Heart Transplantation

Cleveland Clinic’s Cardiac Transplantation and Ventricular Assist Device Therapy Program is one of the largest and most experienced heart transplant programs in the nation and the leading program in Ohio. It marks its 30-year anniversary in 2014.

The program’s patient and graft survival rates exceed both national norms and expected rates, as detailed in the graphs on the following pages. Notable outcomes from the January 2014 report of the Scientific Registry of Transplant Recipients (SRTR) include:

• 92.04 percent one-year adult patient survival (vs. expected rate of 90.85 percent and national average of 90.66 percent)
• 90.0 percent three-year adult patient survival (vs. expected rate of 83.39 percent and national average of 83.29 percent)

Standout capabilities in end-stage heart failure

Beyond its outcomes, Cleveland Clinic’s heart transplant program is distinguished by:

• Robust clinical activity, reflected by the 182 adult and pediatric patients who underwent full evaluation for transplant in 2013 from among 242 patients referred, many from far reaches of the nation and the globe
• Two decades of experience in combined heart-lung transplants (see Lung and Heart-Lung Transplantation, p. 44) and combined heart-kidney and heart-liver transplants
• A highly comprehensive approach to patients with end-stage heart failure, including expert medical and interventional management, participation in numerous clinical trials, use of all approved (and many investigational) devices for mechanical circulatory support, and left ventricular reconstruction surgery
• One of the nation’s few dedicated, specialized ICUs for patients with heart failure
• Close integration with the George M. and Linda H. Kaufman Center for Heart Failure and the rest of Cleveland Clinic’s Sydell and Arnold Miller Family Heart & Vascular Institute, ranked by U.S. News & World Report as the nation’s top heart program for 20 years running

Initiated 1984
UNOS approval 1988
CMS approval 1988

Heart transplant program being initiated at Cleveland Clinic Florida in 2014

One of the few programs placing Berlin Heart Excor LVADs in children

44 heart transplants in 2013, including 1 heart-kidney transplant
67 mechanical circulatory support devices placed in 2013, including:
35 as bridge to transplant
32 as destination therapy
Expansive use of mechanical support devices

Among these points of distinction, the program’s innovative use of mechanical circulatory support devices — dating back a quarter century — is increasingly key. As patients with advanced heart failure continue to outstrip the availability of donor hearts for transplant, the use of these devices — primarily left ventricular assist devices (LVADs) — looms ever larger in the care surrounding heart failure and transplantation.

Mechanical circulatory support devices are used in patients with advanced heart failure either as a bridge to transplantation for patients on the organ waiting list or — increasingly — as destination therapy to improve and prolong the lives of patients who are not candidates for transplantation.

Like many centers, Cleveland Clinic has implanted more LVADs than it has performed heart transplants in recent years, with 67 LVADs implanted in 2013, divided nearly evenly between bridge therapy (n = 35) and destination therapy (n = 32).

Experienced use of LVADs as bridge therapy promises to reduce the mortality rate of patients on the organ waiting list. The proportion of Cleveland Clinic heart transplant patients who had been on mechanical support before transplant has risen steadily from under 15 percent in 2005 to more than half (57.9 percent) by 2013.

Exceptional survival rates in LVAD patients

Comparative trials have consistently shown that mechanical circulatory support lengthens and improves the lives of advanced heart failure patients relative to optimal

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<th>Survival rates of LVAD patients by era of LVAD implantation</th>
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<td>Post-implant follow-up</td>
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2013 QUICK TAKE

7.5% in-hospital mortality among LVAD recipients, less than half the expected rate
medical management. And patient survival is steadily increasing over time (see table on previous page) as device technology improves — such as with the replacement of pulsatile-flow devices by newer continuous-flow LVADs — and as experience grows.

Cleveland Clinic has consistently outperformed expectations in terms of in-hospital mortality rates for LVAD patients in recent years. In 2013, Cleveland Clinic’s 7.5 percent in-hospital mortality among LVAD patients was less than half the expected rate of 18 percent, according to data from the University HealthSystem Consortium (UHC) Comparative Database (discharges from January through November 2013).

**FUTURE OF TRANSPLANTATION: A TOTALLY NEW TOTAL ARTIFICIAL HEART**

Biomedical engineers at Cleveland Clinic have joined with their Cardiac Transplantation and Ventricular Assist Device Therapy Program colleagues — and with partners at Cleveland Heart Inc. — to develop a continuous-flow total artificial heart, or CFTAH.

The NIH-funded, potentially groundbreaking innovation advances artificial heart development in two important ways: with automatic speed control and with self-regulation to balance right-left inlet pressures.

The CFTAH is elegantly simple, with just one moving part and one electromechanical component. This single-moving-part design eliminates the need for sensors that balance function of the two sides of the heart, reducing complexity and the risk that the system will fail or wear out over time.

By combining the best features of left and right VADs, the CFTAH promises to address the needs of patients with both left- and right-side heart failure issues that have not been met by right VADs or biventricular assist devices to date.

A slender cable feeds the CFTAH power, which originates from a rechargeable battery that patients can easily strap on under most garments. The entire device, constructed of titanium, weighs less than a pound.

Results of initial biocompatibility tests of the CFTAH have been encouraging, and survival has been achieved in studies of the CFTAH in large animals, but human trials are years away.
Broad leadership in mechanical circulatory support therapy

As more and more patients live for long periods with LVADs, potential complications are emerging, including pump thrombosis, gastrointestinal bleeding, renal failure, stroke and infections. Cleveland Clinic is at the forefront of identifying and reducing such complications through a multidisciplinary approach with the participation of leading specialists.

Beyond this safety vigilance, Cleveland Clinic is dedicated to ensuring that mechanical circulatory support therapy reaches its full potential in the following ways:

• Through active involvement in multiple studies of emerging devices (see “A hub of high-impact research” below) and in development of innovative VAD designs and a new-generation total artificial heart (see sidebar on previous page)
• Through a tenacious focus on using LVADs to keep patients’ original hearts working well enough to stave off transplant for as long as possible, since few transplanted hearts last longer than 20 years

Additionally, Cleveland Clinic is among the few centers that offer inpatient rehabilitation therapy to LVAD patients and heart transplant recipients. Physiatrists and other rehabilitation specialists in the inpatient rehabilitation facility (IRF) on Cleveland Clinic’s main campus work closely with clinicians in the heart transplant program and undergo training specific to managing LVAD patients. Over a 12-month period spanning 2012 and 2013, average length of stay in the IRF for LVAD patients was 16.4 days.

A hub of high-impact research

Cleveland Clinic’s Cardiac Transplantation and Ventricular Assist Device Therapy Program is deeply involved in a wide range of high-impact clinical trials to improve heart transplantation and mechanical circulatory support. Here is a sampling of major active studies and projects:

CTOT 11. Cleveland Clinic’s Randall Starling, MD, MPH, is national study chair of this phase 2 trial within the NIH-sponsored Clinical Trials in Organ Transplantation cooperative research program. The study is evaluating whether induction therapy that combines the monoclonal antibody rituximab (for B-cell depletion) with conventional immunosuppression reduces antibody-mediated cardiac allograft vasculopathy after heart transplant and thereby improves graft function and patient survival.

ENDURANCE. Cleveland Clinic is participating in this multicenter randomized trial comparing the HeartWare® LVAD with the HeartMate II® LVAD in the setting of destination therapy for patients with end-stage heart failure.

LVAD Therapy and Mesenchymal Precursor Cells. This study, coordinated by the Cardiovascular Cell Therapy Research Network and the Cardiothoracic Surgical Trials Network, aims to determine whether intramyocardial injection of mesenchymal precursor cells (MPCs) during LVAD implantation is safe and effective in improving heart function. The trial includes LVADs used as destination therapy or as a bridge to transplant. Cleveland Clinic is one of several participating North American centers, but enrollment is now closed.

ELLA GREEN: A SWIFT PATH FROM CARDIOGENIC SHOCK TO SUCCESSFUL TRANSPLANT

Diagnosed with congestive heart failure, 58-year-old Ella Green passed out in the fall of 2013 after the pacemaker she wore for an irregular heartbeat began to fire repeatedly. Right heart catheterization revealed cardiogenic shock, and she was admitted to Cleveland Clinic.

Although Ella’s surgical team planned to implant an LVAD, she was too weak to undergo surgery without strengthening via arteriovenous extracorporeal membrane oxygenation (AV ECMO). Less than a week after the start of AV ECMO support, a donor heart became available, and on Oct. 29, 2013, Ella underwent a successful orthotopic heart transplant with pacemaker removal.

A few weeks later, including two weeks in rehabilitation, Ella headed home to Columbus, Ohio, to continue physical therapy. “I feel great!” she said in summer 2014 as she prepared to return to her job as a special-education teacher in the fall. “I feel safe at Cleveland Clinic. I have confidence in the doctors, and the aftercare I’m receiving is great.”

clevelandclinic.org/transplant
Beyond the above ongoing trials, Cleveland Clinic investigators have published multiple important studies in recent years that have led to improvements in the care of LVAD and heart transplant patients.

**Well-established pediatric program**

Within a year of its first successful adult heart transplant, Cleveland Clinic performed its first successful pediatric heart transplant (March 1985) and has since built one of the nation’s premier programs for pediatric cardiac transplantation, with 140 hearts transplanted through the end of 2013 (including seven heart-lung transplants). Nearly 75 pediatric heart transplant patients are still being followed.

The pediatric program has a low operative mortality rate and patient and graft survival rates that routinely meet or exceed national benchmarks and expected rates. It numbers among the few programs that can perform dual-organ heart transplants — including the lung, liver or kidney — in children.

Two pediatric heart transplant surgeons and a pediatric transplant cardiologist make up the program’s core physician team. They are supported by more than a dozen additional pediatric cardiologists in Cleveland Clinic Children’s, a team of allied health professionals specializing in pediatric heart transplant, and Cleveland Clinic’s renowned cadre of pediatric and adult congenital heart disease specialists.

Transplanted patients are followed closely by the pediatric transplant cardiologist — often well into adulthood, thanks to a shared clinic in the Center for Adult Congenital Heart Disease, where adult patients can be seen by both an adult-care congenital disease specialist and their longtime pediatric cardiologist.

**Forestalling pediatric transplant when possible**

The pediatric program’s team does all it can to medically manage failing pediatric hearts and forestall transplant when possible, as few donor hearts last beyond 20 years. This is achieved through intricate medication-based therapy and increasingly with LVADs, which are used in this setting primarily to make patients strong enough to undergo transplantation and buy time until a donor heart becomes available.

Cleveland Clinic placed its first Berlin Heart Excor® LVAD in a child in 2010, under a compassionate-use protocol prior to the device’s FDA approval. Through 2013, the program had bridged four pediatric patients to transplant using the Berlin Heart Excor without a single pump-related major complication. The program’s willingness to use the device as soon as in early infancy requires meticulous management to perfect anticoagulation and avoid infections related to the increased tubing required for small children.

Other LVADs, including the HeartWare and HeartMate II devices, are used in older pediatric patients.

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**HAMZAH CHOUHRY: EXPERT MANAGEMENT AVERTS NEED FOR LVAD DURING TWO-WEEK TRANSPLANT WAIT**

Hamzah Choudhry, a college student in Blue Springs, Missouri, awoke one morning struggling to breathe. A visit to the student health center began a harrowing journey marked by repeated cardiac arrest and culminating in an emergency flight to Cleveland Clinic.

There, Hamzah learned that he has Uhl anomaly, an extremely rare congenital disorder resulting in partial or total loss of myocardial muscle in the right ventricle. He urgently needed a heart transplant.

During the two weeks he waited for a donor heart, Hamzah was able to avoid the need for an LVAD thanks to expert management in Cleveland Clinic’s heart failure ICU, one of the few of its kind in the nation. He was critically ill yet remained stable until he was successfully transplanted when a matched donor heart surfaced.

“Before the transplant I couldn’t walk because I was always out of breath and got really tired,” says Hamzah, who is now 21 and back at school. “Now I’m twice as active as before.”