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Pioneering Developments in Cardiac Transplant and LVAD Therapy Continue at Mayo Clinic



Sudhir S. Kushwaha, MD; Richard C. Daly, MD; Soon J. Park, MD

Mayo Clinic in Rochester has an extremely active cardiac transplant and left ventricular assist device (LVAD) program, managing a wide variety of end-stage heart disease conditions. The heart transplant team has pioneered many innovative approaches to this complex group of patients. Since the program's inception, more than 500 patients have undergone cardiac transplantation at Mayo Clinic in Rochester.

New Approaches to Immunosuppression

Traditional immunosuppressive therapy typically consists of a calcineurin inhibitor (CNI), azathioprine or mycophenolate, and steroids. Although this is an excellent combination for preventing rejection, it does not prevent the long-term complications that occur following heart transplantation, notably the development of cardiac allograft vasculopathy (CAV) and renal dysfunction, which often results in renal failure many years after transplant. The renal dysfunction is a known complication of CNIs and results in a progressive decline over the course of a few

years. In some patients, the decline can be very dramatic and can even occur in the first year after transplant.

CAV is a progressive coronary disease that affects all the coronary vessels of the transplanted heart and remains the major cause of long-term mortality following transplant. The disease is a proliferative process characterized by smooth muscle hypertrophy and intimal proliferation. By 10 to 15 years after transplant, the majority of patients have CAV, for which there is no highly effective treatment. Although percutaneous coronary intervention (PCI) is sometimes performed, it has limited long-term benefit because the disease is generalized.

"Several years ago, our program pioneered the use of sirolimus-based immunosuppression in our heart transplant population," says Sudhir S. Kushwaha, MD, transplant cardiologist at Mayo Clinic in Rochester. In place of a CNI (cyclosporine or tacrolimus), physicians treated transplant patients with sirolimus (rapamycin). This drug is a powerful immunosuppressive, but it also has the additional quality of being an antiproliferative agent, thereby mitigating some

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of the adverse effects seen and improving survival (Figure 1). With sirolimus treatment, renal function improved significantly in all patients. Similarly, the progression of CAV in this patient population has declined and, in a few dramatic cases, has reversed.

Transplantation for Amyloid Cardiomyopathy

Amyloidosis is an infiltrative disease that can affect the heart and eventually lead to a restrictive cardiomyopathy. **AL-type** (amyloid light-chain) amyloidosis is a plasma cell disorder, and severe cardiac involvement carries a poor prognosis, despite advances in chemotherapy. To treat the restrictive cardiomyopathy, cardiac transplantation is performed; this procedure must be followed by bone marrow transplantation to treat the plasma cell abnormality causing the generation of the amyloid protein. Patients receive standard chemotherapy treatment while awaiting transplant. **TTR-type** (transthyretin or familial) amyloidosis is caused by generation of amyloid protein from the liver; patients who go on to transplant require liver as well as heart transplantation to stop the production of amyloid protein.

Because of the very large amyloidosis practice at Mayo Clinic in Rochester, many patients with advanced heart failure due to restrictive cardiomyopathy caused by both types of amyloidosis are seen. During the last 20 years, Mayo Clinic in Rochester has the largest experience in the United States in combined transplantation for treatment of amyloidosis, both with heart transplant followed by bone marrow transplant for

AL amyloidosis and combined heart and liver transplant for familial TTR amyloidosis. Nevertheless, treatment of patients with AL amyloidosis is challenging, as they have limited long-term survival compared to nonamyloidosis patients who undergo cardiac transplantation. Thus, this procedure may be helpful in improving short-term survival and, in selected patients, it may be a life-prolonging therapy.

Combined Organ Transplantation

The program at Mayo Clinic in Rochester also performs combined organ transplants for indications other than amyloidosis. Patients with co-existing renal failure may be listed for combined heart and kidney transplants. Combined heart-lung transplants are performed in patients with pulmonary hypertension and severe right heart failure, and in those with complex congenital heart disease in whom pulmonary hypertension has developed.

The Problem of Preformed Antibodies: Thinking 'Outside the Box'

Many patients awaiting organ transplants may have preformed antibodies to specific antigens, and this may greatly narrow the donor pool for those patients. If a donor becomes available but expresses certain antigens to which the potential recipient has high levels of antibodies, proceeding with the transplant will result in antibody-mediated, or humoral, rejection. This can sometimes result in a situation in which certain

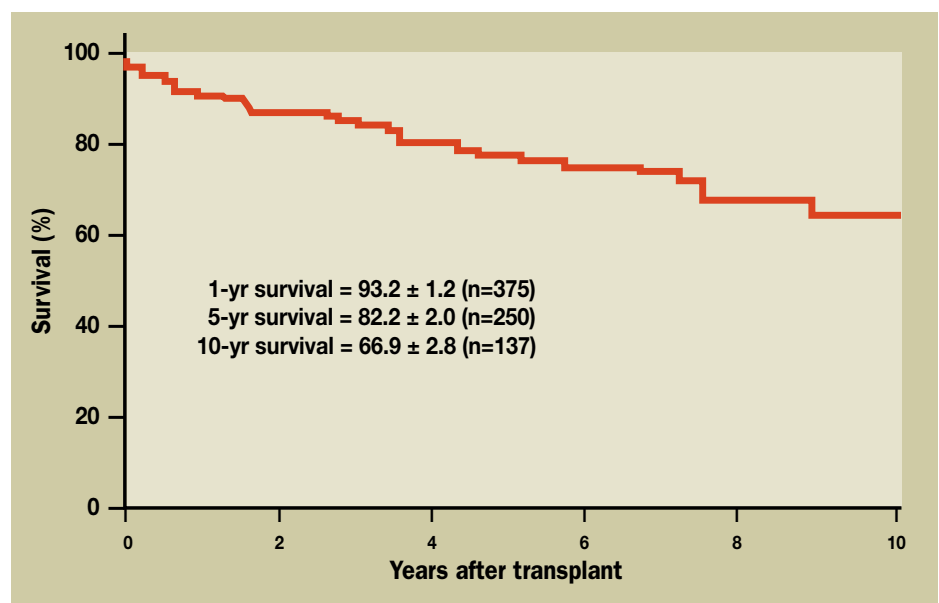


Figure 1. 10-year Kaplan-Meier survival curve for cardiac transplant patients at Mayo Clinic in Rochester (June 1988-December 2012).

patients with very high levels of antibodies can become practically untransplantable because of the number of antibodies with high titers. The waiting period for these patients can become even longer than usual because finding an appropriate donor can be very difficult. Various strategies have been tried to reduce levels of antibodies in these patients, but such "desensitization" protocols have met with very limited success and do not appear to be a durable long-term solution (Box 1).

"Interestingly, combined heart and liver transplantation appears to have a much better survival rate compared to heart transplant alone," according to Richard C. Daly, MD, cardiac transplant surgeon at Mayo Clinic in Rochester. There are several potential reasons for this observation, including the fact that use of both organs from the same donor appears to provide some "immunological protection" for the transplanted heart.

LVAD Program

Currently, LVADs are used in 2 situations: as a bridge to transplant or as destination therapy (Figure 3). The LVAD is used to keep the bridge-to-transplant patient alive until transplantation can occur; these patients are usually younger and must be transplant candidates. LVAD therapy allows many patients to resume an almost-normal lifestyle until the time of transplant. Presently, about half the patients waiting for transplant at Mayo Clinic in Rochester are supported by an LVAD.

Destination therapy patients tend to be older and are not transplant candidates. Therapy is used to treat the heart failure, with no plans for transplantation in the future. Usually, because of age and comorbidities, these patients may be frailer and severely weakened by their heart failure before LVAD implant and thus may have a longer hospital stay, with a more prolonged period of rehabilitation before they are discharged from the hospital. After rehabilitation, many of these patients are restored to an excellent quality of life with improved mortality.

Box 1: First-Ever Liver-Heart Transplant

A 51-year-old woman came to the Mayo Clinic transplant program with a complex medical history of isolated right heart failure with secondary hepatic cirrhosis. She needed both heart and liver transplantation. A right ventricular assist device (RVAD) was placed as a temporizing measure but was not successful. She had multiple preformed antibodies, making it unlikely that an acceptable donor would be identified in a timely fashion.

Based on the observation that significant cardiac rejection has not occurred in any patient who has undergone a combined heart-liver transplant, she received a liver transplant first, followed by the heart transplant. It was hypothesized that the reversed transplant sequence would allow removal of preformed antibodies from the circulation (Figure 2). Presently, she is doing very well without a single episode of rejection more than 2 years after transplant.

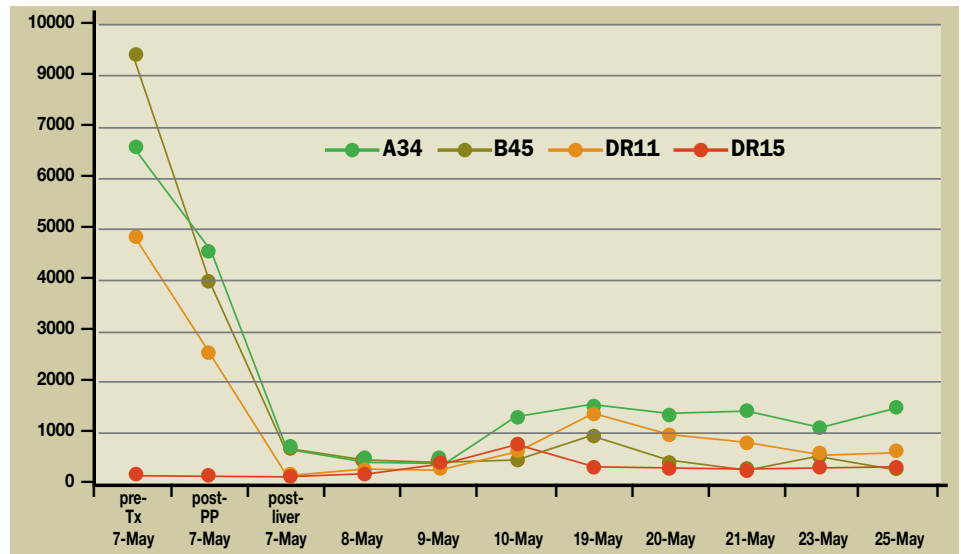


Figure 2. Changes in donor-specific antibodies (A34, B45, DR11, and DR15) following combined sequential liver-heart transplantation. Note the dramatic decline in antibody levels following implantation of the liver and the sustained low levels during follow-up.

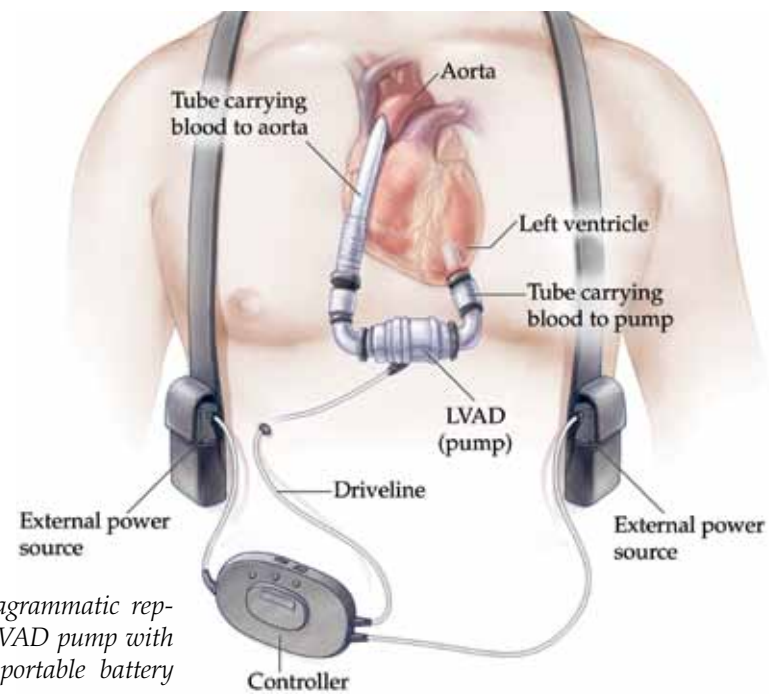


Figure 3. Diagrammatic representation of LVAD pump with controller and portable battery pack.

LVAD Therapy for Restrictive Cardiomyopathy

In restrictive cardiomyopathy, the heart is small, with thick walls and a small ventricular cavity. "LVAD therapy generally has not been used in these patients because the size of the ventricular cavity is not large enough to accommodate the inflow cannula of the LVAD," according to Soon J. Park, MD, cardiac transplant surgeon at Mayo Clinic in Rochester. "While generally true, a small number of patients at Mayo Clinic in Rochester have received LVADs as destination therapy and had reasonable success, in situations where few other options were available." (Box 2)

Summary

The cardiac transplant and cardiac assist device program at Mayo Clinic has been at the forefront in the treatment of end-stage cardiac disease. The program has distinguished itself by its ability to take on challenging cases that would not be considered elsewhere. The transplant program has pioneered the use of innovative immunosuppressive strategies, which have improved patient survival and comorbidities, and become

Box 2: Bridge to Transplant

A 55-year-old man initially presented with severe heart failure due to restrictive cardiomyopathy secondary to senile TTR amyloidosis, and he was listed for cardiac transplant. Over the next 2 years, he had worsening of his cardiac and renal function, and he eventually underwent LVAD implantation. Nevertheless, his renal function continued to deteriorate, and he was listed for renal transplant in addition to cardiac transplant. After 3 years of bridge-to-transplant LVAD therapy, organs became available, and he underwent a combined heart and kidney transplant. He is now doing well and enjoying life to the fullest.

a world leader in the use of combined organ transplant for difficult conditions such as cardiac amyloidosis. The LVAD program has challenged the accepted paradigms of use of this therapy for dilated cardiomyopathy, and demonstrated the feasibility of and good outcomes for the use of LVADs in restrictive heart disease.

IN THE NEWS

Mayo Clinic to Host Hypoplastic Left Heart Syndrome Event

Mayo Clinic in Rochester will host an inaugural Hypoplastic Left Heart Syndrome (HLHS) gathering on October 5, 2013, in an effort to raise awareness for this syndrome. The gathering will focus on HLHS patients and families as well as individuals in the biomedical community who provide care for these children. This event will include tours of Mayo Clinic for HLHS patients, families, and providers, as well as engaging activities with the intent of inspiring hope, showcasing courage, and building support networks of members of the HLHS community.



RECOGNITION



Douglas L. Wood, MD, cardiologist at Mayo Clinic in Rochester, has been selected as the new medical director of the Center for Innovation at Mayo Clinic in Rochester.

Mayo Clinic in Rochester Leads FDA Trial of Next-Generation Sutureless Aortic Valve Replacement Technology



Rakesh M. Suri, MD, DPhil

Since the introduction of surgical aortic valve replacement more than 50 years ago, innovations in valve design and surgical technique, as well as the advent of transcatheter valve technology, have provided an array of new therapeutic options for patients with aortic valve disease. Due to the fact that transcatheter aortic valve implantation (TAVI/TAVR) relies upon the insertion of a new valve within a diseased native aortic valve, debate over whether debris embolization and stroke risks are elevated persists in the cardiac care community.

While the equivalence of TAVR to surgical aortic valve replacement in high-risk surgical patients has been demonstrated in the PARTNER Trial (Edwards SAPIEN valve), whether TAVR is

appropriate for lower risk patients who have very good outcomes after traditional aortic valve replacement will remain less clear until the results of the PARTNER II (Edwards SAPIEN XT valve) and SURTAVI (Medtronic CoreValve) trials become available.

In the interim, patients who are candidates for traditional surgical aortic valve replacement may benefit from a shortening of the time spent supported by the heart and lung bypass machine and performance of the operation through smaller and presumably better tolerated incisions. The new Sorin PERCEVAL valve has offered such an alternative to patients in Europe since 2007 (CE approval 2011) and more recently in Canada. The PERCEVAL valve-insertion strategy is very similar to traditional aortic valve replacement, allowing removal of native aortic disease followed by insertion of a new valve prosthesis, freeing patients of valve calcium burden prior to insertion of a new pericardial aortic valve device. All this is performed without the need for sutures, thereby shortening operative times, decreasing certain complications, and allowing minimally invasive approaches.

Mayo Clinic in Rochester is leading the PERCEVAL multicenter clinical trial nationally and also is a participating site. The trial received investigational device exemption (IDE) approval from the Food and Drug Administration. The objectives of the trial are to establish safety and clinical efficacy in comparison to historical controls.

Cardiothoracic Surgery
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INCLUSION CRITERIA

- Age \geq 18 years of age
- Aortic valve stenosis or combination stenosis/regurgitant of native or prosthetic valve
- Willing to travel for postoperative study follow-up
- The ratio of the sinotubular junction divided by the aortic annulus diameter (assessed by transthoracic or transesophageal echocardiogram) is $<$ 1.3

EXCLUSION CRITERIA

- Preexisting prosthesis or annuloplasty ring in mitral, pulmonic, or tricuspid valves
- Repair or replacement of additional valves required
- Active endocarditis or myocarditis
- Aortic root enlargement
- Ascending aortic dissection or dilation
- Unable to give informed consent
- Substance abuse
- Concomitant life-limiting disease (prognosis $<$ 1 year)
- Hypersensitivity to nickel alloys
- Renal dialysis
- Hyperparathyroidism
- Unresolved acute neurological or cardiac event within past 30 days

For additional information about the trial or enrolling a patient, please contact:

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Radiation Reduction in the Congenital Cardiac Catheterization Laboratory

Improving Patient Safety



Kenneth A. Fetterly, PhD; Allison Cabalka, MD

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The use of ionizing radiation is a necessary component of procedures in the cardiac catheterization laboratory. Individuals with congenital heart disease typically are diagnosed as children or young adults and may undergo many imaging studies involving radiation exposure over their lifetimes. Pediatric cardiologists at Mayo Clinic in Rochester are working to minimize radiation exposure to patients while maintaining appropriate image quality. Their efforts are resulting in lower radiation exposure for all patients undergoing diagnostic and interventional procedures in the cardiac catheterization laboratory.

Beginning in 2008, 11 intentional practice changes were implemented involving the pediatric and adult congenital practice. These changes included both technical alterations related to image acquisition as well as provider education (Table 1). The impact of these changes on all imaging studies in pediatric and adult congenital patients over a 45-month period was reviewed by Daniel A. Mauriello, MD, fellow in pediatric cardiology at Mayo Clinic in Rochester.

Studies were classified based on procedure type and complexity, and patients were classified based on size and age. Logarithmic changes of the cumulative air kerma (K_{ar}), which is the absorbed dose delivered in the absence of scatter (measured in Gy), were modeled. "The practice changes implemented resulted in a dramatic 61% decrease in radiation exposure across the entirety of the practice," according to Kenneth A. Fetterly, PhD, radiation physicist at Mayo Clinic in Rochester.

Subanalysis showed the greatest reduction (74% of K_{ar}) in those patients undergoing simple

Practice changes	Date initiated	Technical changes	Date initiated
Formation of CV Invasive Labs Radiation Safety Committee	Jun 2008	Removal of antiscatter grid for all patients < 20 kg and at provider discretion for patients 20-60 kg	Dec 2008
Initiation of internal reporting when case dose \geq 6,000 mGy	Jun 2008	Standardization of X-ray protocols	Apr 2009
Initiation of intraprocedure announcement when 3,000 mGy reached	Jun 2008	Spectral filtration increased for acquisition imaging	Jun 2009
Air kerma (mGy) included in final report	Dec 2009	Default fluoroscopy setting changed to "low"	Nov 2009
Initiation of compulsory fellows training	Jul 2010	Fluoroscopy frame rate reduced to 7.5 fps	Dec 2009
		Acquisition detector target dose reduced	Jun 2010

Demographics and Results Summary (Total N=1082)		
Age		
Mean	32 y (0 d - 85.1 y)	
Median	31 y	
Sex		
Female	516 (47.7%)	
Weight		
Mean	61 kg (1.6 - 200 kg)	
Median	65.6 kg	
Overall Dose Reduction		
Weight Groups		
<20 kg	211 (19.5%)	20%*
20-60 kg	250 (23.1%)	72%
>60 kg	621 (57.4%)	66%
Procedure Type		
Non Intervention	481 (44.5%)	71%
Simple Intervention	424 (39.2%)	74%
Complex Intervention	177 (16.4%)	-5%*
Age Groups (years)		
<1	85 (7.9%)	-1%*
1-4	107 (9.9%)	31%*
5-9	56 (5.2%)	39%*
10-17	125 (11.6%)	74%
18+	709 (65.5%)	67%
* Not significant		

interventions (atrial septal defect/patent foramen ovale closure, pulmonary valvuloplasty, and patent ductus arteriosus closure) (Table 2). Those patients undergoing noninterventional procedures (hemodynamic catheterization and right ventricular biopsy) also saw a robust 71% decrease in K_{ar} over the study period.

Analyses of weight and age as independent variables revealed that the greatest reductions in K_{ar} were in individuals weighing 20 to 60 kg (72%) and those aged 10 to 17 years old (74%).

"Through a combination of technical changes and provider awareness initiatives, we have been able to dramatically reduce the radiation exposure to the majority of patients undergoing procedures in the pediatric and congenital catheterization laboratory," says Allison Cabalka, MD, pediatric cardiologist at Mayo Clinic in Rochester and director of the Pediatric and Congenital Cardiac Catheterization Laboratory. Continued efforts to minimize radiation exposure to patients are an important part of Mayo Clinic's commitment to safety.

PODCAST: TIPS FOR NEW TAVR CENTERS

The Latest From Mayo Clinic on TheHeart.org

Charanjit S. Rihal, MD, chair of the Division of Cardiovascular Diseases and cardiologist at Mayo Clinic in Rochester, and Kevin L. Greason, MD, cardiovascular surgeon at Mayo Clinic in Rochester, share the expertise of Mayo Clinic in transcatheter aortic valve replacement (TAVR), with insight intended for centers embarking on new programs. They discuss the key determinants of prognosis, the procedural learning curve, the risk of perioperative stroke, appropriate antiplatelet and anticoagulant therapies, vascular access site selection, and the importance of the "preflight checklist." Visit <http://www.theheart.org/columns/mayo-talks/tips-for-new-tavr-centers.do> to listen to or download the podcast.

Check out additional videos and podcasts at www.theheart.org/mayoclinic

RECOGNITION



Samuel J. Asirvatham, MD, and Rick A. Nishimura, MD, were named the 2013 Teachers of the Year by the Mayo Fellows Association in the Division of Cardiovascular Diseases, Department of Internal Medicine, at Mayo Clinic in Rochester.



Fadi E. Shamoun, MD, and Tasneem Z. Naqvi, MD, cardiologists at Mayo Clinic in Arizona, have been selected to join the Council on Vascular Ultrasound of the American Society of Echocardiography.



D. Eric Steidley, MD, cardiologist at Mayo Clinic in Arizona, has been named to the Advanced Heart Failure and Transplant Cardiology Self-Evaluation Process (AHFTC-SEP) committee of the American Board of Internal Medicine.

RECOGNITION



Eugene H. Blackstone, MD, head of Clinical Investigations at the Miller Family Heart & Vascular Institute at Cleveland Clinic, was the 2012 John W. Kirklin Visiting Professor in Cardiac Surgery at Mayo Clinic in Rochester.

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Mayo Clinic welcomes inquiries and referrals, and a request to a specific physician is not required to refer a patient.

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Advanced Catheter Ablation: New Tips, Techniques, and Technologies for Complex Arrhythmias

Sep 8-11, 2013, Boston, MA

Internal Medicine Review for Nurse Practitioners, Physician Assistants and Primary Care Physicians

Sep 18-20, 2013, Rochester, MN

18th Annual Mayo Clinic Cardiovascular Review Course for Cardiology Boards and Recertification With Echo Focus Session

Sep 20-26, 2013, Rochester, MN

10th Annual Mayo Clinic Interventional Cardiology Board Review

Sep 27-29, 2013, Rochester, MN

Individualizing Medicine Conference 2013: From Promise to Practice

Sep 30-Oct 2, 2013, Rochester, MN

Challenges in Clinical Cardiology: A Case-Based Update

Oct 4-6, 2013, Chicago, IL

Echo at the Arch: Practical Review of Ischemic and Myopathic Heart Disease

Oct 12-13, 2013, St. Louis, MO

29th Annual Echocardiography in Pediatric and Adult Congenital Heart Disease

Oct 13-16, 2013, Rochester, MN

23rd Annual Cases in Echocardiography, Cardiac CT and MRI

Oct 23-26, 2013, Napa, CA

Coronary Artery Disease: Prevention, Detection and Treatment

Nov 2-4, 2013, Las Vegas, NV

Echo on Marco Island: Case-Based Approach

Dec 5-8, 2013, Marco Island, FL

2nd Annual Mayo Clinic Heart Rhythm Course: A Case-Based Approach

Dec 5-8, 2013, Scottsdale, AZ

The Heart Beat of Cardiology: Practical Application of Echocardiography

Dec 19-21, 2013, Chicago, IL

Mayo Clinic Cardiology Update at South Beach: A Focus on Prevention

Jan 8-11, 2014, Miami Beach, FL

State-of-the-Art Valvular and Structural Heart Disease Intervention: Building the Heart Team

Jan 16-19, 2014, Fort Lauderdale, FL

Arrhythmias & the Heart: A Cardiovascular Update

Jan 27-31, 2014, Big Island, HI

Hawaii Heart 2014: Case-Based Clinical Decision Making Using Echocardiography and Multimodality Imaging

Feb 3-7, 2014, Kauai, HI

39th Annual Cardiovascular Conference at Snowbird

Feb 3-6, 2014, Snowbird, UT

Advanced Heart Failure Symposium

Spring 2014, Scottsdale, AZ

21st Annual Echocardiographic Workshop on 2-D and Doppler Echocardiography at Vail

Mar 10-13, 2014, Vail, CO

Heart Failure Management for NPs, PAs and Primary Care Providers

Mar 20-22, 2014, Lake Buena Vista, FL

SYMPOSIA

Mayo Clinic Satellite Educational Symposia at AHA 2013

Nov 16-20, 2013, Dallas, TX

- Cardiac Rheumatology: Mechanisms and Management (Nov 16)
- Sports Cardiology: Pushing the Cardiac Limits (Nov 17)
- An Integrated Approach to Evaluation and Management of Pulmonary Hypertension (Nov 18)

Mayo Clinic Satellite Educational Symposia at ACC 2014

Mar 29-Apr 1, 2014, Washington, DC

Symposia to be announced

INTERNATIONAL MEETINGS

British Cardiovascular Society: Cases, Controversies and Updates

Oct 21-23, 2013, Royal College of Physicians, London, England, www.bcs.com

Mayo Clinic Cardiovascular Reviews in Bahrain

Jan 22-25, 2014, Manama, Bahrain

19th Annual Cardiology at Cancun: Topics in Clinical Cardiology

Feb 24-28, 2014, Cancun, Mexico

Mayo Clinic International Vascular Symposium

Mar 27-29, 2014, Buenos Aires, Argentina
www.mayo.edu/cme/internationalvascular2014

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