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Development of a non-transplant left ventricular assist device program

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Abstract

Introduction: Although the established long-term benefit of left ventricular assist device (LVAD) therapy has led to its proliferation as destination therapy (DT), few studies have evaluated LVAD outcomes at nontransplant centers. We undertook this study to better evaluate our experience in building a nontransplant, DT LVAD program.

Methods: We conducted a retrospective review of all LVADs implanted from 2010 to 2021. Patient, operative, and outcome data were extracted from the electronic medical record. Secular trends were evaluated by organizing the data into eras of implant. Survival was assessed using the Kaplan–Meier method. Multivariable Cox proportional hazards regression models further evaluated outcomes.

Results: From 2010 to 2021, 100 primary LVAD implants were performed. Annual volume grew from 1 to 30 implants per year. The average age of our cohort was 65.7 years, most patients (80%) were male, 51% had an ischemic etiology, and 65 (65%) were INTERMACS profile 1 or 2. Our 1- and 2-year survival were 82% and 79%, respectively. Multivariable analysis of 1-year mortality demonstrated that decreasing renal function and increased cardiopulmonary bypass (CPB) time were associated with increased mortality while preoperative hemoglobin was protective. When stratified by era of implant, our most recent patients were more likely to be INTERMACS profile 1 or 2; had shorter CPB and aortic cross clamp times; required fewer reoperations for bleeding; and suffered less right ventricular failure requiring mechanical support.

Conclusions: A single, nontransplant LVAD center can experience significant growth in volume in a high-acuity cohort while maintaining acceptable outcomes and quality of care.

KEYWORD
transplant

Abbreviations: ANOVA, analysis of variance; BTT, bridge to transplantation; CPB, cardiopulmonary bypass; DT, destination therapy; ECMO, extracorporeal membrane oxygenation; IMACS, ISHLT Mechanically Assisted Circulatory Support; INTERMACS, Interagency Registry of Mechanically Assisted Circulatory Support; ISHLT, International Society for Heart and Lung Transplantation; LVAD, left ventricular assist device; MCS, mechanical circulatory support; Momentum 3, Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with Heartmate 3; REMATCH, randomized evaluation of mechanical assistance for the treatment of congestive heart failure; RVAD, right ventricular assist device.

1 | INTRODUCTION

Left ventricular assist devices (LVADs) were initially developed as a bridge to heart transplantation.[1–6] The landmark Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial changed this paradigm, by demonstrating that long-term LVAD therapy was associated with improved survival compared to medical therapy alone.[7] Over time, treatment intent and reimbursement guidelines led to the development of two broad designations for LVAD therapy: bridge to transplantation (BTT) and destination therapy (DT).[8–14]

While LVAD implantation was initially performed predominantly at transplant centers, this technology was gradually disseminated to nontransplant centers.[15–17] As the transplant volume remains inadequate to meet the demands of the end-stage heart failure population, DT-LVAD implantation has become the predominant device strategy.[18–21] Subsequently nontransplant LVAD centers have proliferated throughout the United States. Although there is a robust literature detailing outcomes of both BTT and DT-LVADs, there is scant literature focusing specifically on outcomes at nontransplant centers. Moreover, the extant literature is conflicting.[16,17,22,23] Finally, there is limited literature on how nontransplant centers develop and grow their mechanical circulatory support (MCS) programs.[24] Therefore, we undertook this study to evaluate our experience building a nontransplant, DT-LVAD center.

2 | MATERIALS AND METHODS

2.1 | Study design

We conducted a retrospective review of all LVADs performed at Baylor Scott and White, The Heart Hospital, Plano from January 2010 through December 2021. Programmatic changes during this time are outlined below (Figure 1). All durable LVADs were included. The study was approved by the Baylor Scott and White Institutional Review Board and informed consent was waived.

As a DT center, all adult patients over the age of 18 are considered eligible for LVAD implantation. We consider each patient first as a potential transplant candidate and thus all implants are done in collaboration with an affiliated transplant center and each implanted patient receives a formal denial for transplantation. Patient declined for transplant are considered for LVAD regardless of the reason for transplant denial. We do not have an upper age limit but are highly selective in patients over the age of 80 years. We do not implant BTT patients. Several patients were turned down for both transplant and LVAD at our affiliated transplant center and were subsequently implanted at our facility. As a nontransplant center that only implants patients declined for LVAD, we are very careful to specifically inform patients that they are implanted as DT only.

2.2 | Data collection

Baseline demographics, measures of acuity, laboratory values, operative data, and outcomes were extracted from the medical record. To evaluate changes over time, the LVAD implants were divided into three eras of equal numbers of implants. Throughout the study period, two LVAD devices were used: the Heartmate II and the Heartmate 3 (Abbott Laboratories). For simplicity, bleeding was defined as any return to the operating room regardless of whether it was emergent for ongoing bleeding or a planned return to the operating room when the chest was left open for bleeding or right ventricular dysfunction.

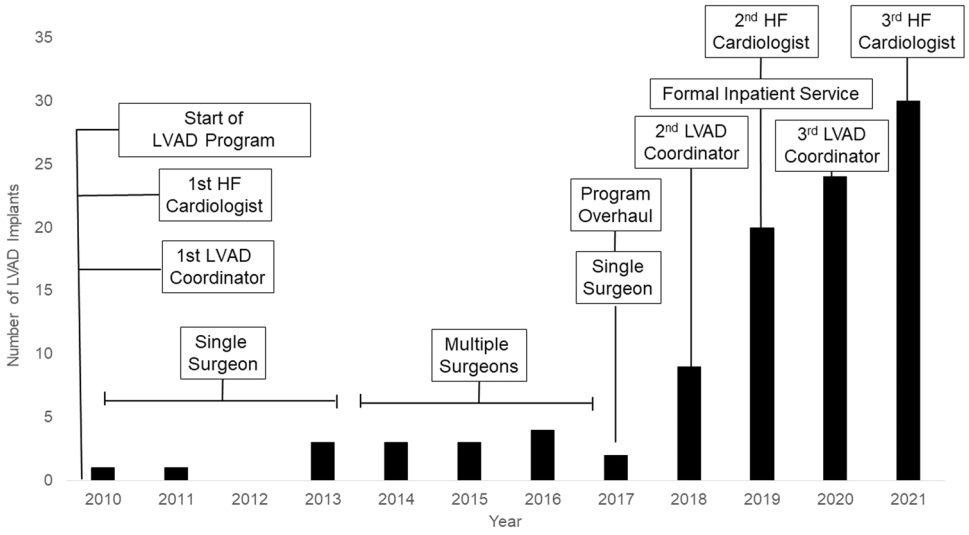

FIGURE 1 Left ventricular assist device program timeline and implant volume

2.3 | Statistical analysis

We compared continuous parametric variables using one-way analysis of variance (ANOVA) testing. For statistically significant ANOVA outcomes, the Tukey Honest Significant Difference test was used for post hoc pairwise comparisons. We compared continuous nonparametric variables using the Kruskal–Wallis test. Categorical variables were compared using the χ^2 test.

Survival was assessed using the Kaplan–Meier method. Survival comparisons were performed using the log-rank test. Risk of 1-year mortality was assessed with multivariable Cox proportional hazards regression modeling. To construct our model, variables were initially tested in univariate fashion. Independent covariates supported by previous literature, biologic plausibility, or with a $p < .20$ on univariate analysis were incorporated in forward and backward stepwise nested fashion using the likelihood ratio test to build a model with maximal explanatory power. Our final model included age, preoperative creatinine, preoperative hemoglobin, INTERMACS profile, cardiopulmonary bypass (CPB) time, and the need for full aortic cross clamping.

For all statistical measures two-tailed $p < .05$ was considered statistically significant. Continuous normally distributed variables are presented as means with standard deviations while continuous nonnormally distributed variables are presented as medians with interquartile ranges. Categorical variables are presented as whole numbers with percentages. Kaplan–Meier estimates of survival and hazard ratios are shown with their 95% confidence intervals. Statistical analysis was performed using Stata/SE 17.0 (StataCorp).

3 | RESULTS

3.1 | Cohort statistics

From 2010 to 2021, 103 patients underwent LVAD implantation including 100 primary implants and 3 exchanges. The 3 exchanges were excluded from further analysis. The average age was 65.7 ± 11.2 years, most patients were male (80.0%), and white (78%; Table 1). Our youngest patient was 21 and our oldest was 81. At the time of implantation, most had moderate kidney dysfunction (creatinine 1.5 ± 0.6), normal synthetic hepatic function (bilirubin 0.9 [0.6–1.4]), and were anemic. A slim majority had an ischemic etiology (51.0%). The majority of patients were INTERMACS profile 1 or 2 (31.0% and 34.0%, respectively). A total of 30% of patients had prior cardiac surgery including coronary artery bypass grafting (2); mitral valve repair or replacement (4); coronary artery bypass grafting and mitral valve replacement (1); Bentall (1); and various other procedures (3). Majority of patients underwent implantation of Heartmate 3 (84, 84.0%) while the rest underwent implantation of Heartmate 2 (16, 16.0%). Although most patients underwent an isolated LVAD implant, 34.0% required a concomitant procedure exclusive of left atrial

TABLE 1 Baseline demographics, measures of acuity, and operative variables

Variable	
Demographics	
Age (years)	65.7 ± 11.2
Male (*n*, %)	80 (80.0%)
Ethnicity	
White (*n*, %)	78 (78.0%)
Black (*n*, %)	15 (15.0%)
Hispanic (*n*, %)	4 (4.0%)
Other (*n*, %)	7 (7.0%)
Body mass index (kg/m^2)	28.8 ± 6.6
Sodium (mmol/L)	136.2 ± 4.4
Creatinine (mg/dl)	1.5 ± 0.6
Blood urea nitrogen (mg/dl)	32 ± 17.2
Bilirubin (mg/dl)	0.9 [0.6–1.4]
Hemoglobin (g/dl)	10.7 ± 2.0
Hematocrit (%)	32.8 ± 5.7
Need for preoperative dialysis (*n*, %)	4 (4.0%)
Ischemic etiology (*n*, %)	51 (51.0%)
Acuity	
INTERMACS 1 (*n*, %)	31 (31.0%)
INTERMACS 2 (*n*, %)	34 (34.0%)
INTERMACS 3 (*n*, %)	22 (22.0%)
INTERMACS 4 (*n*, %)	13 (13.0%)
ECMO (*n*, %)	2 (2%)
Impella (*n*, %)	30 (30.0%)
Dual inotropes (*n*, %)	37 (37%)
Single inotrope (*n*, %)	22 (22%)
Operative data	
Previous cardiac surgery (*n*, %)	30 (30.0%)
Need for concomitant procedure (n, %)	34 (34.0%)
Aortic valve intervention (*n*, %)	7 (7.0%)
Tricuspid valve repair (*n*, %)	29 (29.0%)
Left atrial appendage ligation (*n*, %)	38 (38.0%)
Cardiopulmonary bypass time (minutes)	117.9 ± 38.3
Full aortic cross clamp (*n*, %)	9 (9.0%)
Cross clamp time (minutes)	37.4 ± 19.4

Abbreviations: dl, deciliter; ECMO, extracorporeal membrane oxygenation; INTERMACS, interagency registry for mechanically assisted circulatory support; kg, kilograms; L, liter; m^2, meters squared; mg, milligram; mmol, millimoles.

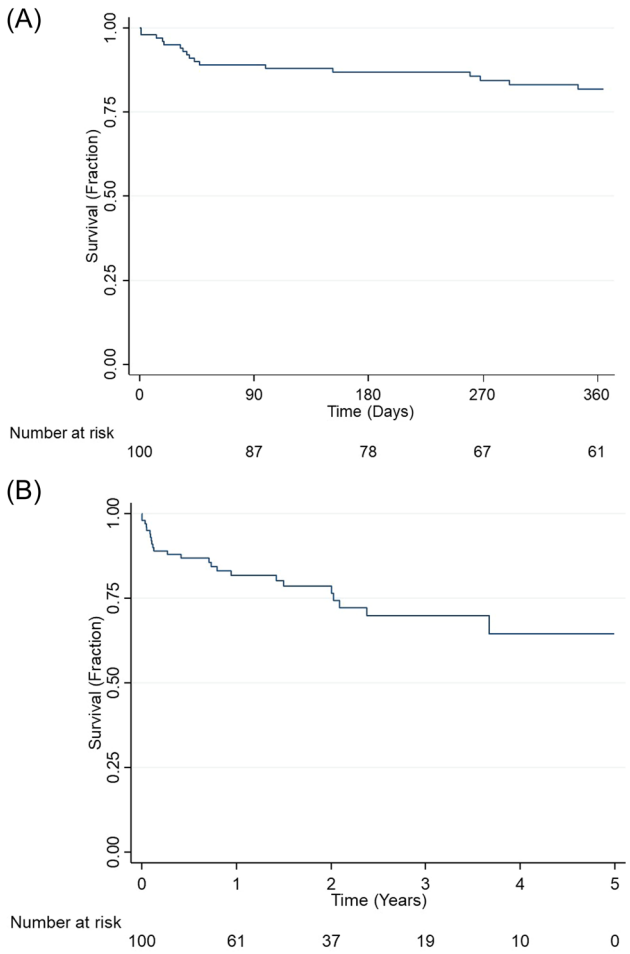

FIGURE 2 (A) 1-Year Kaplan–Meier survival. (B) 5-Year Kaplan–Meier survival

TABLE 2 Kaplan-Meier estimates of survival

Time	All patients	Conditional on survival to discharge
30-Day	95.0 [88.4–97.9]	
1-Year	81.8 [72.2–88.3]	92.0 [82.9–96.3]
2-Year	78.6 [68.3–86.0]	88.4 [77.9–94.1]
3-Year	69.9 [57.1–79.6]	78.6 [64.5–87.6]
4-Year	64.5 [48.2–76.9]	72.5 [53.6–84.8]
5-Year	64.5 [48.2–76.9]	72.5 [53.6–84.8]

Note: Kaplan–Meier estimates of survival are presented with their 95% confidence intervals.

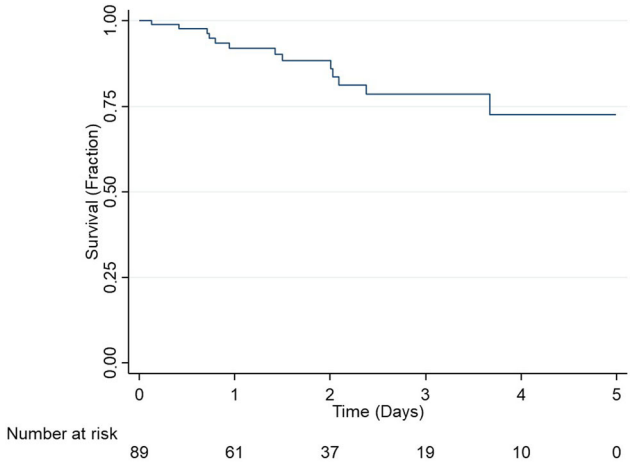

FIGURE 3 5-Year Kaplan–Meier surival conditional on survival to discharge

appendage ligation, Impella (Abiomed) removal, or extracorporeal membrane oxygenation (ECMO) decannulation. Concomitant procedures included 7 aortic valve interventions (4 aortic valve replacements, 2 aortic valve closures, and 1 patch closure of a prior mechanical aortic valve replacement), 1 redo mitral valve replacement, and 29 tricuspid valve repairs.

Thirty of our patients underwent preoperative support with a surgical Impella either for cardiogenic shock or hemodynamic optimization. In each case, Impella support was continued until end-organ perfusion was improved as measured by renal and hepatic function, and right ventricular function was optimized based on echocardiographic assessment.

3.2 | Outcomes

The overall long-term survival was 73.0% with a median follow up of 536.5 [194.5–990] days. Kaplan–Meier estimates of 30-day, 1-year, and 2-year survival were 95.0% [88.4–97.9], 81.8% [72.2–88.3] and 78.6% [68.3–86.0], respectively (Figure 2a,b and Table 2). Mortality after the index surgical admission was low as evidenced by the annual estimates of long-term survival conditional on survival to discharge (Figure 3 and Table 2). When stratified by INTERMACS profile, there were no differences in 30-day ($p = .72$), 1-year survival ($p = .60$), or 5-year survival ($p = .49$; Figure 4 and Table 3).

Operative complications included return to the operative room for bleeding (35, 35.0%), LVAD-related infection (3, 3.0%), cerebrovascular accident (2, 2.0%), and right heart failure requiring a right ventricular assist device (RVAD; 19, 19.0%). Our institutional preference is to place the RVAD immediately postoperatively in the operating room although 5 patients had delayed RVAD. For patients with RV dysfunction not requiring RVAD, our routine practice is to wean inotropes slowly over 7–10 days. 6 DT LVAD patients eventually underwent heart transplantation and 1 patient had sufficient recovery of heart function to undergo LVAD explantation. Of the 6 patients who underwent transplantation, 1 died during the first postoperative year. The mean preoperative length of stay was 9.3 ± 6.6 days with a mean postoperative length of stay of 21.7 ± 11.2 days.

The mean CPB and cross clamp times were 117.94 ± 38.37 and 37.40 ± 19.41 min, respectively. Patients requiring concomitant

operations had longer CPB times (104.17 ± 36.25 vs. 144.21 ± 27.19 min, $p < .01$) but similar cross clamp times (35.33 ± 12.66 vs. 38.29 ± 22.56 min, $p = .84$). Additionally, patients requiring redo sternotomy had longer CPB times (110.34 ± 34.54 vs. 136.39 ± 41.48 min, $p < .01$) but similar ischemic times (38.00 ± 9.79 vs. 36.5 ± 6.51 min, $p = .91$).

3.3 | Multivariable analysis

On multivariable Cox proportional hazards regression model, impaired renal function (3.34 [1.44–7.78] per mg/dl, $p < .01$) and time on CPB (1.02 [1.01–1.03] per minute, $p = .03$) were strongly associated with an increased hazard of mortality while an increased hemoglobin (0.73 [0.54–0.99] per g/dl, $p = .04$) was associated with a decreased hazard of mortality (Table 4). Increasing age, INTERMACS profile, and need for aortic cross clamping were not statistically significant.

3.4 | Temporal changes

LVAD implants increased over time, growing from 1 implant in 2010 to 30 implants in 2021 (Figure 1). The most marked increases in volume occurred after a hospital-wide program overhaul, designation of a single on-site surgeon to oversee the LVAD program, and the addition of a second heart failure cardiologist with concomitant establishment of a formal inpatient heart failure consult service.

When stratified by era, baseline characteristics were similar between the 3 groups (Table 5). The INTERMACS profile changed with an increase in the proportion of INTERMACS profiles 1 and 2 over time. Notably, the median CPB time and aortic cross clamp times declined markedly in the most recent cohort. Additionally, while 30-day and 1-year survival were unchanged, the need for reoperation for bleeding as well as the incidence of RV failure requiring RVAD placement also decreased significantly. Although the rate of return to the operating for bleeding changed over time, in this series it was not related to redo sternotomy ($p = .45$), liver function tests ($p = .57$), the need for concomitant procedures ($p = .15$), or the presence/degree of tricuspid regurgitation ($p = .68$).

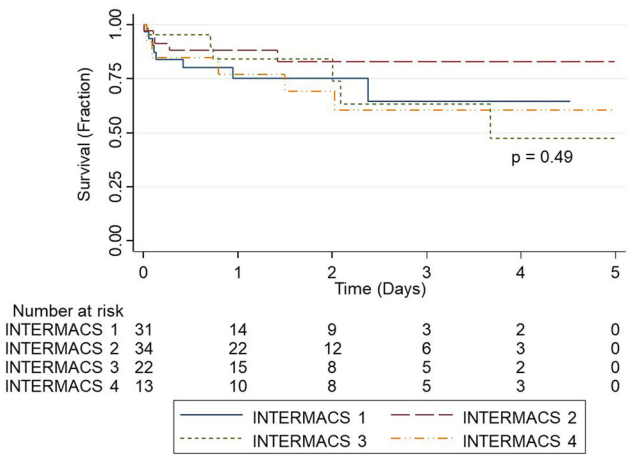

FIGURE 4 5-Year Kaplan–Meier survival estimates stratified by INTERMACS profile. INTERMACS, interagency registry for mechanically assisted circulatory support

4 | DISCUSSION

From 2010 to 2021, our nontransplant, DT LVAD center has performed 100 primary LVAD implants. Our volume increased significantly from 1 implant in 2010 to 30 implants in 2021 with the volume climbing most markedly over the last few years (Figure 1). In this cohort, the 30-day survival was 95% with a 1-year survival of 82% and a 2-year survival of 79%. On multivariable analysis, impaired renal function and time on CPB were associated with an increased hazard of 1-year mortality while increased preoperative hemoglobin was protective. In analyzing changes in our cohort over time, it is evident that our patient acuity continues to increase. Although survival remained unchanged throughout the study period, operative variables including CPB time, cross clamp time, need for reoperation for bleeding, and RV failure requiring RVAD placement all decreased significantly despite a sicker cohort.

4.1 | Survival outcomes

LVAD therapy continues to be a successful therapy for patients with end-stage heart failure.[25–28] Although heart transplantation remains the gold standard, the availability of appropriate organs continues to be inadequate.[20,21] Therefore, the number of LVAD implants generally and DT implants specifically has appropriately increased.[18–21,28] While a concomitant increase in the number of nontransplant centers may help alleviate geographic and

TABLE 3 Survival stratified by INTERMACS class

Time	INTERMACS Class 1	2	3	4	*p* value[a]
Operative survival	28 (93.4%)	33 (97.1%)	21 (95.5%)	12 (92.3%)	.72
1-Year survival	24 (77.4%)	30 (88.2%)	19 (86.4%)	10 (76.9%)	.60

Abbreviation: INTERMACS, interagency registry of mechanically assisted circulatory support.

[a]*p* value determined by Chi-square analysis.

TABLE 4 Cox proportional hazards regression model of 1-year mortality

Variable	HR [95% CI]	*p* value	HR [95% CI]	*p* value
Age (per year)	1.02 [0.97–1.07]	.45	1.00 [0.95–1.06]	.88
Female gender	1.17 [0.37–4.08]	.80		
BMI (per kg/m^2)	1.02 [0.95–1.09]	.64		
Sodium (per mmol/L)	1.00 [0.89-1.12]	.98		
Creatinine (per mg/dl)	3.32 [1.65–6.69]	.001	3.34 [1.44–7.78]	.005
BUN (per mg/dl)	1.03 [1.01–1.05]	.001		
Bilirubin (per mg/dl)	1.13 [0.83–1.53]	.44		
Hemoglobin (per g/dl)	0.78 [0.60–1.00]	.05	0.73 [0.54–0.99]	.04
Hematocrit (per %)	0.92 [0.85–1.01]	.08		
Ischemic etiology	0.69 [0.26–1.82]	.46		
INTERMACS 1	Reference		Reference	
INTERMACS 2	0.49 [0.14–1.66]	.25	1.18 [0.27–5.07]	.83
INTERMACS 3	0.55 [0.14–2.14]	.39	3.11 [0.53–18.33]	.21
INTERMACS 4	0.94 [0.24–3.65]	.93	5.30 [0.92–30.57]	.06
Impella	1.78 [0.68–4.69]	.24		
Dual inotropes	0.68 [0.24–1.94]	.47		
Single inotrope	0.73 [0.21–2.53]	.62		
Previous surgery	0.97 [034–2.76]	.96		
Concomitant procedure	0.53 [0.17–1.61]	.26		
CPB time (per minute)	1.02 [1.01–1.03]	.004	1.02 [1.01–1.03]	.03
Full aortic cross clamp	2.64 [0.76–9.20]	.13	1.99 [0.50–7.89]	.33
Cross clamp time (per minute)	0.99 [0.92–1.05]	.70		

Abbreviations: BUN, blood urea nitrogen; CI, confidence interval; CPB, cardiopulmonary bypass; dl, deciliter; ECMO, extracorporeal membrane oxygenation; HR, hazard ratio; kg, INTERMACS, interagency registry for mechanically assisted circulatory support; kilograms; L, liter; m^2, meters squared; mg, milligram; mmol, millimoles.

socioeconomic barriers to advanced therapies, concerns exist as to whether LVAD implants at nontransplant outcomes are noninferior to those performed at transplant centers.[17]

In assessing outcomes, comparing survival rates may be confounded significantly by variable patient acuity. The Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with Heartmate 3 (Momentum 3) trial represents the largest LVAD trial ever conducted in the United States.[26,27] In this landmark trial, the authors report a 1-year survival of 86.6% and 2-year survival of 79.0% in the Heartmate 3 cohort.[27] Operative mortality was approximately 7%–8% depending on the device utilized. Our reported outcomes compare favorably with these data, with slightly higher 1-year mortality but similar 2-year survival. However, compared to the Momentum 3 population, our cohort had higher baseline acuity and was considerably older, with worse renal and hepatic function and more likely to have had prior cardiac surgery. Additionally, while the trial excluded patients requiring temporary MCS except intra-aortic balloon pumps, 32% of our patients required ECMO or Impella support preoperatively.[29]

Perhaps a more real-world comparison is the most recent analysis of the INTERMACS database. In evaluating contemporary outcomes associated with continuous-flow LVADs, Molina et al.[28] report a 1- and 2-year survival of 82.3% and 73.1%, respectively. When stratified by device strategy, they found 1- and 2-year survivals of 87% and 78% for BTT patients, 84% and 75% for bridge to candidacy (BTC) patients, and 80% and 71% for DT patients. Compared to these data, our results compare favorably to the overall findings, the BTC, and the DT cohorts with slightly higher mortality than the BTT cohort. Nevertheless, when comparing patient acuity by INTERMACS profile, it would seem our cohort is sicker regardless of device strategy. In the INTERMACS database, the proportion of patients implanted as profile 1 ranges from only 10%–21% compared to 31% in our cohort. INTERMACS profile has consistently been shown to impact both short and long-term outcomes.[18,28,30] In fact, in the recent report of the INTERMACS database, 1-year survival was

TABLE 5 Baseline characteristics and outcomes stratified by era

Variable	Era 1 (*N* = 34)	Era 2 (*N* = 33)	Era 3 (*N* = 33)	*p* value[a]
Demographics				
Age (years)	67.6 ± 9.3	65.3 ± 11.1	64.2 ± 12.9	.43
Male (*n*, %)	25 (73.5%)	29 (87.9%)	26 (78.8%)	.33
Ethnicity				
White (*n*, %)	28 (82.4%)	26 (78.8%)	24 (72.7%)	
Black (*n*, %)	6 (17.7%)	5 (15.2%)	4 (12.1%)	
Hispanic (*n*, %)	0 (0%)	0 (0%)	4 (12.1%)	
Other (*n*, %)	0 (0%)	2 (6.1%)	1 (3.0%)	.14
Body mass index (kg/m^2)	30.9 ± 7.6	28.2 ± 6.2	27.2 ± 5.6	.06
Sodium (mmol/L)	137.1 ± 3.8	137.0 ± 5.3	134.4 ± 3.5	.01
Creatinine (mg/dl)	1.6 ± 0.6	1.5 ± 0.6	1.5 ± 0.6	.62
Blood urea nitrogen (mg/dl)	34.9 ± 19.5	32.4 ± 12.6	29.8 ± 18.8	.48
Bilirubin (mg/dl)	1.0 [0.6–1.5]	0.9 [0.6–1.4]	0.8 [0.6–1.2]	.42
Hemoglobin (g/dl)	11.2 ± 1.9	10.5 ± 2.3	10.3 ± 1.8	.18
Hematocrit (%)	34.3 ± 5.2	32.2 ± 6.3	32.0 ± 5.5	.21
Preoperative dialysis (*n*, %)	1 (2.9%)	1 (3.0%)	2 (6.1%)	.76
Ischemic etiology (*n*, %)	16 (47.1%)	16 (48.5%)	19 (57.6%)	.65
Acuity				
INTERMACS 1 (*n*, %)	6 (17.7%)	13 (39.4%)	12 (36.4%)	
INTERMACS 2 (*n*, %)	8 (23.5%)	12 (36.4%)	14 (42.4%)	
INTERMACS 3 (*n*, %)	10 (29.4%)	5 (15.2%)	7 (21.2%)	
INTERMACS 4 (*n*, %)	10 (29.4%)	3 (9.1%)	0 (0%)	.01
ECMO (*n*, %)	0 (0%)	2 (6.1%)	0 (0%)	.13
Impella (*n*, %)	5 (14.7%)	13 (39.4%)	12 (36.4%)	.06
Dual inotropes (*n*, %)	10 (29.4%)	12 (36.4%)	15 (45.5%)	.40
Single inotrope (*n*, %)	10 (29.4%)	5 (15.2%)	7 (21.2%)	.37
Operative data				
Previous surgery (*n*, %)	11 (32.4%)	11 (33.3%)	8 (24.2%)	.68
Concomitant procedure (*n*, %)	9 (26.5%)	16 (48.5%)	9 (27.3%)	.10
CPB time (minutes)	129.1 ± 47.0	129.6 ± 32.1	96.1 ± 22.1[b]	<.01
Full aortic cross clamp (*n*, %)	3 (8.8%)	3 (9.1%)	3 (9.1%)	.99
Cross clamp time (minutes)	52.8 ± 18.4	35.7 ± 12.4	18.7 ± 5.9[b]	.04
Outcomes				
30-Day survival (*n*, %)	30 (88.2%)	32 (96.9%)	33 (100%)	.61
1-Year survival (*n*, %)	26 (76.5%)	28 (84.9%)	29 (87.9%)	.44
Need for RVAD (*n*, %)	8 (23.5%)	9 (27.3%)	2 (6.1%)	.04
Reoperation for bleeding (*n*, %)	10 (29.4%)	12 (36.4%)	5 (15.2%)[b]	.01
Total LOS (days)	28.5 [17–36]	25 [21–39]	27 [23–40]	.76

TABLE 5 (Continued)

Variable	Era 1 (*N* = 34)	Era 2 (*N* = 33)	Era 3 (*N* = 33)	*p* value[a]
Preop LOS (days)	7 [3–12]	8 [6–12]	9 [7–12]	.27
Postoperative LOS (days)	18.5 [13–27]	17 [13–27]	21 [14–32]	.53

Abbreviations: CPB, cardiopulmonary bypass; dl, deciliter; ECMO, extracorporeal membrane oxygenation; INTERMACS, interagency registry for mechanically assisted circulatory support; kg, kilograms; L, liter; LOS, length of stay; m^2, meters squared; mg, milligram; mmol, millimoles; n, number.

[a]*p* value determine by analysis of variance for continuous parametric variables, Kruskal–Wallis test for continuous nonparametric variables, and by Chi-squared test for categorical variables.

[b]Statistically significant by pairwise comparison using post hoc Tukey-Kramer method.

74.2% for profile 1, 82.2% for profile 2, 85.4% for profile 3, and 85.0% for profile 4; and 2-year survival was 66.8% for profile 1, 72.1% for profile 2, 76.7% for profile 3, and 74.7% for profile 4. Based on these data, if we calculated our expected survival based only on INTERMACS profile distribution we would expect a 1-year survival of 80.8% and a 2-year survival of 72.4%. Thus, our reported 1 and 2-year survivals compare favorably to contemporary reported outcomes after adjusting for patient acuity. These findings also compare positively to the international experience.[30] Thus, we conclude that the survival outcomes at our nontransplant, DT center compare favorably to the published national and international experience.

4.2 | Transplant versus nontransplant centers

The question of whether nontransplant center outcomes are comparable to transplant center outcomes is important. Multiple studies would suggest that higher volume centers perform better in high-risk patient cohorts.[31–34] Thus, it would make sense to cohort these patients at a small number of high-volume centers. However, limiting these surgeries to a few centers predominantly in large cities could potentially restrict access to care.[35] Therefore, dissemination of this technology while maintaining fidelity to excellent outcomes is paramount. Unfortunately, the question of whether this therapy can be broadly disseminated to nontransplant centers has received limited attention.

Katz et al.[16] reported a retrospective study of 27 nontransplant centers. Interestingly, in this study, almost one third of the implants were still performed under a BTT strategy. In this series, 30-day mortality was 3% with a 1- and 2-year survival of 88% and 84% in the BTT group and 70% and 63% in the DT cohort. While these outcomes are similar to published national registry data, the inclusion of a significant number of BTT patients may limit this study's broader applicability to most nontransplant centers. Moreover, Brinkley et al.[17] conducted a retrospective study of the INTERMACS database comparing LVADs performed at transplant and nontransplant centers. They found no difference in 1-year or 2-year survival on either unadjusted or adjusted analysis. Although volumes at nontransplant centers were lower, adjustments for volume did not impact the outcome. Our results in combination with these prior studies suggest similar outcomes at transplant and nontransplant centers.

4.3 | DT program strategy

Regardless of the existence of a concomitant transplant program, the establishment and growth of an LVAD program requires substantial resources. Our program began in 2010 with a single cardiologist, a single cardiac surgeon, and an experienced LVAD coordinator (Figure 1). The program was designated a DT center and we partnered with a transplant center which is part of the larger Baylor Scott and White hospital system. These early years established a solid foundation for our program. In the middle years, while the single cardiologist remained unchanged, several different cardiac surgeons from other facilities lead the LVAD program (Figure 1). The decision to outsource LVAD surgery was based on the persistently low volume of LVAD implants relative to a surging surgical valve program. However, the change did not increase volume and adversely affected outcomes.

In 2017, hospital leadership made a conscious recommitment to the heart failure program generally and the LVAD program specifically. A single cardiac surgeon who only operated at the Heart Hospital took over the surgical part of the program (Figure 1). To deal with the increased volume of consults and referrals, a 2nd LVAD coordinator was added in 2018. Constant reassessment of the program suggested that inpatient end-stage heart failure patients were still being overlooked for consideration for advanced heart failure therapies. Therefore, in 2019, we recruited a 2nd heart failure cardiologist and formalized our inpatient heart failure consult service. A 3rd LVAD coordinator was added in 2020. A dedicated LVAD social worker was added in 2021. Amidst a surging inpatient consult volume and outpatient clinic volume, a 3rd heart failure cardiologist was added in 2021.

As a hospital founded on and committed to quality outcomes, our goal was not to increase volume for volume's sake; rather, we are acutely aware that prior reports demonstrate that higher volume hospitals and providers have superior outcomes.[31–34] Previous studies have shown that low hospital volume is a predictor of poor LVAD outcomes with an inflexion point at 20 LVADs per year while others have highlighted the importance of surgeon volume in

particular.[31,32] Therefore, we determined to bolster our successful but low-volume program to better serve our patient population and increase our quality outcomes.

To improve surgeon volume and increase surgical proficiency, we elected to consolidate the program to a single surgeon as the program had started. Additionally, we created an "LVAD team" consisting of a single physician assistant, and a group of operating room nurses in an attempt to foster a team environment with increased familiarity with the surgery, the device, and the patient population. Our anesthesia group chose one anesthesiologist to do the anesthesia for all of these cases to further develop an experienced team approach.

In the intensive care unit, we developed an "LVAD team" of nurses who would focus on the immediate postoperative resuscitation and recovery, channeling our small volume program into a limited number of staff thus increasing experience levels. Although hard to fully assess the impact of such changes, our analysis of LVAD implants over time suggests that these changes resulted in significant improvement in the surgical experience. Interestingly, our 30-day and 1-year survival remained constant despite improving proficiency. Though hard to fully explain, we speculate that this was due to concomitant increase in preoperative patient risk, acuity, and complexity. While our preoperative patient acuity increased, our median CPB and aortic cross clamp times decreased along with a decline in rate of reoperation for bleeding suggesting increased operative efficiency and proficiency as the surgical team became increasingly familiar with the operation. Finally, our need for RVAD support declined over time. Though a complex metric involving preoperative optimization, appropriate selection, operative efficiency, and postoperative support, the finding of less RVAD utilization may suggest that the overall team environment helped us optimizing patients with marginal RV function preoperatively; nursing these RVs through the operative period; and precisely resuscitating the struggling right ventricles postoperatively, thus avoiding the need for mechanical support.

Simultaneous to our surgical efforts, a hospital-wide programmatic approach was undertaken to promote LVAD therapy and the heart failure team. Although we had a long-standing informal heart failure consult service, we added a formal inpatient heart failure service with a dedicated nurse practitioner to help reinvigorate this service line. Thus, the heart failure service became available for consultation and assistance 24/7 with increasing involvement in everything ranging from routine heart failure admissions to cardiogenic shock requiring temporary MCS. Although we lack granular data about inpatient consults, this integrative, hospital-wide approach led to an exponential increase in inpatient as well as outpatient consults, significantly contributing to our ability to identify appropriate candidates for advanced heart failure therapies.

With the increase the inpatient heart failure volume, outpatient volumes, and LVAD implant volumes, the number of advanced heart failure therapy evaluations, LVAD family education, and postoperative follow ups skyrocketed. This led us to sequentially add two LVAD coordinators. As most providers involved with advanced heart failure therapies will attest, the LVAD coordinator may be the most important member of the entire LVAD team.[24] Although hard to quantify, our increase in LVAD coordinator bandwidth significantly improved our ability to build the volume of the program while maintaining its quality. Similar to our experience, previous reports have emphasized the need for team collaboration, highlighting the roles of cardiology, surgery, anesthesiology, critical care, nursing, LVAD coordinators, and social work.[24,35–40]

5 | LIMITATIONS

This report represents a single-center, retrospective analysis. As a single center study, we recognize that there may be aspects of our program that may limit generalizability. For example, our center is located in a metroplex of almost 8 million people. We recognize this may limit the generalizability of our approach to program growth. Second, as a retrospective analysis, our study is susceptible to selection bias. Although we conducted multiple statistical tests to identify and limit this bias, we recognize that the ability to statistically adjust for bias is limited by the sample size. Further investigation is warranted to more fully evaluate these findings. Third, although we exhaustively reviewed the available medical records, some potentially important data are unavailable, including invasive hemodynamics. This deficit may limit the application of these findings. Finally, although limiting the providers involved in LVAD care such as consolidating to a single implanting surgeon or focusing on one anesthesiologist or nursing LVAD teams does increase exposure, we recognize it could hypothetically limit access to care if insufficient team members were temporarily unavailable. Although a logical theoretical concern, this has not thus far been a problem.

6 | CONCLUSIONS

In conclusion, our study suggests that a low-volume, nontransplant center can substantially increase volume over a short period of time while maintaining high quality outcomes in a high-acuity patient cohort. Our findings corroborate those of others that suggest that a nontransplant center can achieve survival outcomes that compare favorably to those of modern large trials and international benchmarks. We further hypothesize that our team approach to program building is responsible for these successes but recognize that further studies are necessary to corroborate these findings.

AUTHOR CONTRIBUTIONS

Study design: Timothy J. George, Robert L Smith, Aasim Afzal, Nitin Kabra, David A. Rawitscher, and J. Michael DiMaio. *Data acquisition and analysis*: Timothy J. George, Allison Aldrich, William H. Ryan, J. Michael DiMiao, and Aasim Afzal. *Interpretation of the data*: Timothy J. George, William H.Ryan, and Aasim Afzal. *Writing of the manuscript*: Timothy J. George and Aasim Afzal. *Review and revision of the*

manuscript: George, Allison Aldrich, Robert L Smith, J. Michael DiMaio, Kabra, Aasim Afzal, David A. Rawitscher.

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CONFLICTS OF INTEREST

Dr. George has acted as a proctor for Heartmate 3 (Abbott Laboratories) implantations. The other authors declare no conflicts of interest.

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