# EMERGING TECHNOLOGY REVIEW

*Gerard R. Manecke, Jr, MD*
*Marco Ranucci, MD*
*Section Editors*

## Real-Time 3-Dimensional Echocardiographic Assessment of Current Continuous-Flow Rotary Left Ventricular Assist Devices

Javier G. Castillo, MD,* Anelechi C. Anyanwu, MD,* David H. Adams, MD,* Thandiwe Nyirenda, MD,† and Gregory W. Fischer, MD†

CONGESTIVE HEART FAILURE (CHF) has been estimated to affect between 62 and 124 million people worldwide.[1] The incidence (2-3/1,000 population) is predicted to increase proportionally as life expectancy of the world's population rises. In the United States alone, about 6 million people suffer from CHF, and approximately 400,000 new cases are diagnosed each year.[2] In addition to the resulting financial burden, this condition shows a merely 20% to 40% survival rate at 5 years, and for those patients in the terminal phase of systolic heart failure (New York Heart Association IV), mortality rates at 1 year are as high as 50% despite optimal maximized medical therapy.[3]

For this group of severely ill patients, heart transplantation has been shown to provide the greatest survival benefit and best quality of life, but only approximately 2,000 heart transplants are performed annually in the United States because of the lack of donor availability.[4] The paucity of donor organs makes this therapy an inadequate solution. Additionally, many of these patients are not suitable candidates for heart transplantation mainly because of age-related issues or diabetes with subsequent end-organ damage. Consequently, this reflects in the incremental worsening of the risk profile for currently referred patients.[5] Therefore, in the post-REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) era, left ventricular assist device (LVAD) therapies have emerged as an extremely attractive alternative either used as bridge to transplant, as bridge to recovery, or as destination therapy.[6,7]

LVADs increasingly are used for the treatment of stage D heart failure. The majority of these devices are placed as a bridge to cardiac transplantation, whereas others are intended for lifetime support ("destination therapy"). In addition, ventricular assist devices are used in the treatment of acute cardiogenic shock such as that caused by myocardial infarction or as a result of cardiac surgery (postcardiotomy shock). The number of patients on mechanical support in the United States at the time of transplantation rose from 3% in 1990 to about 38% in 2004.[8] As the field of mechanical circulatory support advances, transesophageal echocardiography is becoming an even more essential tool for the perioperative management and assessment of patients undergoing LVAD implantation.[9] The important role of echocardiography in providing information for surgical and anesthesiologic decision-making has been well described and shown. The presence of intracardiac shunts, valve dysfunctions (particularly aortic insufficiency and mitral stenosis), suboptimal placement of LVAD cannulae, or intracardiac thrombi can be visualized. The authors believe that the introduction of 3-dimensional echocardiography further improves and facilitates the perioperative echocardiographic evaluation of these patients by allowing real-time imaging of the anatomic location and dynamic relationship between the device and surrounding anatomic structures during the cardiac cycle.[10,11] Herein, the authors' experience with the application of real-time 3-dimensional echocardiography (RT3DE) to the evaluation of patients undergoing LVAD implantation surgery is described.

### LEFT VENTRICULAR ASSIST DEVICES

Current generation LVADs are electromechanical pumps designed to provide circulatory support for patients with end-stage heart failure. Although every device has its own specifics, all LVADs consist of 3 principal components: (1) an inflow cannula to drain blood from the left ventricle or atrium, (2) a pump to propel the blood, and (3) an outflow graft or cannula to return the blood to the aorta (Fig 1).

#### Pulsatile-Flow LVADs

To date, most patients have been supported by "1st-generation" devices that are based on pulsatile volume displacement. These devices are built around an internal chamber, inflow/outflow valves to allow cyclic filling and emptying of the device, and a pneumatic or electrically driven diaphragm that displaces blood when activated. Examples include the HeartMate XVE (Thoratec Corp, Pleasanton, CA), Thoratec PVAD and IVAD (Thoratec Corp), or Novacor (World Heart Corp, Oak-

*From the Departments of *Cardiothoracic Surgery and †Anesthesiology, Mount Sinai Medical Center, New York, NY.*

*Address reprint requests to Gregory W. Fischer, MD, Department of Anesthesiology, Mount Sinai Medical Center, One Gustave L. Levy Place, Box 1010, New York, NY 10029. E-mail: gregory.fischer@mountsinai.org*



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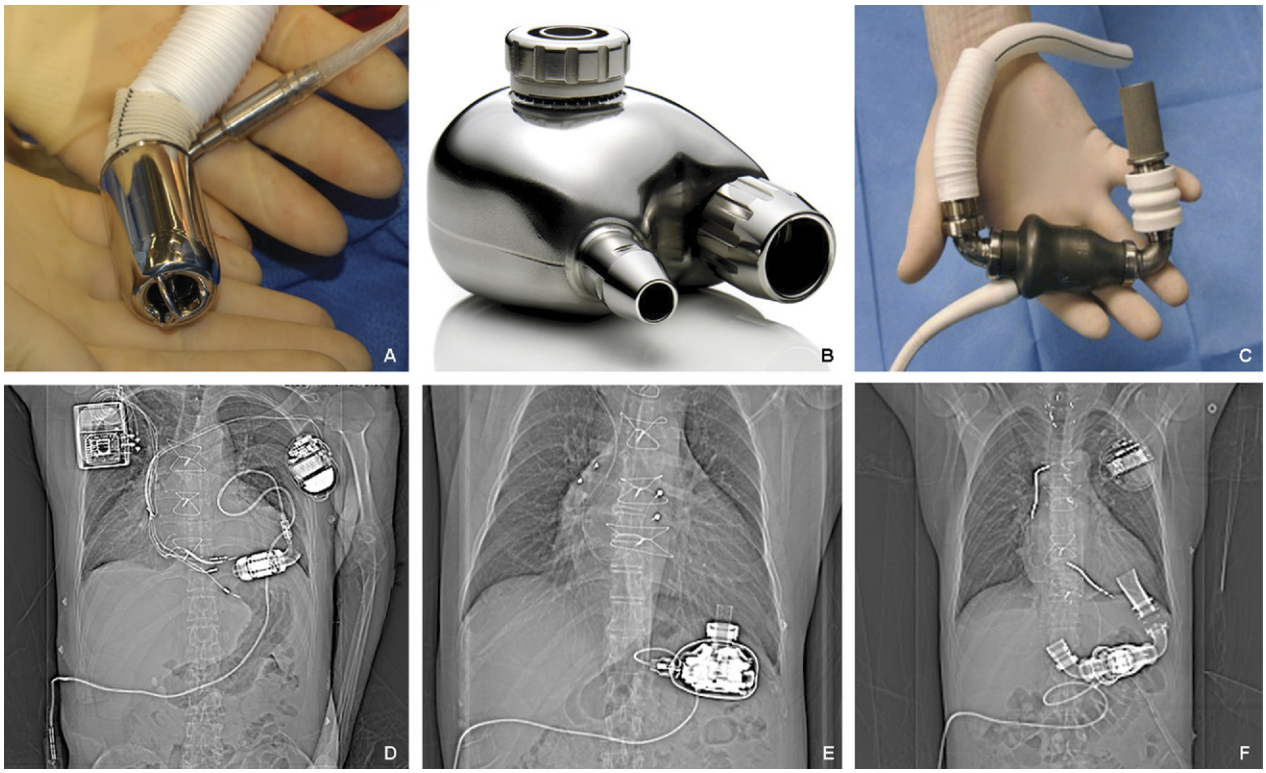


**Fig 1. (A and D) Jarvik 2000, (B and E) Ventrassist, and (C and F) HeartMate II and their respective radiologic images showing the devices in place after surgical insertion. (Color version of figure is available online.)**

land, CA). However, these devices are limited by large pump size, the need for a large-diameter percutaneous lead for air-venting purposes, the requirement of valves in the inflow and outflow position, and a loud functioning sound of the device. In fact, the implantable "1st-generation" LVADs generally cannot be used in patients with body surface areas less than 1.5 $m^2$, therefore excluding small adults, many women, and most children. Furthermore, the size of these pumps requires a large surgical incision with a potential higher associated morbidity, particularly as it relates to bleeding complications. Finally, a very important limitation of these pumps involves the complexity of the engine consisting of multiple interacting parts, which exert frictional forces on each other. Bearings are required at the interface between the moving and stationary parts of the pump, and seals are required to separate these bearings from the blood. These bearings and seals and also the valves within the device have limited durability, which shortens the longevity of pulsatile devices. The most used 1st-generation device, the HeartMate XVE, has been associated with a pump failure rate of 24.6% within the first year, and almost all devices will fail within 2 years.[12]

## Continuous-Flow Rotary LVADs

The majority of the "2nd- and 3rd-generation" LVADs with human clinical experience in the United States are in the late stages of investigational trials; only the HeartMate II (Thoratec Corp) has been granted approval for clinical use by the Food and Drug Administration. These newer generation pumps are smaller and can generate nonpulsatile flow rates of up to 10 L/min with potential advantages such as better durability secondary to simpler mechanics, quiet function, and a lack of valvular structures. Their reduced size facilitates their surgical placement or explantation, allowing for less-invasive implantation techniques as well as their use in smaller patients (body surface area 1.2 $m^2$-1.5 $m^2$). Additionally, in contrast to pusher-plate pulsatile devices, the more advanced technologic configuration of these devices with magnetically coupled motor systems (direct-drive, self-bearing, or bearingless) and no requirement for valves may increase blood flow and reduce stasis resulting in less hemolysis.[13] The authors have consistently used RT3DE to interrogate the Jarvik 2000 (Jarvik Heart Inc, New York, NY), HeartMate II, Ventrassist (Ventracor Ltd, Chatswood, Australia), and TandemHeart (CardiacAssist Inc, Pittsburgh, PA) devices so the discussion is limited to these, but similar principles should apply to other 2nd and 3rd generation devices (Table 1).

### *Jarvik 2000*

The Jarvik 2000 Flow Maker is a cylindrical contact-bearing axial-flow pump currently under investigation. The system mainly consists of a 55-mm long and 25-mm diameter pump, a 16-mm outflow graft, and a direct-current power supply.[14] The pump can be implanted into the left ventricular cavity, usually in the apex, via the left lateral thoracotomy, a median sternotomy, or a left subcostal approach below the diaphragm.[15] The outflow graft is anastomosed to the ascending aorta, the descending thoracic aorta, or the supraceliac aorta when the

**Table 1. Major Characteristics**

| LVAD (Status) | Status | Flow | Mechanism-Bearing | Approach | Placement | Inflow | Outflow |
|---|---|---|---|---|---|---|---|
| Jarvik 2000 | Trial | Axial | Contact bearing | Sternotomy | Apex | Apex | Ascending Ao |
| | | | | Lateral Thoracotomy | | Apex | Descending Ao |
| | | | | Subdiaphragmatic | | Apex | Supraceliac Ao |
| Ventrassist | Trial | Centrifugal | Hydrodynamic levitation | Sternotomy | Rectus Sheath | Apex | Ascending Ao |
| HeartMate II | Approved | Axial | Contact bearing | Sternotomy | Peritoneal | Apex | Ascending Ao |
| TandemHeart | Approved | Centrifugal | Hydrodynamic levitation | Percutaneous | Extracorporeal | LA | Femoral Artery |

Abbreviations: Ao, aorta; LA, left atrium.

surgical approach is subdiaphragmatic.[16] It is important to emphasize that the Jarvik 2000 does not have an integrated hemodynamic sensor, and, therefore, accurate echocardiographic assessment becomes particularly essential in interrogating device performance.[17]

### *HeartMate II*

The HeartMate II left ventricular assist system is a contact-bearing axial-flow rotary blood pump measuring about 40 mm in length and 60 mm in diameter. This device just recently received approval for bridge to transplant use by the Food and Drug Administration. The pump is placed preperitoneally in a surgically created pocket at the diaphragmatic level through a median sternotomy with the inflow cannula inserted into the left ventricular apex. The outflow graft is anastomosed to the ascending aorta.[18]

### *VentrAssist*

The VentrAssist is a continuous-flow rotary pump with a non–contact-bearing design, which is currently under investigation. Its rotor, hydrodynamically suspended and electromagnetically driven, is mounted in a 60-mm diameter device.[19] The pump is implanted via a median sternotomy in the posterior rectus sheath or in a preperitoneal position. The inflow cannula (10 mm) is connected to the left ventricular apex (tapered to stent the ventricular walls), and the outflow graft (10 mm) is anastomosed to the ascending aorta.[20,21]

### *TandemHeart*

The TandemHeart percutaneous ventricular assist device system uses a transseptal cannula that allows direct unloading of the left heart. The system, which can be inserted in the cardiac catheterization laboratory, is able to support patients until cardiac recovery or may be used temporarily during high-risk coronary interventions. The system is based on a left atrial-to-femoral artery bypass system that includes a 21F transseptal inflow cannula (left atrium), a 15F or 17F arterial femoral cannula, and a centrifugal blood pump (hydrodynamic levitation) that provides continuous flow of 3.5 L/min to 4.0 L/min at a maximum speed of 7,500 rpm.[22] A continuous infusion of a heparin solution into the lower inner housing of the pump is required in order to allow lubrication and cooling, additionally aiding in the prevention of thrombosis in the pump's chamber.

## REAL-TIME 3-DIMENSIONAL ECHOCARDIOGRAPHIC ASSESSMENT

### General Considerations

The strength of RT3DE lies in the ability to integrate information that would normally be obtained from multiple 2-dimensional views into a single image and therefore making sonography as a diagnostic tool understandable for even the nonechocardiographer.[23] Additionally, 3-dimensional imaging does not require the use of geometric assumptions to calculate areas and volumes, allowing for a more accurate and precise quantification of anatomic structures and physiologic changes (Table 2). Volume assessment by RT3DE has been shown to be rapid, accurate, and superior to conventional standardized 2-dimensional methods. Ventricular volume and mass obtained by RT3DE have even compared favorably with those obtained from studies with magnetic resonance imaging, further showing advantages in efficacy and accuracy in assessing volumes in remodeled ventricles after myocardial infarction.[24-26]

### Left Ventricle

The evaluation of left ventricular (LV) function before LVAD insertion will commonly show severely depressed function with either a dilated ventricle or a normal-size ventricle in the setting of an acute cardiac event (eg, acute myocarditis or myocardial infarction). Severe LV dysfunction increases the risk of acquiring an intracavitary thrombus that, when present, is commonly located in the apex and therefore around the inflow cannula insertion site.[27,28] This is why it is essential that in every screening protocol the ventricle is interrogated for the presence of an intraventricular thrombus. The presence of an

**Table 2. 3D Echocardiography Modes of Operation**

| | |
|---|---|
| Live mode | Live real-time image |
| | 3D volume pyramids are obtained |
| | ECG independent |
| Zoom mode | Live real-time image |
| | Magnified pyramidal volume 20 × 20 up to 90 × 90 |
| | ECG independent |
| Full volume | Gated |
| | 4-8 subvolumes are placed together |
| | Requires ECG |
| 3D color flow | Gated |
| | 8-11 subvolumes are placed together |
| | Requires ECG |

Abbreviation: ECG, electrocardiogram.

**Table 3. Common Perioperative Echocardiographic Assessment of Patients Undergoing LVAD Insertion**

| Preoperative LVAD Assessment (Patient Screening) | Intra- and Postoperative LVAD Assessment |
|---|---|
| Intracardiac shunts | Intracardiac shunts |
| Intracavitary thrombus | Deairing (left ventricle and device) |
| Atherosclerosis or severe calcifications of the aortic arch | Aortic dissection |
| Aortic regurgitation/mitral stenosis | Aortic regurgitation (valve opening) |
| Right ventricular function (tricuspid regurgitation) | Positioning and flow dynamics of both cannulae |
| Ventricular (apical) scars or aneurysms | Left ventricular unloading |
| | Right ventricular function (tricuspid regurgitation) |
| | Assessment of cardiac tamponade |

intraventricular thrombus can alter the surgical strategy (eg, it would be inappropriate to use an off-pump technique in such cases) (Table 3).

After LVAD insertion and activation, the LV is decompressed (unloading phase) and reduced in size, thus making it difficult to obtain a real and accurate assessment of LV function.[29,30] When the evaluation of LV function is necessary, especially in light of a possible explantation secondary to myocardial recovery, several alternative 2-dimensional echocardiographic methods have been described predicting the ability to successfully wean from LVAD support (eg, LV diameter in end-diastole or the systolic elastance).[31] The introduction of RT3D makes it possible to acquire full-volume images of the left ventricle and reconstruct a virtual model.[32] This model represents the true function of the entire LV without the aid of geometric assumptions as would be required when 2-dimensional techniques are used (eg, Simpson method of discs.) This is especially useful in the setting of ventricular aneurysms or when regional wall motion abnormalities are present, which are frequently encountered in this patient population.

### Right Ventricle

Right ventricular (RV) function becomes a critical parameter particularly in the postoperative management of patients undergoing LVAD insertion. Because RV output determines the LVAD preload and consequently the LVAD output, it has been traditionally shown that up to 30% of patients present with RV dysfunction after LVAD implantation subsequently requiring secondary right ventricular assist device (RVAD) implantation.[33] The etiology of post-LVAD implantation RV dysfunction is multifactorial.[34] Although geometric changes of the RV as a direct result of LV unloading could potentially impact and worsen RV systolic function, recent publications have shown that during continuous-flow LVAD support, pre-existing RV dysfunction does not worsen in the intermediate term.[35] Additionally, the increase in cardiac output that can occur once a functional LVAD is implanted can present the RV with an excessive preload leading to distention and subsequent failure.[36]

Unfortunately, the right ventricle, because of its complex anatomy, does not lend itself to geometric computer-based modeling in the same fashion as its left-sided counterpart. Although continuously evolving, the echocardiographic assessment of RV function has been to date mostly qualitative and very subjective.[37] Three-dimensional echocardiography, which could elegantly side step the geometric restraints limiting the usefulness of 2-dimensional echocardiography, is still in its infancy in this setting.[38] Three-dimensional software, which would enable the imager to create a model of the right ventricle (similar to what already exists for the LV), is starting to emerge onto the market.

## REAL-TIME 3-DIMENSIONAL ECHOCARDIOGRAPHIC EXAMINATION OF THE LVAD COMPONENT

### Ventricular and Device Deairing

Gaseous embolism is a well-known dreadful complication that can potentially occur during cardiac surgery. Traditionally, it occurs as a result of technical errors in the use of the heart-lung machine or from inadvertent entrainment of significant amounts of air into venous lines.[39] In the former case, air gets insufflated directly into the systemic circulation with a risk of cerebral emboli, whereas in the latter an excessive amount of

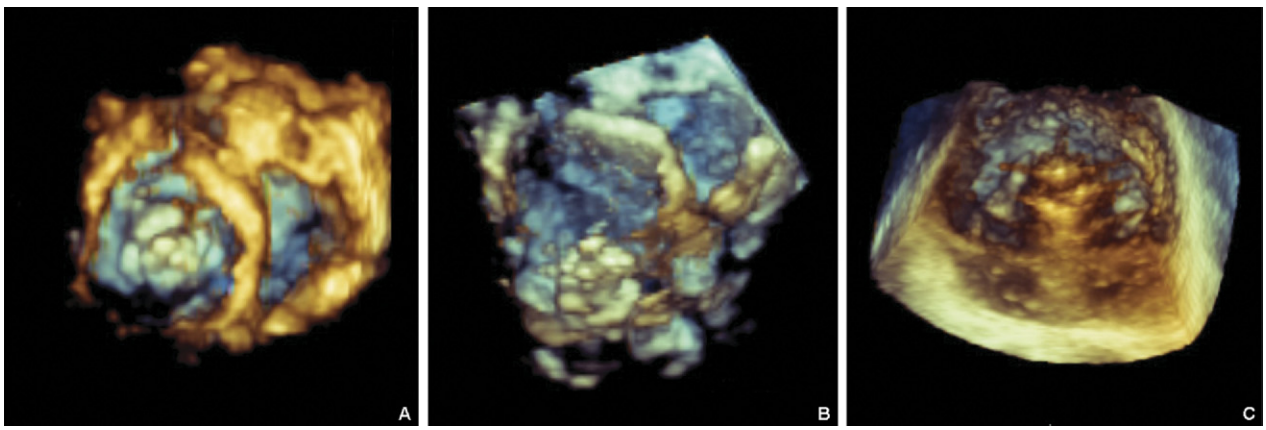


**Fig 2. Jarvik 2000 FlowMaker. Full-volume acquisition of the left ventricle after "offline" cropping of the base. (A) The insertion site of the outflow cannula comes into view. (B) Spatial rotation of the dataset after additional cropping of the lateral wall. (C) Functioning device with acoustic shadows from the impeller rotation.**

air can cause an air lock within the RV outflow tract, resulting in systemic cardiovascular collapse.[40]

In the setting of LVAD implantation, the risk of creating systemic air embolism is higher because the device, its cannulae, and the respective anastomoses may release a significant amount of air once the device is operational. Echocardiography is an extremely useful tool for the detection and management of air embolism (intense echorefringent signals) as well as to detect air collections within the heart before device utilization. If this is the case, meticulous air removal must be performed before full device activation. The stepwise protocol to assess air entrapment or efflux would involve interrogation of the ascending and descending aorta (the long-axis aortic valve view is particularly useful to assess the presence of air coming from the outflow cannula), ventricular chambers, and finally the inspection of the anastomotic sites (the aorta and LV apex play an

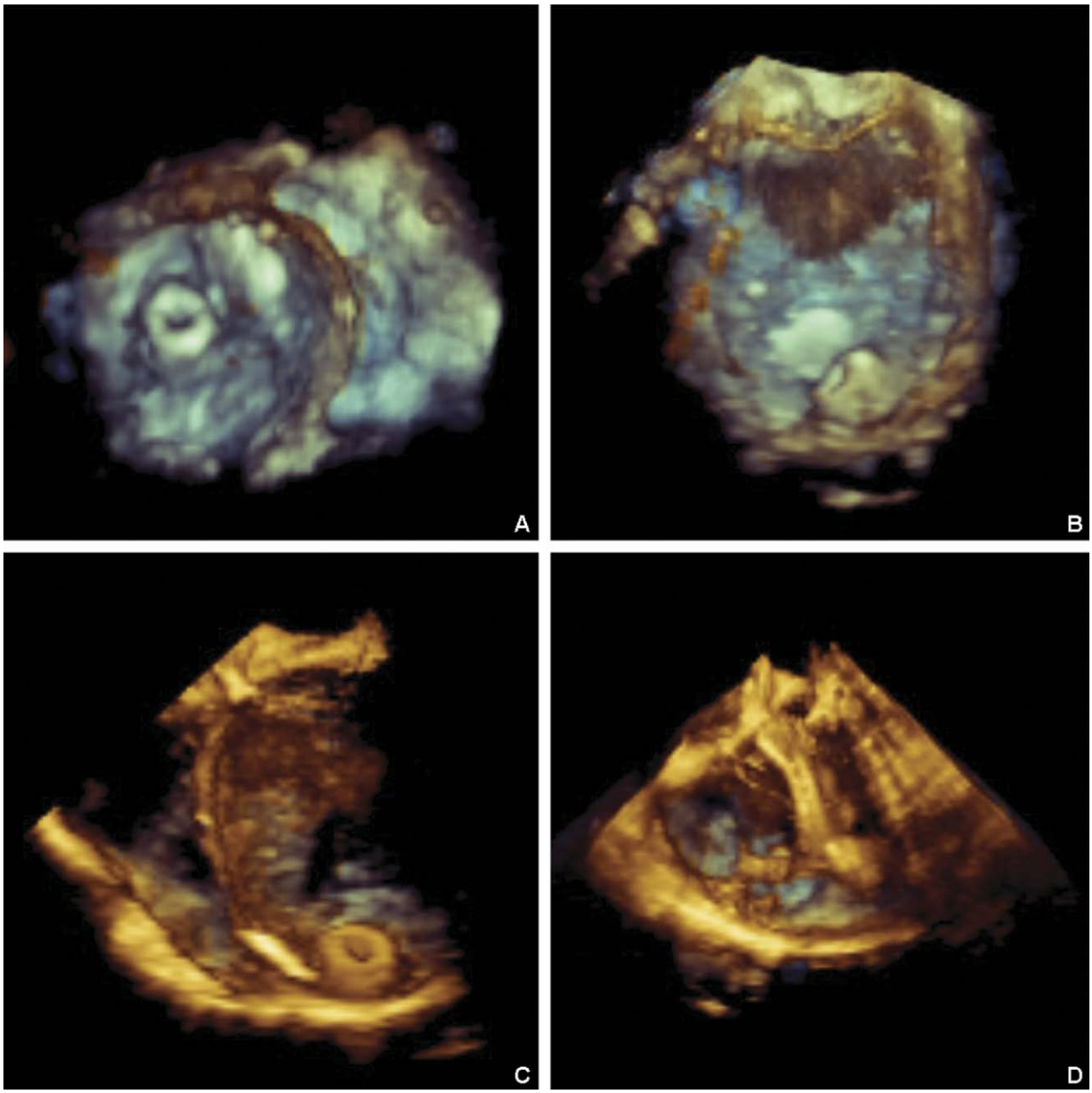


**Fig 3. Heartmate II. Full-volume acquisition of the left ventricle after "offline" cropping of the base. (A) Interrogation of the insertion cannula (note that the Heartmate II will not show acoustic shadowing as the impeller is located out of the cannula). (B) Lateral view of the insertion cannula after further ventricular wall cropping exposing the alignment of the cannula to the inflow axis of the left ventricle. (C) Cropping of the anterior wall revealing slightly anterior directed cannula. (D) "Suck-down" effect with collapse of the left ventricle and dilation of the right ventricle.**

important role in the case of air entry to the device secondary to negative pressures when filling).

## Assessing LVAD Function

Once device and ventricular deairing are complete, the pump is set to work at a slow minimal baseline rate (eg, 1,800 rpm for the Ventrassist and 6,000 rpm for Heartmate II). A well-functioning LVAD is associated with the presence of unidirectional flow into the apical cannula during device filling and intermittent aortic valve opening as a marker of a nonejecting decompressed ventricle.[41]

Prompt device malfunctions may very rarely occur because of failure of the device components (pump, controller, or extracorporeal lead).[42-44] Poor device function is usually caused by technical problems in implantation or physiologic changes that interfere with the correct function of the LVAD. In this line, as mentioned previously, assessing the adequacy of RV function is critical in the early minutes after LVAD activation. In cases of RV failure, echocardiography will show massive RV dilatation, deviation of the intraventricular septum toward the left ventricle, and tricuspid regurgitation with consequent collapse of the left ventricle because of the absence of adequate transpulmonary flow and LV filling.[45,46] This, in turn, can lead to the obstruction of the inflow cannula and other complications such as the influx of air from the sewing cuff ring around the inflow cannula.[43]

## Inflow Cannula

RT3DE represents an evolutionary step in further defining LVAD dysfunction during the perioperative period. It has contributed substantially to ease the inspection and localization of the inflow cannula, commonly located in the LV apex. The echocardiographic examination of the inflow cannula position required at least 2 orthogonal views (4-chamber and 2-chamber long-axis) when assessed by 2-dimensional echocardiography.[41,47] When using RT3DE, a full-volume dataset can be acquired starting from the 2-dimensional 4-chamber view. By spatially orientating the dataset so that the imager views the mitral valve en face, the cropping tool can be used to edit away the basal regions of the left ventricle enabling the echocardiographer to obtain an en face view of the inflow cannula as it enters the left ventricle (Figs 2, 3A, and 4). The cannula orifice should be centrally located entering the apex of the ventricle, aligned with the LV inflow tract (mitral valve orifice) and not abutting any ventricular structures (Fig 3B). Often the cannula ends up being slightly angulated toward the anteroseptal ventricular wall, but as long as the deviation is less than 30°, no hindrance of ventricular drainage should be encountered (Fig 3C).[48]

Inflow cannula patency is obviously critical in achieving adequate device output. In general, patients undergoing LVAD insertion who present with severely dilated ventricles are less prone to cannula misalignment-induced hindrance of ventricular drainage. On the other hand, patients with normal-dimensional ventricles (eg, acute myocarditis or acute MI) are more dependent on proper cannula alignment. Color-flow Doppler is the method of choice to check for unidirectional flows from the ventricle to the device. The presence of abnormal high-velocity turbulent flows or an aliasing flow at the cannula orifice suggests cannula obstruction.[49] The differential diagnosis can include hypovolemia ("suck-down" effect), a thrombotic episode, or misalignment with partial obstruction by ventricular walls (Fig 3D).[50,51] Because the treatment for these disorders is different, it is important to have excellent echocardiographic imaging capabilities. In the scenario of misalignment, the sur-

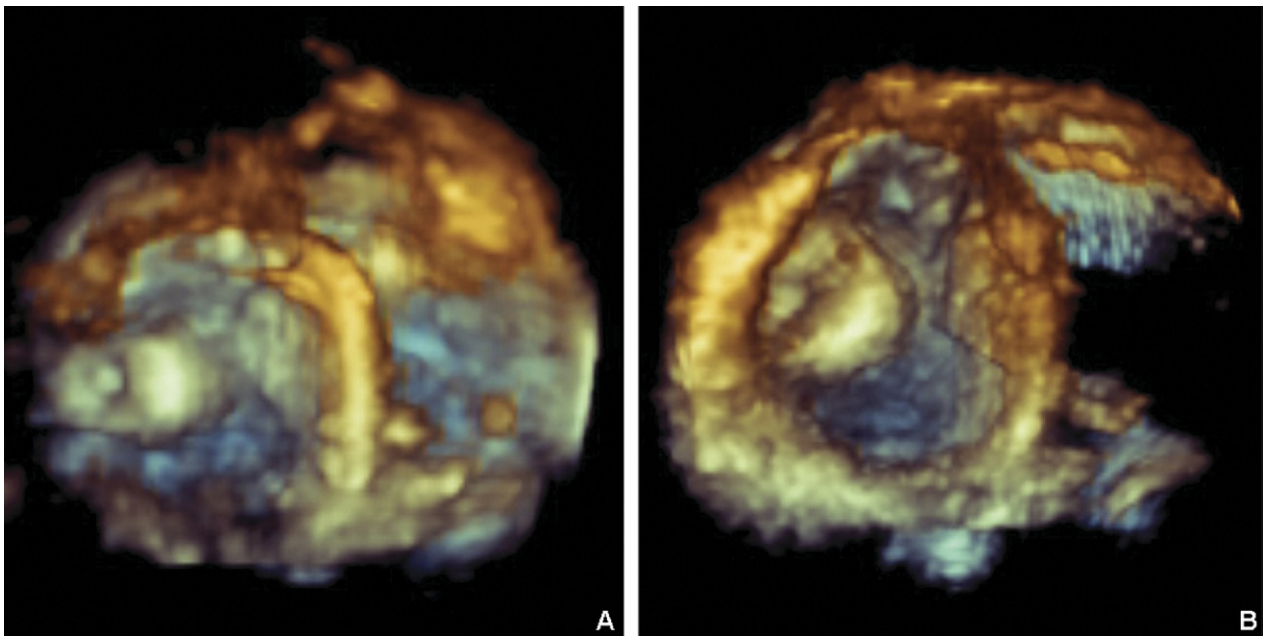


**Fig 4. Ventrassist. Full-volume acquisition of the left ventricle after "offline" cropping of the base. (A) Lateral deviation of the inflow cannula. (B) En face interrogation of the inflow cannula exposes the typical funnel shape of the Ventrassist inflow cannula.**

**Table 4. Perioperative Echocardiographic Assessment of Patients Undergoing LVADs Insertion Stratified by Device**

| LVAD | Preoperative Assessment | Intra- and Postoperative Assessment |
|---|---|---|
| Jarvik 2000 | Ventricular function | Ventricular deairing |
| | Ventricular thrombus | Apical placement of the device |
| | Severe calcification of the thoracic aorta | Device alignment with the mitral valve |
| | Severe aortic regurgitation | Mitral valve |
| | | Ventricular wall thickness |
| | | Thoracic aorta integrity and flows |
| | | Aortic valve opening (LVAD off, LVAD 8K-12K rpm) |
| | | Outflow cannula positioning and flows |
| Ventrassist | Ventricular function | Device and ventricular deairing |
| | Ventricular thrombus | Placement and stenting of the inflow cannula |
| | Moderate-to-severe aortic regurgitation | Mitral valve |
| | Severe tricuapid regurgitation | Ventricular wall thickness |
| | Peripheral vascular disease | Thoracic aorta integrity and flows |
| | | Outflow cannula positioning and flows |
| HeartMate II | Ventricular function | Device and ventricular deairing |
| | Ventricular thrombus | Placement and stenting of the inflow cannula |
| | Moderate-to-severe aortic regurgitation | Mitral valve |
| | Severe calcification of the thoracic aorta | Ventricular wall thickness |
| | Severe aortic regurgitation | Thoracic aorta integrity and flows |
| | | Outflow cannula positioning and flows |
| TandemHeart | Interatrial septum integrity | Trans-septal positioning |
| | Atrial thrombus | Inflow cannula positioning |
| | Aortic and peripheral vascular disease | Aortic flow reversal |

Abbreviation: RPM, revolutions per minute.

geon may be able to reposition the cannula by moving the flexible conduit and reassessing the LVAD hemodynamics, which is routinely done at the time of chest closure.[52] A "suck-down" effect is treated by primarily reducing device flows and volume loading of the patient.

Flow patterns throughout the inflow cannula depend on the LVAD inserted. In this line, axial or centrifugal continuous-flow devices will show a mixed pattern of pulsatile flow synchronous with the patient's rhythm (changes in pressure gradient across the device produced by ventricular contraction) and a continuous pattern of flow because of the device function.

## Outflow Cannula

The outflow cannula anastomoses to the anterolateral aspect of the ascending aorta (alternatively to the descending aorta in case of the Jarvik 2000) should be visualized with the ascending aorta long-axis view.[53] Here too, color-flow Doppler represents the method of choice to evaluate flow patterns and hemodynamics. Several studies have reported the impact that the angulation of the outflow cannula to the ascending aorta has on flow patterns. The incidence of thrombus formation is reduced by decreasing the angle ($<90°$) between both structures and surgically reinforcing the graft.[54,55] Outflow graft kinking is echocardiographically diagnosed by visualizing flow acceleration in the graft distal to the obstruction. Color-flow Doppler is characterized by nonlaminar high-velocity flow.[41]

## SUMMARY AND CONCLUSIONS

Mechanical circulatory support has emerged as a valuable solution for the management of patients with end-stage heart failure either being used as a bridge to transplant/recovery or as destination therapy. As the field is advancing toward a broader spectrum of applications, mechanical and anatomic complications of the surgical procedure have been quickly overcome

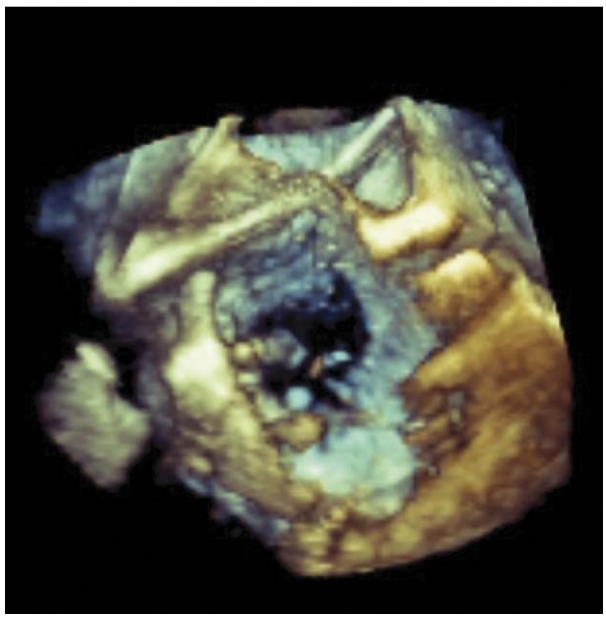

**Fig 5. TandemHeart. Full-volume acquisition of atrial cavities showing proper placement of the inflow cannula through the interatrial septum.**

with experience and comparative outcomes. Echocardiography has contributed tremendously to this process, playing an important role in the perioperative evaluation of the device and timely predicting and consequently avoiding potential pitfalls. Although specific echocardiographic considerations might be applied to every device (Table 4), a routine stepwise examination involves (1) ventricular and device deairing, (2) competency of the device, and (3) cannulae alignment and patency. Although complementary and supplementary to 2-dimensional imaging, the interrogation of cannulae positioning and alignment has been improved significantly and simplified by the introduction of RT3D echocardiography. Intraoperative RT3DE not only provides improved accuracy and reproducibility of ventricular volumes and function, but has also provided better understanding of ventricular spatial relationships.

In conclusion, the present authors think that RT3D echocardiography will be used routinely for perioperative planning and assessment of LVADs and as a guiding tool for several percutaneous procedures, among them the percutaneous implantation of certain types of LVADs (TandemHeart, Fig 5). In the setting of LVAD implantation, there is currently enough evidence to support the addition of 3-dimensional imaging to traditional 2-dimensional echocardiography in 2 particular scenarios: (1) quantification of LV volume and ejection fraction and (2) complete interrogation of the inflow and outflow cannulae.

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