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Clinical Investigation

Clinical Predictors and Outcomes After Left Ventricular Assist Device Implantation and Tracheostomy

Harveen K. Lamba, MD, MSc[1]; Lucy D. Hart, MD[1]; Qianzi Zhang, MPH[2]; Jackquelin M. Loera, MS[1]; Andrew B. Civitello, MD[3,4]; Ajith P. Nair, MD[3,4]; Mourad H. Senussi, MD[3]; Gabriel Loor, MD[1,4]; Kenneth K. Liao, MD, PhD[1,4]; Alexis E. Shafii, MD[1,4]; Subhasis Chatterjee, MD[2,4,5]

[1]Division of Cardiothoracic Transplantation and Circulatory Support, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston, Texas
[2]Division of Cardiothoracic Surgery, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston, Texas
[3]Section of Cardiology, Department of Medicine, Baylor College of Medicine, Houston, Texas
[4]Department of Cardiovascular Surgery, The Texas Heart Institute, Houston, Texas
[5]Division of Trauma and Acute Care Surgery, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston, Texas

Abstract

Background: Postoperative respiratory failure is a major complication that affects up to 10% of patients who undergo cardiac surgery and has a high in-hospital mortality rate. Few studies have investigated whether patients who require tracheostomy for postoperative respiratory failure after continuous-flow left ventricular assist device (CF-LVAD) implantation have worse survival outcomes than patients who do not.

Objective: To identify risk factors for respiratory failure necessitating tracheostomy in CF-LVAD recipients and to compare survival outcomes between those who did and did not require tracheostomy.

Methods: Consecutive patients who underwent primary CF-LVAD placement at a single institution between August 1, 2002, and December 31, 2019, were retrospectively reviewed. Propensity score matching accounted for baseline differences between the tracheostomy and nontracheostomy groups. Multivariate logistic regression was used to identify tracheostomy risk factors and 90-day survival; Kaplan-Meier analysis was used to assess midterm survival.

Results: During the study period, 664 patients received a CF-LVAD; 106 (16.0%) underwent tracheostomy for respiratory failure. Propensity score matching produced 103 matched tracheostomy-nontracheostomy pairs. Patients who underwent tracheostomy were older (mean [SD] age, 57.9 [12.3] vs 54.6 [13.9] years; $P = .02$) and more likely to need preoperative mechanical circulatory support (61.3% vs 47.8%; $P = .01$) and preoperative intubation (27.4% vs 8.8%; $P < .001$); serum creatinine was higher in the tracheostomy group (mean [SD], 1.7 [1.0] vs 1.4 [0.6] mg/dL; $P < .001$), correlating with tracheostomy need (odds ratio, 1.76; 95% CI, 1.21-2.56; $P = .003$). Both before and after propensity matching, 30-day, 60-day, 90-day, and 1-year survival were worse in patients who underwent tracheostomy. Median follow-up was 0.8 years (range, 0.0-11.2 years). Three-year Kaplan-Meier survival was significantly worse for the tracheostomy group before (22.0% vs 61.0%; $P < .001$) and after (22.4% vs 48.3%; $P < .001$) matching.

Conclusion: Given the substantially increased probability of death in patients who develop respiratory failure and need tracheostomy, those at high risk for respiratory failure should be carefully considered for CF-LVAD implantation. Comprehensive management to decrease respiratory failure before and after surgery is critical.

Keywords: ventricular assist device; heart failure; assisted circulation; perioperative care

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Corresponding author: Subhasis Chatterjee, MD, Department of Cardiovascular Surgery, Baylor College of Medicine, One Baylor Plaza, MS: BCM 390, Houston, TX 77030-3411 (subhasis.chatterjee@bcm.edu)

Introduction

Postoperative respiratory failure affects 2% to 10% of cardiac surgery patients.[1-4] Prolonged ventilator dependence necessitates tracheostomy, which can expedite ventilator weaning with less sedation, reduce pneumonia risk, and simplify nursing care,[5] but in-hospital mortality after cardiac surgery plus tracheostomy is high (30%-49%).[1,2,6,7]

Few studies have analyzed tracheostomy after continuous-flow left ventricular assist device (CF-LVAD) implantation. After implantation, the prolonged mechanical ventilation rate is as high as 43%, with an overall tracheostomy rate of 27%.[8] Whether needing a tracheostomy reflects higher patient acuity at presentation or is associated with increased mortality is unclear.

The aim of this study was to identify factors affecting risk for tracheostomy and to analyze survival outcomes related to postoperative respiratory failure necessitating tracheostomy in patients undergoing CF-LVAD implantation. The hypothesis was that patients undergoing tracheostomy would have worse survival than those not undergoing tracheostomy.

Key Points

- This study investigated whether patients who require tracheostomy for postoperative respiratory failure after continuous-flow left ventricular assist device (CF-LVAD) implantation have worse survival than patients who do not.
- Propensity score matching was used to account for baseline differences between the tracheostomy and nontracheostomy groups.
- Both before and after propensity matching, 30-day, 60-day, 90-day, 1-year, and 3-year survival were significantly worse in the tracheostomy group.
- Patients at high risk of tracheostomy should be assessed carefully for CF-LVAD implantation.
- Comprehensive management to decrease respiratory failure is critical before, during, and after CF-LVAD surgery.

Abbreviations and Acronyms

AKI	acute kidney injury
CF-LVAD	continuous-flow left ventricular assist device
CPB	cardiopulmonary bypass
INTERMACS	Interagency Registry for Mechanically Assisted Circulatory Support
KRT	kidney replacement therapy
mRAP/PCWP	mean right atrial pressure/pulmonary capillary wedge pressure
OR	odds ratio
PFT	pulmonary function test

Patients and Methods

The authors conducted a retrospective review of consecutive patients undergoing primary CF-LVAD implantation at a single institution between August 1, 2002, and December 31, 2019. The Baylor College of Medicine Institutional Review Board approved the study (No. H-38751; November 24, 2016).

Study Variables

Baseline characteristics, hemodynamic and echocardiographic variables, and postoperative outcomes were collected from clinical records. Echocardiographic, laboratory, and hemodynamic data were the most recent available before CF-LVAD implantation. The implanted CF-LVADs included the HeartMate II and 3 (Abbott Laboratories), the HeartWare HVAD (Medtronic), and the Jarvik 2000 (Jarvik Heart, Inc.). Right-heart failure was defined as the need for any right-sided mechanical circulatory support during index hospitalization. Preoperative intubation was defined as mechanical ventilation for any reason in the 72 hours before implantation. Data regarding reason for preimplantation intubation (either pulmonary dysfunction from cardiogenic shock or airway protection during preprocedural mechanical circulatory support) were not available.

Perioperative cerebrovascular accident (within 30 days of CF-LVAD implantation) was defined according to the presence of symptoms, brain computed tomography imaging, and confirmatory neurology consultation.

Implantation almost exclusively involved median sternotomy with cardiopulmonary bypass (CPB); the number of implantations that involved thoracotomy was not available. The need for and timing of tracheostomy was determined by a multidisciplinary care team (cardiovascular surgeons, heart failure cardiologists, and intensivists). Patient care was individualized, and there was no prespecified definition of respiratory failure or set timing for tracheostomy; most tracheostomies were performed approximately 2 weeks after CF-LVAD implantation. There was also no set limit on the number of reintubations that would automatically prompt tracheostomy. Most CF-LVAD patients at this center undergo open tracheostomy, although occasionally a percutaneous dilation tracheostomy is performed.

Statistical Analysis

Baseline demographic characteristics were compared between patients who did and did not undergo tracheostomy. Categorical variables are presented as number and percentage; continuous variables are presented as mean (SD) or median (IQR). Unpaired *t* tests were used to analyze normally distributed data. Univariate comparisons were conducted with the Pearson χ^2 test, Fisher exact test, or nonparametric Wilcoxon rank sum test, with $P < .05$ considered statistically significant. Data were analyzed using SPSS Software, version 25 (IBM).

To adjust for confounding variables, a propensity score analysis was conducted with 1-to-1 matching without replacement, the nearest-neighbor method, and a caliper of 0.01 SD of the logit. The propensity score was estimated by using a multivariate logistic regression model with 6 preoperative covariates: age, Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile, previous mechanical circulatory support, preoperative creatinine level, previous sternotomy, and preoperative intubation. Patients were not matched for variables related to prolonged mechanical ventilation (duration of preoperative mechanical ventilation, postoperative tidal volume, driving pressure, other ventilatory parameters). Balance in baseline covariates in the matched cohort was examined using standardized mean differences; successful matching was defined as a standardized mean difference less than 0.10. Matching was carried out using the psmatch2 package in Stata, version 14 (StataCorp).

To identify independent risk factors for tracheostomy, univariate analyses were first performed in the propensity-matched cohort to compare demographic variables between the tracheostomy and nontracheostomy groups. To identify independent risk factors for 90-day mortality, univariate analyses were first performed in the unmatched cohort to compare demographic characteristics between patients who did or did not die within 90 days. Variables that differed significantly between groups at $P = .10$ were included in subsequent multivariate analyses, in which backward selection was applied with a removal value of $P < .05$.

The McNemar test and generalized estimating equation were used to compare postoperative outcomes in the tracheostomy and nontracheostomy groups. Overall survival between groups was compared using the stratified log-rank test. Scaled Schoenfeld residuals examined the assumption of proportional hazards.

Univariate analysis examined early postoperative outcomes, and Kaplan-Meier analysis with log-rank testing compared survival between patients who did vs did not undergo tracheostomy in both unmatched and matched cohorts.

Results

Preoperative and Intraoperative Patient Characteristics

Of 664 patients who underwent primary CF-LVAD implantation during the study period, 106 (16.0%) required tracheostomy (Table I). No patient had had a previous tracheostomy. The median time to tracheostomy was 15.5 days (range, 6-82 days; IQR, 9-21 days) after CF-LVAD implantation. Median follow-up was 0.8 years (range, 0.0-11.2 years). Pulmonary function test data were incomplete; forced expiratory volume was available for 54% of all patients, 45% of the INTERMACS 1 group, and 27% of the tracheostomy cohort. Diffusing capacity for carbon monoxide was available for 23% of patients overall, 13% of the INTERMACS 1 group, and 10% of the tracheostomy group.

Before Propensity Matching

In the unmatched cohorts, tracheostomy patients were older (mean [SD] age, 57.9 [12.3] vs 54.6 [13.9] years; $P = .02$) and more likely to have had a previous sternotomy (45.3% vs 28.7%; $P = .001$), preoperative mechanical circulatory support (61.3% vs 47.8%; $P = .01$), INTERMACS 1 status (24.5% vs 15.6%; $P = .03$), and kidney failure (7.5% vs 1.8%; $P = .001$) (Table I). Tracheostomy patients were more likely to require preoperative dialysis (16.0% vs 3.8%; $P < .001$) as a result of chronic or acute kidney failure. Tracheostomy patients had a higher preoperative mean (SD) serum creatinine level (1.7 [1.0] vs 1.4 [0.6] mg/dL), lower mean (SD) preoperative hemoglobin (10.6 [2.0] vs 11.6 [2.2] g/dL) and albumin (3.3 [0.6] vs 3.5 [0.6] mg/dL) levels (all $P < .001$), and a higher mean (SD) white blood cell count (10.5 [4.8] vs 9.1 [4.7] cells/mm^3; $P = .004$). They were also more likely to have been intubated preoperatively (27.4% vs 8.8%) and to be taking vasopressors (26.4% vs 13.1%) at the time of CF-LVAD implantation (both $P < .001$).

Patients who underwent tracheostomy had a higher mean (SD) right atrial pressure/pulmonary capillary wedge pressure (mRAP/PCWP) (0.6 [0.3] vs

TABLE I. Demographic Characteristics of the Unmatched (n = 664) and Propensity Score–Matched (n = 206) Cohorts

	Unmatched			Propensity score matched		
Characteristic	**Tracheostomy (n = 106)**	**Nontracheostomy (n = 558)**	***P* value[a]**	**Tracheostomy (n = 103)**	**Nontracheostomy (n = 103)**	**SMD[b]**
Age, mean (SD), y	57.9 (12.3)	54.6 (13.9)	.02[a]	58.0 (12.2)	58.1 (10.8)	0.051
Male sex, No. (%)	87 (82.1)	441 (79.0)	.48	84 (81.6)	87 (84.5)	–
Body mass index, mean (SD)	27.7 (7.1)	28.2 (6.4)	.37	27.6 (7.0)	27.7 (5.3)	–
Body surface area, mean (SD), m^2	2.0 (0.3)	2.0 (0.3)	.06	2.0 (0.3)	2.0 (0.2)	–
INTERMACS 1, No. (%)	26 (24.5)	87 (15.6)	.03[a]	25 (24.3)	23 (22.3)	0.049
Primary etiology for heart failure, No. (%)			.38			
Ischemic	57 (53.8)	253 (45.3)		46 (44.7)	38 (36.9)	–
Nonischemic	47 (44.3)	293 (52.5)		57 (55.3)	65 (63.1)	–
Unknown	1 (0.9)	10 (1.8)		0	0	–
Destination therapy, No. (%)	54 (50.9)	236 (42.3)	.21	53 (51.5)	44 (42.7)	–
Device type, No. (%)			.07			–
HeartMate II	73 (68.9)	347 (62.2)		71 (68.9)	81 (78.6)	–
HeartWare HVAD	22 (20.8)	171 (30.6)		22 (21.4)	16 (17.5)	–
HeartMate 3	0	6 (1.1)		0	0	–
Jarvik 2000	11 (10.4)	34 (6.1)		10 (9.7)	6 (5.8)	–
Medical history, No. (%)						–
Previous sternotomy	48 (45.3)	160 (28.7)	.001[a]	46 (44.7)	50 (48.5)	0.08
Mechanical circulatory support	65 (61.3)	267 (47.8)	.01[a]	62 (60.2)	64 (62.1)	0.78
Myocardial infarction	13 (12.3)	75 (13.4)	.66	13 (12.6)	11 (10.7)	–
Hypertension	60 (56.6)	356 (63.8)	.16	59 (57.3)	73 (70.9)	–
Diabetes	49 (46.2)	250 (44.8)	.79	46 (44.7)	48 (46.6)	–
Kidney failure	8 (7.5)	10 (1.8)	.001[a]	7 (6.8)	4 (3.9)	–
Preoperative dialysis (AKI or kidney failure)	17 (16.0)	21 (3.8)	<.001[a]	16 (15.5)	5 (4.9)	–
Chronic obstructive pulmonary disease	14 (13.2)	75 (13.4)	.95	14 (13.6)	17 (16.5)	–
Smoking history	49 (46.2)	252 (45.2)	.70	49 (47.6)	49 (47.6)	–
Peripheral vascular disease	15 (14.2)	59 (10.6)	.28	14 (13.6)	15 (14.6)	–
Cerebrovascular accident	12 (11.3)	71 (12.7)	.67	12 (11.7)	17 (16.5)	–
Preoperative intubation	29 (27.4)	49 (8.8)	<.001[a]	27 (26.2)	26 (25.2)	0.051
Preoperative inotropes[c]	94 (88.7)	468 (83.9)	.21	91 (88.3)	94 (91.3)	–
Preoperative pressors[d]	28 (26.4)	73 (13.1)	<.001[a]	27 (26.2)	23 (22.3)	–

Continued

TABLE I. Demographic Characteristics of the Unmatched (n = 664) and Propensity Score–Matched (n = 206) Cohorts (continued)

Characteristic	Unmatched			Propensity score matched		
	Tracheostomy (n = 106)	Nontracheostomy (n = 558)	*P* value[a]	Tracheostomy (n = 103)	Nontracheostomy (n = 103)	SMD[b]
Preoperative measurements, mean (SD)						
Hemoglobin, g/dL	10.6 (2.0)	11.6 (2.2)	<.001[a]	10.6 (2.0)	11.2 (2.2)	–
White blood cell count, cells/mm^3	10.5 (4.8)	9.1 (4.7)	.004[a]	10.6 (4.8)	9.9 (4.2)	–
Platelets, ×10^9/L	191.0 (100.5)	205.0 (91.3)	.08	191.4 (100.7)	203.7 (99.8)	–
Serum sodium, mEq/L	135.3 (5.3)	135.1 (4.4)	.08	135.2 (5.3)	135.3 (5.0)	–
Creatinine, mg/dL	1.7 (1.0)	1.4 (0.6)	<.001[a]	1.7 (0.8)	1.6 (0.8)	0.07
Blood urea nitrogen, mg/dL	35.2 (21.4)	30.6 (20.2)	.04[a]	35.5 (21.5)	36.9 (19.6)	–
Estimated glomerular filtration rate, mL/min/1.73 m^2	59.3 (33.9)	65.2 (31.2)	.18	59.3 (33.9)	58.7 (50.7)	–
Albumin, g/dL	3.3 (0.6)	3.5 (0.6)	<.001[a]	3.3 (0.6)	3.4 (0.6)	–
Total bilirubin, µmol/L	2.1 (2.7)	1.8 (3.1)	.52	2.1 (2.5)	2.5 (4.1)	–
Aspartate aminotransferase, IU/L	87.6 (237.5)	69.2 (158.1)	.21	88.2 (240.9)	94.1 (134.9)	–
Alanine aminotransferase, IU/L	72.5 (117.0)	84.7 (239.3)	.25	73.8 (118.5)	95.5 (181.5)	–
Lactate dehydrogenase, IU/L	458.3 (365.4)	378.2 (347.2)	.04[a]	449.6 (364.6)	476.1 (473.6)	–
Hemoglobin A_{1C}, %	6.7 (1.0)	6.6 (1.4)	.22	6.7 (1.0)	6.7 (16)	–
Cardiac index, L/min/m^2	1.9 (0.6)	1.9 (0.6)	.19	2.0 (0.6)	1.9 (0.5)	–
mRAP/PCWP	0.6 (0.3)	0.5 (0.3)	.02[a]	0.6 (0.4)	0.5 (0.3)	–
Pulmonary vascular resistance, Wood units	3.6 (3.2)	3.6 (2.8)	.54	3.6 (3.2)	3.6 (2.3)	–
Pulmonary artery pulsatility index	2.9 (3.5)	3.3 (3.4)	.43	3.2 (2.5)	4.3 (3.9)	–
Intraoperative details						
Cardiopulmonary bypass time, median (IQR), min	96 (62-141)	73 (51-100)	.001[a]	98 (65-137)	87 (55-125)	–
No cardiopulmonary bypass, No. (%)	5 (4.7)	35 (6.3)	.53	5 (4.9)	8 (7.8)	–
Operative time, median (IQR), min	316 (237-383)	257 (209-317)	<.001[a]	306 (238-384)	282 (226-358)	–
Total blood product transfusions, median (IQR), units[e]	31 (15-50)	15 (3-30)	.005[a]	33 (16-51)	21 (9-37)	–

AKI, acute kidney injury; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; mRAP/PCWP, mean right atrial pressure/pulmonary capillary wedge pressure; SMD, standardized mean difference.

[a]Significant at $P < .05$.
[b]Propensity score matching was based on INTERMACS profile (SMD = 0.049), previous sternotomy (SMD = 0.08), preoperative serum creatinine level (SMD = 0.07), preoperative intubation (SMD = 0.03), and age (SMD = 0.01). Adequate matching was defined as SMD < 0.10.
[c]Epinephrine, dobutamine, or milrinone.
[d]Norepinephrine or vasopressin.
[e]Includes packed red blood cells, fresh frozen plasma, and platelets.

0.5 [0.3] mm Hg; *P*=.02), whereas the cardiac index and pulmonary artery pulsatility index were comparable between groups. Tracheostomy patients had a longer median operative time (316 vs 257 minutes; *P*<.001); median CPB time (96 vs 73 minutes; *P*=.001); and more intraoperative transfusion units of total blood products, including packed red blood cells, fresh frozen plasma, and platelets (median, 31 vs 15 units; *P*=.005) (Table I). Few (40 of 664 [6.0%]) implantations were performed without CPB. In the non-CPB cases, no differences were noted between the tracheostomy and nontracheostomy groups.

Independent predictors of postoperative respiratory failure necessitating a tracheostomy, as identified in the multivariate analysis (Table II), included higher serum creatinine level (odds ratio [OR], 1.76; 95% CI. 1.21-2.56; *P*=.003), higher white blood cell count (OR, 1.05; 95% CI, 1.00-1.11, *P*=.02), and older age (OR, 1.03; 95% CI, 1.00-1.05; *P*=.03). Higher preoperative hemoglobin appeared to be protective against tracheostomy (OR, 0.85; 95% CI, 0.72-1.00; *P*=.007). Preoperative intubation (*P*=.16) and dialysis (*P*=.15) did not independently predict a need for tracheostomy.

After Propensity Matching

Propensity score matching produced 103 matched tracheostomy-nontracheostomy pairs that were analyzed for differences in preoperative characteristics (Table I). Most variables were comparable between groups, although patients who underwent tracheostomy had a higher mean (SD) cardiac index (2.0 [0.6] vs 1.9 [0.5]; *P*=.02) and mRAP/PCWP levels (0.6 [0.4] vs 0.5 [0.3] mm Hg; *P*=.04) and were more likely to require preoperative dialysis (15.5% vs 4.9%; *P*=.01). Matched patients who underwent tracheostomy had comparable median operative and CPB times but higher transfusion requirements.

Clinically relevant variables identified in the univariate analysis included preoperative creatinine; preoperative intubation; mRAP/PCWP; previous sternotomy; white blood cell count; preoperative mechanical circulatory support; age; preoperative dialysis; INTERMACS 1 status; hemoglobin, albumin, and platelet counts; CPB time; and intraoperative transfusion units.

TABLE II. Independent Risk Factors for Needing Tracheostomy (n = 106)

Risk factor	OR	95% CI	*P* value[a]
Preoperative creatinine	1.76	1.21-2.56	.003[a]
Preoperative intubation	1.76	0.80-3.85	.16
mRAP/PCWP	1.60	0.93-4.52	.22
Previous sternotomy	1.23	0.70-2.17	.47
White blood cell count	1.05	1.00-1.11	.02[a]
Preoperative mechanical circulatory support	1.03	0.50-2.13	.93
Age	1.03	1.00-1.05	.03[a]
Preoperative dialysis	1.03	0.97-1.04	.15
INTERMACS 1 status	0.88	0.43-1.80	0.74
Hemoglobin	0.85	0.72-1.00	.007[a]
Albumin	0.60	0.37-0.97	.38

INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; mRAP/PCWP, mean right atrial pressure/pulmonary capillary wedge pressure; OR, odds ratio.

[a]Significant at *P* < .05.

Postoperative and Survival Outcomes

Before propensity matching, tracheostomy was associated with greater mortality at 30 days (19.8% vs 9.7%; *P*=.003), 60 days (34.9% vs 13.8%; *P*<.001), and 90 days (45.3% vs 18.3%; *P*<.001), along with worse actual 1-year survival (34.9% vs 76.3%; *P*<.001) (Table III). Tracheostomy was also associated with higher reoperation rates for bleeding (36.8% vs 20.4%) and kidney replacement therapy (KRT) (51.2% vs 11.5%) rates and longer hospital stay (61 vs 28 days) (all *P*<.001) compared with no tracheostomy. Deep sternal wound infection occurred in 6.5% of the overall cohort, more frequently in the tracheostomy group (9.4% vs 5.9%; *P*=.004).

In a Kaplan-Meier analysis of midterm (3-year) survival, tracheostomy was associated with worse survival in the unmatched cohorts: survival was worse in the tracheostomy group (22.0%) than in the nontracheostomy group (61.0%), *P*<.001 (Fig. 1).

After propensity matching, tracheostomy was associated with greater mortality at 30 days (20.4% vs 9.7%; *P*=.03), 60 days (35.9% vs 12.6%; *P*<.001), and 90 days (46.6% vs 14.6%; *P*< .001) (Table III). One-year actual survival also was worse (33.0% vs 71.8%; *P*<0.001). Patients with a tracheostomy had higher rates of postoperative acute kidney injury (AKI) (61.5% vs 19.4%; *P*<0.001), including higher rates of postoperative KRT (40.8% vs 16.5%; *P*<0.001). Tracheostomy patients also had a longer median hospital stay (61 vs 31

TABLE III. Postoperative Outcomes for the Unmatched (n = 664) and Propensity Score–Matched (n = 206) Cohorts

	Unmatched			Propensity score matched		
Outcome	Tracheostomy (n = 106)	Nontracheostomy (n = 558)	*P* value[a]	Tracheostomy (n = 103)	Nontracheostomy (n = 103)	*P* value[a]
Mortality, No. (%)						
Survival at 1 y	37 (34.9)	426 (76.3)	<.001[a]	34 (33.0)	74 (71.8)	<.001[a]
30-d mortality	21 (19.8)	54 (9.7)	.003[a]	21 (20.4)	10 (9.7)	.03[a]
60-d mortality	37 (34.9)	77 (13.8)	<.001[a]	37 (35.9)	13 (12.6)	<.001[a]
90-d mortality	48 (45.3)	102 (18.3)	<.001[a]	48 (46.6)	15 (14.6)	<.001[a]
Sternal wound infection, No. (%)	10 (9.4)	33 (5.9)	.004[a]	10 (9.7)	6 (5.8)	.09
Device exchange, No. (%)	9 (8.5)	93 (16.7)	.71	7 (6.8)	18 (17.5)	.15
Reoperation for bleeding, No. (%)	39 (36.8)	114 (20.4)	<.001[a]	37 (35.9)	29 (28.2)	.23
Early right ventricular assist device,[b] No. (%)	3 (2.8)	16 (2.9)	.60	3 (2.9)	1 (1.0)	.32
Early stroke,[b] No. (%)	5 (4.7)	26 (4.7)	>.99	5 (4.9)	6 (5.8)	.76
Gastrointestinal bleed, No. (%)	24 (22.6)	136 (24.4)	.70	24 (23.3)	34 (33.0)	.15
AKI, No. (%)	56 (52.8)	88 (15.8)	<.001[a]	60.5 (61.5)	20 (19.4)	<.001[a]
KRT, No. (%)	43 (51.2)	64 (11.5)	<.001[a]	42 (40.8)	17 (16.5)	<.001[a]
Early readmission,[b] No. (%)	12 (11.3)	99 (17.7)	.17	12 (11.7)	18 (17.5)	.22
Length of stay, median (IQR), d	61 (31.5-96.5)	28 (19.0-40.5)	<.001[a]	61 (31.5-93.0)	31 (19.0-49.0)	<.001[a]

AKI, acute kidney injury; KRT, kidney replacement therapy.

[a] Significant at *P* < .05.
[b] "Early" indicates within 30 days of continuous-flow left ventricular assist device implantation.

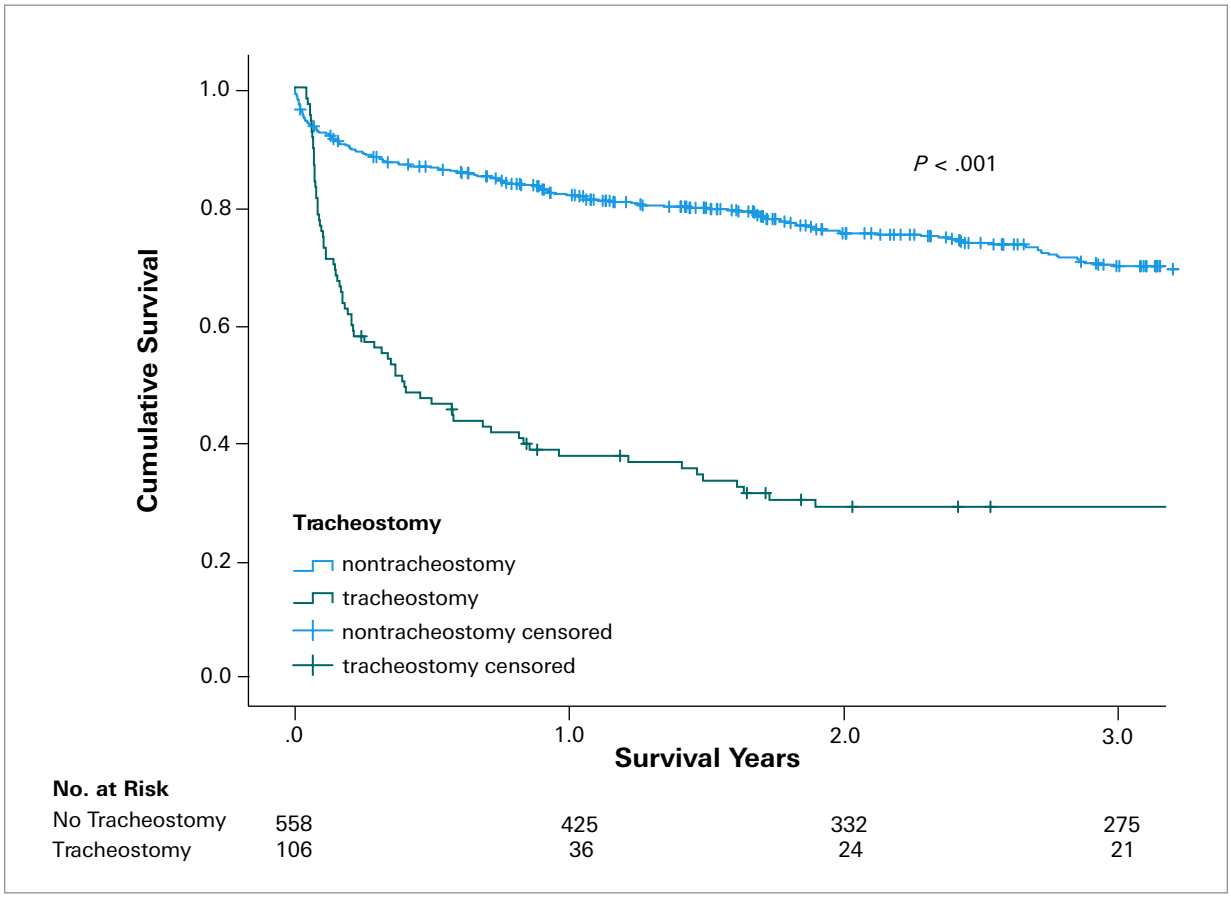

Fig. 1 Kaplan-Meier analysis of the unmatched cohort. The 3-year survival rates for the tracheostomy patients (n = 106) and nontracheostomy patients (n = 558) were 22.0% and 61.0%, respectively ($P < .001$). $P < .05$ was considered statistically significant.

days; $P < .001$). Deep sternal wound infection rates were comparable between the 2 groups.

A Kaplan-Meier analysis of the matched cohort revealed worse 3-year survival for the tracheostomy group (22.4%) than for the nontracheostomy group (48.3%) ($P < .001$) (Fig. 2).

Independent Predictors of 90-Day Mortality

To address differences in early mortality, a binary logistic regression for 90-day mortality was performed in the unmatched cohort. The characteristics identified in the univariate analysis included postoperative respiratory failure requiring tracheostomy; postoperative KRT; reoperation for bleeding; deep sternal wound infections; mRAP/PCWP; preoperative dialysis; preoperative intubation; CF-LVAD implantation as destination therapy; INTERMACS 1 status; previous sternotomy; postoperative creatinine level; age; mechanical circulatory support at the time of implantation; and postoperative albumin level. After multivariate analysis, the only independent predictors (Table IV) were postoperative KRT (OR, 8.2; 95% CI, 2.4-27.6; $P < .001$), postoperative respiratory failure requiring tracheostomy (OR, 5.7; 95% CI, 1.6-20.1; $P = .01$), and preoperative dialysis (OR, 23.3; 95% CI, 1.5-373.9; $P = .03$). Mean RAP/PCWP and INTERMACS 1 status were not independent predictors in this cohort.

Discussion

This study's key findings were that respiratory failure necessitating tracheostomy after CF-LVAD implantation occurred in 16% of cases, was associated with higher mortality in both unmatched and propensity score–matched cohorts, was a strong independent predictor of 90-day mortality, and was associated with a significant difference in later survival. These findings were consistent with the study's hypothesis.

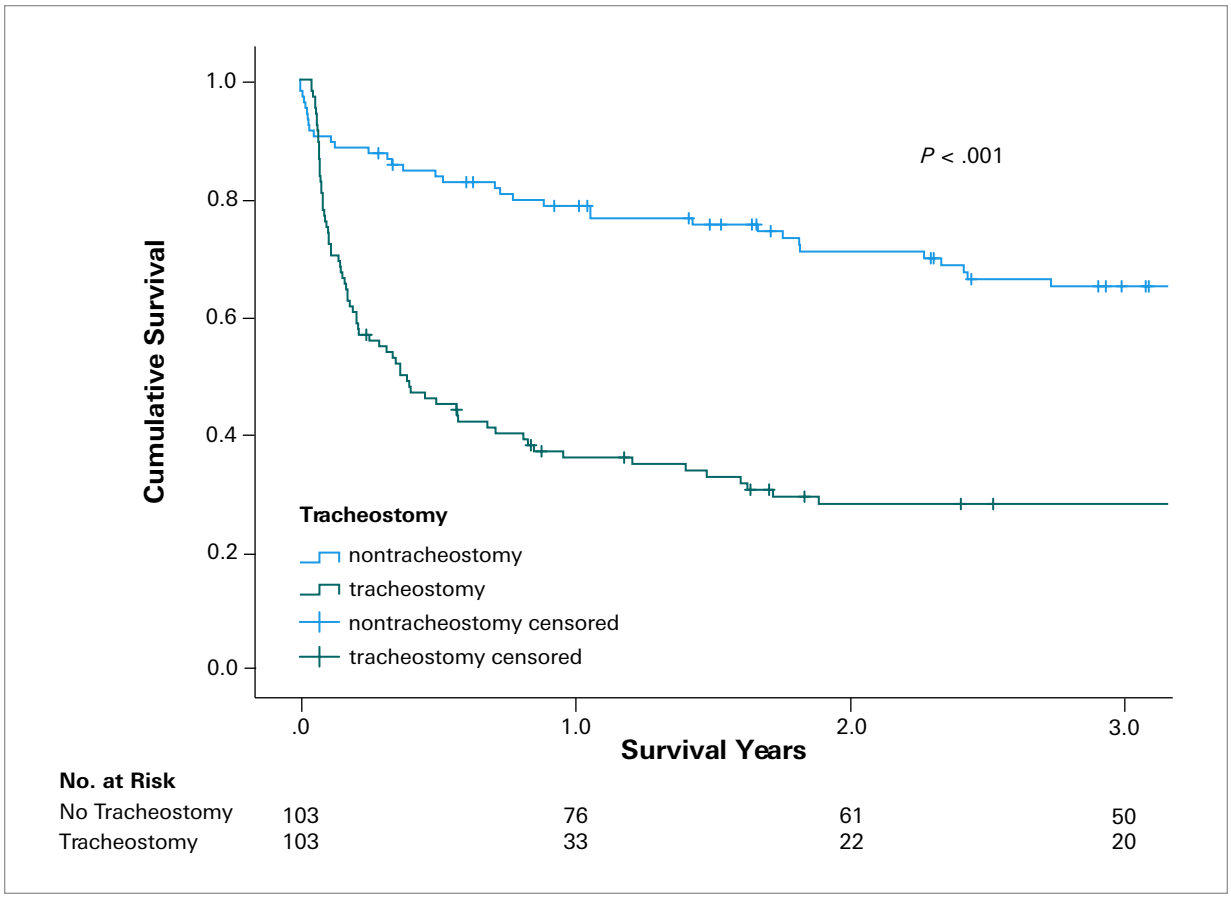

Fig. 2 Kaplan-Meier analysis of the propensity-matched cohort. The 3-year survival rates for the tracheostomy patients (n = 103) and nontracheostomy patients (n = 103) were 22.4% and 48.3%, respectively ($P < .001$). $P < .05$ was considered statistically significant.

To the authors' knowledge, the current study represents the largest single-center report of respiratory failure leading to tracheostomy after CF-LVAD implantation and is unique in that it used a matched comparison to better elucidate the risks associated with respiratory failure requiring tracheostomy. It is important to note that respiratory failure resulting in tracheostomy was an independent predictor of early mortality. These results should not be interpreted as questioning the safety of the tracheostomy: the safety and efficacy of tracheostomy are well established in cardiac surgery patients and CF-LVAD recipients[9,10] and should not be denied or delayed in appropriate candidates.

Unsurprisingly, patients who underwent tracheostomy were more acutely ill, with more comorbidities and a higher likelihood of postoperative complications and death. Both the unmatched and matched tracheostomy cohorts had worse survival rates at 30, 60, and 90 days, as expected. Survival of 46.6% at 90 days in the matched tracheostomy cohort was nearly identical to the 47% to 49% observed by 2 other groups.[1,10]

A major risk factor for developing postoperative respiratory failure is preoperative intubation. In this analysis, 27% of the tracheostomy cohort were intubated preoperatively, and more than one-third of all preoperatively intubated patients required postoperative tracheostomy. In a large INTERMACS analysis of 16,362 patients, 5.5% of patients were intubated before CF-LVAD implantation, and 6.1% developed postoperative respiratory failure, with a 40% 1-year mortality rate.[11] The present study found a more than 2-fold-higher prevalence of preoperative intubation compared with the INTERMACS analysis, probably reflecting higher preoperative acuity. Although preoperative intubation might seem to suggest higher risk for tracheostomy, preoperative mechanical ventilation did not independently predict postoperative tracheostomy in this analysis (Table II). Similarly, whereas preoperative pulmonary function

TABLE IV. Independent Risk Factors for 90-Day Mortality in the Total Patient Cohort (N = 664)

Risk factor	OR	95% CI	*P* value[a]
Preoperative dialysis	23.3	1.5-373.9	.03[a]
Kidney replacement therapy	8.2	2.4-27.6	<.001[a]
Postoperative tracheostomy	5.7	1.6-20.1	.01[a]
Preoperative intubation	4.1	0.9-17.9	.06
Postoperative serum albumin	3.4	0.8-15.0	.11
mRAP/PCWP	3.1	0.5-21.1	.25
Preoperative mechanical circulatory support	2.5	0.4-13.8	.31
Reoperation for bleeding	2.2	0.4-12.3	.35
INTERMACS 1	2.0	0.2-18.9	.54
Previous sternotomy	1.1	0.5-3.1	.65
Postoperative serum creatinine	1.1	0.6-2.0	.83
Age	1.0	0.97-1.05	.75
Destination therapy	1.0	0.2-4.1	>.99
Deep sternal wound infection	0.6	0.1-3.5	.59

INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; mRAP/PCWP, mean right atrial pressure/pulmonary capillary wedge pressure; OR, odds ratio.

[a]Significant at $P < .05$.

tests (PFTs) would intuitively be considered predictive of the need for postoperative tracheostomy, 2 other investigators did not find any relationship.[12,13] Rather, poor PFT results correlated with pulmonary congestion. Of note, PFTs were performed in 54% of the overall cohort, comparable to the percentages in 3 other investigations analyzing PFTs in LVAD patients, which ranged from 16% to 72%.[12,14,15]

Patients for whom CF-LVAD implantation is planned may be in cardiogenic shock with decompensated heart failure and may need intubation before temporary mechanical circulatory support is initiated. Nationwide, 20% of patients admitted for heart failure and 40% of those admitted for cardiogenic shock require mechanical ventilation.[16] These patients are typically extubated expeditiously to permit meaningful discussion with the patient and family about therapeutic options before proceeding, if feasible, to durable CF-LVAD implantation. Combined preoperative and postoperative mechanical ventilation may promote muscle wasting from sustained immobility, ventilator-associated infections, and exacerbated left and right ventricular dysfunction,[17-19] contributing to poor survival. In the present study, preoperative mechanical ventilation was not associated with 90-day mortality; however, another study found that preoperative mechanical ventilation increased postimplantation mortality nearly 12-fold.[20] These discordant findings may result from differences in the duration of preoperative mechanical ventilation and whether patients were extubated before implantation.

Kidney injury and respiratory failure were clearly related in this study. After propensity matching, preoperative dialysis was more frequent in the tracheostomy group (15.5% vs 4.9%, adjusted for serum creatinine and kidney failure). Nevertheless, the tracheostomy group had significantly higher rates of postoperative AKI (61.5% vs 19.4%) and need for KRT (40.8% vs 16.5%). These relationships are further strengthened by the finding that baseline serum creatinine was the strongest predictor of the need for tracheostomy, whereas preoperative dialysis was not an independent risk factor. Conversely, preoperative dialysis independently predicted 90-day mortality, whereas serum creatinine did not. Indeed, early mortality in CF-LVAD recipients with preopera-

tive dialysis for AKI exceeds 80%.[21] Although a clear association between tracheostomy and AKI has not been reported, prolonged mechanical ventilation increases risk for kidney failure after cardiac surgery.[22,23] In an INTERMACS registry analysis, kidney failure followed by respiratory failure was the most common adverse-event sequence leading to early death after LVAD implantation.[24] We previously reported that 36% of patients needing KRT after CF-LVAD implantation had respiratory failure necessitating tracheostomy and that right ventricular dysfunction was associated with the need for KRT.[25] Thus, strategies to reduce the risk of AKI may also reduce the risk of respiratory failure.[25]

Other important risk factors for respiratory failure have been identified. In the present analysis, reoperation for bleeding was significantly more common in the tracheostomy group, similar to results from other studies that found associations between prolonged mechanical ventilation and reoperation for bleeding after cardiac surgery,[26] thoracic aortic surgery,[27] and CF-LVAD implantation.[8,26,27] Blood-product transfusions combined with transfusion-related acute lung injury can increase respiratory failure,[28] and even 1 or 2 units of packed red blood cells can double the risk for pneumonia. Therefore, meticulous surgical technique and blood conservation are recommended.[29,30] This study found that higher preoperative hemoglobin protected against needing tracheostomy, possibly because higher preoperative hemoglobin may reduce the need for postoperative transfusions or may indicate less baseline kidney dysfunction or chronic disease. This finding suggests that anemia should be treated before CF-LVAD implantation.

No differences were observed in the need for a right ventricular assist device in either the unmatched or matched groups, despite the tracheostomy groups' higher mRAP/PCWP ratios—possibly because some patients who received a right ventricular assist device did not survive to tracheostomy.

Tracheostomy was associated with worse early and midterm survival in both the unmatched and matched groups, signifying that optimal patient selection is critical. Patients intubated preoperatively and needing KRT may have too high a risk for early (or any) durable CF-LVAD implantation; bridging with an axial-flow pump (eg, Impella 5.5 [Abiomed]) and several weeks of rehabilitation and physical therapy may reduce the risk for postoperative respiratory failure. This decision is complex because delaying durable CF-LVAD implantation may provoke otherwise-preventable complications.

This study design did not include tracheostomy timing, which prevented meaningful comparison of early (within 7 days of surgery) vs later tracheostomy. A systematic review of 10,088 patients who underwent tracheostomy after cardiac surgery found comparable rates of sternal wound infection and short-term mortality for both early and late tracheostomy.[31] In this study, a similar deep sternal wound infection rate that was significantly higher in the tracheostomy group before propensity matching (9.4% vs 5.9%) was noted but was not significantly higher after matching. Although the overall stroke rate (approximately 5%) was comparable between the tracheostomy and nontracheostomy groups, no information was available on what proportion would be classified as disabling in each group.

Strategies to reduce the rate of respiratory failure are essential. First and foremost, thoughtful patient selection is necessary. Before surgery, nutrition should be optimized whenever possible. Preoperative mobility may be difficult to achieve if a mechanical circulatory support device is in place. Intraoperatively, lung-protective ventilation that optimizes driving pressure, tidal volume, and positive end-expiratory pressure can limit postoperative respiratory failure.[32] Postoperative strategies to reduce risks from prolonged mechanical ventilation include adherence to the ABCDEF Bundle (A = assessment, prevention, and management of pain; B = both spontaneous awakening trials and spontaneous breathing trials; C = choice of sedation and analgesia; D = delirium assessment, prevention, and management; E = early mobility and exercise; and F = family engagement and empowerment)[33] and early mobilization with physical therapy.[34] In patients who are borderline candidates for liberation from mechanical ventilation, noninvasive ventilation can permit earlier extubation.[35] Going forward, larger-scale, multicenter trials will be important not only to identify additional risk factors but also to determine whether better preoperative optimization or enhanced perioperative management can improve respiratory failure outcomes and reduce the need for tracheostomy.

Study Limitations

This study is limited primarily by its retrospective, single-center design, which affected the number of variables available for analysis. First, preoperative factors

that may have been informative, such as ambulation, were not captured in the database. Second, the study could not determine whether tracheostomy was needed because of isolated postoperative respiratory failure or was secondary to respiratory failure driven by kidney, neurologic, or right ventricular dysfunction (patients with isolated respiratory failure would probably have more favorable outcomes than patients with multisystem organ dysfunction). Third, database limitations precluded accurate assessment of the proportion of patients decannulated after tracheostomy during late follow-up. Finally, this study did not include patients with the newer HeartMate 3 CF-LVAD. Although the HeartMate 3 is associated with a lower incidence of bleeding and pump thrombosis, the type of CF-LVAD model is unlikely to affect the need for postoperative tracheostomy.[36]

Conclusion

In both the overall cohort and propensity-matched groups, tracheostomy was associated with increased early mortality and worse survival. These outcomes highlight the need for careful patient selection and optimal perioperative management. The risk for respiratory failure requiring tracheostomy—especially in patients at high risk of severe AKI—may prompt reevaluation before CF-LVAD implantation. Future multicenter studies aimed at patient selection, optimal timing for tracheostomy, and perioperative management may provide insight for improving survival and reducing morbidities associated with CF-LVAD implantation.

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Harveen K. Lamba contributed to conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing (original draft); and writing (review and editing). Lucy D. Hart contributed to conceptualization; data curation; formal analysis; investigation; methodology; project administration; resources; software; validation; visualization; writing (original draft); and writing (review and editing). Qianzi Zhang contributed to conceptualization; formal analysis; methodology; project administration; resources; software; supervision; validation; visualization; writing (original draft); and writing (review and editing). Jackquelin M. Loera contributed to conceptualization; data curation; formal analysis; investigation; methodology; resources; software; validation; visualization; writing (original draft); and writing (review and editing). Andrew B. Civitello contributed to conceptualization; formal analysis; investigation; methodology; resources; supervision; validation; visualization; writing (original draft); and writing (review and editing). Ajith P. Nair contributed to conceptualization; formal analysis; investigation; methodology; resources; supervision; validation; visualization; writing (original draft); and writing (review and editing). Mourad H. Senussi contributed to conceptualization; formal analysis; investigation; methodology; resources; supervision; validation; visualization; writing (original draft); and writing (review and editing). Gabriel Loor contributed to conceptualization; formal analysis; investigation; methodology; resources; supervision; validation; visualization; writing (original draft); and writing (review and editing). Kenneth K. Liao contributed to conceptualization; formal analysis; investigation; methodology; resources; supervision; validation; visualization; writing (original draft); and writing (review and editing). Alexis E. Shafii contributed to conceptualization; formal analysis; investigation; methodology; resources; supervision; validation; visualization; writing (original draft); and writing (review and editing). Subhasis Chatterjee contributed to conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing (original draft); and writing (review and editing).

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