

Interventional Heart Failure

A new clinical subspecialty emerges.

BY NAVIN K. KAPUR, MD, FSCAI, FACC

Heart disease remains the number one cause of mortality in the United States.¹ During the past 50 years, pharmacologic advancements for cardiovascular risk factors and device innovation for the management of coronary disease, including acute myocardial infarction (AMI), have radically changed the landscape of heart disease. No longer is AMI considered a terminal event, as in-hospital mortality rates have been reduced to less than 10%. As a result, more individuals are now surviving their incident and subsequent heart attacks. However, with each myocardial insult, nearly 25% of individuals develop chronic heart failure after an AMI,² leading to a virtual tsunami of patients with heart failure now entering the catheterization laboratory.

A NEW DEMAND

An estimated 2.6% of the American population suffers from heart failure, which is defined as “a syndrome caused by cardiac dysfunction, generally resulting from myocardial muscle dysfunction or loss and characterized by either LV dilation or hypertrophy or both.”³ The spectrum of heart failure can be broadly categorized into two groups: acutely decompensated heart failure/cardiogenic shock and chronic progressive heart failure. Regardless of their clinical presentation, nearly all patients with heart failure will pass through the catheterization laboratory at some point in their clinical evaluation and management. As a result, every interventional cardiologist encounters patients with heart failure on a daily basis.

For this reason, the concept of interventional heart failure is less of a radical new subspecialty, but rather a response to the increasing demand for interventionists who are trained in advanced invasive hemodynamics, can interface with an advanced heart failure/mechanical support/cardiac transplant program, and have experience with emerging cutting-edge technologies for the management of patients with heart failure.

Part of the reason for this growing demand for the interventional heart failure subspecialist is that surgical innovation has now created an exit strategy for patients who were considered medically futile (Figure 1). Surgically implanted, durable mechanical support devices were once large,

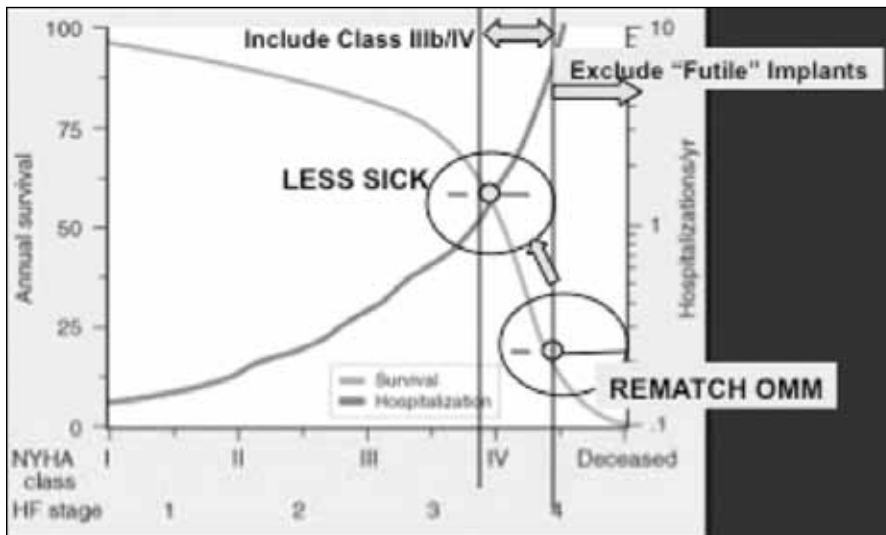


Figure 1. Due to a shift in the target population for surgical left ventricular assist devices (LVADs) away from end-stage to “less sick” patients, the modern-day interventional cardiologist may be asked to manage patients with severely advanced heart failure and cardiogenic shock using percutaneous circulatory support devices as a bridge-to-decision option. (REMATCH OMM: Randomized Evaluation of Mechanical Assistance in Treatment of Chronic Heart Failure Optimal Medical Management). Reprinted with permission from Miller LW. Left ventricular assist devices are underutilized. *Circulation*. 2011;123:1552–1558.

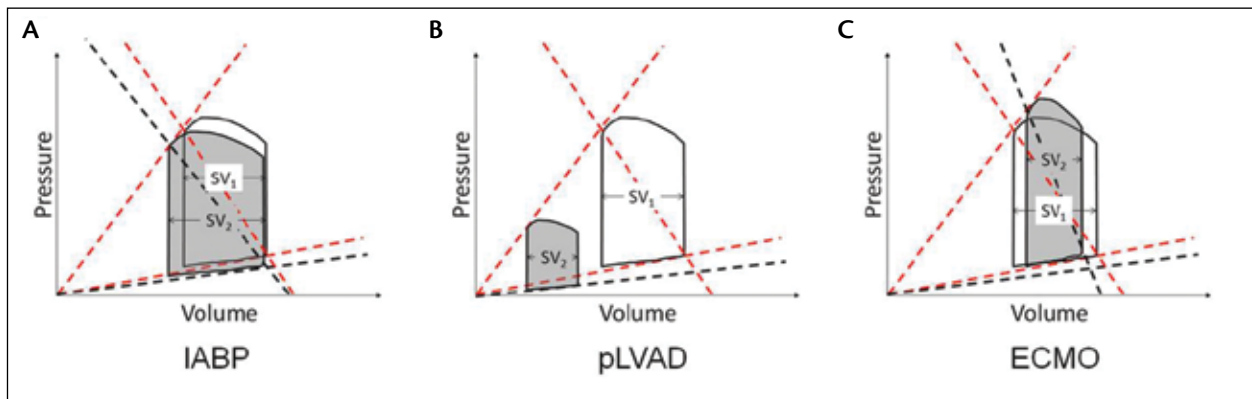


Figure 2. Cardiac effects of mechanical support. Illustrations of pressure-volume loops after treatment with intra-aortic balloon pump counterpulsation (A), percutaneous LV assist devices (TandemHeart or Impella 5.0) (B), or venoarterial extracorporeal membrane oxygenation (C). Shaded loop represents left ventricular stroke work and stroke volume after device activation.

bulky pulsatile pumps designed to temporarily bridge a patient to cardiac transplantation for a few weeks or months. In the modern era, miniaturized continuous-flow ventricular assist devices are now demonstrating nearly 75% 2-year survival rates with improved patient functionality.⁴ As a result, the 70-year-old patient with cardiogenic shock for whom medical treatment held minimal promise, may now be a viable candidate for advanced mechanical therapies. Given this option, interventional cardiologists are now being asked to adopt a more aggressive approach to salvaging patients from cardiogenic shock with percutaneously delivered mechanical circulatory support systems.

ACUTE CIRCULATORY SUPPORT

In parallel to the growth of surgical devices, acute circulatory support devices have also evolved from pulsatile systems to miniaturized, continuous-flow pumps. These pumps, which include the intra-aortic balloon pump (IABP), venoarterial extracorporeal membrane oxygenation (VA-ECMO), a catheter-mounted axial-flow pump (Impella; Abiomed Inc., Danvers, MA), and the pLA-FA centrifugal bypass (TandemHeart; Cardiac Assist Inc., Pittsburgh, PA) system are used primarily to support high-risk coronary intervention in patients with advanced heart failure and to sustain multiorgan perfusion, while reducing cardiac workload in cardiogenic shock. Newer applications for these devices include adjunct support for transcatheter aortic balloon valvuloplasty and valve replacement, high-risk ventricular ablation, and right ventricular failure.

Each pump is associated with a unique hemodynamic signature (Figure 2). The well-established IABP displaces blood volume from the descending aorta by inflating during diastole and deflating during systole. The net effect of an IABP is to augment coronary blood flow while reducing native

left ventricular systolic pressure and increasing native stroke volume. Major advantages of the IABP are ease of insertion, rapid deployment, and global familiarity with the technology. Disadvantages of the IABP include a limited degree of ventricular unloading and reduced pump function during tachycardia.

In contrast to IABPs, rotodynamic pumps are nonpulsatile systems that transfer rotational kinetic energy into the bloodstream and generate forward flow. The two primary rotodynamic pumps used to unload the left ventricle in the catheterization laboratory are the TandemHeart and the Impella systems. An emerging axial flow catheter in development is the percutaneous heart pump (PHP; Thoratec Inc., Pleasanton, CA). VA-ECMO is often used in cases of respiratory failure or to stabilize patients with severe hemodynamic instability who cannot be transported to the catheterization laboratory. Importantly, VA-ECMO will not effectively reduce left ventricular workload unless an accompanying pump is used, such as an IABP or Impella device. Alternative venting strategies with VA-ECMO are actively being explored.

The TandemHeart device is an extracorporeal centrifugal pump that uses two percutaneously delivered cannulas to pump oxygenated blood from the left atrium to the systemic circulation via the femoral artery. For left heart support, the TandemHeart device requires a transseptal puncture for delivery of the 21-F inflow cannula and a separate arterial access site for a 15-, 17-, or 19-F arterial cannula. Depending on the size of the outflow cannula, directly measured flow through the device ranges from 3.5 to 5 L/min. The hemodynamic effect of the TandemHeart device is to reduce left ventricular preload and thereby decrease native ventricular volume and pressure. The net effect is a significant reduction in left ventricular wall stress and stroke work. Major advantages of the TandemHeart

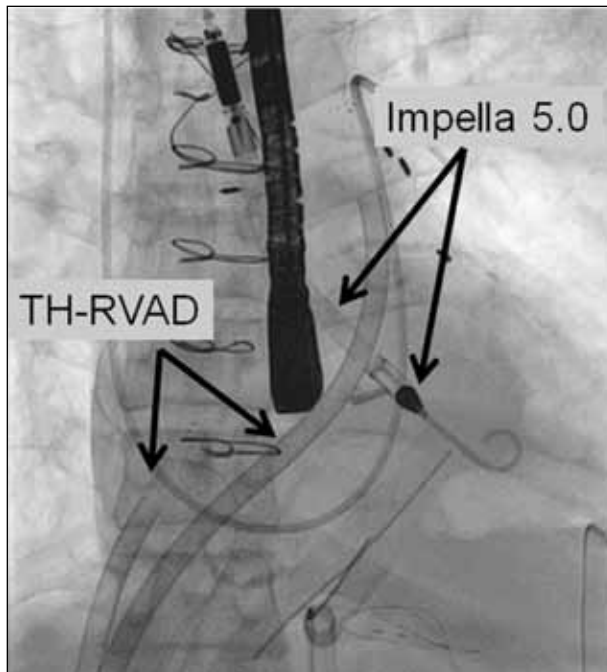


Figure 3. Percutaneous biventricular support.

pump are the magnitude of ventricular unloading without the need for surgical vascular access and avoidance of penetration in the left ventricle, which is helpful in the cases involving ventricular thrombus and aortic regurgitation. Disadvantages of the device include the need for trans-septal puncture, two vascular access sites, and the need for an arterial cannula up to 19 F in size to achieve maximal unloading.

The Impella pumps are axial-flow catheters that directly displace blood from the left ventricle into the ascending aorta. The devices can be placed via femoral arterial access in retrograde fashion across the aortic valve into the left ventricle. Three distinct catheters can be used for left ventricular support and include the 2.5 LP, the CP, and the 5.0 LP devices. Estimated flows achievable with each device are 2.5, 3.5, and 5 L/min, respectively. Both the 2.5 LP and the CP device can be deployed via percutaneous arterial access, whereas the 5.0 LP device requires surgical vascular access. In contrast to the TandemHeart device, the Impella systems can be deployed via surgical access through the axillary artery, thereby providing ventricular support via a supradiaphragmatic approach and allowing for longer-term support with improved patient mobilization. Major advantages of the 2.5 LP and CP devices are ease of insertion, rapid deployment, and emerging familiarity with the devices in most catheterization laboratories. The major disadvantage of the Impella pumps is the need for surgical access to deploy the 5.0 LP pump, which provides the greatest amount of unloading among the Impella device options.

DISCUSSION

As experience with each device grows, catheterization laboratories are identifying which devices work best for them in various clinical scenarios, including high-risk coronary intervention, AMI complicated by cardiogenic shock, acutely decompensated heart failure, and right heart failure. One of the major issues in the field of temporary circulatory support is the apparent disconnect observed between hemodynamic improvement and clinical outcomes in patients with cardiogenic shock. Several possible reasons may contribute to this observation and include (1) patient selection, (2) device selection, (3) delays to device activation, and (4) no viable exit strategy. Of these possibilities, delays to device activation in patients with cardiogenic shock refractory to medical therapy alone is a modifiable factor that requires a better understanding of how these devices work and better crosstalk among interventionists, heart failure specialists, and critical care teams.

For example, several studies have shown that activation of either an IABP or catheter-mounted axial flow pump, such as the Impella device, before coronary occlusion can reduce myocardial infarct size in surgical models of AMI.^{5,6} More recently, we reported the effects of reducing left ventricular wall stress with the TandemHeart device in a porcine model of acute myocardial infarction.⁷ In this study, device activation was followed by a 30-minute delay in coronary reperfusion, suggesting that first reducing ventricular wall stress may be an approach to reduce myocardial damage in patients with AMI.⁷

Based on these collective findings, the TRIS (TandemHeart to Reduce Infarct Size) trial will evaluate the effectiveness of ventricular unloading on the reduction of infarct size for patients who have had a severe heart attack. If proven effective, several paradigms could change. First, the concept of door-to-balloon may instead refocus to now include “door-to-unload” as a therapeutic approach in AMI. Second, the number of patients surviving their initial heart attack who develop chronic heart failure may be reduced, suggesting that mechanical therapy is an approach to prevent the development of subsequent heart failure after a heart attack. To date, however, translating preclinical studies of myocardial salvage into clinical benefits has remained elusive.

Another major advancement in the field of interventional heart failure has been the development of percutaneous strategies to address right heart failure. As more patients develop chronic left heart failure, the importance of right ventricular function has begun to take center stage because reduced right ventricular function portends a worse prognosis in AMI, cardiogenic shock, chronic left heart failure, and pulmonary hypertension. Several recent reports have examined the clinical utility of the

TandemHeart device as a right atrial-to-pulmonary arterial bypass system for right ventricular support and have shown that early device activation may be associated with better outcomes,⁸ and further, that concomitant left ventricular failure is an important contributor to mortality despite right ventricular support.⁹ With the recent launch of the Impella RP system, the RECOVER RIGHT trial will explore the clinical utility of a percutaneous, single-access site approach to mechanically supporting the failing right ventricle. Furthermore, developments in right ventricular support technology now open the door to biventricular support for severe cardiogenic shock (Figure 3).¹⁰

CONCLUSION

Heart failure was once considered a terminal diagnosis, and management focused on symptom management, palliation, and the rare opportunity for cardiac transplantation. With major advances in mechanical circulatory support technology, the light at the end of the tunnel has become brighter for patients with advanced heart failure. Given the growing number of patients with heart failure and the therapeutic options available to them, the next generation of interventional operators will be asked to think like heart failure specialists. As a result,

the subspecialty of interventional heart failure is now an expanding movement and an emerging reality. ■

Navin K. Kapur, MD, FSCAI, FACC, is with the Division of Cardiology, Tufts Medical Center Molecular Cardiology Research Institute in Boston, Massachusetts. He has disclosed that he received research support from Cardiac Assist, Abiomed, Maquet, Heartware; is a consultant for Thoratec; and receives speaker honoraria from Maquet. Dr. Kapur may be reached at nkapur@tuftsmedicalcenter.org.

1. Roger VL, Go AS, Lloyd-Jones DM, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Executive summary: heart disease and stroke statistics—2012 update: a report from the American Heart Association. *Circulation*. 2012;125:188-197.
2. Kloner RA, Schwartz Longacre L. State of the science of cardioprotection: challenges and opportunities—proceedings of the 2010 NHLBI Workshop on Cardioprotection. *J Cardiovasc Pharmacol Ther*. 2011;16:223-232.
3. Heart Failure Society of America, Lindenfeld J, Albert NM, Boehmer JP, et al. HFSA 2010 comprehensive heart failure practice guideline. *J Card Fail*. 2010;16:e1-194.
4. Kirklin JK, Naftel DC, Kormos RL, et al. Fifth INTERMACS annual report: risk factor analysis from more than 6,000 mechanical circulatory support patients. *J Heart Lung Transplant*. 2013;32:141-156.
5. Achour H, Boccalandro F, Felli P, et al. Mechanical left ventricular unloading prior to reperfusion reduces infarct size in a canine infarction model. *Catheter Cardiovasc Interv*. 2005;64:182-192.
6. Meyns B, Stolinski J, Leunens V, et al. Left ventricular support by catheter-mounted axial flow pump reduces infarct size. *J Am Coll Cardiol*. 2003;41:1087-1095.
7. Kapur NK, Paruchuri V, Urbano-Morales JA, et al. Mechanically unloading the left ventricle before coronary reperfusion reduces left ventricular wall stress and myocardial infarct size. *Circulation*. 2013;128:328-336.
8. Kapur NK, Paruchuri V, Korabathina R, et al. Effects of a percutaneous mechanical circulatory support device for medically refractory right ventricular failure. *J Heart Lung Transplant*. 2011;30:1360-1367.
9. Kapur NK, Paruchuri V, Jaganathan A, et al. Mechanical circulatory support for right ventricular failure. *JACC Heart Failure*. 2013;1:127-134.
10. Nagy CD, Jumean MF, Pham DT, et al. Percutaneous circulatory support for biventricular failure. *Circ Cardiovasc Interv*. 2013;6:e12-14.