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Experience With SynCardia Total Artificial Heart as a Bridge to Transplantation in 100 Patients

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Abstract

BACKGROUND—The SynCardia temporary total artificial heart (TAH-t) is an effective bridge to transplantation for patients with severe biventricular failure. However, granular single-center data from high-volume centers are lacking. We report our experience with the first 100 TAH-t recipients.

METHODS—A prospective institutional database was used to identify 100 patients who underwent 101 TAH-t implantations between 2012 and 2022. Patients were stratified and compared according to Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile 1 vs 2 or greater. Median follow-up on device support was 94 days (interquartile range, 33–276), and median follow-up after transplantation was 4.6 years (interquartile range, 2.1–6.0).

RESULTS—Overall, 61 patients (61%) were successfully bridged to transplantation and 39 (39%) died on TAH-t support. Successful bridge rates between INTERMACS profile 1 and INTERMACS profile 2 or greater patients were similar (55.6% [95% CI, 40.4%-68.3%] vs 67.4% [95% CI, 50.5%-79.6%], respectively; $P = .50$). The most common adverse events (rates per 100 patient-months) on TAH-t support included infection (15.8), ischemic stroke (4.6), reoperation for mediastinal bleeding (3.5), and gastrointestinal bleeding requiring intervention (4.3). The

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DISCLOSURES

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most common cause of death on TAH-t support was multisystem organ failure (n = 20, 52.6%). Thirty-day survival after transplantation was 96.7%; survival at 6 months, 1 year, and 5 years after transplantation was 95.1% (95% CI, 85.4%-98.4%), 86.6% (95% CI, 74.9%-93.0%), and 77.5% (95% CI, 64.2%-86.3%), respectively.

CONCLUSIONS—Acceptable outcomes can be achieved in the highest acuity patients using the TAH-t as a bridge to heart transplantation.

The SynCardia temporary total artificial heart (TAH-t) has been a US Food and Drug Administration-approved bridge to transplantation device since 2004, after landmark findings demonstrating improved survival to transplantation and improved survival after transplantation with the TAH-t compared with medical management.[1] Despite promising early results, adoption of the TAH-t has been limited, accounting for less than 2% of all durable mechanical circulatory support (MCS) implants in the modern era.[2]

Although left ventricular assist device implantation represents the majority of durable MCS implants for patients with advanced heart failure, as many as 20% to 30% will subsequently have right heart failure requiring extended inotrope therapy or short-term MCS support.[3–5] In the subset of patients with biventricular failure who are transplant eligible, the TAH-t offers an alternative mechanical support strategy. Given the ongoing shortage of donor cardiac allografts, the TAH-t may provide the necessary intermediate- or long-term biventricular support needed to stabilize and subsequently transplant these patients.

Although more than 1700 SynCardia TAH-t implantations have been performed worldwide, very few centers have performed 100 or more TAH-t implantations.[6,7] Because the knowledge and experience gained from the current SynCardia TAH-t will play an important role in the future management of patients with severe biventricular failure, we reported our center's experience with the first 100 TAH-t recipients.

PATIENTS AND METHODS

DATA SOURCE.

Using a prospectively collected single-institution database, we identified 101 TAH-t implantations performed in 100 patients as a bridge to heart transplantation between January 16, 2012, and February 4, 2022. One patient required TAH-t replacement due to device malfunction. Median duration of follow-up while on device support was 94 days (interquartile range [IQR], 33–276), and median follow-up after transplantation was 4.6 years (IQR, 2.1–6). Completeness of follow-up was 100%, and the last date of follow-up was August 8, 2022. Patients were stratified according to Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile at the time of implantation into those with INTERMACS profile 1 and INTERMACS profile 2 or greater. In secondary analyses, patients were stratified by whether they required extracorporeal membrane oxygenation (ECMO) before TAH-t implantation and by implantation era.

This study was approved by the Institutional Review Board at Cedars-Sinai Medical Center, with a waiver of informed consent (protocol ID: STUDY00001188, approval date 2/19/2021).

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PRIMARY AND SECONDARY OUTCOMES.

The primary outcome was survival to heart transplantation. Secondary outcomes included postimplantation adverse events while on device support and posttransplant survival among patients who were successfully bridged. Neurologic events included transient ischemic attack, ischemic stroke (defined as neurologic deficit lasting longer than 24 hours), intracranial hemorrhage (defined as intraparenchymal or subarachnoid hemorrhage), seizures, encephalopathy, and anoxic brain injury. Infectious events included respiratory, urinary tract, gastrointestinal, sternal wound, bloodstream, driveline infections, and mediastinitis. Bleeding complications were defined as mediastinal bleeding requiring reoperation and gastrointestinal bleeding requiring endoscopic intervention.

STATISTICAL ANALYSES.

Baseline patient characteristics were reported as mean ± SD or median with IQR for continuous variables depending on the distribution. Categoric variables were reported as absolute numbers and percentages. Between-group comparisons for continuous variables were performed with Student's *t* test or Wilcoxon rank sum test depending on distribution, and between-groups comparisons for categoric variables were performed with Pearson's χ^2 test.

The cumulative incidences of death while on the device and heart transplantation were constructed utilizing a competing risk analysis. Patients were stratified by INTERMACS category, ECMO support before TAH-t implant, and era of implant (first 10 implants vs subsequent implants), and between-group differences were compared utilizing Gray's test. Posttransplant survival was analyzed using the Kaplan-Meier method and compared between strata using the log rank test. Multivariable analyses were not performed owing to the limited overall sample size. Missing baseline characteristic data are represented in Table 1 as total number (n) of patients with available data for each variable.

All tests were two-tailed with an alpha level of 0.05. All statistical analyses were performed with SAS 9.4 (SAS Institute).

RESULTS

PATIENT POPULATION.

Over the study period, 101 TAH-t implantations were performed in 100 patients. The annual volume increased from 1 case in 2012 to 24 cases in 2014, and subsequently declined thereafter to 1 case in 2022 (Figure 1). Fifty-four patients had INTERMACS profile 1, and 46 patients had INTERMACS profile 2 or greater, including 29 (63%) with INTERMACS profile 2, 10 (21.7%) with INTERMACS profile 3, 6 (13%) with INTERMACS profile 4, and 1 (2.2%) with INTERMACS profile 5. The median length of TAH-t support was 94 days (IQR, 33–276; range, 0–849).

Table 1 demonstrates baseline patient characteristics. In the overall cohort, 83 patients (83%) were male, and the median age was 53 years (IQR, 41.5–60.5). The primary diagnosis necessitating TAH-t implantation included idiopathic dilated cardiomyopathy in 42 patients,

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ischemic dilated cardiomyopathy in 25 patients, and restrictive amyloidosis in 9 patients. Left ventricular ejection fraction was severely reduced (less than 20%) in 54 patients, and the median left ventricular enddiastolic diameter was 6.8 cm (IQR, 5.5–7.6 cm). Right ventricular dysfunction was moderate in 33 patients and severe in 37 patients. The 50 cc device was placed in 7 patients (1 patient, body surface area less than 1.5 m^2; 4 patients, body surface area 1.5–1.75 m^2; and 2 patients, body surface area greater than 1.75 m^2).

Compared with patients with INTERMACS profile 2 or greater, INTERMACS profile 1 patients had a shorter median length of TAH-t support (73.5 days [IQR, 25–150] vs 159 days [IQR, 45–402], $P = .02$), more frequent pre-implantation ECMO use (53.7% vs 0%, $P < .001$), and increased use of the 50 cc device (13.2% vs 0%, $P = .01$). INTERMACS profile 1 patients also had lower systemic systolic blood pressure (96 mm Hg [IQR, 89–104 mm Hg] vs 101 mm Hg [IQR, 94–110 mm Hg], $P = .04$) and increased need for inotropic support at time of implantation (86.4% vs 62.8%, $P = .01$). A numerically higher proportion of INTERMACS profile 1 patients required dialysis before TAH-t implantation (10% vs 2.3%, $P = .13$) and had severe right ventricular dysfunction (46.3% vs 26.1%, $P = .08$).

POST-TAH-T IMPLANTATION OUTCOMES.

After TAH-t implantation, 61 patients (61%) survived to heart transplantation and 39 (39%) died on TAH-t support. The cumulative incidence of transplantation at 30 days, 6 months, and 1 year after TAH-t implantation was 6% (95% CI, 2.4%-11.9%), 34% (95% CI, 24.8%-43.4%), and 46% (95% CI, 35.9%-55.5%), respectively. The cumulative incidence of death on TAH-t support at 30 days, 6 months, and 1 year was 18% (95% CI, 11.2%-26.1%), 33% (95% CI, 24%-42.3%), and 34% (95% CI, 24.9%-43.3%), respectively (Figure 2A).

When stratified by INTERMACS profile, the cumulative incidence of transplantation was 55.6% (95% CI, 40.4%-68.3%) for INTERMACS profile 1 patients and 67.4% (95% CI, 50.5%-79.6%) for INTERMACS profile 2 or greater patients ($P = .50$). The cumulative incidence of death on TAH-t support was 44.4% (95% CI, 30.5%-57.5%) for INTERMACS profile 1 patients and 32.6% (95% CI, 19.3%-46.6%) for INTERMACS profile 2 or greater patients ($P = .22$; Figures 2B, 2C).

Of the patients supported by ECMO before TAH-t implantation, 48.3% survived to heart transplantation vs 66.2% of patients not requiring ECMO support ($P = .43$). Of the institution's first 10 implants, 70% survived to heart transplantation vs 60% of the subsequent implants ($P = .54$).

Causes of death while on TAH-t support included multisystem organ failure (52.6%), neurologic dysfunction (29.0%), major infection (7.9%), major bleeding (2.6%), device malfunction (2.6%), and withdrawal of support (5.2%). Causes of death stratified by INTERMACS groups are shown in Table 2.

Adverse events under TAH-t support are highlighted in Table 3. The most common adverse events were infection (particularly respiratory), ischemic stroke, and major mediastinal or gastrointestinal bleeding requiring intervention. There were a total of 28 ischemic strokes occurring after TAH-t implantation at a median 15.5 days (IQR, 6.5–30.5), as

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well as 9 intracranial hemorrhages occurring after implantation at a median 13 days (IQR, 5–14; Supplemental Figure 1). There were no statistically significant differences in incidence of neurologic or infectious complications between INTERMACS groups, whereas a significantly higher proportion of INTERMACS profile 2 or greater patients required at least one reoperation for mediastinal bleeding (26.1% vs 7.4%, $P = .01$).

CHARACTERISTICS AND OUTCOMES OF HEART TRANSPLANT RECIPIENTS.

Baseline characteristics before heart transplantation for the 61 successfully bridged patients are summarized in Supplemental Table 1. Sixteen patients (26.2%) were outpatient at the time of organ offer. Nine patients (14.8%), none of whom was ventilator dependent, underwent transplantation from the intensive care unit. Sixteen patients (26.2%) were dialysis-dependent, all of whom underwent concomitant kidney transplant. End organ recovery is depicted in Supplemental Figure 2. Survival after transplant for the 61 TAH-t patients who survived to transplantation is depicted in Figure 3A. Thirty-day survival was 96.7%; survival at 6 months, 1 year, and 5 years after transplantation was 95.1% (95% CI, 85.4%-98.4%), 86.6% (95% CI, 74.9%-93%), and 77.5% (95% CI, 64.2%-86.3%), respectively. There was no difference in 5-year posttransplant survival between outpatient and inpatient transplant recipients ($P = .38$; Figure 3B).

COMMENT

In this study, we report our experience using TAH-t as a bridge to transplantation, with a successful bridge rate of 61% and 1-year posttransplant survival rate of 86.6%. Our results are consistent with the most recent INTERMACS report, which demonstrated a successful bridge rate of 62%, as well as with a multicenter study of six high-volume North American centers that demonstrated a 1-year posttransplantation survival rate of 84%.[8,9] Furthermore, our posttransplant survival rates compared favorably with the 79.5% 1-year survival reported in recent analyses of the national United Network for Organ Sharing database.[10,11]

Our center has performed a greater proportion of implants in INTERMACS profile 1 patients, accounting for 53.5% of our cohort as compared with 43% in the national cohort.[8] These patients are typically referred to as “crash and burn” patients, with worsening cardiogenic shock despite the escalation of multiple inotropes necessitating mechanical circulatory support.[12] Indeed, more than 50% of our INTERMACS profile 1 patients required ECMO before TAH-t implantation. A recent analysis of combination therapy of ECMO and TAH-t as a bridge-to-bridge approach highlighted the feasibility of this strategy, with more than 60% of patients surviving to transplantation and a 1-year posttransplant survival rate of 94%.[13] In our study, although INTERMACS profile 1 patients were less frequently bridged to transplantation, this difference did not reach statistical significance. Our findings thus support the use of TAH-t in this extremely high-risk population of patients who may have no other option for survival.

The morbidity of TAH-t implantation is not to be underestimated. The proportion of patients having at least one ischemic or hemorrhagic stroke was 23%, with rates of 4.6 ischemic strokes and 1.5 hemorrhagic strokes per 100 patient-months, consistent with previous reports.[8] Furthermore, despite an institutional policy of delayed chest closure,[14]

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16% of patients required at least one urgent/emergent redo sternotomy in the setting of tamponade. These adverse events, in combination with the considerable rate of endoscopic intervention for gastrointestinal bleeding, highlight the critical balance between appropriate anticoagulation therapy and the prothrombotic state of the TAH-t.[15]

Although severe biventricular failure remains the primary indication for TAH-t implantation, only 37% of our patients had severe right ventricular dysfunction. In the remaining cohort, indications for TAH-t implantation included refractory ventricular arrhythmias, failed isolated left ventricular support, intraoperative worse right ventricular dysfunction than determined preoperatively, and severe cardiac allograft vasculopathy. Other indications amenable to TAH-t implantation previously reported include primary cardiac malignancies, post-infarction ventricular septal defects, high-burden left ventricular thrombus, and congenital heart lesions such as failed Fontan circulation.[16,17]

The role of center volume in outcomes after implantation among TAH-t patients has been well established. The 2018 INTERMACS report demonstrated that center volume less than or equal to 10 total cases of TAH-t implantation was a significant risk factor for mortality, with a 12-month survival of 36.7% vs 64.8% at high-volume centers.[8] This observation was further supported by Itagaki and colleagues[10] who demonstrated markedly improved device and survival after transplantation at higher volume centers. Notably, our institutional data comparing outcomes between the first 10 TAH-t implants and subsequent implants demonstrated no significant difference in successful bridging, suggesting that, with careful guidance, other centers could adopt the TAH-t without excessive morbidity and mortality.

The utilization of TAH-t at our center has decreased dramatically. That decrease is in large part due to improvements in short-term MCS options such as ECMO and improved outcomes with left ventricular assist device therapy.[3,18] In addition, the 2018 adult heart allocation policy revisions altered the landscape of MCS use in heart transplantation. Whereas they were formerly listed as the most urgent status 1A, TAH-t patients are now listed as status 2 and those on ECMO and nondischargeable ventricular assist devices are listed as status 1.[19–21] Because of that, patients on ECMO can obtain a higher priority status and donor organ offers in a more expeditious manner.

Despite the relative benefits of short-term MCS in the new allocation era, there remains a select subset of patients who meet our institutional criteria for TAH-t evaluation. That includes the following groups: transplant-eligible patients on ECMO for greater than 5 to 7 days with severe biventricular failure; patients with refractory ventricular arrhythmias; patients with severe amyloidosis who cannot accommodate a left ventricular assist device; and patients with severe biventricular failure and very large body habitus or type O blood who are expected to have longer-than-normal waitlist times.

The future of the TAH-t remains uncertain. Nationally, despite the increasing volume of heart transplantation and ongoing donor organ shortage, the utilization of TAH-t as a bridge to transplant remains scarce, accounting for only 6 cases in the year 2020.[11] Although the TAH-t is currently approved by the Food and Drug Administration only as a bridge to transplantation, there are ongoing clinical trials of the device as destination therapy

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(NCT0223265). Nonetheless, our experience with the TAH-t over the last decade has proven it effective in bridging patients with advanced heart failure to transplantation.

STUDY LIMITATIONS.

Our study is limited by the inherent biases present in a single-center retrospective study. Namely, this cohort represents a highly selected group of patients at a high-volume transplant center and hence patient selection likely played a significant role in outcomes. In addition to their preoperative workup and selection, these patients were also treated with institutional policies that may limit generalizability. Owing to the limited number of patients in our cohort, our study may be underpowered to detect subtle differences in outcomes. Furthermore, the purpose of this study was to provide a realistic benchmark of the application of the TAH-t from a high-volume center. Given the sample size and unique characteristics of patients supported with TAH-t, we did not perform comparisons with other forms of MCS bridge strategies. Finally, most of our TAH-t implants were performed before the implementation of the new United Network for Organ Sharing heart allocation system; therefore, the observed rates and time to transplantation may not be representative or reproducible with the current policy.

CONCLUSION.

Our center's experience with TAH-t demonstrates the excellent bridging and posttransplant survival that can be obtained with this device even when used in the highest-acuity patients. Although the use of TAH-t at our center and across the United States has decreased markedly, the TAH-t may continue to serve as an effective therapeutic option in a select subset of patients with advanced heart failure who may not survive otherwise.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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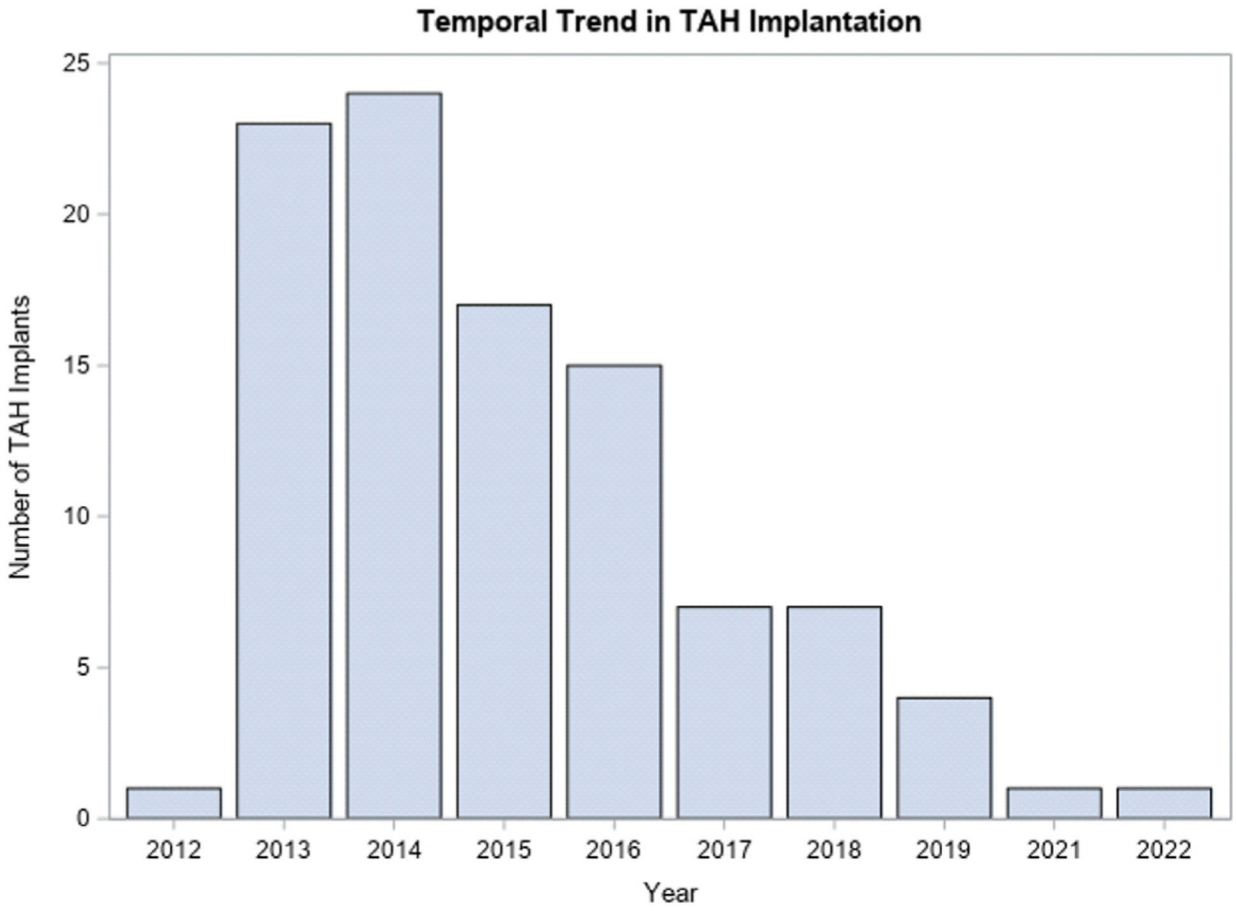

FIGURE 1.
Temporal trend in total artificial heart (TAH) implantation.

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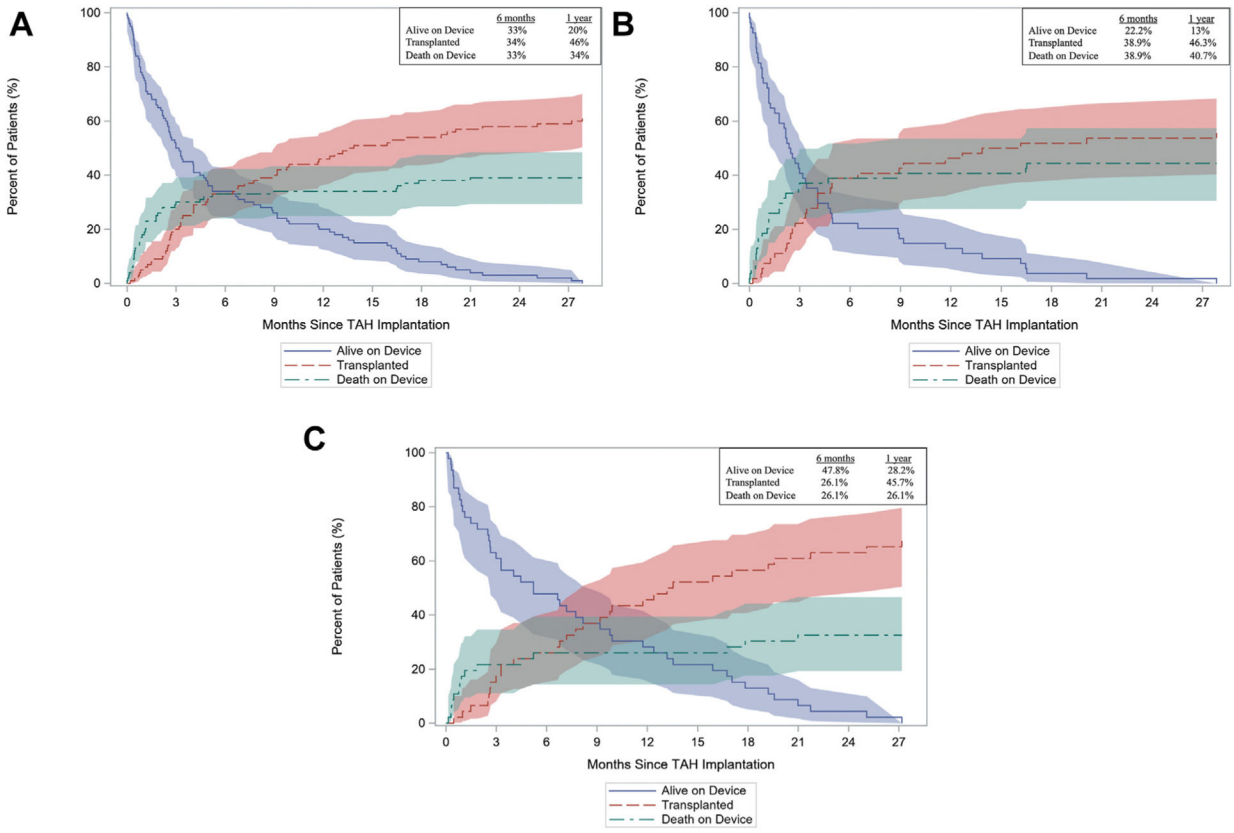

FIGURE 2.

Competing risk analysis of the mutually exclusive events of death on device (green line), transplantation on device (red line), and remaining alive on device support (blue line) for (A) entire cohort, (B) INTERMACS profile 1 patients, and (C) INTERMACS profile 2 or greater patients. Shaded areas indicate 95% confidence limits. (INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; TAH, total artificial heart.)

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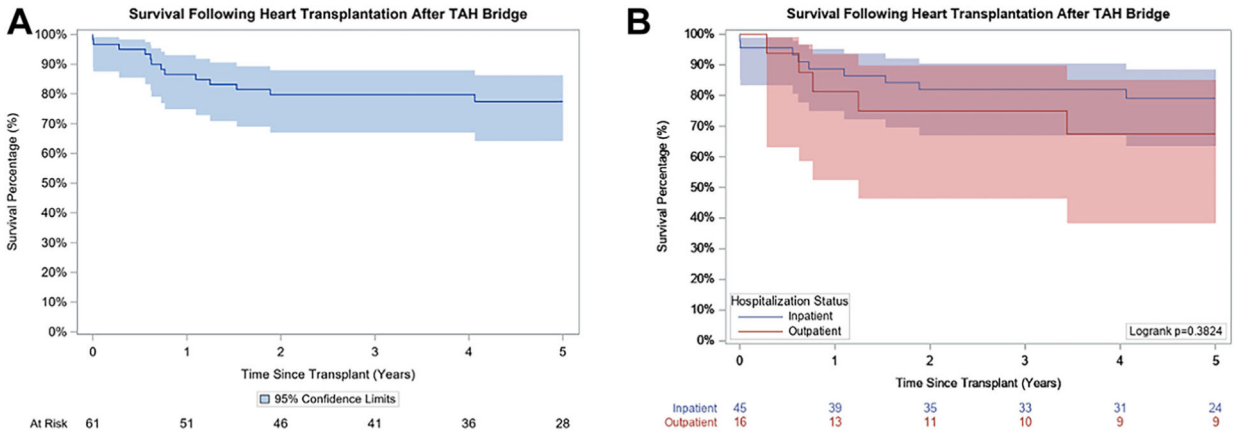

FIGURE 3.

(A) Total survival after heart transplantation after total artificial heart (TAH) bridge. (B) Survival stratified by inpatient (blue line) vs outpatient (red line) status at transplantation. Shaded areas indicate 95% confidence limits.

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TABLE 1

Baseline Patient Characteristics

Characteristics	Total (N = 100)	INTERMACS 1 (n = 54)	INTERMACS 2+ (n = 46)	*P* Value
Length of support, d (n = 100)	94 (33–276)	73.5 (25–150)	159 (45–402)	.02
Length of support (n = 100)				
>6 months	34 (34)	12 (22.2)	22 (47.8)	.01
>1 year	19 (19)	6 (11.1)	13 (28.3)	.03
>18 months	8 (8)	2 (3.7)	6 (13.0)	.09
Age at implant, y (n = 100)	53 (41.5–60.5)	51 (40–60)	53.5 (47–61)	.41
Sex (n = 100)				
Female	17 (17)	12 (22.2)	5 (10.9)	.13
Male	83 (83)	42 (77.8)	41 (89.1)	
Race (n = 100)				.17
White	72 (72)	38 (70.4)	34 (73.9)	
African-American/Black	18 (18)	8 (14.8)	10 (21.7)	
Asian	7 (7)	6 (11.1)	1 (2.2)	
Hawaiian/Pacific Islander	1 (1.0)	0 (0)	1 (2.2)	
Other	2 (2.0)	2 (3.7)	0 (0)	
Body surface area, m^2				.48
<1.5	4 (4)	3 (5.6)	1 (2.2)	
1.5–1.75	9 (9)	6 (11.1)	3 (6.5)	
>1.75	87 (87)	45 (83.3)	42 (91.3)	
BMI, kg/m^2 (n = 98)	26.6 (24.2–30.2)	27.1 (24.5–31)	26.4 (23.6–29.3)	.49
Preimplant stroke (n = 95)	8 (8.4)	4 (7.8)	4 (9.1)	.83
Diabetes mellitus (n = 100)	22 (22)	11 (20.4)	11 (23.9)	.40
Preimplant Cr, mg/dL (n = 87)	1.4 (1.0–2.2)	1.4 (1.0–1.9)	1.6 (1.0–2.3)	.36
Chronic kidney disease (n = 95)	32 (33.7)	16 (31.4)	16 (36.4)	.61
Previous dialysis (n = 95)	6 (6.3)	5 (9.8)	1 (2.3)	.13
Hypertension (n = 95)	38 (40)	18 (35.3)	20 (45.5)	.31
Smoking history (n = 95)	42 (44.2)	22 (43.1)	20 (45.5)	.82
History of AF (n = 95)	50 (52.6)	26 (51.0)	24 (54.6)	.73

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Characteristics	Total (N = 100)	INTERMACS 1 (n = 54)	INTERMACS 2+ (n = 46)	*P* Value
History of VT/VF (n = 95)	70 (73.7)	36 (70.6)	34 (77.3)	.46
Prior malignancy (n = 95)	5 (5.3)	3 (5.9)	2 (4.5)	.77
Prior cardiac surgery (n = 100)	23 (23)	15 (27.8)	8 (17.4)	.22
ECMO before TAH-t (n = 100)	29 (29)	29 (53.7)	0 (0)	<.001
Device type (n = 100)				.01
50 cc	7 (7)	7 (13)	0 (0)	
70 cc	93 (93)	47 (87)	46 (100)	
INTERMACS profile (n = 100)				
1	54 (54)	54 (100)	0 (0)	
2	29 (29)		29 (63.0)	
3	10 (10)		10 (21.7)	
4	6 (6)		6 (13.0)	
5	1 (1)		1 (2.2)	
Primary diagnosis (n = 100)				.57
Congenital heart disease	2 (2)	2 (3.7)	0 (0)	
Dilated myopathy, idiopathic	42 (42)	21 (38.9)	21 (45.7)	
Dilated myopathy ischemic	25 (25)	16 (29.6)	9 (19.6)	
Dilated myopathy, other	10 (10)	6 (11.1)	4 (8.7)	
Hypertrophic cardiomyopathy	2 (2)	0 (0)	2 (4.4)	
Restrictive, amyloidosis	9 (9)	3 (5.6)	6 (13)	
Restrictive myopathy, other	7 (7)	5 (9.3)	2 (4.4)	
Valvular heart disease	3 (3)	1 (1.9)	2 (4.4)	
CI, L/min/m^2 (n = 50)	2.0 (1.6–2.6)	1.9 (1.5–2.4)	2.0 (1.6–2.6)	.39
SBP, mm hg, n = 81	99 (91–108)	96 (89–104)	101 (94–110)	.04
DBP, mm hg, n = 81	65 (59–73)	67 (59–72)	64.5 (58–73)	.68
PASP, mm hg, n = 60	47 (38.5–59.5)	47 (IQR, 34–60)	48 (42–59)	.41
PADP, mm hg, n = 60	27 (22–30.5)	28 (20–32)	27 (23–30)	.70
PAWP, mm hg, n = 23	27 (22–32)	28 (25–30)	25.5 (21–32)	.80
CVP, mm hg, n = 65	12 (7–16)	11 (7–15)	13 (6–18)f	.49
LVEDD, cm (n = 64)	6.8 (5.5–7.6)	6.6(4.7–7.3)	6.8 (5.5–7.6)	.42
LVEF (n = 100)				.98

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Characteristics	Total (N = 100)	INTERMACS 1 (n = 54)	INTERMACS 2+ (n = 46)	*P* Value
≥50, normal	5 (5)	3 (5.7)	2 (4.4)	
40–49, mild	8 (8)	4 (7.4)	4 (8.7)	
30–39 moderate	9 (9)	5 (9.3)	4 (7.7)	
20–29, moderate/severe	24 (24)	14 (25.9)	10 (21.7)	
<20, severe	54 (54)t	28 (51.9)	26 (56.5)	
RV function (n = 100)				.08
Normal	13 (13)	4 (7.4)	9 (19.6)	
Mild dysfunction	17 (17)	7 (13)	10 (21.7)	
Moderate dysfunction	33 (33)	18 (33.3)	15 (32.6)	
Severe dysfunction	37 (37)	25 (46.3)	12 (26.1)	
IV inotrope Therapy, n = 87	65 (74.7)	38 (86.4)	27 (62.8)	.01
INTERMACS modifier, n = 64				<.001
Arrhythmia	15 (23.4)	2 (4.6)	13 (65)	
TCS	44 (68.8)	37 (84.1)	7 (35)	
Arrhythmia and TCS	5 (7.8)	5 (11.4)	0 (0)	

Values are median (interquartile range) or n (%). AF, atrial fibrillation; BMI, body mass index; CI, cardiac index; Cr, creatinine; CVP, central venous pressure; DBP, diastolic blood pressure; ECMO, extracorporeal membrane oxygenation; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; IV, intravenous; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; PADP, pulmonary artery diastolic pressure; PASP, pulmonary artery systolic pressure; PAWP, pulmonary artery wedge pressure; RV, right ventricular; SBP, systolic blood pressure; TAH-t; temporary total artificial heart; TCS, temporary circulatory support; VT/VF, ventricular tachycardia/ventricular fibrillation.

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TABLE 2

Cause of Death While on Total Artificial Heart Support

Mechanism of Death	Total (N = 38)	INTERMACS 1 (n = 23)	INTERMACS 2+ (n = 15)	*P* Value
Multisystem organ failure	20 (52.6)	13 (56.5)	7 (46.7)	0.45
Neurologic dysfunction	11 (29)	5 (21.7)	6 (40.0)	
Major infection	3 (7.9)	2 (8.7)	1 (6.7)	
Major bleeding	1 (2.6)	1 (4.4)	0 (0)	
Device malfunction	1 (2.6)	0 (0)	1 (6.7)	
Withdrawal of support	2 (5.3)	2 (8.7)	0 (0)	

Values are n (%). INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support.

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TABLE 3

Adverse Events Under Total Artificial Heart Support

Adverse Event	Patients With ≥1 Event (n [%])	Total Number Events	Events per 100 Patient-Months
Neurologic			
Transient ischemic attack	4 (4)	5	0.82
Ischemic stroke	17 (17)	28	4.60
Intracranial hemorrhage	8 (8)	9	1.48
Seizures	4 (4)	4	0.66
Anoxic brain injury	1 (1)	1	0.16
Encephalopathy	1 (1)	1	0.16
Infectious			
Any major infection	45 (45)	96	15.77
Respiratory	30 (30)	36	5.91
Urinary tract	13 (13)	16	2.62
Gastrointestinal	11 (11)	11	1.81
Sternal wound	1 (1)	1	0.16
Mediastinitis	3 (3)	3	0.49
Bloodstream	5 (5)	6	0.99
Driveline	4 (4)	7	1.15
Bleeding			
Mediastinal[a]	16 (16)	21	3.45
Gastrointestinal[b]	18 (18)	26	4.27

[a]Requiring reoperation;

[b]Requiring endoscopic intervention.

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