 months, there was no significant difference across all pump types in the primary outcome of time to first moderate to severe RVF by surgical approach (Figure 2). When evaluated by device type, moderate to severe RVF occurred in 54 of the 214 (25.2%) axial flow patients, 35 of 230 (15.2%) CF-FML patients, and 372 of 1512 (24.6%) CF-HL devices, which also did not reach statistical significance (Figure 3). In CF-HL implants, moderate to severe RVF occurred in 195 of 763 (25.6%) patients implanted by thoracotomy approach and 177 of 749 (23.6%) patients implanted by sternotomy which was not statistically significant (Figure 4). For CF-FML devices, 20 of 108 (18.5%) patients implanted by thoracotomy and 15 of 122 (12.3%) patients implanted by sternotomy developed moderate to severe RVF which also did not reach statistical significance (Figure 5). When compared by surgical approach, there was no difference in survival over the study period with 150 deaths (15.3%) in the thoracotomy group and 154 deaths (15.7%) in the sternotomy group (Figure 6).

For patients discharged alive on a device, sternotomy patients had a median LOS of 18 days (IQR 14-27) compared to 17 days (IQR 13-25) for thoracotomy patients ($p = 0.009$). Center volume in 2016 showed 65 centers did 0 thoracotomy implants, 69 centers did 1-5 thoracotomy implants, with a small number of centers doing more than 5 thoracotomy implants (Table 2).

Discussion

Our investigation of the Intermacs data registry of over 1900 matched continuous flow LVAD implants is the largest evaluation of a thoracotomy approach to LVAD implantation to date. In a propensity matched sample, it demonstrated that a thoracotomy approach to LVAD placement did not significantly reduce RVF as compared to traditional sternotomy approaches. When compared by device type, there were also no significant differences in RVF. With CF-HL and CF-FML devices, which were more commonly implanted by thoracotomy approach, there was no difference in RVF based on surgical approach. Thoracotomy approach overall was also not associated with any significant difference in survival, but was associated with a significant reduction in length of stay. In 2016, which was the midpoint of the study period, most centers did a low volume of thoracotomy implants with 134 of 164 (82%)

Table 1 LVAD Patient Pre-implant Characteristics After Propensity Matching

Pre-implant Characteristics	Sternotomy n = 978	Thoracotomy n = 978	*p* value
Age (yrs)	54.93	55.50	0.31
Albumin (g/dl)	3.60	3.57	0.22
Total bilirubin (mg/dl)	1.15	1.18	0.62
Body Mass Index (kg/m^2)	27.67	27.66	0.96
BNP (pg/ml)	1144.55	1154.16	0.90
Body Surface Area (m2)	2.03	2.04	0.74
BUN (mg/dl)	27.36	26.98	0.58
Cholesterol (mg/dl)	129.89	129.03	0.73
Cardiac index (L/min per sq meter)	2.16	2.14	0.78
Creatinine (mg/dl)	1.33	1.33	0.88
Diastolic blood pressure (mmHg)	66.53	66.16	0.48
haemoglobin	11.31	11.32	0.90
Heart Rate	89.87	89.77	0.91
INR (international units)	1.27	1.28	0.34
LDH	366.76	360.53	0.86
LVEDD (cm)	6.84	6.84	0.92
Platelet (K/ul)	202.61	196.41	0.10
Pre-albumin	20.36	19.40	0.04
Pulmonary diastolic pressure (mmHg)	24.93	24.98	0.90
Pulmonary systolic pressure (mmHg)	49.35	49.35	0.99
Pulmonary wedge pressure (mmHg)	23.56	23.99	0.36
Pulmonary vascular resistance (PVR) using cardiac output (wood units)	4.18	4.17	0.95
RA pressure (mmHg)	11.51	11.66	0.71
SGOT/AST (u/l)	44.28	43.71	0.90
SGPT/ALT (u/l)	61.64	57.27	0.65
Sodium (mmol/l)	135.48	135.34	0.49
Systolic blood pressure (mmHg)	104.92	104.95	0.96
WBC (K/ul)	8.26	8.26	1.00
Alcohol Abuse	6.2%	7.3%	0.37
Aortic Regurg (Moderate/Severe)	1.0%	1.2%	0.56
Ascites	4.3%	4.6%	0.77
Blood Type O	51.0%	48.5%	0.28
Cancer	3.8%	4.3%	0.57
College	56.1%	53.7%	0.35
Concommitant surgery	23.5%	23.2%	0.87
Current Smoker	4.5%	4.5%	1.00
Drug Abuse	8.9%	7.9%	0.41
Bridge to Transplant: Listed	45.8%	46.3%	0.82
Bridge to Transplant: Likely to be listed	17.1%	17.3%	0.90
Bridge to Transplant: Moderately likely to be listed	8.4%	7.4%	0.40
Bridge to Transplant: Unlikely to be listed	1.1%	1.4%	0.55
Destination Therapy	26.3%	26.5%	0.92
Failure to wean	1.2%	0.9%	0.51
History of Hepatitis	1.0%	0.8%	0.64
History of CABG	16.5%	16.7%	0.90
History of Valve Surgery	5.4%	7.0%	0.16
ICD	79.0%	80.8%	0.32
INTERMACS Patient Profile Level 1: Critical Cardiogenic Shock	15.7%	14.7%	0.53
INTERMACS Patient Profile Level 2: Progressive Decline	31.6%	31.2%	0.85
INTERMACS Patient Profile Level 3	38.3%	38.8%	0.85
INTERMACS Patient Profile Level 4	11.9%	12.7%	0.58
INTERMACS Patient Profile Level 5	1.9%	1.7%	0.74
INTERMACS Patient Profile Level 6	0.2%	0.5%	0.26
INTERMACS Patient Profile Level 7	0.3%	0.4%	0.70
Inotropes	81.2%	81.3%	0.96
Dialysis	1.1%	0.9%	0.65
ECMO	2.1%	1.7%	0.51
IABP	11.1%	11.1%	1.00

(*continued on next page*)

Table 1 (*Continued*)

Pre-implant Characteristics	Sternotomy n = 978	Thoracotomy n = 978	*p* value
Ventilator	3.4%	3.6%	0.81
LVEF (< 20 severe)	69.5%	69.9%	0.87
Male	76.5%	77.7%	0.52
Married	59.3%	60.4%	0.60
Patient Profile Modifier-Arrythmia	32.2%	30.6%	0.45
Patient Profile Modifier-Frequent Flyer	18.1%	20.9%	0.57
Patient Profile Modifier-FF Home	22.1%	20.1%	0.52
Mitral Regurg (Moderate/Severe)	51.5%	50.8%	0.75
NYHA = 4	81.7%	81.6%	0.96
Previous Cardiac Surgeries	28.1%	27.5%	0.76
Peripheral vascular disease	3.1%	3.3%	0.80
Race: White	67.0%	68.5%	0.47
RVEF (severe)	13.3%	14.1%	0.67
Severe Diabetes	6.7%	7.0%	0.86
Patient Profile Modifier-TCS	31.3%	31.0%	0.86
Tricuspid Regurg (Moderate/Severe)	36.4%	36.7%	0.89
CF-Axial	10.9%	10.9%	0.61
CF-HL	78.0%	76.6%	
CF-FML	11.0%	12.5%	

doing either 0 or 1-5 and only 8 (5%) performing more than 10.

The first major trial to demonstrate the potential benefit of a thoracotomy approach in continuous flow LVADs was the LATERAL trial. In this non-randomized trial, the implantation of the HVAD (Medtronic) via a thoracotomy approach in select bridge to transplant patients was safe and effective when compared to historical sternotomy data.[8] For the thoracotomy group in LATERAL, the initial hospital LOS was significantly shorter. The overall incidence of RVF did not differ with the thoracotomy approach, but the incidence of moderate RVF decreased dramatically by the first month of follow up and remained low over the study follow up time. Based on this data, the HVAD received FDA label expansion for thoracotomy implant in July 2018. In a single center study, the safety of a less invasive sternal-sparing implantation of the HeartMate 3 (Abbott) was also demonstrated.[9] Of 105 consecutive HeartMate 3 implants, 41 were implanted by thoracotomy approach with no intraoperative conversions. The thoracotomy approach patients had significantly lower incidence of severe RVF, required fewer blood products, and had a shorter index LOS. The HeartMate 3 received an FDA indication for less invasive implantation in January of 2020. Consistent with this

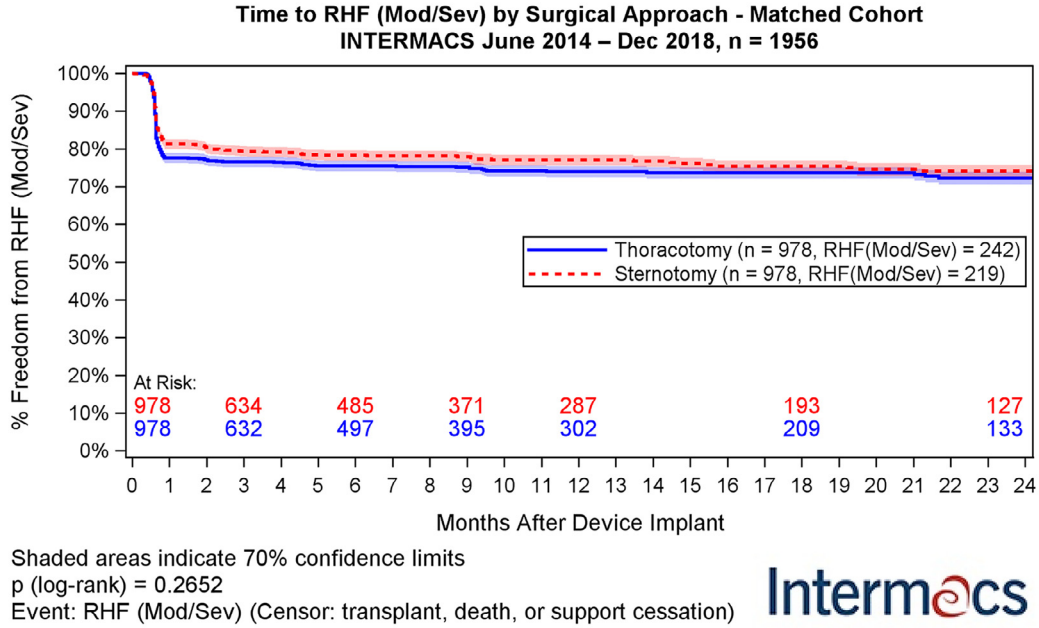

Figure 2 Time to first RVF (Moderate/Severe) on original device by surgical approach.

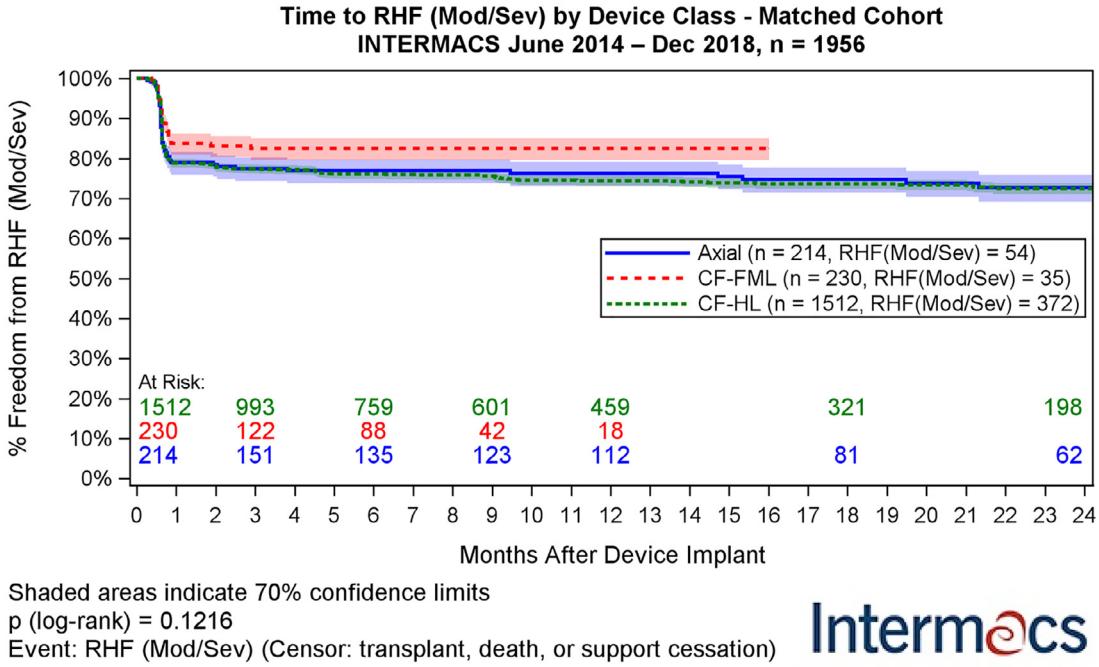

Figure 3 Time to first RVF (Moderate/Severe) on original device by device flow type.

timeline, our analysis also revealed that clinical uptake of thoracotomy implant has been the greatest for the CF-HL device with 18.3% of implants being done by thoracotomy across the study period compared to 11% of CF-FML implants and only 1.8% of implants of axial devices. Since our study period began several years prior to the FDA approval of thoracotomy implant for CF-HL and CF-FML devices, it is likely that the recent experience has an even greater percentage of thoracotomy implants.

RVF remains an all too common complication after LVAD placement.[11] There have been numerous risk scores developed using clinical, echocardiographic, and hemodynamic factors to predict RVF.[4] However, no single factor or score has been reliable for patient selection given the complicated interplay of patient characteristics and intraoperative factors that result in RVF. This deficiency in preventing RVF is a major barrier to more widespread utilization of continuous flow LVADS for the treatment of

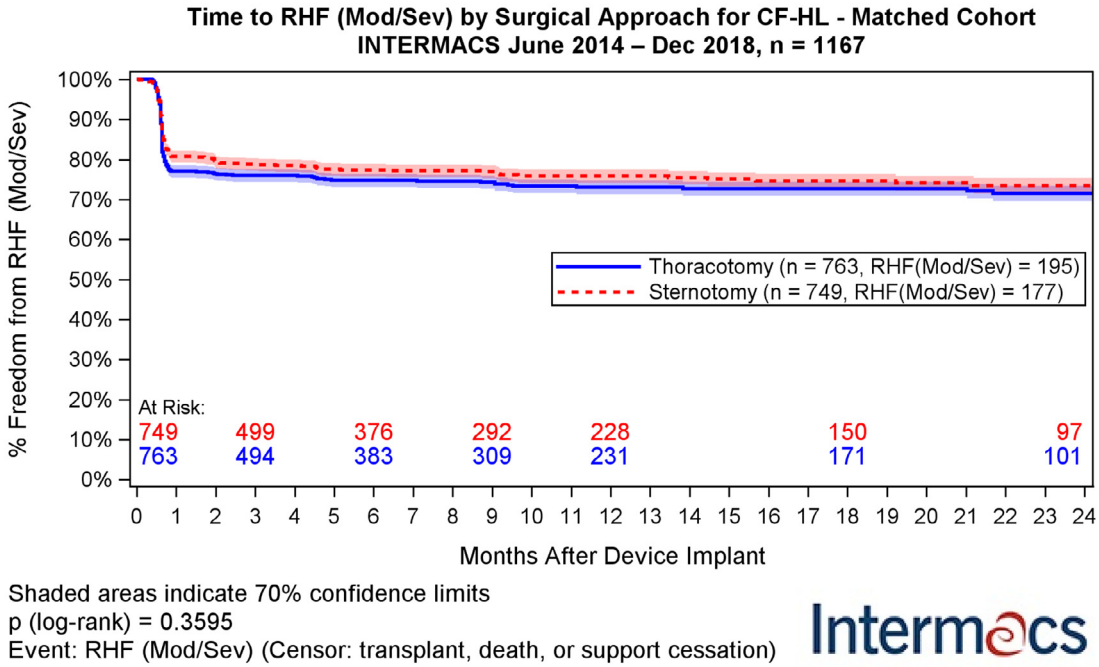

Figure 4 Time to first RVF for CF-HL device by surgical approach, sternotomy or thoracotomy.

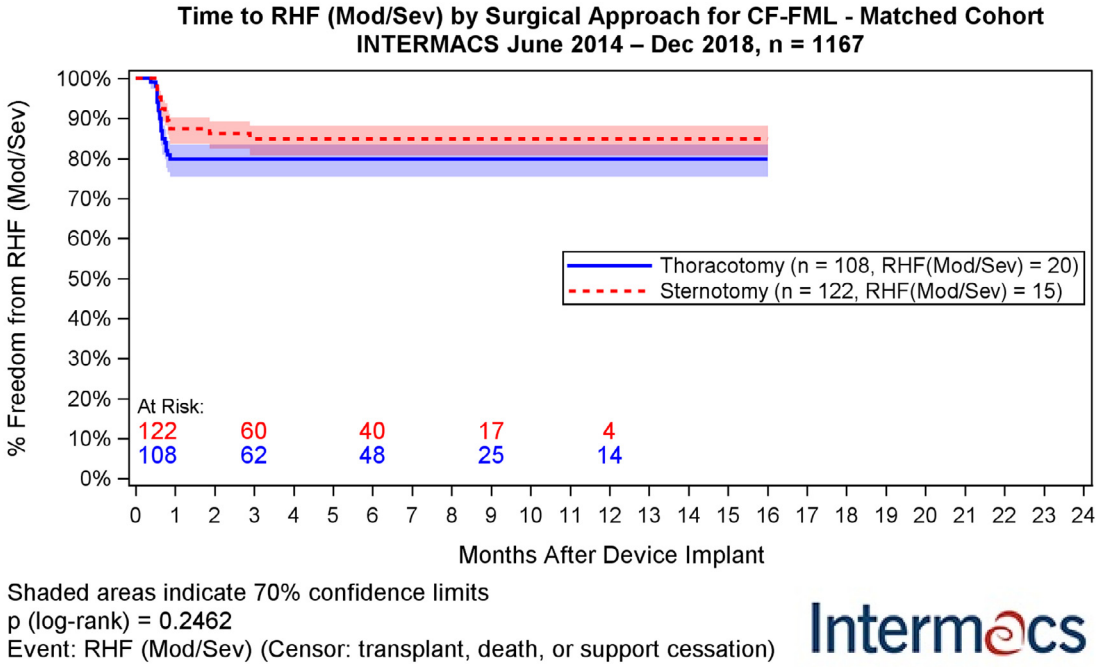

Figure 5 Time to first RVF for CF-FML device by surgical approach, sternotomy or thoracotomy.

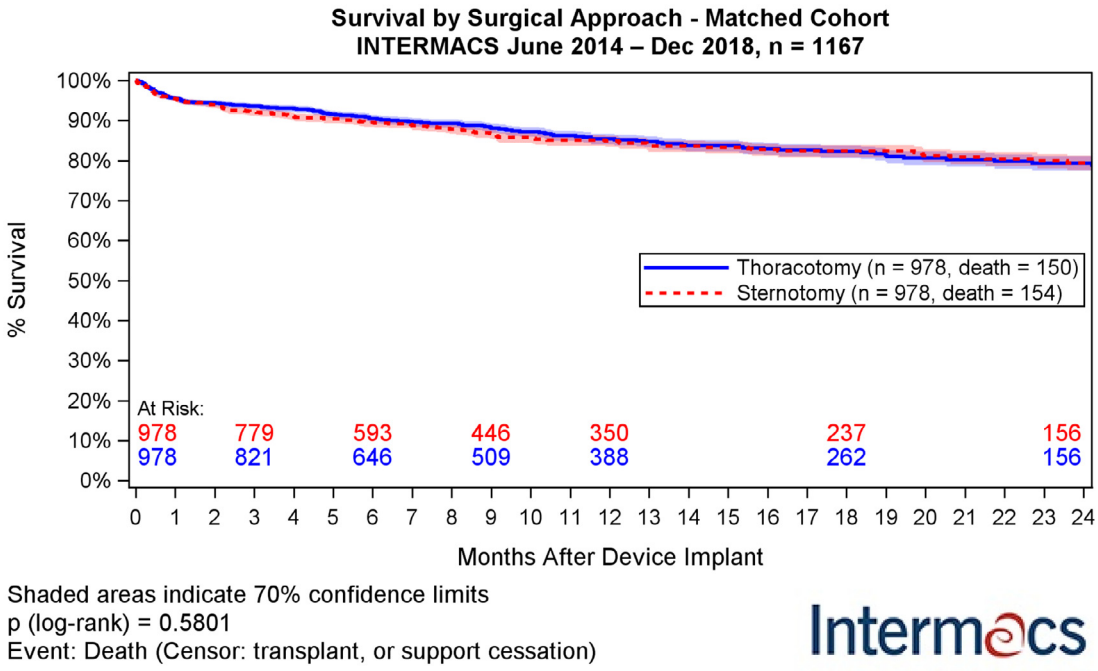

Figure 6 Survival from time of implant to death or last follow up or transplant on original implant device by surgical approach.

Table 2 Distribution of Thoracotomy Implants in 2016 by Center (centers=164)

# Thoracotomy implants in 2016	Number of centers	Percent
0	65	39.63
1-5	69	42.07
6-10	22	13.41
11+	8	4.88

advanced heart failure. Surgical LVAD implantation by thoracotomy approach carries several theoretical advantages. Preservation of the pericardium may maintain normal right ventricular geometry, limit dilation, and preserve normal pressure volume relationship decreasing the incidence of post-operative RV failure. [12,13] Additionally, in the thoracotomy approach the heart is not manipulated during inflow anastomosis and by maintaining its normal anatomical position may reduce right ventricular hypoperfusion. [12,14,15] Smaller sternal incisions may reduce the risks of

bleeding and other complications for future cardiac operations, which is particularly important in bridge to transplant candidates.

Our analysis of a large, multicenter, "real world" population contradicts prior small reports that suggested less RVF with the thoracotomy approach. There are several potential explanations for this discrepancy. To date, none of the prior studies were randomized. While our analysis was also not randomized, propensity matching reduces significant differences in baseline characteristics influencing surgical approach and subsequent outcomes. As demonstrated in supplementary Table 2, before propensity matching in our sample there were considerable baseline differences with patients implanted by thoracotomy approach in general being "less sick." This intangible surgical acumen is difficult to account for in retrospective analysis. There is undoubtedly clinical gestalt that the surgical team takes into account in evaluating body habitus, trends in central filling pressures and hemodynamics, trends in renal and hepatic function as well as assessments of frailty. Balancing the morbidity of the surgical approach with a need for concomitant procedures (if necessary), pump size, patient body habitus (small stature or morbid obesity), prior surgical procedures (particularly patent coronary artery bypass grafts), and frailty/osteopenia are patient variables which need to be accounted for in determining the optimum surgical approach for a particular patient.

Moreover, as with any surgical or procedural technique, outcomes improve with increasing operator experience. For the majority of our study period, thoracotomy approach was not FDA approved and the overwhelming majority of centers did a low volume of the less invasive approach. In early adopters of new techniques and technologies, there may be an inherent bias to select patients who may tend toward a more favorable outcome to ensure early successes and program adoption. As the volume and surgical experience with thoracotomy approach increase, further investigation into outcomes is warranted. These future evaluations will be critical to translate the benefits of a less invasive surgical approach to a broader patient profile.

While our propensity matched analysis did not identify a difference in RVF, we were able to demonstrate a statistically significant shorter post-operative length of stay for patients with the thoracotomy approach. This reduction in length of stay is an important factor for a field where cost and resource utilization remain one barrier to wider utilization and access. However, the absolute decrease in length of stay for the thoracotomy group was only 1 day making the clinical relevance of this finding debatable. It will be important to monitor if the length of stay benefit for thoracotomy approach improves as operators gain more experience with this technique. With the data available, we were not able analyze the long-term impact of a less invasive surgical approach to LVAD implantation. In particular, thoracotomy approach may have the benefit of improving outcomes for bridge to transplant patients with shorter LOS and need for fewer blood products during the subsequent heart transplant. [16] The less invasive approach may also improve the transplant operation in terms of less surgical trauma, perhaps shorter operative length and less bleeding. Randomized trials comparing surgical approach to LVAD implantation will be critical to accurately answering these questions.

Limitations

This analysis has some limitations most of which are associated with large administrative datasets. In this analysis of the Intermacs registry, we utilized retrospective data, subjecting the analysis to selection bias, however we attempted to account for this through propensity matching. Despite propensity matching, the results are only applicable to LVAD patients eligible for both surgical approaches. Additionally, not all institutions report to the registry and the data are isolated to the United States practices. Numerous clinically relevant data are not collected in the Intermacs registry, limiting some of the granularity of the data available for analysis which could impact the aforementioned selection bias. In particular, we were unable to assess individual surgeon volume, surgeon experience with thoracotomy approach, pretreatment frailty, or account for institutional practices and biases on inotropic support or initiation of RV mechanical support. The basis of our model and comparison consisted of a predetermined set of variables based on clinical interest. While data coverage was good for most variables a few had a large percent missing. We elected to keep this small number of covariates in the propensity score model despite their messiness and it is unlikely their inclusion significantly impacted the assigned propensity score for a patient. In our analysis, we also did not investigate the impact of dependence induced by propensity matching on our treatment effect. Since the purpose of our analysis was to determine outcomes based on surgical approach, our propensity matching was completed based on the probability of receiving a thoracotomy. Surgical approach is closely associated with device type. Therefore, device type was included as a covariate in the propensity model. This does not guarantee covariate balance by device type and could potentially bias the device effect estimates. However, in this specific analysis our comparison groups had similar distributions of device types. Finally, updated definitions of adverse events, including RVF, for trials and registries of LVAD patients were recently proposed.[17] The Intermacs definition analyzed historically and, in this manuscript, considered RVF a "condition" based on the need for prolonged inotropes or RVAD support. The definition of RVF was devised after concerns were raised about how to translate this "condition" into "adverse events" in research and regulatory evaluation of devices. While the updated definition published in 2020 is recommended going forward, these definitions are only now being considered for extensive mapping of prior data within the Intermacs database and it is not feasible to apply to the data collected during our study period.

Conclusion

In our multi-institutional, propensity matched analysis of The Society of Thoracic Surgeons' Intermacs registry

comparing 1956 patients receiving durable LVAD, we found that the less-invasive, thoracotomy approach to implantation did not decrease RVF in short term follow up, as compared to traditional sternotomy approaches. While there were unadjusted differences, we did not identify any difference in RVF between or within pump types based on surgical approach and no difference in mortality in the matched sets. Thoracotomy approach was associated with shorter post-operative LOS. Most centers performed a low volume of thoracotomy implants during the study period. Future randomized investigations of surgical approach are needed to clarify which patients benefit from the traditional sternotomy and what best practices are for thoracotomy approaches.

Disclosure statement

Dr. Teuteberg reports personal fees from Medtronic, personal fees from Abbott, personal fees from CareDx, personal fees from Abiomed, personal fees from Paragonix, outside the submitted work. Dr. Cowger reports grants and personal fees from Abbott Inc, grants and personal fees from Medtronic, Inc, personal fees and other from Procyrion, other from Cordella/Endotronix, outside the submitted work. Dr. Mokadam reports grants and personal fees from Abbott, grants and personal fees from SynCardia, grants and personal fees from Medtronic, personal fees from Carmat, outside the submitted work. Dr. Kirklin receives research support from STS Intermacs. Dr. Pagani is a member, Scientific Advisory Board, FineHeart, Inc. Dr. Whitson is a consultant for Abbott Laboratories and serves on the Clinical Events Committee of TransMedics OCS. The COPPER Lab has received in-kind support from XVIVO Perfusion. All other authors have no relevant disclosures.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.healun.2021.05.022.

References

1. Slaughter MS, Rogers JG, Milano CA, et al. Advanced heart failure treated with continuous-flow left ventricular assist device. N Engl J Med 2009;361:2241-51.
2. Kormos RL, Cowger J, Pagani FD, et al. The society of thoracic surgeons intermacs database annual report: evolving indications, outcomes, and scientific partnerships. Ann Thorac Surg 2019;107:341-53.
3. Lampert BC, Teuteberg JJ. Right ventricular failure after left ventricular assist devices. J Heart Lung Transplant 2015;34:1123-30.
4. Lampert BC. Perioperative management of the right and left ventricles. Cardiol Clin 2018;36:495-506.
5. Schmitto JD, Molitoris U, Haverich A, Strueber M. Implantation of a centrifugal pump as a left ventricular assist device through a novel, minimized approach: upper hemisternotomy combined with anterolateral thoracotomy. J Thorac Cardiovasc Surg 2012;143:511-3.
6. Popov AF, Hosseini MT, Zych B, Simon AR, Bahrami T. HeartWare left ventricular assist device implantation through bilateral anterior thoracotomy. Ann Thorac Surg 2012;93:674-6.
7. Maltais S, Davis ME, Haglund N. Minimally invasive and alternative approaches for long-term LVAD placement: the Vanderbilt strategy. Ann Cardiothorac Surg 2014;3:563-9.
8. McGee E, Danter M, Strueber M, et al. Evaluation of a lateral thoracotomy implant approach for a centrifugal-flow left ventricular assist device: the LATERAL clinical trial. J Heart Lung Transplant 2019;38:344-51.
9. Gosev I, Wood K, Ayers B, et al. Implantation of a fully magnetically levitated left ventricular assist device using a sternal-sparing surgical technique. J Heart Lung Transplant 2020;39:37-44.
10. Mokadam NA, McGee E, Wieselthaler G, et al. Cost of thoracotomy approach: an analysis of the LATERAL trial. Ann Thorac Surg 2020;110:1512-9.
11. Teuteberg JJ, Cleveland JC, Cowger J, et al. The society of thoracic surgeons intermacs 2019 annual report: the changing landscape of devices and indications. Ann Thorac Surg 2020;109:649-60.
12. Mohite PN, Sabashnikov A, Raj B, et al. Minimally invasive left ventricular assist device implantation: a comparative study. Artif Organs 2018;42:1125-31.
13. Burger W, Straube M, Behne M, et al. Role of pericardial constraint for right ventricular function in humans. Chest. 1995;107:46-9.
14. Dell'Italia LJ. Anatomy and physiology of the right ventricle. Cardiol Clin 2012;30:167-87.
15. Topilsky Y, Oh JK, Shah DK, et al. Echocardiographic predictors of adverse outcomes after continuous left ventricular assist device implantation. JACC Cardiovasc Imaging 2011;4:211-22.
16. Rabin J, Ziegler LA, Cipriano S, et al. Minimally invasive left ventricular assist device insertion facilitates subsequent heart transplant. Innovations (Phila) 2021. Online ahead of print.
17. Kormos RL, Antonides CFJ, Goldstein DJ, et al. Updated definitions of adverse events for trials and registries of mechanical circulatory support: a consensus statement of the mechanical circulatory support academic research consortium. J Heart Lung Transplant 2020;39:735-50.