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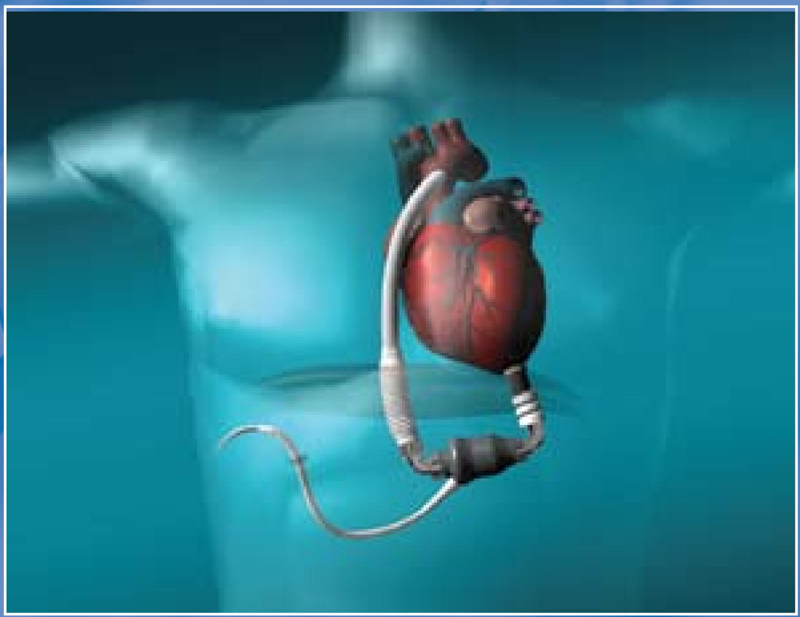


Mechanical Circulatory Support Devices: Technology Improves Quality of Life for Advanced Heart Failure Patients

By William Kessler, MD, FACS

Heart failure (HF) affects a staggering number of patients in the United States and worldwide. It is a leading cause of hospital admissions and deaths as well as visits to emergency rooms. Patients with advanced heart failure have a 15-25 percent annual mortality, and patients with the most severe heart failure have >25 percent annual mortality.

The increase in HF hospitalizations has been even more dramatic than the rise in the numbers of patients with HF during the past two to three decades according to the American Heart Association's Heart Disease and Stroke Statistics – 2007 Update. The National Hospital Discharge Survey showed that there has been a 189 percent increase in the number of patients hospitalized with HF as the primary discharge diagnosis from 1979 through 1999.

Current estimates by the association indicate that the direct cost of HF will be >25 billion dollars with hospital charges accounting for nearly 60 percent of this cost. A substantial proportion of HF-related hospitalizations are accounted for by readmission of patients previously hospitalized with HF.

In industrialized countries, the prevalence and incidence of HF are estimated to be around 1.5 percent and 0.15 percent of the population respectively (Hunt et al., 2005; Deng, 2002). An estimated 10 percent of persons with HF are in advanced stages (NYHA Class III and IV).

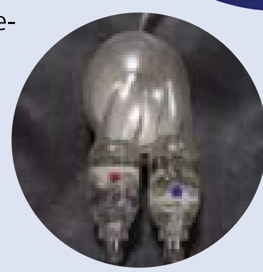
In the United States and Europe alone, with >700 million inhabitants and >7 million patients with HF, the prevalence of advanced HF – constituting between 1 percent to 10 percent of the HF population – is estimated to total between 70,000 and 700,000 patients (Deng, 2005). Interestingly, with the improvement in the management of acute coronary syndromes resulting in improved longevity, a growing number of patients living longer with HF will need to be cared for.

Each year, 40,000 patients are diagnosed with failing hearts. Worldwide, only 2,200 donor hearts become available for transplant annually. Additionally, the waiting list is in excess of 4,000 patients. The only way to keep up with the need is to improve mechanical devices.

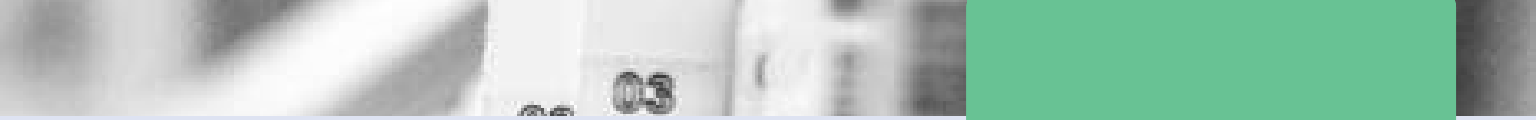
Treatment of Heart Failure

The evolution of new medical therapies has advanced the treatment of HF dramatically. These include medical treatments such as ACE inhibitors and beta-blockers. Nonpharmacologic therapies, such as biventricular pacing, implantable cardioverter defibrillators and the intra-aortic balloon pump, have also improved outcomes. These therapies have become the standard of care and continue to help decrease mortality.

The latest type of therapy to be developed and used in treating advanced HF is mechanical circulatory support devices (MCSD). Mechanical circulatory support, namely left ventricular assist devices (LVAD), is rapidly revolutionizing HF therapy.



The recent REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) trial showed that LVAD support lengthened life by two times and improved quality of life to twice that of standard medical therapies alone. More recent studies with even more modern pumps show still greater outcomes.



Causes of Heart Failure

Acute cardiogenic shock is another area having a high incidence with significant mortality if left inadequately treated. It affects 90,000 patients per year with acute myocardial infarctions (AMI) just in the US.

The 2004 American Heart Association's statistics account for 1.2 million new and recurrent AMIs each year. Cardiogenic shock is a complication in 7.5 percent of MIs of which 60 percent of these patients die. If one does the math, one reasons that cardiogenic shock is a complication in 7.5 percent of the 1.2 million new and recurrent MIs each year which would equal 90,000 patients. Of those 90,000, 60 percent – or a total of 56,000 people – die each year from cardiogenic shock.

Other less common but prevalent causes of HF also continue to carry high mortalities including postpartum cardiomyopathy (CM), viral CM, idiopathic CM, myocarditis and alcohol/polysubstance CM.

Other Etiologies of Heart Failure

Postpartum CM
Viral CM
Idiopathic CM
Myocarditis
EtoH/polysubstance CM

Mechanical Circulatory Support Devices

Mechanical Circulatory Support Devices (MCSDs) are blood pumps used to support the failing heart in critically ill patients with end-stage HF. Other uses for the pumps also include treatment of cardiogenic shock, ischemic heart disease and post-cardiotomy shock.

Statistics indicate that at least 25 percent of patients requiring LVAD support after heart surgery can be fully recovered. Previously, patients who had difficulty coming off of cardiopulmonary bypass used during heart surgery had extremely high mortality. Studies have shown that patients who are on an IABP and three inotropic infusions have a >80 percent mortality.

Whether these pumps are placed intracorporeally or paracorporeally, these pumps take over the function of the damaged left (or right) ventricle and restore more normal hemodynamics and end-organ perfusion.

LVADs are used in three main clinical situations: (1) as a bridge to transplantation in patients who are listed for transplantation but decompensate before a suitable donor heart becomes available, (2) as a bridge to recovery in patients who are expected to recover left ventricular function, or (3) as a permanent alternative to transplantation in patients who are not considered to be candidates for transplantation.

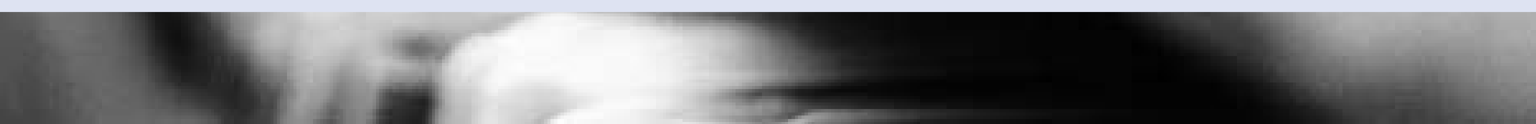
Seton Medical Center Austin's Arsenal

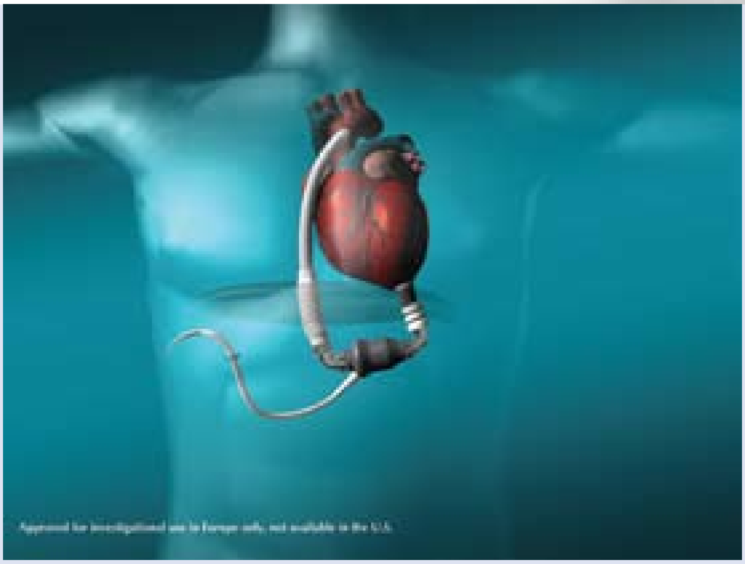
The Seton Heart Specialty Care and Transplant Center's mission is to provide quality health care for people living with or affected by Class III and IV HF with an interdisciplinary team focusing on physical, psychological and spiritual symptoms from the time of referral to the center through the process of living and dying.

The interdisciplinary team provides patient-centered quality care that is safe, effective and efficient, which also leads to patient and family satisfaction.

A wide range of services provided to patients and families include:

- Access to cardiologists and cardiothoracic surgeons who specialize in heart failure and heart transplant
- Patient evaluation to establish clinical, psychological and spiritual status to determine therapeutic interventions that may include advanced medical therapy such as titration of medications and infusions, heart transplant, implantation of a LVAD or referral to a palliative care or hospice program
- Education of patients and families about the disease process, medications, diet, activity, monitoring of health and symptom management
- Case management of the center's outpatients and inpatients
- Outpatient inotropic infusion and other IV therapy for heart failure administered by ACLS-trained nurses
- Ongoing collaboration with referring physicians including periodic updates on patient conditions
- Participation in research studies as available





A comprehensive MCSD program, in conjunction with an outstanding transplant program, is the key to good outcomes. A number of LVAD devices for both the short and long term are required to be able to treat the wide variety of HF states. These LVADs help in improving a patient's survival and quality of life by assisting the left ventricle in delivering blood to different parts of the body. Seton has these devices available when needed.

At Seton, mechanical devices for temporary support and acute coronary syndromes include the ABIOMED ventricle/blood pumps and the Thoratec Centrimag. LVAD support has been shown to allow complete physiologic and mechanical recovery of the heart in some patients.

The ABIOMED BVS 5000 is the most widely used mechanical cardiac assist device for patients with a potentially recoverable heart. This pump can also support one or both sides of the failing heart with a typical length of support of approximately seven to10 days.

The Thoratec Centrimag has a spinning impeller that imparts rotary motion to the incoming blood, directing it through the outflow port. It is intended for use in extracorporeal circulatory procedures and is designed to move blood by centrifugal force created by the rotating impeller, which would decrease trauma that would be associated with circulatory support during cardiopulmonary bypass.

The devices available at Seton for short-term support or bridge to transplant include the ABIOMED ventricle, the Thoratec PVAD, HeartMate XVE and HeartMate II.

The Thoratec PVAD can be used to provide left, right or biventricular support. An external control console uses air to compress the pumping sac that ejects blood through the mechanical valves controlling the direction of the blood flow. The pump can be operated at up to 100 beats per minute, resulting in blood flow rates of up to seven liters per minute.

Seton is the only facility in Central Texas to offer the newly FDA-approved HeartMate II LVAD. This small, continuous flow (axial flow) device offers LVAD technology to a larger spectrum of advanced HF patients.

The HeartMate II's compact design allows this device to be implanted into more patients because each patient's overall size differs. This pump is different from its predecessors in that it has only one moving part, therefore increasing the product's durability. The pump and its battery supply make it easier for a patient to be highly functional once discharged from the hospital.

One of the most rapidly growing areas of HF therapies is mechanical circulatory support without plans for heart recovery or transplant. Known as destination therapy (DT), this strategy involves implantation of a pump and then discharge home.

The HeartMate XVE is the only FDA-approved device for DT. Patients who may not be a candidate for an orthotopic heart transplant but in whom standard HF therapy is inadequate

Dr. William Kessler, a cardiothoracic surgeon with Cardiothoracic and Vascular Surgeons, PA (CTVS), has been instrumental in developing the first MCSD program in Central Texas and currently serves as medical director of the program at Seton Medical Center Austin.

For more information about MCSD, please contact CTVS at **(512) 459-8753, (800) 766-2365** or ***doc@ctvstexas.com***. You can also visit their Web site at ***www.ctvstexas.com.***

Dell Children's at Forefront of Advances in Pediatric Cardiovascular Intervention

By D. Byron Holt, MD

When new or persistent heart murmurs are heard in the pediatrician's office, the major concern is the possibility of congenital heart disease and the child is referred for evaluation by a pediatric cardiologist. Depending on the ultimate diagnosis, the treatment options have dramatically changed during the last 10 years.

In the past, many lesions required an invasive surgical procedure to allow for appropriate growth and development when medications alone were unsuccessful. With advances in medical technology, we are now able to avoid many of those surgeries in favor of less-invasive transcatheter techniques. As a result, the patient avoids a surgical incision, separation of the sternum, bleeding, cardiopulmonary bypass, scarring within the chest and/or pain that can follow many surgical procedures. Patients typically exhibit a speedy recovery, with most patients returning home the same day or the following morning, and often resume all normal activities within days. Many of these techniques are relatively new and the following information serves as a brief overview of what is now possible in the cardiac catheterization lab.

Common Procedures

A number of procedures are now commonplace and have become the standard of care for many patients based on their age, size and particular defect. These include balloon valvuloplasty, device closure of an atrial septal defect (ASD), device/coil occlusion of a patent ductus arteriosus (PDA) and endovascular stent placement.

Valvuloplasty

Balloon valvuloplasty was first described by Kan in 1982. Much has changed in equipment design and, in the past few years, the required sheath size to accommodate the balloons has decreased significantly. Balloon sizes up to 10mm can now be introduced through a 4 French sheath and used for neonatal aortic and pulmonary valvuloplasties. The smaller size is critical in allowing for femoral access with diminished long-term risk of vessel occlusion in small newborns.

Dell Children's Medical Center of Central Texas is the only stand-alone children's hospital in Central Texas and has the only pediatric cardiac catheterization lab in Austin. The cath lab features state-of-the-art Phillips equipment with flat panel biplane imaging, which is essential for many of the most complex interventional procedures. The facility is staffed with experienced pediatric cath lab personnel, pediatric nurses and pediatric anesthesiologists who provide an additional level of experience and safety.

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might benefit from this device. The textured surfaces within the blood chamber promote the development of a cellular lining that helps prevent blood clots and infection.

For patients whose daily activities are greatly curtailed by the debilitating symptoms of advanced HF, these technological advances vastly improve their quality of life, offering less discomfort and more mobility.

As the number of Americans with advanced HF continues to climb, LVADs become more of the way of the future. Education efforts are being used to identify and treat Class III and IV HF in a timelier manner. With the program's efforts, we will continue to push forward in helping patients sustain a better quality of life with superior outcomes for the patients, families and referring physicians served by Seton Medical Center Austin.

ASD Closure

Device closure of an ASD was first described by King and Mills in 1974, leading to a number of investigational device trials in the 1980s. The initial devices such as the Starflex and Cardioseal have been largely replaced by Amplatzer (AGA Medical) devices in recent years, which gained full FDA approval in late 2001. These devices are made of nitinol metal, an alloy of nickel and titanium that has "memory" of its original shape. It allows the device to be distorted and withdrawn into a stiff delivery catheter and later deployed at the level of the atrial septum where it resumes its shape to close the ASD. A piece of Dacron fabric is fixed within the disks of the device to promote thrombosis and allow complete closure of the defect over time. New endothelium forms over the framework of the device and, within six months, is completely covered and incorporated into the atrial septum. They are used for closure of secundum ASDs ranging in size from 4mm to 40mm, which is typically chosen by balloon sizing the defect under echocardiographic guidance until no flow is seen across the atrial septum.

Most patients are larger than 12kg, but exceptions can be made in extraordinary circumstances and alternative approaches to delivery are well described. Surgery remains the only option in small children with very large defects, but it is increasingly unusual to see surgical closure of isolated secundum ASDs. To date, tens of thousands of Amplatzer atrial septal occluder devices have been placed in children worldwide.

PDA Closure

Device occlusion of a PDA was first described by Porstmann in 1967 and coil occlusion of a PDA was first described by Gianturco in 1992. Embolization coils are metal loops of stainless steel with attached Dacron fibers giving them a "fuzzy" appearance. Ductal occluder devices are made of the same material as the septal occluders described above, but with a different shape to resemble a plug. Coil or device occlusion of a PDA is now one of the most common procedures performed in the pediatric cardiac catheterization lab.

Stent Placement

Even though the stent was invented by Dr. Julio Palmaz in 1969, the first stent was not placed in a human coronary artery until 1986 and not approved for use in the United States until 1994. Most had the limitation of deployment at a specific size or limited range of diameters (the focus was on coronary arteries) and did not allow further expansion without sacrificing the integrity and strength of the stent. This limitation is especially important in growing children whose vessels will continue to grow beyond the time of intervention.

Improvements in design and architecture during the last five to 10 years have led to the ability to deploy the stent at one size and then later dilate the stent to a larger size as the child grows. The stent maintains most, if not all, of its radial strength to maintain vessel patency, which has allowed for long-lasting palliation in larger vessels such as coarctation of the aorta, branch pulmonary artery stenosis, superior vena cava (SVC) stenosis and others.

Several studies have shown that primary stenting versus angioplasty alone actually decreases the incidence of vessel dissection and the development of aneurysms when treating coarctation of the aorta and is a valuable alternative to surgery. This procedure can be performed in children with a minimum weight of approximately 20kg who can accommodate the large sheath in the femoral artery. While stent design has evolved, the material used remains stainless steel for the vast majority of those used in children.

Recently Developed and Advanced Procedures

Other interventional procedures are performed in the cardiac catheterization lab that were developed more recently and occur much less frequently than those mentioned earlier. Some are adaptations of existing technology, while others are changing the basic ways we approach the repair of certain types of congenital heart disease.

Muscular VSD Device

The muscular VSD device received approval for use from the FDA in 2008. There is significant experience using this device both in Europe and in the United States as part of the clinical trials and through HDEs (humanitarian device exemption). It is made of the same material as the ASD and PDA occluders, but the waist is wider to accommodate the ventricular septum and the two disks are evenly sized. The uses for this device are somewhat limited and are reserved for patients with hemodynamically significant muscular VSDs or those with complex congenital heart disease that includes a muscular VSD.

A hybrid surgical and catheter approach has been used to treat lesions such as transposition of the great arteries with a muscular VSD. The chest is opened by the surgeon, a sheath is placed directly through the ventricular wall and the device is deployed within the VSD under echocardiographic guidance. This is all done off of cardiopulmonary bypass, after which the arterial switch procedure is performed. This limits the total bypass time, limits ischemic and inflammatory injuries to organs including the brain and diminishes the incidence of significant residual VSDs. These and other uses of this newly approved device are now being employed with higher frequency in catheterization labs across the country.

Radiofrequency Perforation

Patients with pulmonary valve atresia and intact ventricular septum have presented an interesting challenge to cardiologists. In patients with a well-formed ventricular outflow tract, obvious valve plate and well-formed main pulmonary artery, a variety of attempts have been made to establish antegrade pulmonary blood flow in the cardiac catheterization lab. This was initially attempted with long needles that were introduced through rigid catheters. Baylis Medical gained FDA approval of a flexible, insulated wire/catheter system through which electricity could be introduced to "burn" through the pulmonary valve plate. This is low voltage energy, typically 5-7 Watts for 2 seconds. Once a separate wire is placed across the valve plate and in good position, a balloon is then introduced to perform valvuloplasty. This is one of the most high-risk interventions performed in the neonate and must be considered carefully. But the potential benefit is avoiding a neonatal open-heart surgery and postponing it for months or years when the patient is significantly larger and the surgical repair presumably easier. Appropriate patient selection and technical proficiency are critical to successfully performing this procedure.

Stent-Mounted Pulmonary Valves

One of the newest developments in interventional cardiac catheterization is the transcatheter deployment of prosthetic valves. Several stent-mounted valves are currently undergoing human clinical trials for placement in the pulmonary valve position. The Cribier-Edwards, Edwards SAPIEN and Medtronic Melody valves differ in the composition of stent structure and valve leaflet material, but all have the limitation of a relatively large delivery sheath. Close assessment of the clinical trial data will determine which of these valves suits the patient's immediate and long-term needs best. The devices could ultimately result in significant therapeutic improvement in patients who have undergone numerous surgeries during the course of their lifetime and are at high risk of surgical complications.

Dr. Byron Holt received his undergraduate degree from Rice University, and his medical degree from the University of Texas Health Science Center in San Antonio. He went on to complete his pediatric residency, pediatric cardiology fellowship, and interventional catheterization fellowship at Washington University School of Medicine in St. Louis. He is the only fourth-year fellowship-trained pediatric interventional cardiologist in the Central Texas area and has performed more than 500 cardiac catherizations in children. Dr. Holt joined Dr. Ron Shapiro and Dr. Frank Wong at Pediatric Cardiology of Austin in July 2007.

To refer a patient to Dr. Holt, please call Pediatric Cardiology of Austin at (512) 320-8388 or e-mail at *drholt@pediatriccardiologyofaustin.com.* For more information about Dell Children's Regional Heart Program, visit *www.dellchildrens.net.*