ADVANCED

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MINI-FOCUS ISSUE ON HEART FAILURE

CASE REPORT: CLINICAL CASE SERIES

Percutaneous Management of Outflow Graft Obstruction in Patients With Continuous Flow Left Ventricular Assist Devices



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ABSTRACT

Outflow graft obstruction (OGO) has been reported as a cause of left ventricular assist device dysfunction. The incidence, diagnosis, and treatment of OGO remains poorly understood. We present our experience with the diagnosis and management of OGO in the cardiac catheterization laboratory. (Level of Difficulty: Advanced.)

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eft ventricular assist devices (LVADs) as bridges to transplantation or destination therapy have shown clear benefits in the population with advanced heart failure (1). LVAD

LEARNING OBJECTIVES

- Outflow graft obstruction is an infrequent but potentially disastrous complication with an unknown incidence.
- Although surgical exchange has been traditionally undertaken to address this issue, it can be technically challenging and associated with a high morbidity, mortality, and economic burden.
- An evolving field in interventional cardiology is the development of techniques to percutaneously manage LVAD complications, including OGO when done by experienced operators.

dysfunction remains a major cause of morbidity and mortality. Recently, outflow graft obstruction (OGO) has been reported as a cause of device failure (2). Diagnosis and management of OGO remains poorly understood. This report describes a series of patients with LVAD dysfunction caused by OGO who underwent invasive hemodynamic assessment and successful percutaneous intervention with resolution of LVAD dysfunction.

CASE 1

A 40-year-old male with nonischemic cardiomyopathy and HeartWare LVAD (HVAD) (HeartWare, Framingham, Massachusetts) as a bridge to transplantation presented with decompensated heart failure 9 months after implantation. Initial parameters, hemodynamics, and laboratory data are shown in Table 1. The patient

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was unable to undergo cardiac computed tomography angiography (CTA) because of renal dysfunction. Pulmonary artery catheter data showed elevated filling pressures and low cardiac index. An intra-aortic balloon pump (IABP) was placed and his cardiac index improved to 2.2 l/min/m² and mixed venous oxygen saturation (SVo2 improved to 49%. Examination of the HVAD console waveforms after IABP placement failed to demonstrate the expected inverted flow deflection during diastolic IABP inflation (Figure 1). The patient was taken to the catheterization laboratory for hemodynamic assessment of suspected OGO. Use of a double-lumen catheter, simultaneous left ventricle (LV), and aortic (Ao) pressure tracings identified elevated LV end diastolic pressure (LVEDP), and no effect of IABP inflation on LV pressure. Outflow graft (OG) pullback demonstrated a mid-graft gradient of 40 mm Hg, confirmed by graft angiography. An EV3 model Visi-Pro (Medtronic, Dublin, Ireland) 10- \times 20mm bare metal stent was deployed across the stenosis, which resolved the OGO. HVAD flows immediately improved from 4.8 to 7.1 l/min with subsequent discontinuation of inotropes and removal of IABP.

TABLE 1 Baseline Characteristics of Patients Presenting with OGO

CASE 2

lution of OGO.

A 47-year-old man with nonischemic cardiomyopathy, prior HVAD exchange due to pump thrombosis, and inotrope-dependent right ventricular failure was admitted with persistent low-flow alarms and symptoms of congestive heart failure. CTA showed possible OG disruption. The patient's HVAD parameters and invasive hemodynamics while on milrinone are summarized in Table 1. Simultaneous LV-Ao tracing was consistent with inadequate LV unloading. OG pullback demonstrated a distal graft gradient of 85 mm Hg, confirmed by graft angiography. A 10- \times 37-mm balloon expandable stent (Boston Scientific, Marlborough, Massachusetts) was deployed with resolution of the stenosis and a residual gradient of 15 mm Hg. HVAD flows immediately improved from 2.2 to 6.0 l/min. The patient subsequently underwent orthotopic heart transplantation 4 months after percutaneous reso-

ABBREVIATIONS AND ACRONYMS

Ao = aorta CTA = computed tomography angiography IABP = intra-aortic balloon pump LV = left ventricular LVAD = left ventricular assist device LVEDP = left ventricular end diastolic pressure OG = outflow graft OGO = outflow graft obstruction

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	Case 1	Case 2	Case 3
Age, yrs	40	47	63
Males	М	М	М
Time to OGO diagnosis, days	251	1,000	362
Type of LVAD	HW	HW	HM-II
Indication for LVAD	BTT	BTT	BTT
Prior LVAD exchange	No	Yes	Yes
Ancillary test at admission			
Admission LDH, U/l normal (100-190 U/l)	500	272	403
International normalized ratio	4.2	2.4	1.3
Diagnosis of OGO based on CTA	Normal	Inconclusive	Conclusive
LVAD parameters			
LVAD alarms	Low flow	Low flow	None
LVAD flow pre-stenting, l/min	4.8-5	2.2	3.4
LVAD speed, rpm	3,300	2,900	9,200
LVAD power, W	5.8	3.5	5.7
Invasive hemodynamics at admission			
Right atrial pressure, mm Hg	22	22	12
Pulmonary capillary wedge pressure, mm Hg	36	36	33
Mixed venous saturation, %	30	55	50
Cardiac output/index, l/min-l/min/m ²	4.2/1.75	5.2/2.1	3.88/1.92
Gradient across OGO pre-stenting, mm Hg	70	85	65
Gradient across OGO post-stenting, mm Hg	0	17	0
Clinical outcomes			
Survival to discharge	No	Yes	Yes
Heart transplantation	No	Yes	No

BTT = bridge to transplant; CTA = computed tomography angiography; HM-II= Heart Mate II; HW = HeartWare; LDH = lactate dehydrogenase; LVAD = left ventricular assist device; OGO = outflow graft obstruction.





CTA of patient presenting with LVAD dysfunction. (A) Stenosis of an anastomotic segment between outflow graft and ascending aorta with complete resolution after percutaneous stenting (B). CTA = cardiac computed tomography angiography; LVAD = left ventricular assist device; OGO = outflow graft obstruction.



evaluation of the LVAD, subjects with suspected LVAD dysfunction may undergo invasive hemodynamic assessment (a), including a ramp study (b) (2). If filling pressures are elevated, then proceed with simultaneous LV-Ao waveform analysis through a 5- or 6-F double-lumen pig tail (c), which can suggest proper or improper unloading by the LVAD. When possible, a biplane left ventriculogram (d) may help visualize the components of the LVAD circuit and the presence and location of obvious stenosis. Selective interrogation of the outflow graft is performed by engaging the outflow graft with a right Judkin catheter over a 0.035-inch J-wire and performing a pullback using a double-lumen pig tail catheter (e). When a significant pressure gradient is identified and localized to a particular segment, percutaneous stenting is feasible (f). Ao = aorta; CTA = cardiac computed tomography angiography; HW-LVAD = HeartWare left ventricular assist device.

CASE 3

A 63-year-old male with a history of ischemic cardiomyopathy, coronary artery bypass grafting, and 2 LVAD exchanges, currently with a HeartMate II LVAD (Abbott Laboratories, Minneapolis, Minnesota) was transferred to the authors' center due to LVAD dysfunction after presenting with worsening heart failure symptoms to an outside hospital, despite initiation of milrinone therapy. A complete workup was completed, including CTA, which was "conclusive" for OGO (**Figure 2**). Relevant laboratory findings included international normalized ratio of 1.3 and lactate dehydrogenase concentration of 403 mg/dl. OG pullback revealed a 65-mm Hg gradient near the anastomosis site of the OG and the ascending aorta. A 10- \times 37-mm balloon expandable stent was deployed without complications and with resolution of the OGO. The patient was weaned from inotropes within the next 12 h. The patient eventually required a VAD exchange 25 months after percutaneous intervention due to pump thrombosis.

DISCUSSION

This case series describes a stepwise approach for the diagnosis and management of OGO in patients presenting with LVAD dysfunction (**Figure 3**, middle panels) (3). This report highlights potential indications, contraindications, safety concerns, and areas of further investigation and innovation for managing OGO in the cardiac catheterization laboratory.

Primary determinants of flow-through LVADs include the speed of the rotor, the calibers of the inflow and outflow conduits, and the gradient of pressure across the pump (3). With LVAD dysfunction, each of these 3 determinants must be examined carefully. When assessing LVAD dysfunction, physicians must collectively evaluate the patient's symptoms, laboratory values, device parameters, pumpconsole integrity, valvular function, and hemodynamic status. If bedside examination, laboratory testing, and imaging studies fail to identify a cause for LVAD dysfunction, an invasive hemodynamic assessment should be considered.

INDICATIONS AND CONTRAINDICATIONS FOR INVASIVE LVAD INTERROGATION. The most common indications for invasive diagnostic evaluation of LVAD dysfunction in the cardiac catheterization laboratory include the following: 1) refractory heart failure; 2) chest pain; 3) abnormal LVAD alarms; 4) recurrent and refractory arrhythmias; or 5) hypotension. Conversely, the same contraindications to cardiac catheterization apply to LVAD as to non-LVAD patients with a few noteworthy considerations. First, arterial access under direct visualization may be facilitated by using ultrasonography and micropuncture technique, given that arterial flow is nonpulsatile in patients with continuous flow LVADs, and this patient population is chronically anticoagulated. Second, as the LVAD inflow cannula is positioned at the cardiac apex, the operator must avoid catheter or wire entrapment in the LVAD, which can be fatal. Third, nearly 50% to 75% of LVAD patients develop some degree of commissural fusion of the aortic valve, and aortic root thrombus can develop due to stasis when an LVAD is fully functional. For these reasons, visualization of the aortic root to rule out thrombus and to evaluate aortic valve opening should be performed in advance of left heart catheterization or coronary angiography. Finally, prior to cardiac catheterization, all patients should be evaluated by an interventional cardiologist, heart failure/transplant specialist, and cardiac surgeon. This multidisciplinary approach can reduce complications and unnecessary procedures.

ROLE OF IMAGING IN CASES OF OUTFLOW GRAFT

OBSTRUCTION. Although there are limited data for the use of multi-imaging modalities for the diagnosis of LVAD dysfunction, prior studies have shown that transthoracic Doppler echocardiography can be used as a screening method to assess for OGO (4). Moreover, transesophageal echocardiography is suitable in the overall assessment of LVADs and can provide information for device position, ventricular function, valvular structure and hemodynamics, thrombus, aortic root anatomy, and inflow and outflow graft angulation. However, these imaging modalities are limited by surgical changes, acoustic windows, artifacts, interobserver variability, body habitus, and the need for sedation. CTA has been reported as an adjuvant imaging modality to aid diagnosing LVAD dysfunction. Different techniques include retrospectively gated contrast enhancement, bolus tracking, and electrocardiographic dose modulation (5). Disadvantages of CTA include the need for ionized contrast and radiation exposure. Additionally, there are limited reports detailing the use of CTA in diagnosing LVAD malfunction.

COMPREHENSIVE LVAD EVALUATION USING INVA-SIVE HEMODYNAMICS. No standardized approach to evaluating LVAD function using invasive hemodynamics has been defined. This study's proposed protocol includes the following:

- A. An assessment of right heart hemodynamics to determine filling pressures, cardiac output, pulmonary pressures, and right ventricular function. Elevated left filling pressures while on LVAD support is suggestive of LVAD dysfunction.
- B. A "ramp" study to measure hemodynamic variables and LVAD parameters at incremental levels of flow through the device help to identify LVAD dysfunction.
- C. Insertion of a double-lumen pigtail catheter into the LV to simultaneously measure Ao and LV pressure is recommended. Elevated LVEDP, normal Ao pulse pressure, and a normal LV-Ao gradient throughout the respiratory cycle are indicative of LVAD dysfunction. These authors recommend performing diagnostic catheterization using a 5- or 6-F system initially through the radial access.
- D. Ventriculography could be performed to evaluate the flow of blood through the LVAD motor and both inflow and outflow conduits.
- E. When OGO is suspected, placement of a doublelumen pigtail into the OG can be performed to measure a gradient between the OG and the Ao.

Based on the present authors' experience, a gradient >10 mm Hg may be suggestive of OGO.

- F. Outflow graft stenting: outflow graft balloon angioplasty and stenting offers an attractive therapeutic intervention for management of OGO without the need for a surgical intervention, as shown in this case series. A given stent size, femoral arterial access, and an 8-F system are required followed by closure devices for the arteriotomy site.
- G. As for antiplatelet therapy, the authors' experience indicates that the addition of aspirin to this chronically anticoagulated is safe.

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REFERENCES

1. Rose EA, Gelijns AC, Moskowitz AJ, et al. Longterm use of a left ventricular assist device for endstage heart failure. N Engl J Med 2001;345: 1435-43.

2. Alnabelsi T, Shafii AE, Gurley JC, Dulnuan K, Harris DD II., Guglin M. Left ventricular assist device outflow graft obstruction: a complication specific to polytetrafluoroethylene covering. A Word of Caution! ASAIO J 2019;65: e58–62. **3.** Moazami N, Fukamachi K, Kobayashi M, et al. Axial and centrifugal continuous-flow rotary pumps: a translation from pump mechanics to clinical practice. J Heart Lung Transplant 2013;32:1-11.

4. Grinstein J, Kruse E, Collins K, et al. Screening for outflow cannula malfunction of left ventricular assist devices (LVADs) with the use of Doppler echocardiography: new LVAD-specific reference values for contemporary devices. J Card Fail 2016; 22:808-14. Raman SV, Sahu A, Merchant AZ, Louis LBt, Firstenberg MS, Sun B. Noninvasive assessment of left ventricular assist devices with cardiovascular computed tomography and impact on management. J Heart Lung Transplant 2010;29: 79–85.

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