Endovascular stenting of an HVAD™ outflow graft pseudoaneurysm that exerts compression and kinking stenosis on the soft portion of the prosthesis

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Key Clinical Message: Complex presentations of MCS patients may necessitate a multidisciplinary approach involving HF cardiologists, CT surgeons, advanced cardiac imagers, and interventional cardiologists in order to define the optimal management strategy.

Abstract: Left ventricle assist devices (LVADs) provide life-sustaining treatment for patients with terminal heart failure, but their intricacy allows for complications. One complication is LVAD outflow graft obstruction due to the graft's intraluminal thrombus or extraluminal compression. It may be treated endovascularly with stenting. We report an endovascular stenting of an outflow tract in HVAD™ (HeartWare Inc.) due to a pseudoaneurysm causing compression and kinking stenosis.

KEYWORDS

case report, endovascular stenting, Medtronic/HeartWare HVAD

1 | INTRODUCTION

Left ventricular assist device (LVAD) implantation is a well-established therapy for individuals with refractory heart failure that improves survival and quality of life.[1] Although bleeding, infection, thromboembolism, device malfunction, and right-side heart failure are all known consequences of LVAD implantation, the prevalence of life-threatening outflow tract obstruction remains unknown. Other investigators have mainly used device replacement or heart transplantation to treat obstructive issues caused by kinking or malposition of an inflow or outflow cannula.[2] Other researchers treated patients in this case series percutaneously with balloon angioplasty and stenting with balloon-expandable endovascular prostheses, with post-intervention significant improvement in LVAD flow rates.[3]

2 | CASE PRESENTATION

We present a 54-year-old- male (1.8 m, 90.7 kg, body surface area: $2.1 m^2$, body mass index: $28 kg/m^2$) with non-compaction cardiomyopathy and class IV New York Heart Association heart failure who underwent implantation of HVAD™ (HeartWare Inc.) as a bridge to transplant therapy 3 years prior.

The patient presented to the emergency department of our institution with sustainable "low-flow" alarms, angina pectoris, and progressive dyspnea. The patient denied

any history of thorax trauma. On presentation, he had a pulsatile blood pressure of 90/50 mmHg and a heart rate of 120 beats per minute.

HVAD interrogation showed a reduced average flow of 0.5 L/min and power of 2.9 Watts at the speed of 2800 rpm.

Transthoracic echocardiography showed a dilated left ventricle and low-velocity flow of 0.2 m/s in the inflow cannula, regarded as minimal LVAD output. The aortic valve was seen to open in every systole. Hemolysis laboratory values were normal, including lactate dehydrogenase, plasma-free hemoglobin, and bilirubin. He was afebrile and had no physical or laboratory evidence of infection.

A computed tomography angiogram did not reveal inflow cannula obstruction. However, it yielded a sizeable xiphoidal pseudoaneurysm exerting a mass effect on the outflow graft, causing compression of the Dacron prosthesis (Figure 1).

Because of the withdrawal of HVAD™ from the market on June 3, 2021 and extensive comorbidities, open repair via repeat sternotomy was considered a risk-prohibitive, and an endovascular repair was pursued. Informed consent was obtained, and the patient was swiftly shifted to the hybrid operating room.

Initial angiography demonstrated the large pseudoaneurysm at the base of the outflow graft causing compression of the prosthesis and a significant reduction of the pump flow (Figure 2).

Through femoral access, a guidewire could be advanced retrograde to an outflow graft, and a 10×79 mm balloon expandable covered stent (Gore Viabahn VBX) was placed at the site of the pseudoaneurysm (Figure 3) and post-dilated with a 12×40 mm plain balloon (Abbott Armada 35) (Figure 4).

Immediately after stenting of the outflow graft, the alarm of the low flow ceased, and the pump flow returned to normal for the patient (4.1 L/min). Transesophageal echocardiography showed a marked increase in flow in both inflow and outflow cannulae.

Post-intervention angiography revealed a patent outflow graft (Figure 5). A control computed tomography angiography demonstrated a well-positioned stent graft without evidence of endoleak and complete resolution of the pseudoaneurysm (Figure 6). Anticoagulation treatment before and during the stenting was aspirin and intravenous unfractionated heparin. Following the procedure, an oral vitamin K antagonist with an international normalized ratio between 2.5 and 3 was reintroduced. Moreover, aspirin as a mono antiplatelet therapy twice daily was maintained.

HVAD interrogation before discharge showed a normal average flow of 4.1 L/min and power of 4.3 Watts at the speed of 2800 revolutions per minute (rpm).

Six months follow- up the patient remained free of symptoms and without any evidence of LVAD dysfunction or thromboembolic events.

3 | DISCUSSION

On June 3, 2021, Medtronic withdrew the HeartWare Ventricular Assist Device (HVAD) from the global market. It was one of only two commercially available Federal Drug Administration (FDA)-approved ventricular assist devices at the time. Leaving HeartMate 3™ (HM3) as the only available centrifugal pump in the market; however, HM3 does not fit into the HVAD sewing ring: the click-in mechanism for pump fixation of HM3 does not work with the HVAD ring. Thousands of patients on HVAD assistance worldwide face significant limitations in pump exchange in case of complications.[4]
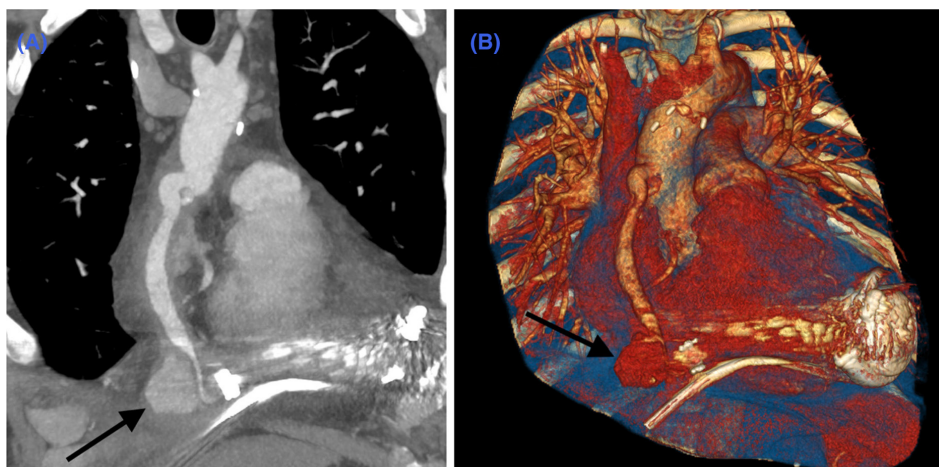

FIGURE 1 (A) Coronal computed tomography angiography image demonstrating the pseudoaneurysm causing significant compression on the outflow graft of the pump (black arrow). (B) Three-dimensional computed tomography angiography reconstruction demonstrating the pseudoaneurysm (black arrow).

FIGURE 2 Initial angiography run demonstrating the large pseudoaneurysm at the base of the outflow graft.
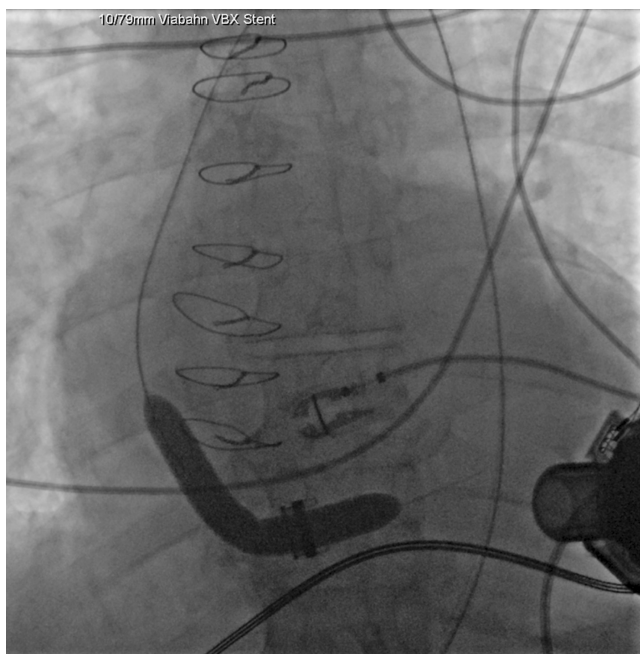

FIGURE 3 Stenting of the left ventricular assist device outflow graft with a balloon-expandable endoprosthesis (Gore Viabahn VBX 10/79 mm).

Given the currently limited options, it is incumbent upon us as clinicians to call on all disciplines to collaborate on creating novel ways to promote the health and well-being of our patients, a multidisciplinary approach involving HF cardiologists, CT surgeons, advanced cardiac
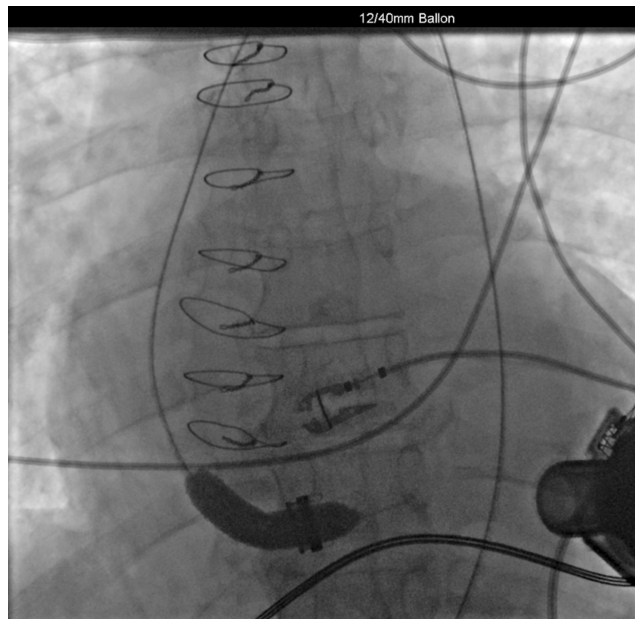

FIGURE 4 Angiography run showing the stent in situ before the over-dilatation (Gore Viabahn VBX 10/79 mm).

imagers, and interventional cardiologists may be needed to define the right approach.

Flow obstruction of the HVAD can be classified into pre, in, and post-pump. The diagnosis of the in-pump occlusion is straightforward due to the evidence of intra-vascular hemolysis and high energy consumption of the pump.

However, differentiating between pre- and post-pump flow obstruction can be challenging. In these types of obstruction, a bedside pump challenging test with increasing the speed (rpm) will not lead to unloading of the ventricle. The differentiation between the two types is possible by computed tomography scan and angiogram of the left ventricle and outflow graft.

The pre-pump occlusion would present with the same pump interrogation (low flow, low energy consumption of the pump, and no evidence of hemolysis in the serum work-up of the patient), that is why it makes it a very likely differential diagnosis. Usually, radiological imaging, mostly a computed tomography scan, can identify the accurate location of the occlusion. A retrograde washout of a pre-pump HVAD thrombus maneuver to avoid the dilemma of pump exchange seems promising in selected patients.[5]

An endovascular repair can offer a less invasive non-inferior outcome for post-pump flow obstruction in selected patients.[6,7] Outflow graft intervention could show evidence of efficacy in outcome in terms of recovery of LVAD flow, unloading of the left ventricle, decrease in the aortic valve opening time, and a subsequent improvement of the right heart function due to decrease of afterload in the pulmonary circulation.[8]
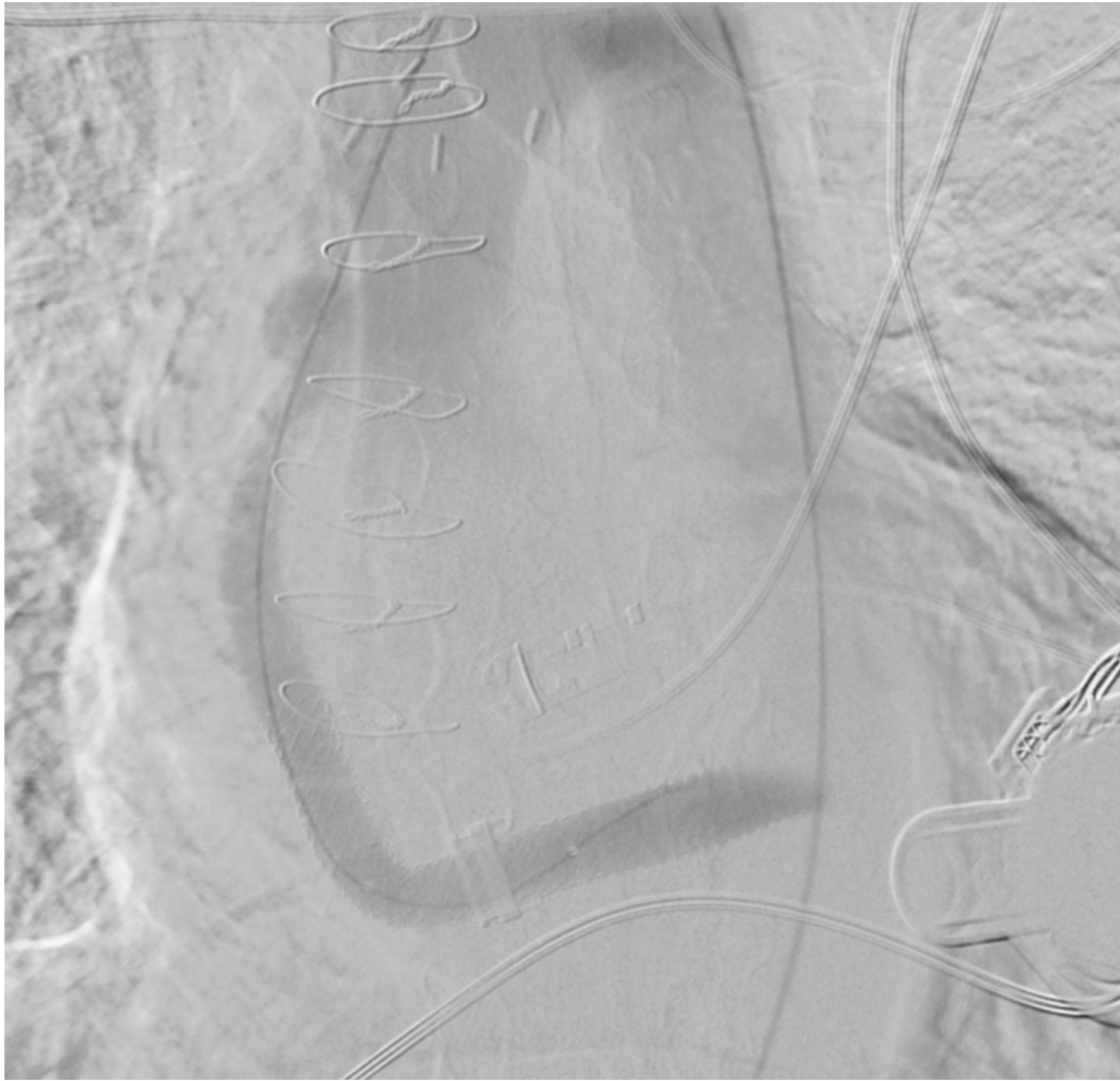
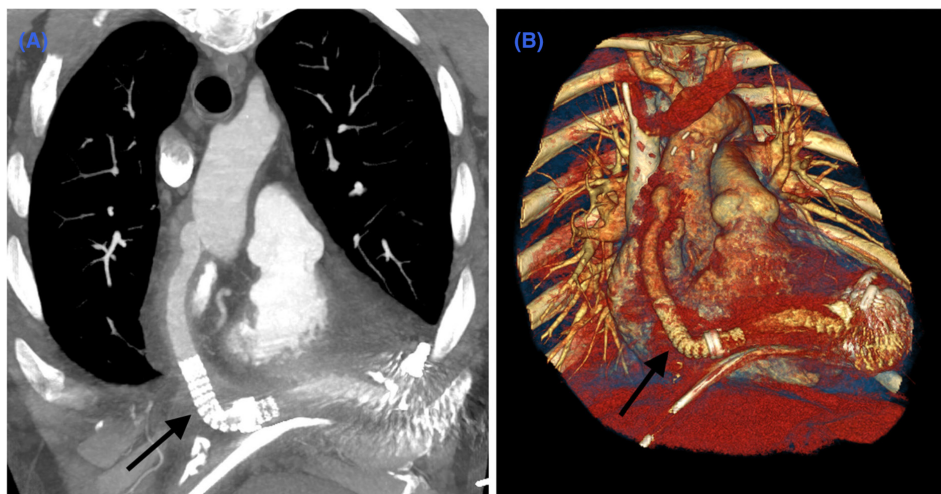**FIGURE 5** Over-dilatating the stent using a 12/40 mm plain balloon (Abbott Armada 35).

FIGURE 6 (A) Control coronal computed tomography angiography image with outflow graft showing a sufficient lumen and stent in situ (black arrow). (B) Three-dimensional computed tomography angiography reconstruction showing the stent in situ (black arrow).

An international multicentre retrospective analysis could provide valuable data concerning the external compression of the outflow graft causing obstruction (eOGO) in a patient under HM3 support. Percutaneous stent implantation played an important role in managing this cohort of patients (15 out of 62 patients). However, the mortality of eOGO with therapeutic intervention reached 17%.[9]

Endograft infection, the risk for LVAD-related thrombosis, damage to the pump mechanism from catheters or wires, wire or catheter entrapment, and endoleaks are potential hazards of the repair technique. Nevertheless, the endovascular approach outlined appears to be a novel, safe, and viable treatment for LVAD outflow tract pseudoaneurysm that avoids a potentially morbid open operation in a compromised patient population.

4 | CONCLUSION

The endovascular stent approach is a realistic alternative in patients with LVAD outflow occlusion.

AUTHOR CONTRIBUTIONS
Mohamed Elbayomi: Conceptualization; writing – original draft. **Michael Weyand:** Supervision. **Michael Uder:** Supervision. **Matthias S. May:** Methodology; validation. **Katrin Steger:** Project administration. **Jan-Peter Roth:** Methodology. **Rene Tandler:** Supervision; writing – review and editing.

DATA AVAILABILITY STATEMENT
The raw data supporting the conclusions of this article will be made available by the authors without undue reservation to any qualified researcher.

DISCLOSURES
The authors declare that they have no commercial or financial relationships that could be construed as a potential conflict of interest to disclose.

DISCLOSURE STATEMENT
None of the authors has a financial relationship with a commercial entity interested in the subject of the presented manuscript or other conflicts of interest to disclose.

CONSENT
Written informed consent was obtained from the patient to publish this report in accordance with the journal's patient consent policy.

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