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device decommissioning

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Percutaneous approach to left ventricular assist

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Abstract

Objective: To assess the outcomes of a single-center experience with percutaneous left ventricular assist device (LVAD) decommissioning.

Background: Patients with LVADs may eventually require their removal, either due to recovery of left ventricular function or recurrent complications. Traditionally, withdrawal of LVAD support has been managed with surgical device explantation, which carries significant procedural risks. Transcatheter LVAD decommissioning, with outflow graft occlusion and driveline transection, has recently been described as an alternative to surgical removal.

Methods: Here, we report on a retrospective cohort of five consecutive cases treated with transcatheter LVAD decommissioning.

Results: The procedure was effective in all cases, and no patient experienced procedurerelated complications. At midterm follow-up, the three patients who had myocardial function recovery were alive and had not experienced heart failure-related symptoms or complications.

Conclusion: Percutaneous LVAD decommissioning appears to be a safe and effective approach to LVAD treatment discontinuation.

KEYWORDS

cardiac function, cardiac remodeling, heart assist device, heart failure, ventricular assist device

1 | INTRODUCTION

For patients with end-stage heart failure, left ventricular assist devices (LVADs) improve quality of life and extend survival as either a bridge to transplantation or destination therapy.¹ In a minority of patients, approximately 1% at 1 year of support, cardiac function recovers, and the LVAD is no longer necessary.² An LVAD cannot simply be turned off, as the conduit from ascending aorta to left ventricle would result in

severe regurgitation. The traditional approach to withdrawal of LVAD support has been open surgical pump removal, but the inherent risks of mediastinal dissection and apical ventriculoplasty result in an operative mortality of around 10%.³ A less invasive approach, LVAD decommissioning, involves LVAD deactivation and outflow graft ligation, which is generally achieved via a right thoracotomy or subcostal surgical access.⁴ This is followed by severing the driveline at the exit site and leaving the device in place.⁵ To date, the experience with

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decommissioning is limited, but follow-up data suggest comparable midterm outcomes with respect to LVAD explantation.⁵ More recently, a transcatheter approach to LVAD decommissioning, with occlusion of the outflow graft followed by surgical driveline removal, has been described.⁶ This approach avoids chest re-entry altogether, potentially increasing procedural safety. The published experience of transcatheter LVAD decommissioning is limited, with few cases reported worldwide.^{7–9} Here, we present our experience with transcatheter LVAD decommissioning and report acute and midterm follow-up of a cohort of five patients treated at a single institution. Since beginning this approach, it was used in all patients referred for LVAD decommissioning.

2 | METHODS

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All procedures were carried out under conscious sedation. Right common femoral artery access was obtained under ultrasound guidance and an $8F \times 90$ cm sheath was advanced to the aortic insertion of the outflow graft. A Judkins Right 4 or Multipurpose diagnostic catheter

was used to direct a Glide wire into the outflow graft, and the sheath was advanced over the diagnostic catheter and the wire up to the proximal end of the outflow graft, where it exits the pump housing. The catheter and wire were then removed. After turning off the LVAD, the outflow graft was occluded with Amplatzer vascular plugs (AVPs; Abbott Cardiovascular-), typically an AVP-1 for the proximal and mid portion, but an AVP-2 for the aortic anastomosis, to be as flush as possible with the aorta and minimize any residual pouch (Figure 1). Initially, we tried two plugs per patient (at the proximal and distal graft insertions) with an occasional third plug (mid graft), but because some outflow grafts took longer to thrombose, we began routinely using three plugs per case. A fourth plug was used in one case where the third plug was not flush with the aortic anastomosis. In a single patient, the sheath could not reach the proximal outflow graft hence the devices were deployed through an 8F Multipurpose guide catheter. No systemic anticoagulation was administered during the procedure, to ensure rapid vascular plug occlusion; no wire remained exposed in the aorta to minimize the risk of thrombosis, and the sheath was regularly flushed with heparinized saline. Three subjects underwent concomitant right



FIGURE 1 Percutaneous left ventricular assist device (LVAD) decommissioning procedure. (A) A 7F × 90 cm sheath (arrowhead) is advanced to the outflow graft and a 14-mm Amplatzer Vascular Plug (AVP) 1 (arrow) is deployed at its insertion into the LVAD housing (asterisk). (B) A second device, 16 mm AVP-1 (arrow), is subsequently deployed in the middle of the graft. (C) A third device, 14 mm AVP-2 (arrow), is placed at the aortic anastomosis of the outflow graft. (D) Final angiogram shows effective occlusion of the outflow graft.



FIGURE 2 Aortic and pulmonary artery pressure tracings during different stages of percutaneous left ventricular assist device (LVAD) decommissioning. (A) Baseline tracings while the LVAD is active. Aortic pressure (red tracing) displays physiologic pulsatility, which is consistent with recovered native heart function. Periodic pressure dips superimposed on physiological pulsatile flow (arrowheads) are consistent with HeartMate 3 intrinsic pulsatility. (B) Upon deactivating the LVAD (white arrow), there is an abrupt decrease in mean aortic pressure (MAP) and increase in mean pulmonary artery pressure (PAP, azure tracing). (C) After LVAD deactivation but before outflow graft occlusion is complete, the MAP remains below baseline, while aortic pulse pressure increases and mean PAP rises. These findings are consistent with withdrawal of LVAD unloading and aortic regurgitation-like effect of retrograde flow through the device. (D) Upon effective occlusion of the outflow graft, aortic pulse pressure decreases and MAP increases, while PAP decreases, yet neither returns to baseline levels. This likely reflects the increased workload of the left ventricle in the absence of LVAD support. [Color figure can be viewed at wileyonlinelibrary.com]

heart catheterization, from an internal jugular vein approach, to monitor the hemodynamic effects of each stage of the procedure (Figure 2). At the end of the procedure, sheaths were removed with deployment of Angioseal closure devices.

All subjects underwent driveline truncation and surgical debridement and closure of the driveline tract after a median of 4 days from graft occlusion (range: 1–8 days). All procedures were successful, with no acute complications. All patients were discharged from the hospital alive after a median of 5 days (range: 3–14 days). Antithrombotic treatment of choice was warfarin (target international normalized ratio between 2 and 3) in three cases, and apixaban 5 mg twice daily in two cases.

3 | RESULTS

3.1 | Patient population

Between October 2018 and August 2021, five patients underwent percutaneous LVAD decommissioning at our institution. Median age at time of decommissioning was 53 years (range: 45–64) and three patients were male. LVAD support duration ranged between 203 and 2096 days at time of decommissioning. Reason for LVAD decommissioning was heart function recovery in three cases, resistant, intractable LVAD thrombosis treated with failed pump exchange in one case, and end-stage heart failure with patient preference for palliative care in another case. Table 1 reports the clinical characteristics of the patients, and Table 2 reports the devices employed in each subject.

3.2 | Clinical follow-up

Clinical follow-up was available for all subjects. Patient 1, who had been discharged to hospice care after LVAD decommissioning in the setting of severe, end-stage biventricular heart failure, died 27 days after the intervention. Patient 3, who underwent LVAD decommissioning for refractory LVAD thrombosis, was discharged on outpatient milrinone but experienced progressive worsening of

TABLE 1 Clinical characteristics of the patients

Patient, n	Sex	Age	LVAD type	Baseline heart disease	Duration of support (days)	Reason for decommissioning
1	F	53	Heartmate 2	Cardiac sarcoidosis	2096	Severe, refractory, biventricular heart failure. Transition to palliative care as per patient preference.
2	М	57	HVAD	Idiopathic dilated cardiomyopathy	203	Heart function recovery
3	F	51	Heartmate 2	Post-partum cardiomyopathy	1659	Intractable pump thrombosis, failed thrombolysis, and pump exchange
4	М	64	Heartmate 3	Idiopathic dilated cardiomyopathy	631	Heart function recovery
5	М	45	Heartmate 3	Alcohol-induced cardiomyopathy	657	Heart function recovery

Abbreviations: F, female; LVAD, left ventricular assist device; M, male.

TABLE 2 Device type, size, and location used to occlude the outflow graft during the percutaneous stage of the left ventricular assist device (LVAD) decommissioning.

Patient	LVAD type	Total number of AVPs	Proximal outflow graft	Mid outflow graft	Distal outflow graft	Antithrombotic treatment
1	Heartmate 2	3	• AVP-1 16 mm	• AVP-1 16 mm	• AVP-2 16 mm	Warfarin
2	HVAD	2	• AVP-1 16 mm		• AVP-2 16 mm	Warfarin
3	Heartmate 2	3	• AVP-1 14 mm	• AVP-1 16 mm	• AVP-2 14 mm	Warfarin
4	Heartmate 3	3	• AVP-1 14 mm	• AVP-1 16 mm	• AVP-2 14 mm	Apixaban
5	Heartmate 3	4	• AVP-1 14 mm	• AVP-1 16 mm	AVP-2 14 mmAVP-2 14 mm	Apixaban

Abbreviation: AVP, Amplatzer vascular plug.

biventricular heart failure leading to total artificial heart implant 162 days after the procedure. The remaining three subjects, who underwent decommissioning due to cardiac function recovery, were free from heart failure symptoms on the last follow-up (follow-up duration: Patient 2: 563 days; Patient 4: 173 days; and Patient 3: 138 days).

4 | DISCUSSION

Current experience with LVAD decommissioning is limited, with few reports of using a transcatheter approach.⁷ Previously published case reports and series of percutaneous LVAD decommissioning are summarized in Table 3. Our experience, applied to consecutive patients, builds on this previous experience and expands the evidence regarding this technique in several ways. First, we described a standardized, streamlined approach, using conscious sedation and a single arterial access. Previous reports described the use of bi-femoral access and transesophageal echocardiographic monitoring, which required general anesthesia.⁷ Second, we were able to show the safety of a heparin-free approach, which has the potential to reduce time to outflow graft occlusion, thereby minimizing hemodynamic instability. Third, we describe in detail the hemodynamic changes in both aortic and pulmonary artery

pressures during the procedure, which can be used to monitor for adequate outflow graft occlusion. Finally, we showed that apixaban may be safe for thromboprophylaxis after LVAD decommissioning. The use of direct oral anticoagulants is not standard of care among patients with LVADs, yet they were shown to be safe and effective in a small series of patients at high bleeding risk.¹⁰ Further study is clearly necessary before recommending this approach for routine use.

LVAD decommissioning appears to be a lower risk procedure as compared to LVAD explantation, with no procedural mortality currently reported in the literature.⁵ In addition, leaving the device in place could maintain the apical orifice if reimplantation were eventually needed, while avoiding the development of adhesions that would occur after surgical explantation, making subsequent procedures even more difficult. Both considerations make transcatheter LVAD decommissioning an attractive option, especially for those subjects who are considered at high risk of heart failure recurrence. On the downside, leaving the device in place may expose patients to systemic thromboembolism due to the potential thrombogenicity of the inflow cannula, requires continued anticoagulation, and may pose an infection risk. Long-term follow-up involving more patients is required to evaluate the optimal treatment course in these patients.

TABLE 3 Review of put	olished case serie	s and case reports about percutane	ous left ventricular a	assist device (LVAD) decor	mmissioning.	
Author, year	LVAD Type	Indication for decommissioning	Closure devices	Device size	Antithrombotic medication	Outcomes
Zeigler et al., 2014 ¹¹	II MH	Recovery	1× AVP II	22 mm	Warfarin	Alive at 3.5 years
Sainte et al., 2014 ¹²	CircuLite	Recovery	1× AVP II	Not reported	Not reported	Alive at 2 years
Pettit et al., 2015 ¹³	HVAD	Recovery	2× AVP II	14 mm	Not reported	Alive at 2 years
El Sayed Ahmed, 2016 ¹⁴	II MH	Recovery	2× AVP II	16 and 14 mm	Warfarin	Alive at 6 months
Grinstein et al., 2016 ¹⁵	HVAD	Infection and thrombosis	1× ASO	14 mm	None	Alive at 8 months (palliative care)
Soon et al., 2017 ⁶	HVAD	Recovery	2x AVP II	14 and 16 mm	Aspirin 100 mg daily	Alive at 5 months
Pendyal et al., 2017 ¹⁶	II MH	Thrombosis	1× AVP II	20 mm	Warfarin	Transplant at 3 months
Kidambi et al., 2018 ¹⁷	II MH	Infection	1× AVP II	22 mm	Not reported	Not reported
Chowdhury et al., 2020 ⁷	II MH	Thrombosis (palliation)	3× ASO	20 and 2× 18 mm	Warfarin + ASA 325 mg	In-hospital death
	HVAD	Recovery	2× AVP II	14 mm	Warfarin	Alive at 1.5 years
	HVAD	Thrombosis (palliation)	2× ASO	12 mm	Warfarin + ASA 325 mg	In-hospital death
	II MH	Recovery	2× AVP II	20 and 18 mm	Warfarin + ASA 325 mg	Alive at 2 years
Albulushi et al., 2020 ⁹	HVAD	Thrombosis	3× AVP II	Not reported	Not reported	Transplant at 2 months
	II MH	Thrombosis and recovery	3× AVP II	Not reported	Not reported	Alive at time of reporting
	HVAD	Recovery	3× AVP II	Not reported	Not reported	Alive at time of reporting
	III MH	GI bleed and recovery	3× AVP II	Not reported	Not reported	Transplant at 3 months
	II MH	Recovery	3× AVP II	Not reported	Not reported	Alive at time of reporting
	III MH	GI bleed and recovery	3× AVP II	Not reported	Not reported	Alive at time of reporting
	III MH	Recovery	3× AVP II	Not reported	Not reported	Alive at time of reporting
Alkattan et al., 2021 ¹⁸	III MH	Recovery	2× AVP II	AVP II: 20 and 16 mm	Warfarin	Alive at 2 months
			2× AVSD	AVSD: 2× 12 mm		
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Note: Relevant articles were identified through systematic search of MEDLINE using a combination of the following keywords: "LVAD", "left ventricular assist device," "heart function recovery," "discontinuation," "withdrawal," "decommissioning," and "percutaneous decommissioning."

Abbreviations: ASA, aspirin; ASO, Amplatzer septal occluder; AVP, Amplatzer vascular plug; AVSD, Amplatzer ventricular septal defect muscular occluder; HM II, HeartMate II; HM III, HeartMate III; HVAD, Medtronic HVAD Support system.

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5 | CONCLUSION

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Transcatheter LVAD decommissioning is a promising approach to mechanical circulatory support withdrawal. Further studies are needed to assess the long-term result of transcatheter decommissioning.

CONFLICTS OF INTEREST

Dr. Shah reports receiving consulting honoraria from Akcea Therapeutics. Other authors report no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author.

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