

Evaluation of Bend Relief Disconnection in Patients Supported by a HeartMate II Left Ventricular Assist Device

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Left ventricular assist devices (LVADs) are an established treatment for patients with end-stage heart failure as either a bridge to cardiac transplantation¹ or as lifelong support, also known as destination therapy.² The HeartMate II (HM II) LVAD (Thoratec Corporation, Pleasanton, CA) is a continuous-flow device that was approved by the US Food and Drug Administration in 2008, after a pivotal trial in 133 patients awaiting transplantation.³ More patients have been implanted with the HM II than any other durable LVAD. Actuarial survival with continuous-flow LVADs has improved to 80% at 1 year and 70% at 2 years, leading to a growing population of patients with heart failure living with long-term mechanical circulatory support.⁴

The HM II titanium axial flow rotary pump is placed in the abdominal musculature or within a preperitoneal pocket in the left upper quadrant. Blood enters the LVAD via an inflow cannula at the LV apex and exits through an outflow cannula connected via a graft to the ascending aorta. The outflow bend relief is a polytetrafluoroethylene tube at the junction of the outflow cannula and the pump housing designed to prevent kinking of the outflow cannula.

In February 2010, Thoratec modified the outflow cannula bend relief with a snap ring design that allowed disconnection of the bend relief to facilitate assessment of the underlying cannula for bleeding or malposition. Between February 2010 and February 2012, the manufacturer distributed >3800 modified outflow cannula bend reliefs to 226 hospitals and distributors worldwide. In April 2012, the US Food and Drug Administration issued a class I recall for the HM II LVAD after reports of disconnection of the bend relief from the outflow grafts.⁵

The initial reported worldwide incidence of disconnected outflow graft bend reliefs was 0.75% (29 of 3852 patients), with 1 death from multisystem organ failure.^{5,6} Surgical interventions related to disconnected outflow graft bend reliefs was reported to be 0.13% (5 of 3852).^{5,6} Although 29 patients had disconnected outflow graft bend reliefs, the 3823 patients

in this report did not undergo systematic screening. A subsequent single-center cohort of 59 patients who had surveillance imaging revealed a prevalence of bend relief disconnection of 34% (11% with complete disconnection and 23% with partial disconnection).⁶ Other centers have also reported complete disconnections in the range of 6% to 15%.⁶

Patients with bend relief disconnection may be asymptomatic. In other patients, the outflow graft may kink or deform, leading to low effective pump flow, hemolysis, fluctuations in LVAD pump speed or power, worsening heart failure, or even bleeding if the outflow graft is punctured by the sharp metal edge of the bend relief. In August 2012, a titanium outflow bend relief collar (Thoratec Corporation) was released to prevent future bend relief disconnections. In patients implanted with the HM II between February 2010 and February 2012, the collar can be surgically placed around the bend relief snap ring with a limited abdominal incision, providing direct visualization of the bend relief connection and without the need for cardiopulmonary bypass.

Although the prevalence of bend relief disconnections is unknown, if the remaining 3823 patients in the initial report were screened, there may be 330 to 570 patients (1 in 17 or 1 in 7 patients, respectively) with a complete disconnection and 1 in 4 patients with partial disconnection. Some patients with asymptomatic bend relief disconnection may be found to have graft erosion and impending graft failure at the time of surgery. Because the consequence of bend relief disconnection may be prevented with early detection in asymptomatic patients, routine surveillance of all patients with this version of HM II has been recommended.⁶

The bend relief connection is normal when the bend relief snap ring and graft are well aligned (Figure 1A and 1B). A partial disconnection (Figure 1C) is diagnosed when the snap ring appears disconnected or poorly aligned with the graft, but without exposure of the underlying outflow graft material. In a full disconnection between the bend relief and the graft, there is exposure of the underlying outflow graft (Figure 1D).

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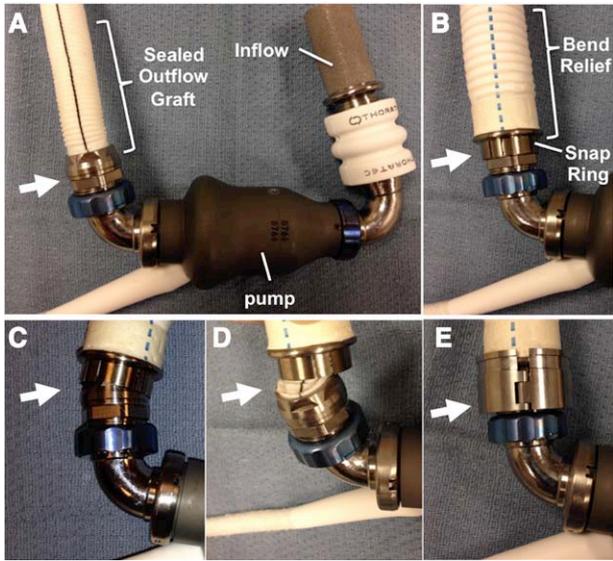


Figure 1. Photographs showing an example of a normal Heart-Mate II left ventricular assist device before (A) and after (B) the bend relief is attached over the sealed outflow graft. Additional photographs demonstrate a partial (C) and complete (D) disconnection of the bend relief and an intact bend relief with a protective titanium collar (E).

Figure 1E shows a normal bend relief connection with the titanium outflow bend relief collar.

This review describes and illustrates HM II LVAD bend relief failure using different imaging modalities, focusing on diagnostic imaging findings that can assist patient management.

Chest and Abdominal Radiography

Chest radiographs are routinely obtained on all patients after LVAD placement. Posterior–anterior and lateral chest radiographs give a projectional overview of the pump and

component positions. However, the LVAD may not be seen on routine 2-view chest radiography because of body habitus (high image noise or poor penetration) or difficulty in patient positioning (device outside the field of view). The acquisition of multiple oblique views and the higher penetration of abdominal radiographs may provide better radiographic delineation of the LVAD bend relief.

In a normal bend relief connection, the bend relief and the graft nut are aligned well and coaxial (Figure 2A). A partial disconnection is when the snap ring appears disconnected from the graft nut and the outflow graft is not exposed (Figure 2B). A full disconnection is when the snap ring appears completely disconnected from the graft nut and the outflow graft is exposed with or without kinking of the outflow graft (Figure 2C).

Routine surveillance abdominal radiographs have been recommended every 3 to 6 months in all patients who were implanted with the modified version of HM II as a screening tool to detect outflow bend relief disconnection.⁶ Radiographs may serve as the initial testing option; however, if the images are inconclusive, a chest and abdominal computed tomographic (CT) scan is recommended.

Echocardiography and LVAD Ramp Study

Echocardiography is routinely used during the perioperative and postoperative period of LVAD implantation. Echocardiography can be used for evaluation of the velocities of the inflow and outflow cannulae at their ostia, ventricular filling and unloading, and circulatory or mechanical complications such as thrombus formation. Echocardiography is used routinely to guide LVAD speed adjustments based on the position of the interventricular septum and the degree of intermittent aortic valve opening, while maintaining appropriate unloading of the LV.⁷ A ramp study is a transthoracic echocardiography assessment of LV decompression and aortic valvular function while LVAD device speed is increased (or decreased) from 8000 to

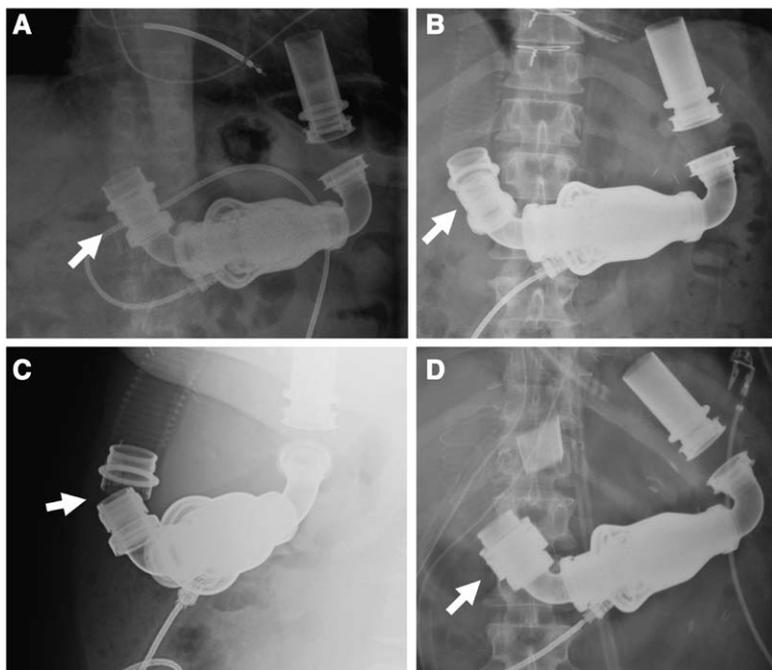


Figure 2. Abdominal x-ray images demonstrate a normal (A) outflow bend relief, partial (B) and complete (C) disconnection, and a bend relief with a protective titanium collar (D).

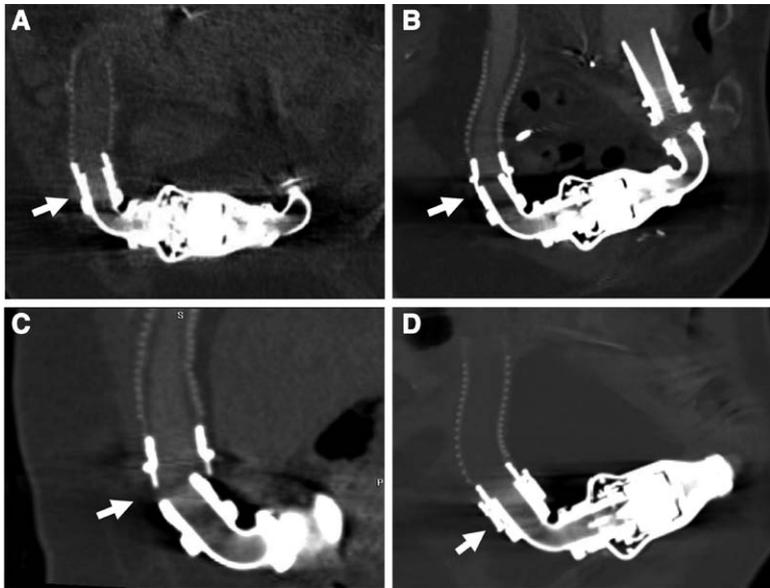


Figure 3. Computed tomographic multiplanar reformatted images that best demonstrated the outflow cannula were constructed on a 3-dimensional workstation: normal (A) outflow bend relief orientation, partial (B) and complete (C) disconnection, and a bend relief with a protective titanium collar (D).

12000 rpm in predefined increments every 2 to 5 minutes.⁸ The ramp study is routinely performed to optimize LVAD function and assess device malfunction.

During a normal LVAD ramp study with pump speed increasing from 8000 to 12000 rpm, changes in LV end-diastolic dimensions are routinely seen. Transient increases in pump power, low-speed LVAD operation, or no change in LV end-diastolic dimensions are indirect findings suggestive of device thrombosis or obstruction. A completely or partially disconnected bend relief may lead to kinking or obstruction of the outflow graft, mimicking device thrombosis.⁹ However, poor acoustic windows and acoustic shadowing because of metallic artifact from the LVAD device limits direct interrogation of the outflow and inflow cannulas and surrounding structures by echocardiography. Transesophageal echocardiography, although less affected by poor acoustic windows, does not provide adequate visualization of the entire inflow or outflow cannula because of limited imaging coverage.¹⁰ The advantages of echocardiography are portability, ability to evaluate real-time changes in LV dimensions with changes in LVAD pump speeds, and ability to perform the test without iodinated contrast material or radiation. Despite the various abnormalities that can be identified by a ramp study, an abnormal study is not specific for partial or complete bend relief disconnection, and patients with a disconnection may have a normal ramp study. Therefore, a ramp study likely has both low sensitivity and specificity for the diagnosis of bend relief disconnection, precluding appropriate clinical management based on echocardiography alone.

Computed Tomography

CT noninvasively images LVAD components with a high resolution and scan times on the order of seconds. CT imaging also assesses critical structures not visualized by echocardiography: bend relief, outflow cannula position, and inflow cannula position. CT is also superior to echocardiography in defining the relationship of LVAD to other structures.¹¹ Retrospective ECG gating allows for image acquisition throughout

the cardiac cycle and provides functional LVAD assessment similar to echocardiography, such as determining LV dimension and middle interventricular septum position.¹⁰ A CT of a normal LVAD should demonstrate the inflow cannula relationship to the LV cavity without obstruction or thrombus, a middle interventricular septum position, persistent aortic valve closure or a small degree of aortic valve opening during systole with closure of the aortic valve during diastole, a coaxial bend relief, and an outflow cannula directed to the ascending aorta without obstruction or thrombus.

The bend relief connection may be seen on the scout image. The CT images should be reformatted and displayed in a window and level setting to optimize the assessment of metal

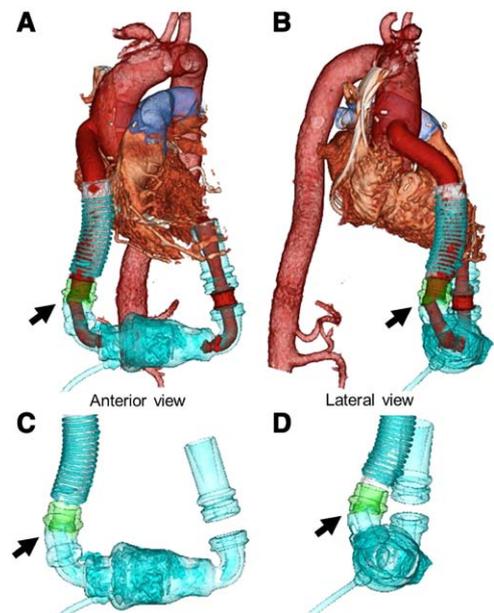


Figure 4. Computed tomographic 3-dimensional volume-rendered images with multibject segmentation of the surrounding structures (A and B) and the left ventricular assist device (C and D) demonstrating a complete disconnection of the bend relief from the sealed outflow graft (black arrow).

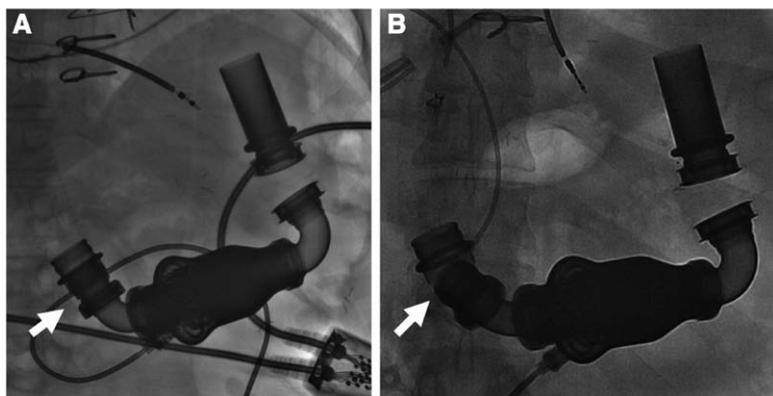


Figure 5. Fluoroscopy images demonstrate a normal (A) outflow bend relief and a complete (B) disconnection (white arrows).

structures to demonstrate the junction between the bend relief and the graft nut. Figure 3 demonstrates examples of a normal bend relief (Figure 3A), a partial bend relief disconnection (Figure 3B), a complete disconnection (Figure 3C), and a normal bend relief connection with the titanium outflow bend relief collar (Figure 3D). Three-dimensional volume-rendered images with color-coding multiobject segmentation can be used to demonstrate pathology (Figure 4; Movies 1 and 2 in the Data Supplement).

A comprehensive protocol to evaluate an LVAD would include retrospective ECG gating (with radiation dose modulation), intravenous contrast material, and coverage from the aortic arch through the abdomen to include the outflow cannula, the entire pump, and exit of the driveline through the skin. A limited evaluation of an LVAD could be performed with ECG gating and without intravenous contrast material in patients with a contraindication to iodinated contrast material, such as renal failure.

Fluoroscopy

Right heart cardiac catheterizations are routinely performed in patients who are being bridged to transplantation. When right heart catheterizations are performed in the cardiac catheterization laboratory, fluoroscopy can be used to visualize projections of the LVAD outflow bend relief at multiple angles. Fluoroscopy and selective angiography of the conduits can be useful to assess the orientation of the inflow and outflow cannulae.^{12,13} The left anterior oblique or right anterior oblique cranial views or an anterior posterior view, depending on positioning, can be diagnostic in evaluating the orientation of the LVAD outflow bend relief communication (Figure 5A and 5B).

Other Imaging Modalities

Based on the material composition of the LVAD, MRI is absolutely contraindicated.

Comparison of Imaging Modalities

There are no studies that compared the diagnostic utility among imaging modalities for patients with suspected bend relief disconnects. When deciding between various imaging modalities, the advantages and limitations of each modality should be considered. Although chest or abdominal radiographs are simple and can be obtained at the bedside or on follow-up, radiographs may be limited by poor penetration or

poor visualization of the bend relief. We recommend that all patients with a clinical, device, or radiographic suspicion of a complication undergo CT imaging for comprehensive assessment for bend relief disconnection, LVAD position, and function. Although echocardiography can provide indirect signs of bend relief disconnection, it has limited sensitivity and specificity to diagnose a disconnected or partially disconnected bend relief and should not guide clinical management for this complication.

Conclusions

Advances in imaging techniques have contributed to our ability to diagnose and monitor complications of LVADs; familiarity with normal and abnormal imaging findings is critical for the detection of a bend relief complication. More data are needed to delineate the comparative utility of different imaging techniques, as well as understand the potential complementary role of integrated approaches.

Based on our current experience and that of others,⁶ our imaging protocol is to perform routine surveillance imaging every 3 to 6 months in patients who were implanted with the modified version of HM II as a screening tool to detect outflow bend relief disconnections. Abdominal radiographs may serve as the initial testing option. Although if right heart catheterization is performed under fluoroscopy in these patients for evaluation of intracardiac pressures as a bridge to cardiac transplantation, we do use fluoroscopy in place of conventional abdominal radiographs to evaluate bend relief. The presence of disconnection on radiographs or fluoroscopy can be diagnostic. However, in patients where chest or abdominal imaging are inconclusive, chest and abdominal CT may be best suited for determining the presence of bend relief disconnection. Future studies are needed to compare the findings of various imaging modalities and better identify LVAD complications.

Disclosures

None.

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KEY WORDS: echocardiography ■ fluoroscopy ■ heart-assist devices ■ heart failure ■ multidetector computed tomography ■ radiography

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Supplemental Material

Video 1. CT three dimensional volume rendered image with multi-object segmentation of the left ventricular assist device and surrounding structures, demonstrating complete disconnection of the outflow bend relief.

Video 2. CT three dimensional volume rendered image with multi-object segmentation of the left ventricular assist device alone, demonstrating complete disconnection of the outflow bend relief.