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INVITED EXPERT REVIEWS

HVAD to HeartMate 3 Left Ventricular Assist Device Exchange: Best Practices Recommendations



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The HeartWare HVAD System (Medtronic) is a durable implantable left ventricular assist device that has been implanted in approximately 20,000 patients worldwide for bridge to transplant and destination therapy indications. In December 2020, Medtronic issued an Urgent Medical Device Communication informing clinicians of a critical device malfunction in which the HVAD may experience a delay or failure to restart after elective or accidental discontinuation of pump operation. Moreover, evolving retrospective comparative effectiveness studies of patients supported with the HVAD demonstrated a significantly higher risk of stroke and all-cause mortality when compared with a newer generation of a commercially available durable left ventricular assist device. Considering the totality of this new information on HVAD performance and the availability of an alternate commercially available device, Medtronic halted the sale and distribution of the HVAD System in June 2021. The decision to remove the HVAD from commercial distribution now requires the use of the HeartMate 3 left ventricular assist system (Abbott, Inc) if a patient previously implanted with an HVAD requires a pump exchange. The goal of this document is to review important differences in the design of the HVAD and HeartMate 3 that are relevant to the medical management of patients supported with these devices, and to assess the technical aspects of an HVAD-to-HeartMate 3 exchange. This document provides the best available evidence that supports best practices.

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The HeartWare HVAD System (Medtronic) is a durable left ventricular assist device (LVAD) approved for bridge to transplant indication in 2012 and destination therapy indication in 2019, based on data from the ADVANCE + Continued Access Protocol, ENDURANCE, and ENDURANCE Supplemental clinical studies.¹⁻⁵ To date, the device has been implanted in approximately 20,000 patients worldwide and had gained wide adoption, particularly in clinical scenarios that use a left anterolateral thoracotomy approach for device placement,⁶ for patients with smaller body size and for off-label pediatric applications.⁷ In December 2020, Medtronic issued an Urgent Medical Device Communication informing clinicians of a critical device malfunction in which the HVAD System may experience a delay or failure to restart after elective or accidental discontinuation of pump operation.⁸ In addition, mounting evidence from retrospective comparative effectiveness studies demonstrated a significantly higher risk of stroke and all-cause mortality in HVAD recipients when compared with those receiving a newer generation of a commercially available durable LVAD, the HeartMate 3 left ventricular assist system (Abbott, Inc).⁹⁻¹³ In a recent report, the HVAD was associated with a higher incidence of major neurologic adverse events in the late constant hazard phase (hazard ratio, 5.71)¹³ and higher risk of risk of mortality (hazard ratio, 3.20) compared with the HeartMate 3 device.⁹ Considering the totality of new information on HVAD performance, Medtronic halted its sale and distribution in June 2021.

Understandably, numerous concerns and questions have arisen from clinicians and patients. The most pressing question is how to treat the patients who remain supported with an HVAD. In particular, 2 options have been advanced: (1) continue ongoing support with the HVAD, only changing to a HeartMate 3 “for cause” (ie, pump malfunction or infection); or (2) electively perform an HVAD-to-HeartMate 3 exchange to reduce the potential risk of patient harm that may occur from a device malfunction related to the “failure to restart” mode of device failure. Current recommendations from Medtronic support the former strategy. Recent analyses from The Society of Thoracic Surgeons Interagency Registry for Mechanically Assisted Circulatory Support registry has similarly supported a “for cause” approach because continued support on a normally functioning HVAD was associated with less risk than that associated with exchange to a HeartMate 3.¹⁴ Furthermore, the early risk of exchange from an HVAD-to-HeartMate 3 was similar to that of exchange from an HVAD-to-HVAD, suggesting that patients were not disadvantaged by requiring an exchange to the HeartMate 3.¹⁴

The decision to remove the HVAD from commercial distribution now requires surgeons to use the HeartMate

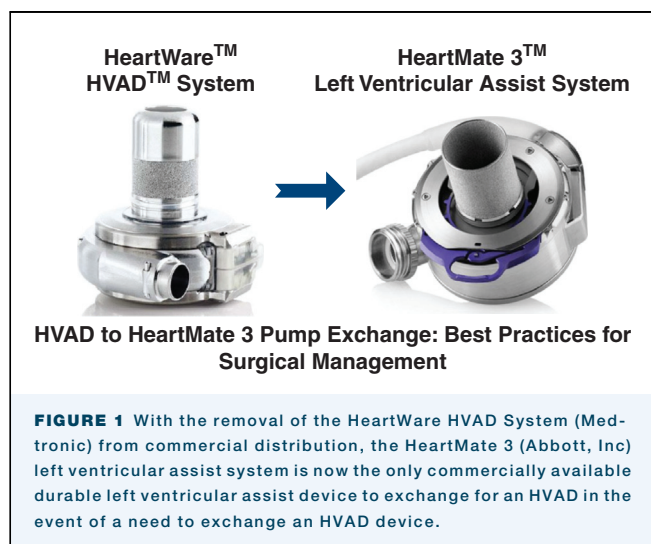
3 as the only commercially available device for primary implantation as well as for exchanging a previously implanted HVAD (Figures 1 and 2). The goal of this document is to (1) highlight differences in the design of the HVAD and HeartMate 3 that are relevant to patient management; and (2) review the surgical management of an HVAD-to-HeartMate 3 exchange. This document provides the best available evidence and consensus opinion that support best practices.

MATERIAL AND METHODS

DIFFERENCES IN DEVICE DESIGN AND IMPLICATIONS FOR MEDICAL MANAGEMENT. Both pumps are continuous-flow LVADs with centrifugal flow design.^{15,16} The HVAD uses a hybrid engineering design to levitate the internal impeller with passive magnetic levitation and a hydrodynamic bearing. It incorporates an optional proprietary pump speed management algorithm, termed the “Lavare Cycle,”¹⁷ that is designed to reduce pump and ventricular blood stasis and improve washout. The HeartMate 3 is designed with complete magnetic levitation of the internal impeller that permits greater distances between the motor housing and the impeller compared with the gaps that can be achieved with a hydrodynamic bearing. Its pump operation includes an obligatory change in pump speed that achieves a reduction in flow stagnation in the pump.¹⁸ Recent data have suggested that the 2 pumps significantly differ in the rates of hemocompatibility-related adverse events, particularly with respect to stroke.⁹⁻¹³ Whether these dissimilarities are related to the differences in pump design or their dynamic pump speed modulation algorithms remains unknown.

Additional features of the HVAD include a real-time display of pump waveforms on the HeartWare monitor that depict the variability of blood flow through the pump and the ongoing collection of pump parameters and performance data in the Controller logfiles. Information gleaned from logfiles, when used in combination with clinical data and assessment, provides critical information on pump performance to support clinical decision making.¹⁹ The HeartMate 3 uses the HeartMate Touch Communication System that provides clinicians with the ability to wirelessly monitor the HeartMate 3 system, program system parameters such as pump speed, assess and track alarm conditions, and view and save performance data. The Touch Communication System provides data on pump speed, pump power, pump flow, and pulsatility index.

PATIENT MANAGEMENT. It is important to note that anticoagulation, antiplatelet, and blood pressure (BP) management recommendations for the HVAD System have not been altered as a result of the HVAD device recall.



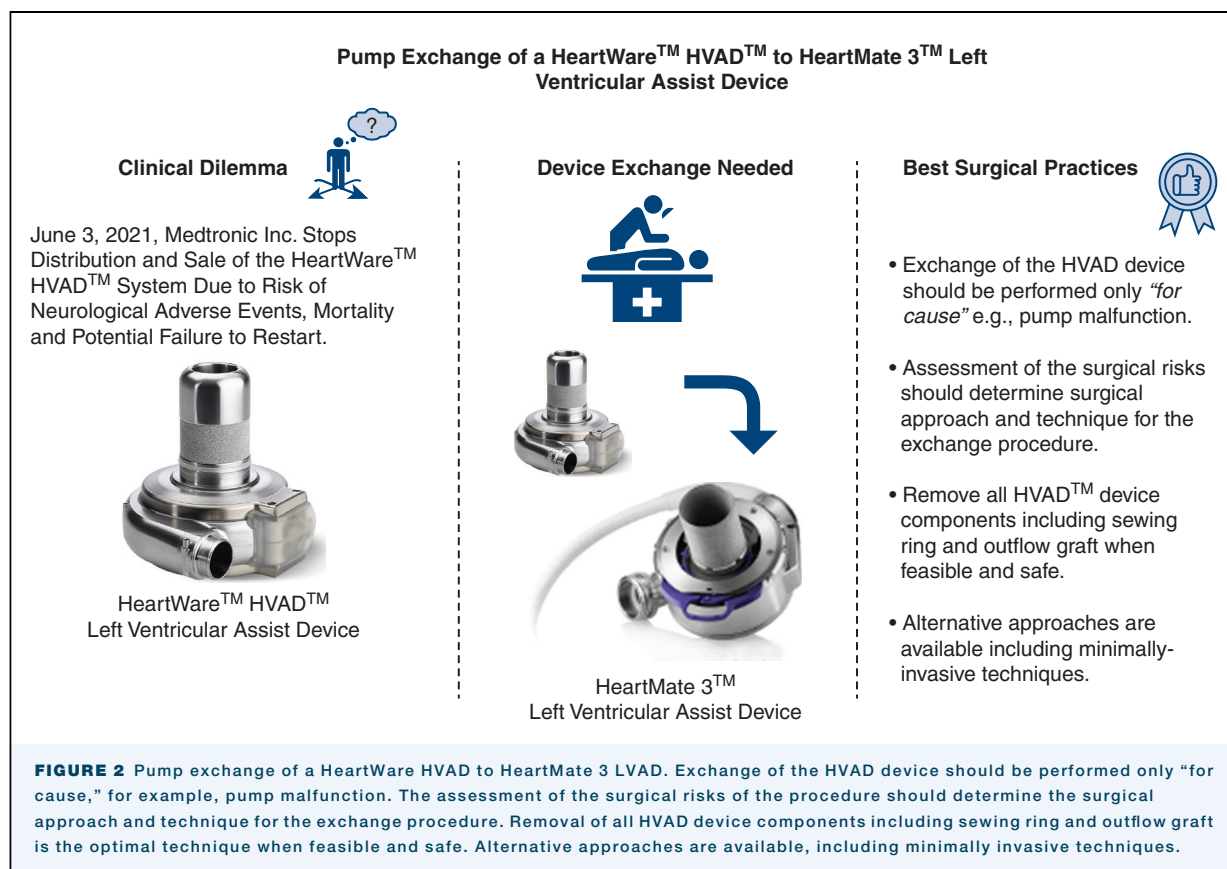
ANTICOAGULATION AND ANTIPLATELET MANAGEMENT.

Antithrombotic recommendations for the HVAD are based on clinical experience in the ADVANCE + Continued Access Protocol,^{1,3} ENDURANCE,⁴ and ENDURANCE Supplemental clinical studies.⁵ Recommended antithrombotic therapy included warfarin anticoagulation targeted to an international normalized ratio of 2.0 to 3.0 as well as antiplatelet therapy with aspirin at more

than 81 mg daily. Initial aspirin dosing of 81 mg was associated with an increased risk of pump thrombosis and stroke.^{20,21} In ENDURANCE, 29.7% of patients experienced a stroke with the HVAD device compared with 12.1% of patients receiving the comparator device, the HeartMate II (Abbott Labs).⁴ In the ENDURANCE Supplemental clinical study, 14.7% of patients experienced a stroke with the HVAD device compared with 12.1% of patients with the HeartMate II device.⁵

Antithrombotic recommendations for the HeartMate 3 are based on the clinical experience from the MOMENTUM 3 and HeartMate 3 Conformité Européenne Mark clinical studies.²²⁻²⁵ It calls for warfarin anticoagulation with an international normalized ratio targeted to 2.0 to 3.0 and antiplatelet therapy with aspirin 81 mg daily. In the MOMENTUM 3 clinical study, 9.9% of patients receiving the HeartMate 3 experienced a stroke compared with 19.4% receiving the HeartMate II.²² The safety of discontinuing aspirin therapy is currently being evaluated in a multicenter, prospective, randomized, double-blinded clinical trial.²³

BLOOD PRESSURE MANAGEMENT. BP management is important for both HVAD and HeartMate 3 devices because continuous-flow devices are afterload sensitive and designed to optimally perform within a narrow



range of BP. Data from the ENDURANCE Supplemental clinical study demonstrated that an enhanced BP protocol significantly reduced mean arterial pressure (MAP) and reduced the overall stroke rate by 24.2%, with a 50% reduction in hemorrhagic strokes compared with the original ENDURANCE clinical study in which said protocol was absent.^{4,5} Current recommendations for BP management for HVAD recipients include a target MAP less than 85 mm Hg if the patient has a palpable pulse or less than 90 mm Hg if the patient does not have a palpable pulse.^{5,26} A manual cuff and Doppler is the preferred method for measuring BP.

Conversely, BP management for patients supported by the HeartMate 3 is less well defined. Patients supported on the HeartMate 3 should be maintained with a MAP between 80 and 90 mm Hg unless symptoms of lightheadedness, poor organ perfusion, or other symptoms due to low pressure supervene, thereby mandating a higher MAP goal. The risk of hemorrhagic stroke with higher BP goals has not been definitively established as with the HVAD. It is thought that the artificial pulse algorithm used in the HeartMate 3 may cause inaccuracies in determination of MAP, causing clinicians to overestimate actual MAP²⁷ (Table 1).

SURGICAL CONSIDERATIONS FOR LEFT VENTRICULAR ASSIST DEVICE PUMP EXCHANGE.

The global risk associated with LVAD exchange is often related to the preoperative status of the patient and is also driven by the reasons for the exchange procedure. A recent systematic review estimated the risk of 30-day mortality for pump exchange in the setting of changing devices was approximately 10% but varied by pump type.²⁸ In addition to pump failure, comorbidities may include right ventricular failure, hepatic or renal dysfunction, a history of prior stroke, and ongoing hemolysis, coagulopathy, and platelet dysfunction. All these comorbidities should be considered when deciding on the operative method of exchange. Preoperative medical management should include (1) discontinuation of long-acting agents that may suppress the sympathetic nervous system (eg, beta-blockers, angiotensin receptor neprilysin inhibitor/angiotensin-converting enzyme inhibitor) to reduce risk of vasoplegia; (2) optimization of right ventricular function with inotropes, diuretics, or temporary mechanical support; and (3) optimization of hemostatic function.

First, the appropriate position and angle of the HVAD inflow cannula must be determined using transesophageal echocardiography or cross-sectional contrast study to assess inflow cannula position within the left ventricular chamber. If malposition of the inflow cannula is present, all components of the HVAD sewing ring should be removed and the new HeartMate 3 sewing ring should be attached to the apex. The inflow cannula position of the HeartMate 3 pump can then be optimized

TABLE 1 Medical Management: Best Practices Recommendations

BP management

- BP management goals should be individualized to the patient's condition. Patients and caregivers should be trained to obtain BP readings and record values before index hospital discharge and should be provided specific MAP targets to notify their clinician for possible intervention.
- For patients supported with an HVAD without a palpable pulse, a manual cuff and Doppler is the preferred method for measuring BP with a MAP targeting <90 mm Hg.
- For HVAD patients with a palpable pulse, MAP targets should be <85 mm Hg.
- The target goals for BP management for patients supported with the HeartMate 3 are not as well established as those for the HVAD. Patients supported on the HeartMate 3 should be maintained with a MAP between 80 and 90 mm Hg unless this BP goal is associated with symptoms of lightheadedness, poor organ perfusion, or other symptoms due to low pressure in which a higher BP goal should be established. The risk of hemorrhagic stroke with higher BP goals has not been definitively established as with the HVAD.

Anticoagulation

- Patients supported on the HVAD and the HeartMate 3 should be maintained on warfarin anticoagulation with a target international normalized ratio of 2.0 to 3.0.

Antiplatelet therapy

- Patients supported on the HVAD should be maintained on antiplatelet therapy with aspirin at a dose of >81 mg/d.
- Patients supported on the HeartMate 3 should be maintained on antiplatelet therapy with aspirin 81 mg/d.

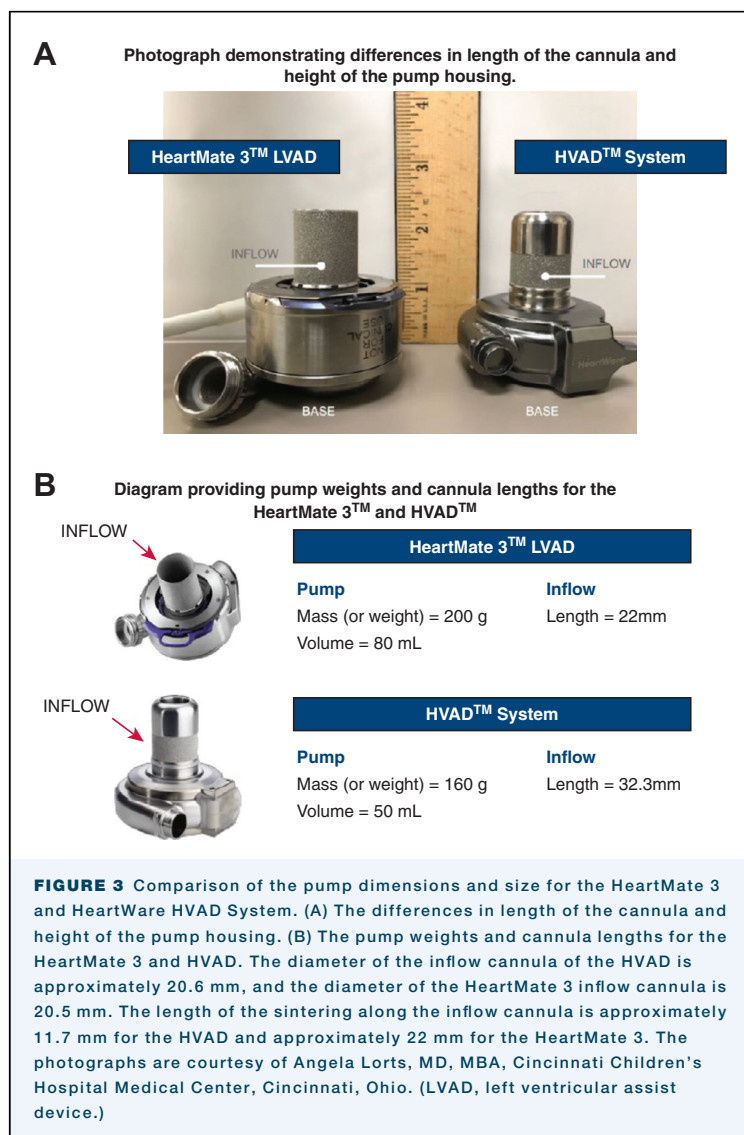
Device Management and Monitoring

- For the HVAD, clinicians should continue to monitor waveforms in ambulatory and inpatient settings and use Autologs/HVADLogs to better understand pump performance and to support clinical decision making, including evaluation of suspected pump thrombus, suction events, and so forth. The Autologs report provides detailed information and trends regarding pump speed/flow/power, medium and high priority alarms, power source data, and system setting changes.
- For the HeartMate 3, clinicians should continue to monitor pump parameters on a routine basis to assess changes in pump parameters.
- For both devices, it is important to assess the clinical condition of the patient in addition to assessing pump parameters.

BP, blood pressure; MAP, mean arterial pressure.

with transesophageal echocardiography guidance and traction sutures placed from the pump to the chest wall or adjusting the length of the outflow graft. Generous dissection to free adhesions of the heart may be necessary to permit apical traction to optimize inflow cannula alignment. Extending the pericardial incision, creating a small preperitoneal space at the left ventricular apex, or opening the left pleura may aid in accommodating the larger HeartMate 3 pump housing to ensure proper inflow cannula alignment.

HVAD-TO-HEARTMATE 3 DEVICE EXCHANGE. There are several important technical aspects of the exchange procedure to consider (Figure 3; Supplemental Figures 1-3; Video 1). First is the difference in size and design of the apical connector/sewing ring between the 2 systems. Second is the discrepancy of the outflow graft diameter between the 2 systems. Third is the surgical approach for device exchange: sternotomy versus anterolateral



thoracotomy. For surgeons with appropriate experience in alternative approaches, an anterolateral thoracotomy approach can be used to prevent injury to cardiac structures or damage to the outflow graft if adherent to the posterior sternal table.

Apical sewing ring/connectors. The apical sewing ring of the HVAD differs significantly from that of the HeartMate 3 (Supplemental Figures 4 and 5). The diameter, including the sewing cuff of the HVAD sewing ring, measures 43 mm in size. The inflow cannula of the HVAD measures 25 mm from the "O" ring to cannula tip and 32.3 mm from pump housing to cannula tip with a 21-mm outer diameter. The HVAD pump is fabricated of smooth titanium with sintering halfway up and contains a silicone O-ring to ensure a seal with the sewing ring. The HVAD inflow cannula has a larger diameter compared with the inflow cannula of the HeartMate 3.¹⁶

The HVAD sewing ring is constructed of titanium and Dacron polyester and secures the pump inflow cannula in position with the aid of a torque wrench. The inner portion of the metallic sewing ring is a C-clamp that can be adjusted by turning a screw inside the clamp to secure the base of pump's inflow cannula for optimal placement of the inflow cannula.

The HeartMate 3 device has 2 choices for apical connectors: a larger size sewing ring with metal housing to maintain a flat geometry of the felt sewing cuff and a second, smaller design in which the metal housing has been removed and the size of the felt sewing ring is reduced in size (Supplemental Figure 5). The HeartMate 3 inflow cannula measures 22 mm in length from the pump housing to cannula tip and 20 mm in external diameter. The outer diameter of the inflow cannula for the HeartMate 3 is smaller than that of the HVAD and measures only 20.5 mm (this dimension includes the sintering surface) compared with 20.6 mm for the outside diameter of the HVAD inflow cannula.^{15,16} Thus, the inlet cannula of the HeartMate 3 cannot simply be placed through the HVAD metallic sewing ring and obtain a hemostatic seal and requires deviations from the HeartMate 3 implant technique as developed in the MOMENTUM 3 clinical study and described in the HeartMate 3 Instructions for Use.²⁹⁻³¹ Previous reports have described use of a rubber seal to obtain hemostasis at the inflow connection^{29,30} (Supplemental Figure 6). The long-term consequences of using an improvised seal are unknown.

Outflow graft. The outflow grafts of the HVAD and HeartMate 3 differ in diameter, measuring 10 mm and 14 mm, respectively (Supplemental Figure 7). This difference in outflow graft diameter has important implications in the exchange procedure and recommendations for best practices. During the exchange procedure, complete removal of the HVAD outflow graft would eliminate the concern for discrepancy in outflow graft sizes. Suturing of the HeartMate 3 outflow graft to a remnant of the HVAD outflow graft will necessitate a significant reduction in outflow graft diameter at the anastomosis or distal to it. This reduction in size would increase afterload to the HeartMate 3³² (Supplemental Figure 8). The long-term consequences of this increase in afterload to the HeartMate 3 are unknown and may potentially increase the risk of hemocompatibility-related adverse events or result in inadequate left ventricular unloading and manifestations of heart failure. In vitro studies suggest that suturing the 14-mm outflow graft of the HeartMate 3 to varying lengths of remnants of the HVAD 10-mm outflow graft increases afterload to the HeartMate 3.³² Additional data suggest that this added resistance may be overcome by adjustment of pump speed.³² The unknown clinical consequences of higher rotor speeds on hemocompatibility risks, battery runtime, and pump performance with

retention of an HVAD remnant should be balanced against other procedural considerations.

Exchange procedure. The technique for exchange that is most consistent with the HeartMate 3 Instructions for Use³¹ is to completely excise the preexisting HVAD sewing ring and replace it with a new apical connector specific to the HeartMate 3 device (Supplemental Figure 9). Use of circulatory support with cardiopulmonary bypass or extracorporeal membrane oxygenation is recommended for the exchange procedure to allow inspection of the left ventricular cavity and to ensure that the pannus and left ventricular thrombus are completely removed (Supplemental Figure 10). The HeartMate 3 apical connector can then be sewn to the left ventricular apex using a series of interrupted, pledgetted, horizontal mattress sutures (~12 individual sutures) for the standard cuff (Supplemental Figure 11). Alternatively, 4 pledgetted sutures followed by a running polypropylene suture can be used to obtain a secure attachment of the “mini” apical connector to the left ventricular apex.

In addition to removal of the HVAD sewing ring, complete removal of the outflow graft with enlargement of the aortotomy to accommodate the 14-mm outflow graft of the HeartMate 3 completely eliminates the discrepancy in outflow graft size mismatch (Supplemental Figure 12). This technique will prevent a pressure drop across the reduced size HVAD outflow graft and avoid an increase in afterload to the HeartMate 3. However, other procedural considerations must be weighed, including the additional complexity of having to clamp the ascending aorta partially or fully. Moreover, the use of a left anterolateral thoracotomy approach often requires using a remnant of the HVAD outflow graft.^{33,34}

Alternative surgical techniques for securing the HeartMate 3 to the left ventricular apex. Other options for securing the HeartMate 3 to the left ventricular apex have been advanced.^{29,30,33,34} Each has important potential benefits and limitations. If full sternotomy or complete replacement of the HVAD sewing ring with the HeartMate 3 apical connector poses unacceptable risk as assessed by the surgical team, the following modifications can be considered.^{29,30}

A. Implantation of the HeartMate 3 by sewing the HeartMate 3 apical connector over the existing HVAD sewing ring

The HeartMate 3 sewing ring can be sewn to the left ventricle over the existing HVAD sewing cuff. This is feasible because the sewing ring of the HeartMate 3 is larger. This approach reduces surgical time because it obviates the amount of dissection needed to remove the existing HVAD apical sewing ring. However, hemostasis of this approach must be ensured and may be more technically difficult to achieve compared with full

TABLE 2 Surgical Management: Best Practices Recommendations

Indication for exchange

- Current data do not support “elective” HVAD-to-HeartMate 3 exchange to reduce the potential risk of adverse events arising from a failure to restart device malfunction.¹¹ Exchange from an HVAD-to-HeartMate 3 should be performed only “for cause” (ie, device thrombosis or device electrical failure, or device infection not responsive to medical management).

Technique for exchange

- Under optimal clinical scenarios, an HVAD-to-HeartMate 3 exchange should include removal all components of the HVAD device and the apical sewing cuff of the HeartMate 3 device is sewn to the apex of the left ventricle. The outflow graft of the HVAD System is completely removed to reduce the discrepancy in outflow graft diameter between the 2 systems.
- It is both safe and feasible to implant a HeartMate 3 device through an anterolateral thoracotomy approach. However, this technique does not address the issue of discrepancy in size of the outflow graft between the 2 LVAD systems. An upper right anterior thoracotomy or an upper hemi-sternotomy incision to tunnel the HeartMate 3 outflow graft through the right chest to anastomose to the ascending aorta may be added to the anterolateral thoracotomy approach for device exchange to exclude all remaining remnants of the HVAD outflow graft. This technique must be balanced against using a remnant of the HVAD outflow graft.
- Alternative approaches may be considered, if in the opinion of the surgical team, complete excision of all HVAD components poses a unacceptable surgical risk.

LVAD, left ventricular assist device.

excision and replacement of the existing HVAD sewing ring. Moreover, this technique reduces the depth of insertion of the HeartMate 3 inflow cannula into the left ventricular cavity, a configuration with unknown sequelae (ie, hemocompatibility-related adverse events). Alternatively, the metal connector portion of the HVAD sewing ring can be removed while leaving only the fabric portion of the sewing ring. This technique can reduce operative time and potentially have less effect on the depth of insertion of the HeartMate 3 inflow cannula.

B. Implantation of the HeartMate 3 using the existing apical sewing ring of the HVAD system

For the implantation of the HeartMate 3 inflow cannula into the remaining HVAD metallic sewing ring, a sterile rubber seal can be placed around the inflow cannula of the HeartMate 3 to avoid leakage between the HVAD metallic sewing ring and the inflow cannula of the HeartMate 3.^{29,30,33,34} (Supplemental Figure 6). The inflow cannula of the new HeartMate 3 can then be placed into the established HVAD metallic sewing ring, and the screw of the HVAD sewing ring can be tightened. The advantage of this technique is the reduction in the time needed to replace the HVAD sewing ring and extent of apical dissection. However, if a reliable seal is not obtained, bleeding and potential for pseudoaneurysm formation could occur.

Anterolateral left thoracotomy approach versus sternotomy approach. An anterolateral left thoracotomy approach may offer several advantages to the redo-sternotomy approach for device exchange.^{33,34} In view of the larger dimensions of the HeartMate 3, a wider incision is generally required when using an anterolateral thoracotomy approach.³³ A major limitation of

this approach is that a longer remnant of the HVAD outflow graft is left in place because the graft-to-graft anastomosis is typically performed over the acute margin of the right ventricle just behind the sternum. As suggested, this could significantly increase afterload to the HeartMate 3 and necessitate increasing the pump speed of the HeartMate 3 to accommodate the increase in resistance.³² A preoperative computed tomography angiogram should be obtained to exclude luminal thrombus or extra-luminal compression or kinking of distal segments of the retained HVAD outflow graft. Alternatively, a right upper anterior thoracotomy, tunneling the HeartMate 3 outflow graft through the right chest, and anastomosis to the ascending aorta at the site of the previous HVAD outflow graft can be considered. This technique, although adding an additional incision and complexity, can completely exclude all the HVAD outflow graft. Less desirable alternatives to exclude the HVAD outflow graft include anastomosis of the HeartMate 3 outflow graft to the descending thoracic aorta or the subclavian artery, although these would require leaving a blind HVAD outflow graft in place. Data on the safety of these approaches are not available (Table 2).

CONCLUSIONS

This document outlines important differences that exist in both patient management and techniques for surgical exchange of an HVAD-to-HeartMate 3 exchange. Current data support the recommendation that patients supported with a normally functioning HVAD should remain on support and only undergo exchange “for cause” because the risk of death due to device exchange likely exceeds the risk of death remaining on a normally functioning HVAD device. It is likely that future analyses of data from registries of durable LVAD devices will be performed to continue to monitor evidence to support any changes to this recommendation. Preferably, patients requiring an HVAD-to-HeartMate 3 exchange should undergo removal of all HVAD system components and replacement with HeartMate 3 components unless, in the opinion of the surgical team, this approach poses unacceptable risk, in which case, alternative procedures that reduce the extent of dissection and reduce surgical time can be used.

CONFLICT OF INTEREST STATEMENT

J.C.: Consultant-Abbott, Steering Committees-Medtronic, Abbott, Endotronix, Procyron, Speaker-Zillow, Abbott. E.F.: Advisory Boards/Consultant-Medtronic (receives honoraria). D.G.: Consultant/Medical Advisory Board/National Co-PI -MOMENTUM 3 Trial for Abbott. S.H.: Consultant/Advisory Board-Medtronic, Abbott, Abiomed, CareDx, Natera. C.H.: Consultant-Abbott, Medtronic LLC (receives honoraria). D.K.: Speaking Fees/Advisory Board-Medtronic; Speaking Fees-Abiomed. A.K.: Speaker/Consultant - Abbott; Abiomed. A.L.: Consultant/Educational Grant-Abbott, Berlin Heart, SynCardia, Medtronic, Abiomed; N.A.M.: Consultant-Abbott, Medtronic, SynCardia, Carmat. F.D.P.: Advisory Board (non-compensated)-FineHeart, CH Biomedical, Abbott, Medtronic. D.T.P.: Consultant/Speaker-Abbott, Abiomed, Medtronic. E.P.: Institutional Grants/Consulting/Proctoring-Medtronic, Abbott, Abiomed. D.S.: Consultant-Abbott, Medtronic, Abiomed. C.T.S.: Consultant-Abbott, Medtronic. M.S.S.: National PI-EvaHeart 2 Clinical Trial, Clinical Site PI-Carmat. E.S.: Consultant-Abbott, Abiomed, Atricle. S.T.: Consultant/Advisor-The British Standards Institute, Chief Medical Officer-3R Life Sciences Ltd. D.Z.: Consultant/Research Grants/Speaker Fees-Abbott, Medtronic, Berlin Heart, Abiomed. All other authors reported no conflicts of interest.

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