

Outcomes of heart transplant recipients with prior left ventricular assist device associated stroke

Aaron Shoskes, DO,^a Merry Huang, MD,^a Catherine Hassett, DO,^b
Randall C Starling, MD, MPH,^c Eileen Hsich, MD,^c Edward Soltesz, MD,^d
Sung-Min Cho, DO, MHS,^e and Ken Uchino, MD^b

Background: Left ventricular assist devices (LVADs) improve survival in patients with end-stage heart failure but are associated with ischemic stroke and intracranial hemorrhage (ICH). The impact of LVAD-associated stroke on transplant candidacy and outcomes has not been characterized. **Methods:** Adult patients undergoing LVAD implantation at Cleveland Clinic between 2004 to 2021 were reviewed and patients who developed ischemic stroke or ICH were identified. Post-transplant survival analysis was performed between patients with LVAD-associated stroke vs. without. **Results:** 917 patients had an LVAD implantation of whom 244 (median age 57, 79% male) underwent subsequent transplant including 25 with prior LVAD-associated stroke. The 1- and 2-year survival after transplant in patients with LVAD-associated stroke were 100% and 95% respectively, compared with 92% and 90% in patients without stroke ($p=0.156$; $p=0.323$). Similarly, there was no difference in stroke incidence at 1- and 2 years after transplant between patients with LVAD-associated stroke (4% and 5%) and those without prior stroke (5% and 6%, $p=0.884$; $p=0.744$). **Conclusions:** In this single-center retrospective study, patients with LVAD-associated stroke were significantly less likely to undergo heart transplant, but those who underwent heart transplant had similar post-transplant outcomes as patients without history of LVAD-associated stroke. Given the similar outcomes seen in this population, history of LVAD-associated stroke should not be viewed as an absolute contraindication to subsequent heart transplant.

Keywords: Stroke—Ischemic stroke—Intracranial hemorrhage—Left ventricular assist device—Transplant

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Introduction

Left ventricular assist device (LVAD) implantation for advanced heart failure is associated with improved survival and quality of life.¹ LVADs are frequently used as a bridge to transplantation (BTT) allowing for more patients

to survive until a donor organ becomes available. Despite these benefits, durable LVADs have a high incidence of device-associated complications, and LVAD-associated stroke may be the most devastating of these complications due to its impact on disability and mortality. Several

Abbreviations: BTT, Bridge to Transplant; EDIT, Electronic Data Interface for Transplantation; ICH, Intracranial Hemorrhage; IPH, Intraparenchymal Hemorrhage; IQR, Interquartile Range; LVAD, Left Ventricular Assist Device; MRI, Magnetic Resonance Imaging; NIHSS, National Institutes of Health Stroke Scale; SAH, Subarachnoid Hemorrhage; SDH, Subdural Hemorrhage

From the ^aDepartment of Neurology, Neurological Institute, Cleveland Clinic, 9500 Euclid Avenue s100a, Cleveland, OH 44195, USA; ^bCerebrovascular Center, Neurological Institute, Cleveland Clinic, Cleveland, OH, USA; ^cDepartment of Cardiovascular Medicine, Heart, Vascular, and Thoracic Institute, Cleveland Clinic, Cleveland, OH, USA; ^dDepartment of Thoracic and Cardiovascular Surgery, Heart, Vascular, and Thoracic Institute, Cleveland Clinic, Cleveland, OH, USA; and ^eDivision of Neuroscience Critical Care, Departments of Neurology, Neurosurgery, Anesthesiology, and Critical Care Medicine, Johns Hopkins University, Baltimore, MD, USA.

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Corresponding author. E-mail: Aaron.Shoskes@gmail.com.

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factors unique to LVADs place this population at increased risk of stroke.² Ischemic stroke may result from embolic events secondary to pump or cardiac thrombus,³ while intracranial hemorrhage (ICH) can occur due to the necessary use of anticoagulant medication to prevent this thrombosis. Additionally, device-associated infection can result in ischemic stroke via septic embolism as well as ICH caused by mycotic aneurysm⁴

Stroke is among the most common LVAD-associated complications with an estimated incidence of 0.06–0.16 events per patient year,^{5–7} although this number has decreased with improvements in device technology with Heartmate 3 having an incidence of 0.04 events per patient year.⁷ Stroke may be viewed as a contraindication to heart transplantation due to concern for worse transplant outcomes, increased risk of subsequent stroke after transplant, and decreased ability of the patient to care for themselves after transplant.⁸ Despite these concerns, some patients with LVAD-associated stroke experience sufficient neurologic recovery and eventually undergo transplant. However, information on characteristics and outcomes of patients who receive a transplant after LVAD-associated stroke have not been previously described.

In this study, we primarily aimed to compare mortality and stroke incidence after transplant among patients with and without prior LVAD-associated stroke to see whether LVAD-associated stroke was associated with worse transplant outcomes. Secondarily, we compared patients with LVAD-associated stroke who underwent transplant against those BTT patients with LVAD-associated stroke who were not able to be transplanted to investigate patient and stroke characteristics associated with successful transplantation.

Methods

Consecutive patients who underwent LVAD implantation at the Cleveland Clinic between October 2004 and September 2021 were included in this analysis. Baseline characteristics including patient demographics, medical history, social history, device type, and reason for LVAD implantation were prospectively collected in our Electronic Data Interface for Transplantation (EDIT) database while electronic medical records were also retrospectively reviewed from the time of LVAD implantation until their death, transplant, or LVAD explantation. Inclusion criteria for this investigation included age ≥ 18 years and implantation of a durable LVAD. Exclusion criteria were placement of a biventricular assist device or total artificial heart. The study was approved by the Cleveland Clinic institutional review board (number 17-363).

Stroke was defined as the development of acute neurologic deficit attributable to focal injury with evidence of ischemic stroke or ICH on computed tomography (CT) brain imaging. All patients diagnosed with stroke were

evaluated by a vascular neurologist and images were reviewed by a neuroradiologist at the time of stroke. Magnetic resonance imaging (MRI) was not available due to incompatibility with LVADs. ICH included intraparenchymal hemorrhage (IPH), subarachnoid hemorrhage (SAH), and subdural hemorrhage (SDH). Patients with multiple concurrent subtypes of stroke were coded in each category. Details of the patients' initial neurologic status at the time of stroke including National Institutes of Health Stroke Scale (NIHSS)⁹ were retrospectively collected. Ischemic stroke and IPH volume were estimated by ABC/2.¹⁰ The primary outcomes were 1- and 2- year mortality and stroke incidence after transplant among patients with and without LVAD-associated stroke prior to transplant. Secondary analyses included patient and stroke characteristics associated with subsequent transplant after LVAD-associated stroke.

Statistical analyses were performed using IBM SPSS statistics version 28.0. Data are presented as counts with percentages and medians with interquartile ranges (IQRs). Mann-Whitney U test was used to compare continuous variables while chi-Square and Fisher exact tests were used for categorical variables. The incidence of post-transplant mortality and stroke recurrence was calculated with the Kaplan-Meier method and the Mantel-Cox log-rank test was used to compare the statistical significance level. P values less than 0.05 were considered statistically significant.

Results

During the study period, 917 patients underwent durable LVAD implantation and of these patients 439 (48%) patients had LVAD implanted as BTT (Fig. 1). 244 patients underwent transplant (median age 57 years, 79% male) including 25 (10%) patients who underwent transplant after LVAD-associated stroke. BTT patients without LVAD-associated stroke were more likely to undergo transplant (182 of 361, 50%) compared to those with LVAD-associated stroke (22 of 78, 28%, $p < 0.001$). The 244 patients with transplant after LVAD implantation included 204 BTT patients, 39 initially destination therapy (DT) patients, and 1 bridge to recovery patient. Patient age, sex, race, and comorbidities did not differ between transplant patients with LVAD-associated stroke and those without LVAD-associated stroke (Table 1). Median time from LVAD implantation to transplant was similar (335 days vs 281 days, $p = 0.548$).

The median age of patients with transplant after LVAD-associated stroke was 59 years (IQR=41–64), 76% were male, and 80% were white. Eighteen patients (72%) had LVAD-associated ischemic stroke and eight patients (32%) had LVAD-associated ICH (including 3 IPH and 5 SAH) prior to transplant; one patient had concomitant ischemic stroke and SAH. The median NIHSS was 3 (IQR=1–9). Median ischemic stroke volume was 3mL

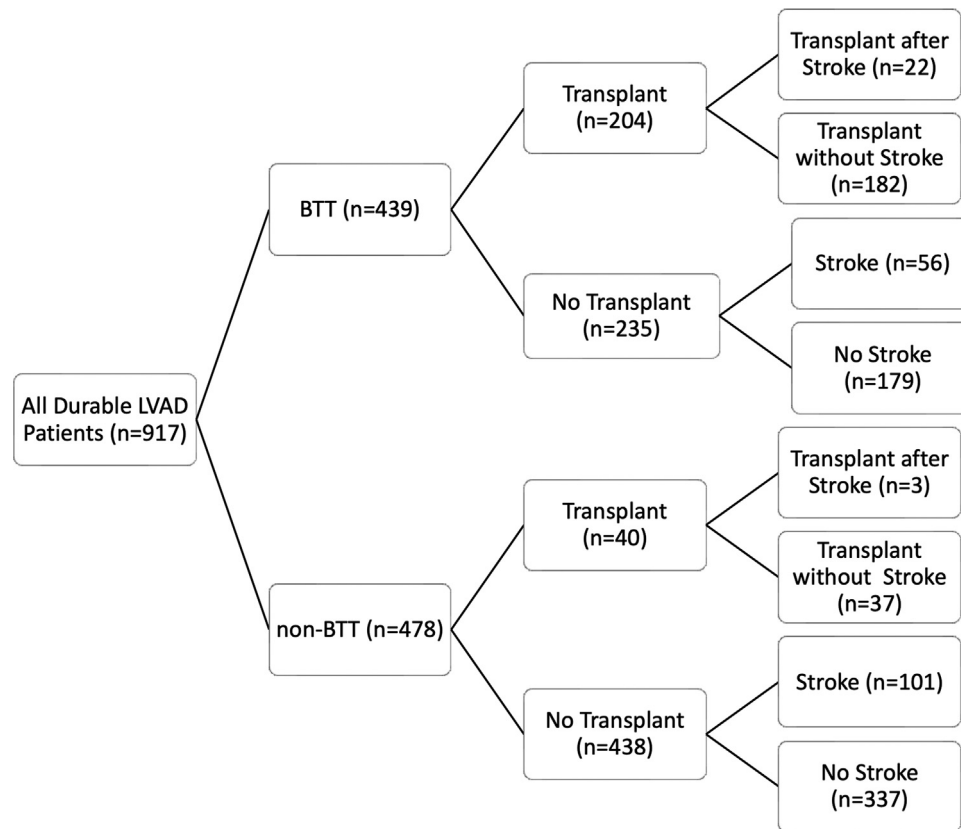


Fig. 1. Study flow diagram. BTT: Bridge to Transplant. LVAD: Left Ventricular Assist Device, Transplant: Heart Transplant.

(IQR=2-9), while median IPH volume was 65mL. The median time from LVAD-associated stroke to transplant was 155 days (IQR=28-486).

Survival and stroke after transplant

Death occurred in 17 patients at one year and 22 patients at two years after heart transplant. Post-transplant survival did not vary between patients with LVAD-associated stroke and patients without LVAD-associated stroke at 1 year (100% vs 92%, $p=0.156$) or 2 years (95% vs 90%, $p=0.323$) (Fig. 2). Stroke occurred in 11 patients by one year and 13 patients by two years after transplant. There was no difference in post-transplant stroke at 1 year (4% vs 5%, $p=0.884$) or 2-years ($p=0.744$) after transplantation between patients with prior LVAD-associated stroke and those without prior LVAD-associated stroke (Fig. 3). Three patients who died after transplantation had mortality related to new acute stroke or ICH; none of these patients had history of LVAD-associated stroke prior to heart transplantation.

Stroke with or without subsequent transplant

Patients with LVAD-associated stroke who were able to undergo transplant were subsequently compared with patients with LVAD-associated stroke who were not able

to undergo transplant in order to identify patient or stroke characteristics associated with successful transplant (Table 2). Patients who underwent transplant after LVAD-associated stroke were more likely to have LVAD implantation as BTT (88% vs 36%, $p < 0.001$). Additionally, transplanted patients had a lower prevalence of multiple medical comorbidities including hypertension (48% vs 77%, $p=0.006$), coronary artery disease (16% vs 51%, $p < 0.001$), chronic obstructive pulmonary disease (0% vs 15%, $p=0.048$), and tobacco abuse (36% vs 66%, $p=0.012$). Patients with heart transplant after LVAD-associated stroke had lower median NIHSS (3 vs 17, $p < 0.001$) and were less likely to have had intracranial hemorrhage (32% vs 55%, $p=0.031$), intraparenchymal hemorrhage (12% vs 41%, $p = 0.006$), or subdural hematoma (0% vs 13%, $p=0.048$). None of the twenty-one patients with recurrent stroke during LVAD went on to transplant (Table 3).

Subsequent sensitivity analyses were performed to control for differences between BTT and non-BTT patients. Patients who underwent transplant after LVAD-associated stroke were compared against BTT patients who had LVAD-associated stroke and did not undergo subsequent transplant ($n=56$). Patient demographics (including age and race), comorbidities, and LVAD device type were similar between patients with LVAD-associated stroke who underwent transplant and BTT patients who did not

Table 1. Characteristics and outcomes of patients who underwent heart transplant after left ventricular assist device as a bridge to transplant.

	All Transplants (n=244)	LVAD Stroke (n=25)	LVAD without Stroke (n=219)	P value
Patient Demographics				
- Male (%)	192 (78%)	19 (76%)	173 (79%)	0.797
- Median age at transplantation, years	57 (45-63)	59 (41-64)	57 (46-63)	0.789
- Race				
-White (%)	196 (80%)	20 (80%)	176 (80%)	1.00
-Black (%)	37 (15%)	3 (12%)	34 (16%)	0.776
LVAD				
- BTT (%)	204 (84%)	22 (88%)	182 (83%)	0.53
- Median implant to transplant, days	286	335	281	0.548
- Device type (%)				0.450
- Heartmate 2	135 (55%)	11 (44%)	124 (57%)	
- Heartmate 3	30 (12%)	2 (8%)	28 (13%)	
- Heartware	56 (23%)	9 (36%)	47 (21%)	
- Other	23 (9%)	3 (12%)	20 (9%)	
Past Medical History				
- Diabetes (%)	73 (30%)	9 (36%)	64 (29%)	0.494
- Hypertension (%)	123 (50%)	12 (48%)	111 (51%)	0.835
- Cardiac arrhythmia (%)	171 (70%)	14 (56%)	157 (72%)	0.112
- Chronic obstructive pulmonary disease (%)	18 (7%)	0	18 (8%)	0.230
- Peripheral vascular disease (%)	6 (2%)	0	6 (3%)	1.000
- Myocardial infarction (%)	72 (30%)	9 (36%)	63 (29%)	0.490
- Coronary artery disease (%)	65 (27%)	4 (16%)	61 (28%)	0.241
- Coronary artery bypass (%)	35 (14%)	2 (8%)	33 (15%)	0.546
- Any valve surgery (%)	21 (9%)	1 (4%)	20 (9%)	0.705
- Percutaneous coronary Intervention (%)	50 (20%)	7 (28%)	43 (20%)	0.307
- Dialysis (%)	8 (3%)	1 (4%)	7 (3%)	0.584
- Defibrillator (%)	196 (80%)	16 (64%)	180 (82%)	0.058
- Malignancy (%)	12 (5%)	0	12 (5%)	0.618
- Tobacco (%)	123 (50%)	10 (40%)	115 (53%)	0.200
- Alcohol (%)	18 (7%)	1 (4%)	17 (8%)	0.703
- Recreational drug use (%)	9 (4%)	0	9 (4%)	0.604
- Ischemic stroke (%)	28 (11%)	5 (20%)	23 (11%)	0.181
- Intracranial hemorrhage (%)	1 (<1%)	0	1 (<1%)	1.000
Post-Transplant Outcomes				
- Death by 1 year	17/244 (7%)	0/25	17/219 (8%)	0.230
- Death by 2 year	22/228 (10%)	1/22 (5%)	21/206 (10%)	0.704
- Stroke by 1 year	11/244 (5%)	1/25 (4%)	10/219 (5%)	1.000
- Stroke by 2 year	13/228 (6%)	1/22 (5%)	12/206 (6%)	1.000

Abbreviations: BTT: Bridge to Transplant. LVAD: Left Ventricular Assist Device

undergo transplant after stroke (Supplemental Table 1). Patients with LVAD-associated stroke who went on to transplant were more likely to have had ischemic stroke (72% vs 45%, $p=0.023$) and less likely to have developed ICH (32% vs 61%, $p=0.008$) compared with BTT patients with LVAD-associated stroke without transplant and had lower median stroke severity as measured by NIHSS (3 vs 20, $p<0.001$) (Supplemental Table 2).

Discussion

In this single-center retrospective study, we aimed to compare rates of heart transplant between patients with prior LVAD-associated stroke and those without this history as well as compare subsequent outcomes after heart transplant. Stroke during LVAD support was associated with lower prevalence of subsequent heart transplant.

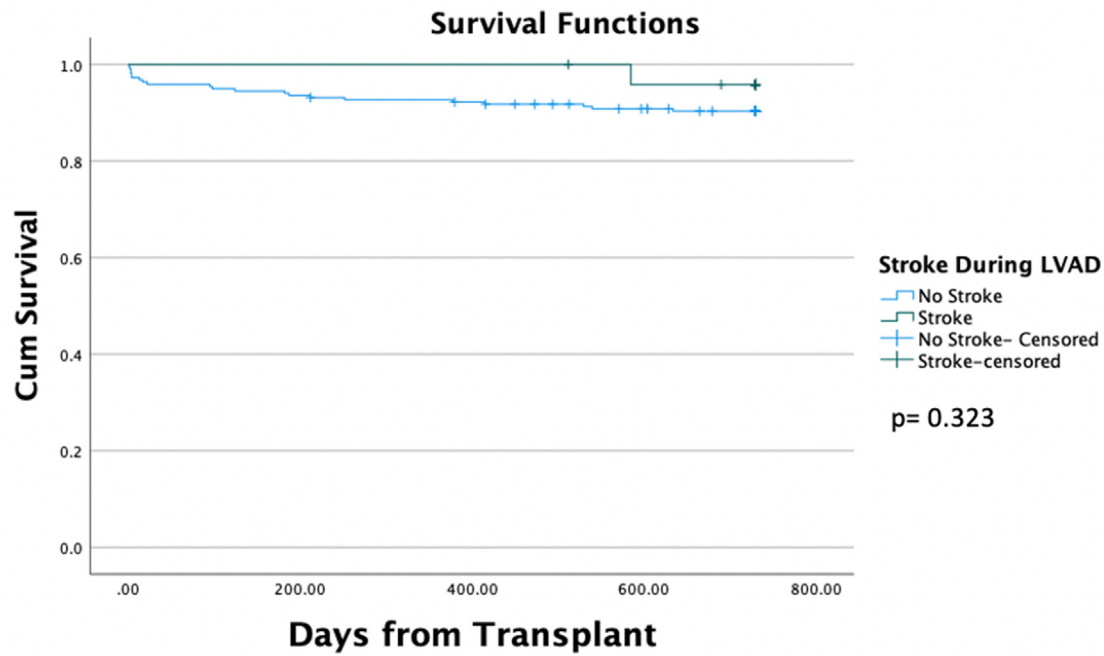


Fig. 2. Kaplan Meier curve for survival at 2 years after transplant.

Among patients with LVAD-associated stroke, higher stroke severity and the presence of ICH were associated with decreased ability to receive heart transplant. However, patients with LVAD-associated stroke who underwent a heart transplant had a similar risk of post-

transplant mortality and post-operative stroke compared to patients without LVAD stroke.

Similar to prior studies, LVAD stroke was associated with decreased probability of transplant in our cohort. One study of BTT LVAD recipients found a decrease in

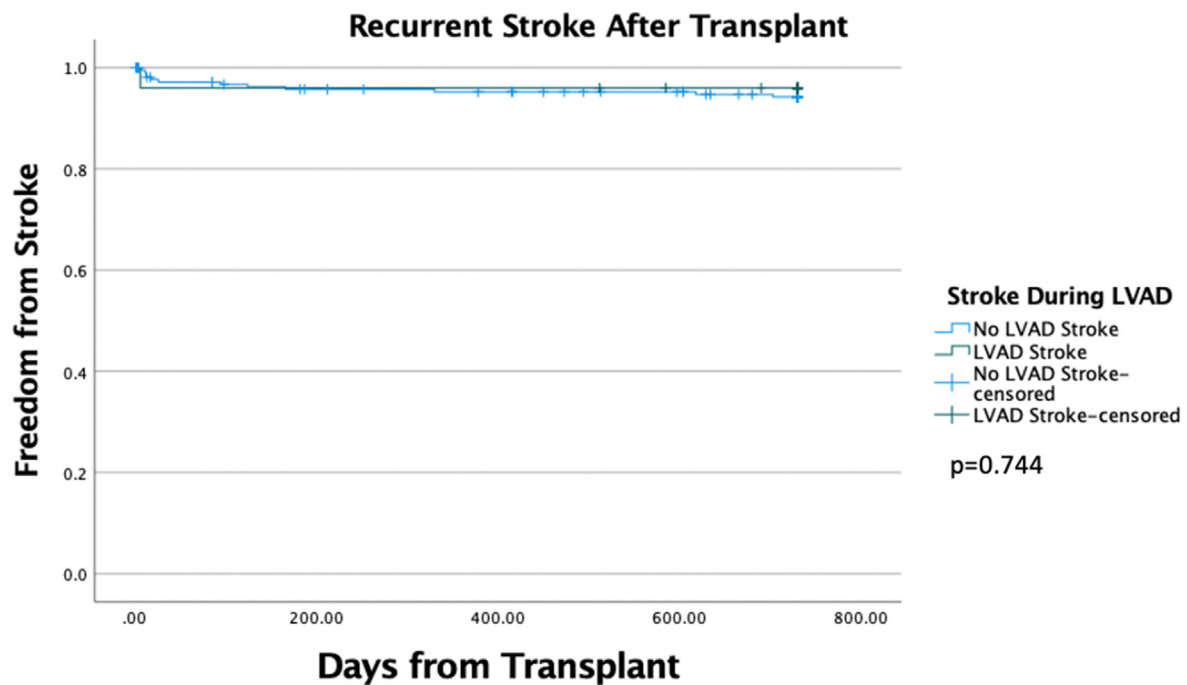


Fig. 3. Kaplan Meier curve for stroke freedom at 2 years after transplant.

Table 2. *Characteristics of patients with left ventricular assist device that developed stroke.*

	All Strokes (n= 179)	Stroke with Subsequent Transplant (n=25)	Stroke Without Subsequent Transplant (n=154)	P-value
Patient Demographics				
- Male (%)	140 (78%)	19 (76%)	121 (79%)	0.773
- Median age at LVAD implantation, years	59 (51-66)	59 (41-64)	60 (52-66)	0.062
- Race				
-White (%)	133 (74%)	20 (80%)	113 (73%)	0.624
-Black (%)	38 (21%)	3 (12%)	35 (23%)	0.297
LVAD as BTT (%)	78 (44%)	22 (88%)	56 (36%)	<0.001
Device type (%)				0.251
- Heartmate 2	78 (44%)	11 (44%)	67 (44%)	
- Heartmate 3	39 (22%)	2 (8%)	37 (24%)	
- Heartware	48 (27%)	9 (36%)	39 (25%)	
- Other	14 (8%)	3 (12%)	11 (7%)	
Patient Medical History (%)				
- Diabetes	78 (44%)	9 (36%)	69 (45%)	0.516
- Hypertension	130 (73%)	12 (48%)	118 (77%)	0.006
- Cardiac arrhythmia	112 (63%)	14 (56%)	98 (64%)	0.508
- Coronary artery disease	83 (46%)	4 (16%)	79 (51%)	<0.001
- Chronic obstructive pulmonary disease	23 (13%)	0	23 (15%)	0.048
- Peripheral vascular disease	10 (6%)	0	10 (6%)	0.361
- Myocardial infarction	83 (46%)	9 (36%)	74 (48%)	0.288
- Dialysis	3 (2%)	1 (4%)	2 (1%)	0.365
- Malignancy	14 (8%)	0	14 (9%)	0.223
- Tobacco	110 (61%)	9 (36%)	101 (66%)	0.012
- Alcohol	23 (13%)	1 (4%)	22 (14%)	0.207
- Recreational drug use	14 (8%)	0	14 (9%)	0.223
- Ischemic stroke	18 (10%)	5 (20%)	13 (8%)	0.141
- Intracranial hemorrhage	2 (1%)	0	2 (1%)	1.000
- Coronary artery bypass	36 (20%)	2 (8%)	34 (22%)	0.175
- Any valve surgery	16 (9%)	1 (4%)	15 (10%)	0.703
- Percutaneous coronary intervention	63 (35%)	7 (28%)	56 (36%)	0.502
- Defibrillator	129 (72%)	16 (64%)	113 (73%)	0.343

Abbreviations: BTT: Bridge to Transplant. LVAD: Left Ventricular Assist Device

transplants per person-year from 0.20 to 0.007 after stroke,¹¹ and in another study only 12 of 32 LVAD patients with ischemic stroke (38%) and no patients with ICH were able to undergo transplant.¹² Reluctance to transplant patients after LVAD-associated stroke may stem from assumption that they will be at increased risk of poor outcomes, as well as concern that a patient's stroke may preclude their ability to care for themselves after transplantation. A prior study comparing transplant outcomes among patients with prior stroke demonstrated higher rates of post-transplant stroke or death as well as functional decline.¹³ However, this study evaluated all patients undergoing transplant without specific analysis of those on mechanical circulatory support at the time of stroke. One prior study demonstrated a decreased risk of stroke among patients with advanced heart failure after heart transplantation¹⁴ but did not specifically look at patients with LVAD who are at higher risk for of pre-

transplant ischemic stroke and ICH. LVAD-associated stroke is unique in that it may be largely attributed to device specific factors, and explantation of the LVAD during heart transplant should ameliorate this and return the patient to their baseline cerebrovascular risk. This theory was supported by the finding of no differences in stroke recurrence after transplantation in our cohort.

The ability to undergo transplantation in our population was associated with milder stroke symptoms at time of onset (as measured by NIHSS) as well as ischemic stroke (versus intracranial hemorrhage), both of which factors are known to be associated with better outcomes among stroke patients.^{15,16} While ICH among LVAD patients is associated with a high rate of morbidity and mortality,¹⁷ 10% of BTT patients with ICH were able to undergo heart transplant in our cohort at a median of 210 days from ICH to transplant. These patients included three patients with IPH with a median volume of 65 mL, a

Table 3. Details of stroke subtype prevalence and severity among patients who developed left ventricular assist device-associated stroke.

	All Strokes (n=179)	Transplant after Stroke (n= 25)	No Transplant After Stroke (n=154)	P Value
Median implant to stroke, days (IQR)	123 (17-401)	57 (6-307)	132 (20-405)	0.311
Median NIH Stroke Scale (IQR)	14 (3-26)	3 (1-9)	17 (3-27)	<0.001
Ischemic stroke (%)	105 (59%)	18 (72%)	87 (57%)	0.080
- Median NIH Stroke Scale (IQR)	13 (3-25)	5 (2-11)	17 (3-26)	0.039
Intracranial hemorrhage (%)	93 (52%)	8 (32%)	85 (55%)	0.034
- Median NIH Stroke Scale (IQR)	14 (3-29)	1 (0-3)	18 (3-30)	0.002
- Intraparenchymal hemorrhage (%)	66 (37%)	3 (12%)	63 (41%)	0.006
- Subarachnoid hemorrhage (%)	28 (16%)	5 (20%)	23 (15%)	0.553
- Subdural Hematoma (%)	21 (12%)	0	21 (14%)	0.048
Recurrent stroke (%)	21 (12%)	0	21 (14%)	0.048

Abbreviations: IQR: Interquartile Range, NIH: National Institutes of Health

large hemorrhage size which has been independently associated with poor outcomes.¹⁸ This finding emphasizes that many patients with strokes considered to be moderate or severe in nature may be able to successfully undergo transplant assuming initial recovery.

Limitations

The present study has several limitations. Our relatively small sample size limits the analysis's power and ability to determine differences of the primary end points given the overall low number of events of the primary outcomes (post-operative stroke and mortality) and hence limited availability to adjust for potential confounders. Additionally, our study represents the experience of a single center and may not be generalizable to practice at other institutions, especially regarding heart transplantation which could have significant center variability. Some clinical variables that may be relevant to transplant mortality and stroke recurrence (including body mass index) were not available as part of the database. Additionally, while many aspects of the data were prospectively collected as part of the EDIT registry, details regarding stroke severity were retrospectively obtained which may impact their accuracy. Information about patients' neurologic recovery after stroke was limited due to retrospective review, and neurologic status at 30 or 90 days after stroke would be an additional helpful marker of recovery after stroke which may be more correlated with subsequent transplant than initial symptoms at time of stroke. Ischemic stroke volume was estimated using the volume of hypodensity on CT scan which may underestimate true infarct volume and the presence of LVAD precluded the ability for patients to undergo MRI which would have allowed for more accurate measurements of stroke size. The identified finding that BTT patients without LVAD-associated stroke were more likely to undergo transplant than those with LVAD-associated stroke may actually be in part reverse causation; patients who go on to transplant may have a lower

prevalence of stroke because they are transplanted early and thus are not able to have LVAD-associated stroke after explantation. However, the duration of LVAD support among transplant patients was not significantly different between patients with LVAD-associated stroke and those without LVAD-associated stroke.

Future directions

Our findings suggest that well-selected patients with LVAD-associated stroke can undergo heart transplant with equivalent outcomes to their counterparts without stroke. However, many patients are significantly disabled after LVAD-associated stroke, and the optimal selection criteria for which patients should go on to transplantation remain uncertain. Future research should investigate the best manner to select appropriate patient for transplant as well as the optimal timing of transplantation after stroke.

Conclusion

LVAD-associated stroke resulted in lower rates of transplant in BTT patients. Among patients with LVAD-associated stroke, milder initial symptoms and ischemic stroke were associated with a greater likelihood of heart transplant. Patients with LVAD-associated stroke had similarly low rates of post-transplant stroke recurrence and mortality.

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None.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary materials

Supplementary material associated with this article can be found in the online version at [doi:10.1016/j.jstrokecerebrovasdis.2023.107128](https://doi.org/10.1016/j.jstrokecerebrovasdis.2023.107128).

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