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Outcomes following left ventricular assist device exchange

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Abstract

Introduction—Left ventricular assist device (LVAD) exchange has been historically associated with a significant risk of morbidity and mortality. It is unknown, however, whether these outcomes have improved. We aimed to compare clinical outcomes following LVAD exchange to those following initial LVAD implant in a contemporary patient cohort.

Methods—A total of 115 LVAD patients were enrolled between 2014 and 2017 and followed for 1 year. Of these, 15 patients (54.5 ± 13.3 years old, 87% male) underwent LVAD exchange at 277 (IQR 191–597) days following LVAD implantation and 100 patients (57.5 ± 12.3 years old, 76% male) did not undergo an LVAD exchange (non-exchange group).

Results—One-year survival rate following LVAD exchange tended to be higher than the non-exchange patients (93% vs 76%, $P = .15$). Readmission rates for each comorbidity did not significantly differ between the two groups ($P > .05$ for all) except for the higher rate of pump thrombosis in the LVAD exchange group ($P < .05$).

Discussion—LVAD exchange cohorts seem to have comparable clinical outcome with the non-exchange cohorts.

Conclusion—LVAD exchange might be an increasingly appropriate therapeutic option for the management of pump thrombosis, although careful monitoring for recurrent pump thrombosis is required.

Keywords

heart failure; HeartMate; pump thrombosis; subcostal

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

1 | INTRODUCTION

Rates of pump thrombosis in patients with HeartMate II left ventricular assist devices (LVAD) were reported at 2% to 4% in the initial device efficacy trials.^{1,2} However, the 1-year rate of pump thrombosis increased from 3% to 10% following the original trials between 2008 and 2013.³ Recently, the MOMENTUM 3 trial showed 0.12 event/patient-year of pump thrombosis in the HeartMate II arm.⁴ Although intensive antiplatelet and anticoagulation therapies are initially delivered for suspected pump thrombosis, device exchange remains as the definitive and gold-standard treatment strategy.^{5,6} Despite being the accepted mode of therapy, device exchange has historically been reported to carry a significant risk of morbidity and mortality.^{7,8}

Considering recent improvements in surgical technique (ie transition from total median sternotomy to the subcostal approach),^{9–12} and the surgical and medical management protocol outlined in the PREVENT trial¹³; outcomes following LVAD exchange might improve in a contemporary patient cohort. In this study, we compared the clinical outcomes between the pre-exchange period and the post-exchange period (intra-group comparison) and between the LVAD exchange group and the non-exchange group (intergroup comparison).

2 | METHODS

2.1 | Patient selection

In this study, patients who underwent LVAD implantation (HeartMate II or HeartWare ventricular assist device [HVAD]) between April 2014 and February 2017 were followed over 12 months post-implant. During LVAD implantation, the inflow cannula was positioned parallel to the intraventricular septum and oriented to the central left ventricle. Patients who underwent LVAD exchange were enrolled as an exchange group. Patients who did not experience device exchange were enrolled as a non-exchange group. For the exchange group, one-year data following the first LVAD implantation were also obtained (pre-exchange period). An intra-group analysis between pre-exchange and post-exchange periods was performed (Figure 1A). Intergroup comparison was also reported between the exchange group and the non-exchange group (Figure 1B). The study protocol was approved by the University of Chicago Institutional Review Board.

2.2 | Diagnosis and management of device thrombosis

Following LVAD implantation or exchange, anticoagulation therapy was initiated immediately except in situations of unexpected bleeding. Patients were started on intravenous heparin targeting activated partial thromboplastin time 40 to 50seconds, which was bridged to the warfarin and aspirin therapies.

During the observational period, all patients received guideline-directed medical therapy including aspirin and warfarin with a goal international normalized ratio (INR) appropriate for each device.¹⁴ For monitoring of pump thrombosis in HeartMate II devices, serum lactate dehydrogenase (LDH) level was obtained monthly.^{5,15,16} When serum LDH increased 2.5 times over the normal range, risk factors including abnormal cannula position,

subtherapeutic INR, genetic hematological abnormalities, and history of non-device related thrombotic events were assessed. In addition, the initiation of intensified antithrombotic therapy with continuous heparin infusion (target activated partial thromboplastin time 80-100), increase aspirin dose from 81 to 325 mg daily, or considering additional dipyridamole 150 mg daily, were considered. Furthermore, an echocardiographic ramp test was performed to additively confirm a suspicion of device thrombosis.¹⁷ If the ramp test was consistent with an inability to decompress the LV during stepwise increases in device speed, we considered device exchange. If the study was negative, we continued an intensified antithrombotic regimen with careful LDH monitoring.

HVAD devices are known to have lower baseline LDH values than the HeartMate II devices because of differences in shear stress, with LDH cutoffs for the HeartMate II not applicable for use in HVADs.⁵ Also, echocardiographic ramp studies to assess for device thrombosis in patients with HVADs are not well validated.¹⁸ Instead, log file analysis and acoustic spectral analysis are often used with computerized tomography imaging to aid in the diagnosis of device thrombosis,¹⁹ with tissue-plasminogen activator therapy most often used for treatment.²⁰

2.3 | Follow-up protocol and data collection

Data regarding rates of death and hospital readmissions due to major causes (heart failure [HF], ventricular tachyarrhythmia [VT], gastrointestinal bleeding [GIB], stroke, and pump thrombosis) were collected. LVAD speed and medication at the time of first discharge from index hospitalization were obtained. The angle between the inflow cannula and HeartMate II pump body was measured from the chest X-ray obtained at the time of discharge from the index hospitalization.²¹ The measurements were performed by the two independent investigators blinded to the results of this study and then averaged.

Readmission rates were standardized by calculating readmission numbers per patient-year. Readmission etiology were adjudicated into one of the following categories: (a) HF, defined as hospitalizations to treat volume overloaded and/or pulmonary congestion with IV diuretics; (b) VT, requiring chemical or electrical cardioversion by either anti-tachycardia pacing or device shock; (c) GIB, described by Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) as any clinically suspected or documented bleeding from the GI tract; (d) stroke, defined by INTERMACS as symptomatic ischemic cerebral infarction or intracranial hemorrhage, diagnosed by the attending neurologist; (e) pump thrombosis, defined as those treated medically as described above or device exchange.

2.4 | Statistical methodology

Two comparison studies were performed: clinical outcomes of the post-exchange group were compared with the pre-exchange period (intra-group analysis) and also with a non-exchange group (intergroup analysis). Observational periods were one-year for all groups, unless death, heart transplantation, or LVAD exchange occurred.

Statistical analyses were performed with SPSS Statistics 22 (SPSS Inc, Chicago, IL). Two-sided *P*-values < .05 were considered significant. Continuous variables were compared between groups using the Mann-Whitney U test. Categorical variables were compared

between groups using Fisher's exact test. Paired continuous and categorical variables were compared using the Wilcoxon signed-rank test and McNemar test, respectively. To assess the accuracy of the measurement of the device angle, inter-rater reliability was calculated.

Time-to-event analyses were assessed using Kaplan–Meier analysis and were compared with the log-rank test for the intergroup analysis and with the Mantel-Cox test for the intra-group analysis. Time zero was at the time of device implantation (or exchange) for the survival analyses and was at the time of index discharge for the readmission analyses.

3 | RESULTS

3.1 | Baseline characteristics

A total of 115 LVAD patients (57.0 ± 13.1 years old and 89 male) were enrolled (Table 1). Most patients were implanted as destination therapy (89/115 [77%]) 39/115 (34%) had an ischemic etiology for HF.

LVAD exchange was performed in 15/115 (13%) patients at a median 277 (IQR 191–597) days following the initial LVAD implantation due to pump thrombosis (the exchange group). Within this subgroup, 11/15 (73%) had visible thrombus seen within the device. Only three cases were considered emergent, and the median serum LDH level at the time of exchange was 1148 (910, 1581) U/L. No other LVAD exchanges occurred due to reasons other than device thrombosis. Overall, 13 patients with HeartMate II pumps underwent exchange via a subcostal approach, one patient from HeartMate II to HVAD via median sternotomy, and one patient from HVAD to HVAD via median sternotomy.

There were 13 suspected device thromboses that were treated medically. Of them, there were no recurrences of device thrombosis and device exchange in 10/13 cases, whereas device exchange occurred in 3/13 cases. No patients received heart transplantation for the suspected device thrombosis.

3.2 | Intra-group comparison between the pre-exchange period and the post-exchange period

Therapeutic parameters including aspirin use, INR, and LVAD speed remained unchanged between the pre-exchange and the post-exchange periods ($P > .05$ for all), whereas the angle between inflow cannula and HeartMate II pump body became wider following LVAD exchange (from 68.2 ± 9.6 to 71.8 ± 10.9 degrees, $P = .046$; Table 2). Inter-rater reliability for the angle between two reviewers was 0.990. The serum level of C-reactive protein tended to decrease following LVAD exchange (from 92.9 ± 45.4 to 47.0 ± 71.8 mg/L, $P = .091$).

During the one-year observation period, eight patients experienced their first LVAD exchange whereas one patient experienced a second LVAD exchange thereafter. As a result, the 1-year LVAD exchange-free rate was significantly higher in the post-exchange period compared to the pre-exchange period (93% vs 47%, $P = .011$; Figure 2A). In other words, patients rarely experienced multiple device exchanges.

During 1-year following the initial LVAD implantation, 12 patients experienced 23 readmissions. Following LVAD exchange, one patient died due to sepsis (during index hospitalization), two patients received heart transplantation, and seven patients experienced 12 readmissions during the 1-year observation period. Freedom from the readmission rate was significantly higher in the post-exchange period compared to the pre-exchange period (54% vs 20%, $P = .047$; Figure 2B).

During both periods, nobody experienced stroke events. Readmission rates due to HF, VT, and GIB were statistically comparable between two periods, whereas pump thrombosis rate was significantly lower in the post-exchange period compared to the pre-exchange period ($P = .004$; Figure 3): During the pre-exchange period, patients had 11 pump thrombosis (three medically managed and eight pump exchange), whereas there were only five pump thrombosis (four medically managed and one pump exchange) following LVAD exchange. As a result, the total readmission rate was significantly lower in the post-exchange period compared to the pre-exchange period ($P = .006$).

Serum LDH levels remained lower in the post-exchange period compared to the pre-exchange period (Figure S1).

3.3 | Intergroup comparison between the exchange group and the non-exchange group

There were no statistically significant differences in background characteristics between the exchange group ($N = 15$) and non-exchange group ($N = 100$) except for that the exchange group had higher body mass index and INR at discharge ($P < .05$ for both; Table 1).

Among 100 non-exchange group patients, 24 patients died (eight patients during the index hospitalization and 16 after the discharge), three patients received heart transplantations, and 40 experienced 61 readmissions. Causes of death were stroke ($N = 8$), perioperative multiple organ failure ($N = 5$), sepsis ($N = 4$), and seven with unknown etiologies.

The exchange group tended to have higher survival compared to the non-exchange group (93% vs 76%, $P = .15$; Figure 4A). The readmission-free rates did not statistically differ between the two groups (48% vs 55%, $P = .61$; Figure 4B). Readmission rates by etiology did not differ between the two groups except for those due to pump thrombosis (Figure 5). A history of LVAD exchange was a significant predictor of pump thrombosis (including both medically and surgery managed) with an odds ratio of 2.97 (95% confidence interval 1.38-6.38, $P = .005$) demonstrated by the logistic regression analysis.

4 | DISCUSSION

In this study, we assessed clinical outcomes following LVAD exchange by comparing with (a) pre-exchange period (intra-group comparison) and (b) non-exchange group (Intergroup comparison). Our main findings are as follows: (a) 15/115 (13%) patients underwent LVAD exchange due to pump thrombosis; (b) Patients rarely experienced multiple device exchanges; (c) Survival following device exchange was noninferior to those without device exchange; (d) Total readmission rates following the device exchange was statistically comparable with those without device exchange.

4.1 | Intra-group comparison between pre-exchange period and post-exchange period

Patients rarely experienced multiple device exchanges. The 7% 1-year re-exchange rate is lower than previously published reports of 22%, which Stulak et al⁷ reported in 2013 from a relatively older patient cohort including pulsatile LVAD devices. The total readmission rate was lower during the post-exchange period mainly due to decreased pump thrombosis rate. In addition, the rate of clinically relevant hemolysis occurred less during the post-exchange period compared to the pre-exchange period.¹⁵

Reasons for low recurrence of pump thrombosis are multifactorial. Antiplatelet and anticoagulation therapies along with the set LVAD speed affect the occurrence of pump thrombosis.²² However, these therapeutic strategies remained unchanged before and after LVAD exchange.

This may be explained by the angle between the inflow cannula and HeartMate II pump body. The narrow-angle is associated with an increased risk of pump thrombosis,²¹ and this angle was increased from the initial HeartMate II to the exchanged HeartMate II, likely due to an intention to widen the angle given the clinical history of device thrombosis. However, it is uncertain whether a mean increase of just 3.6 degrees in the angle has any clinical implication. Drastic changes in the device position may sometimes be challenging due to anatomical limitations.

Another reason may lie in the postsurgical inflammation, which may also be associated with the development of pump thrombosis although this hypothesis is challenging to accurately test.²³ All initial LVAD implantations were performed using median sternotomy, whereas most of the LVAD exchange was performed through a less-invasive subcostal approach. Future innovations in less invasive device implantation techniques including off-pump extraperitoneal subcostal surgical approach might further improve the postoperative outcomes.²⁴

4.2 | Intergroup survival comparison

The survival rate following LVAD exchange was found to be noninferior to the non-exchange group (93% vs 76%). The survival rate of the non-exchange group is comparable with an estimated 81% rate published in the most recent INTERMACS report.²⁵ Shaikh et al²⁶ also reported a 93.7% of survival rate of patients with LVAD exchanges at discharge. In their study, 56% of patients received an LVAD exchange through a median sternotomy. Other groups have also reported a >70% of survival rate at 3 months following HeartMate II exchange.²⁷ Our data is in line with previous reports demonstrating promising short-term survival in patients who undergo device exchange.

4.3 | Intergroup readmission comparison

The total readmission-free rate following the LVAD exchange was as high as those of the non-exchange group (48% vs 55%). Particularly, no strokes occurred following LVAD exchange, possibly due to appropriate targeted INR goals.²⁸ Furthermore, GIB rates were comparable between the two groups.

The rate of pump thrombosis (both medically and surgically managed) decreased following LVAD exchange (from 2.3 to 0.4 events/patient-year) but was still higher when compared with the non-exchange group (0.4 vs 0.1 events/patient-year). More careful monitoring of LDH levels may be required following the LVAD exchange. Earlier decision to proceed with device exchange instead of continuing medical therapy may also improve clinical outcomes,⁶ although the risks and benefits of surgical intervention should be carefully evaluated in each individual case. Future studies are needed to determine if specific protocols for post-LVAD exchange management, such as an increase in target INR and LVAD speed, up-titration of aspirin dose, or use of direct anticoagulation should be implemented. LVAD exchange bridging from HeartMate II or HVAD to HeartMate 3 may also be the solution to avoid the recurrence of pump thrombosis,⁴ though little data is currently available to validate this strategy.

4.4 | Study limitations

This study consisted of a moderate-sized cohort performed at a single center and was retrospective in nature, with a limited follow-up time studied. Furthermore, nonsignificant results with $P > .05$ do not necessarily indicate the similarity between two groups given the unbalanced sample sizes. Larger, more contemporary studies incorporating new protocols are needed to more meaningfully compare outcomes between patients with and without LVAD pump exchanges. Outcomes need to be considered in light of differing management protocols for each type of adverse event as they likely vary between institutions. Also, the influence of center-specific surgical experience, perioperative care, and outpatient management protocols should be considered in the context of data presented. Variation in time to device exchange in the intra-group comparisons is a limitation to be considered given the small sample size. Intergroup comparison has selection bias with different background characteristics between two groups.

5 | CONCLUSION

LVAD exchange might be an increasingly appropriate therapeutic option for the management of pump thrombosis given favorable clinical outcomes. Nevertheless, careful monitoring is still required for the recurrence of pump thrombosis.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

CONFLICT OF INTERESTS

Nir Uriel receives grant support from Abbott and Medtronic; Gabriel Sayer is a consultant for Medtronic; Valluvan Jeevanandam is a consultant for Abbott. Any other authors have nothing to disclose.

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FIGURE 1.

Flowsheet of the present study. Fifteen patients received LVAD exchange, whereas 100 patients did not. One patient died during the hospitalization following LVAD exchange, whereas eight patients in the non-exchange group died during the index hospitalization. Intra-group comparison between the pre-exchange and post-exchange periods (A) and Intergroup comparison between the exchange group and non-exchange group (B) were performed. LVAD, left ventricular assist device

FIGURE 2.

Comparison in LVAD exchange-free rate (A) and readmission-free rate (B) between the pre-exchange period and post-exchange period. Intra-group data were compared by the Mantel-Cox test. LVAD, left ventricular assist device

FIGURE 3.

Readmission rate of each cause in the pre-exchange period and post-exchange period. Intra-group data were compared by the Wilcoxon signed-rank test

FIGURE 4.

One-year survival rate between the exchange group (N = 15) and non-exchange group (N = 100) (A) and 1-year readmission-free rate between the exchange group (N = 14) and non-exchange group (N = 92) (B). Intergroup data were compared by the log-rank test

FIGURE 5.

Readmission rate of each cause in the exchange and non-exchange group. Intra-group data were compared by the Mann-Whitney U test

TABLE 1
Comparison of baseline characteristics between the LVAD exchange group and non-exchange group

	Total (N = 115)	LVAD exchange (N = 15)	LVAD non-exchange (N = 100)	P value
Demographics				
Age, y	57.0 ± 13.1	54.5 ± 13.3	57.5 ± 12.3	.31
Body mass index	31.0 ± 7.1	35.3 ± 5.8	29.5 ± 6.3	.002*
Male gender	89 (77%)	13 (87%)	76 (76%)	.29
Destination therapy	89 (77%)	10 (67%)	79 (79%)	.23
Ischemic etiology	39 (34%)	3 (20%)	36 (36%)	.18
Device type				.11
HeartMate II	79 (69%)	13 (87%)	66 (66%)	...
HVAD	36 (31%)	2 (13%)	34 (34%)	...
Hypertension	64 (56%)	9 (60%)	55 (55%)	.47
Diabetes mellitus	38 (33%)	6 (40%)	32 (32%)	.37
History of stroke	21 (18%)	5 (33%)	16 (16%)	.11
Atrial fibrillation	42 (37%)	5 (33%)	37 (37%)	.51
History of VTs	37 (32%)	4 (27%)	33 (33%)	.43
Management at discharge				
Aspirin use (N = 106)	79 (69%)	12 (80%)	67 (67%)	.23
PT-INR (N = 106)	2.20 ± 0.44	2.46 ± 0.50	2.16 ± 0.45	.030*
LVAD speed				
HeartMate II (N = 72)	9159.5 ± 360.8	9246.2 ± 233.2	9141.6 ± 380.8	.28
HVAD (N = 34)	2673.6 ± 122.0	2820	2669.1 ± 121.0	...

Note: Continuous variables were compared by using the Mann-Whitney U test. Categorical variables were compared by using Fisher's exact test.

Abbreviations: HVAD, HeartWare ventricular assist device; LVAD, left ventricular assist device; PT-INR, prothrombin time-international normalized ratio; VT, ventricular tachyarrhythmia.

TABLE 2

Comparison of clinical parameters before and after LVAD exchange

	At the time of discharge following initial LVAD implantation (Pre-LVAD exchange) (N = 14)	At the time of discharge following LVAD exchange (Post-LVAD exchange) (N = 14)	P value
Aspirin use	14 (100%)	12 (86%)	.22
PT-INR	2.37 ± 0.76	2.46 ± 0.48	.94
LVAD speed			
HeartMate II (N = 13)	9284.3 ± 413.3	9246.2 ± 233.2	.83
HVAD (N = 1)	2700	2820	...
Inflow cannula-pump body angle (N = 13)	68.2 ± 9.6	71.8 ± 10.9	.046*
C-reactive protein, mg/L (N = 7)	92.9 ± 45.4	47.0 ± 71.8	.091

Note: Categorical variables were compared by using the McNemar test. Continuous variables were compared by using the Wilcoxon signed-rank test. One patient who died before the first discharge following the LVAD exchange was excluded from this analysis

Abbreviations: HVAD, HeartWare ventricular assist device; LVAD, left ventricular assist device; PT-INR, prothrombin time-international normalized ratio.