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## Prevention and Management of Device Infection Current Practice Guidelines



Larry M. Baddour, MD; Michael J. Osborn, MD

Cardiovascular device therapy has become increasingly commonplace and is now applied not only to patients with manifest rhythm disturbances but also in anticipation of events (such as implantable cardioverter-defibrillators [ICDs] for primary prevention) and for improvement in cardiac function in the absence of cardiac arrhythmia (cardiac resynchronization therapy [CRT]). Approximately 400,000 cardiac devices are implanted yearly in the US, and it is estimated that more than 3 million patients have implanted devices. Presently, one of the most vexing and morbid complications of device therapy is the development of infection.

The incidence of device infection is low but has increased. "Until 2004, the rate of infection was constant at approximately 1.5% per year, but then it steadily increased to a rate of 2.5% per year as reported in 2008," according to Larry M. Baddour, MD, chair of the Division of Infectious Diseases at Mayo Clinic in Rochester. This increase coincides with the expanded use of

ICDs and CRT and is likely related to longer procedure times, the increased bulk of larger generators, and multiple leads, all undermining wound and skin integrity.

Other factors known to be associated with the risk of device infection include chronic renal insufficiency, the presence of chronic intravenous lines (including dialysis catheters), chronic anticoagulation, multiple device leads ( $\geq 3$ ), number of device-related procedures ( $\geq 3$ ), and immunosuppression, either related to an underlying disease process or therapy with corticosteroids.

Early device reoperation (especially within days) is associated with the greatest risk of infection, increasing it by 15 fold. Also contributing are the increasing longevity of patients with devices and the subsequent need for generator replacement and lead revision.

Appropriate antibiotic prophylaxis at the time of device procedure is a crucial step in device infection prevention. In most centers, cefazolin is administered 1 hour prior to device placement and is continued for less than 24 hours. In contrast, there are no data to support "secondary" prophylaxis for patients with devices who undergo dental and other invasive procedures, and therefore it is not recommended.

In the majority of patients (60%), a device infection will involve the device pocket. "The most obvious sign is a pocket abscess, but the presenting symptoms may be subtle, such as pocket erythema, induration, or pain," says Michael J. Osborn, MD, electrophysiologist at Mayo Clinic in Rochester. "The latter symptom should not be overlooked, as pocket pain persisting for more

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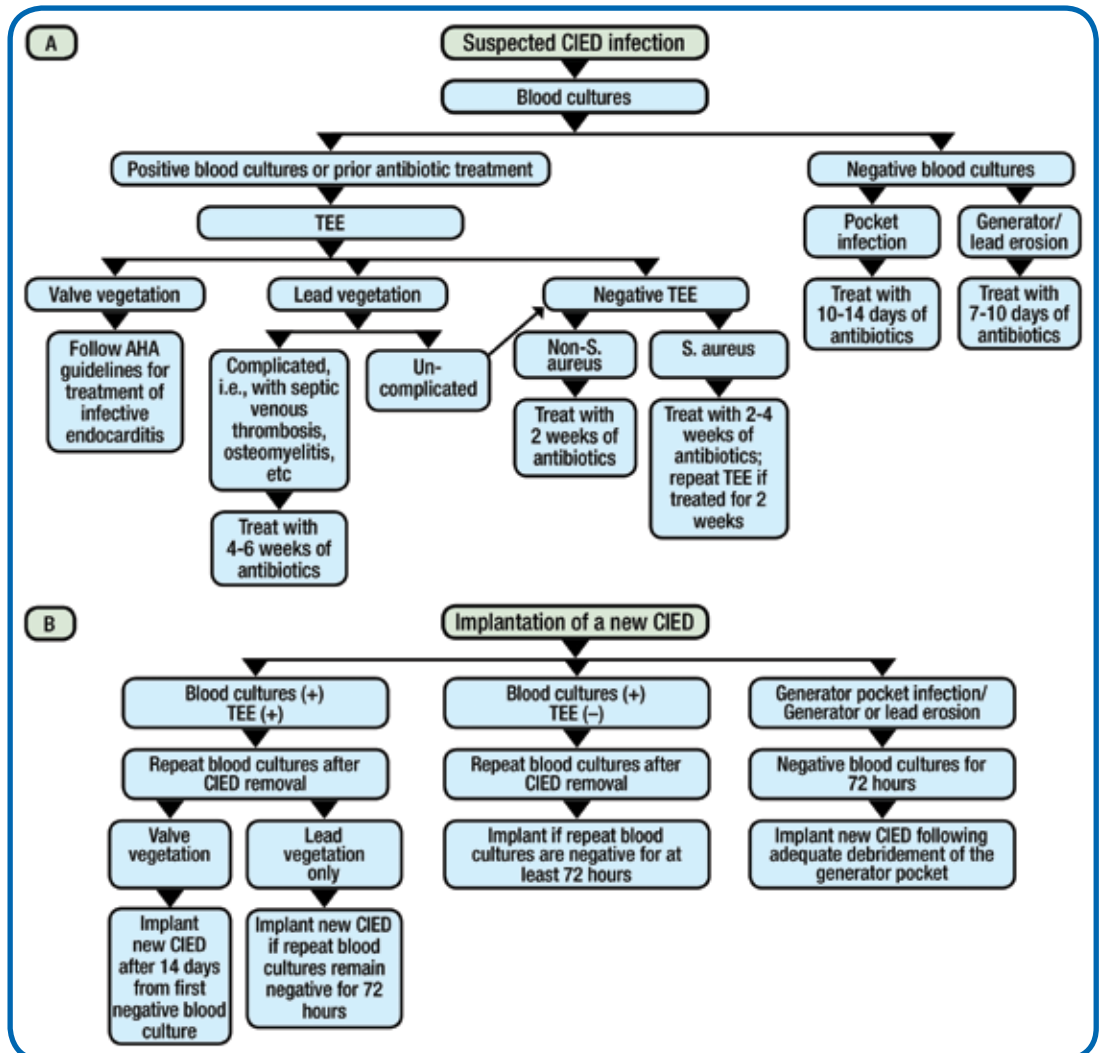
than a few days postprocedure or developing after a symptom-free period is extremely unusual and should be vigorously evaluated." A draining sinus is a very common manifestation of pocket infection. Those that develop shortly after a device procedure may represent stitch abscesses, which may respond to antibiotics and careful removal of protruding suture material. Any more-aggressive therapy should be avoided.

A chronic draining sinus, especially one that develops late after a procedure, is worrisome. If the sinus has clear communication with the pocket or if more pronounced pocket erosion occurs, the entire pocket should be considered contaminated, and the device and leads should be removed. If there is no clear communication with the pocket, a trial of appropriate antibiotic therapy is reasonable as long as there are no signs of systemic infection (chills, fever, or valve or lead endocarditis seen on an echocardiogram). If the sinus does not heal or recurs after therapy, the device should be managed as an infection.

In about 40% of patients, bloodstream infection occurs as the only sign of device infection.

Bloodstream infection due to staphylococci or relapsing bloodstream infection should prompt concern for device infection, even when the pocket site appears normal. "Echocardiography should be done to determine if there is evidence for complicating valve infection. The finding of a mobile mass on an intracardiac lead is much less reliable as a sign of lead infection, as many leads develop an irregular fibrinous coating over time in noninfected patients," says Dr Osborn. Device infection requires complete system removal for attempted cure. Antibiotic therapy without complete device and lead removal is associated with an increase in 30-day mortality.

Despite proper therapy, there is still a significant mortality risk with infection, especially when associated with staphylococcal bacteremia. The in-hospital mortality rate following successful extraction of an infected system ranges from 3% to 11% with a posthospital (up to 2-year) mortality rate of 10% to 20%. The risk of death is 2 to 3 times higher in patients with staphylococcal bacteremia compared to infection limited to the pocket. This significant mortality risk is re-



**Figure.** A stepwise approach to management of suspected cardiovascular implantable electronic device infection in adults based on most recent guidelines. (Circulation 2010;121:458-77.)

lated to the virulence of the organism and also frequently to delays in delivery of appropriate therapy because of slow recognition of the infection, delays in device removal, and attempts at more-conservative therapy.

"Patients with devices who present with staphylococcal bacteremia have a high incidence of associated device infection and should be evaluated promptly by physicians with expertise in infected device removal," says Dr Baddour. In contrast, patients with gram-negative bacteremia have associated device infection much less frequently, and as a result device removal can be delayed to allow assessment of appropriate antibiotic therapy if there is no other evidence of device infection. Obvious signs of pocket site infection, lead endocarditis, valve endocarditis, or relapsing or sustained bloodstream infection despite antibiotic therapy should be managed aggressively with complete device removal.

The Heart Rhythm Society and American College of Cardiology have established appropriateness criteria for lead extraction in patients with infections based on prior experience managing patients in a more-conservative fashion (Figure). Complete extraction is recommended in any definite device infection: valve or lead endocarditis, bloodstream infection and associated pocket infection (abscess erosion or chronic draining sinus), and an occult gram-positive bacteremia. Extraction is reasonable in patients with persistent gram-negative bacteremia. Extraction is not recommended when there is no clear evidence of pocket infection or in the rare patients who have a significant underlying morbidity that would preclude aggressive therapy.

There is a standard approach to lead extraction in patients with infection. Blood cultures are obtained when a diagnosis of device infection is suspected. The pocket is opened and inspected. If there is obvious infection, the pocket is extensively debrided, and tissue is sent for microbiologic studies. The leads are dissected free of all fibrous material within the pocket and from the sleeves that anchor them to the pectoralis muscle. Stylets are inserted, and extraction by traction is attempted. If this is not entirely successful, the proximal portions of the leads are amputated, and a locking stylet is inserted into the lead and advanced under fluoroscopic control to the distal tip of the lead and locked in place. Traction is attempted again, and if not successful, a powered sheath (typically a laser sheath) is advanced over the lead to the first area of resistance or binding scar. The laser is activated until the fibrous tissue is ablated, and the sheath is then advanced to the next area of binding scar, with the process repeated until the lead is freed and removed from the heart. The extracted device and leads are sent for microbiologic studies.

Power extraction tools have improved the rate of successful lead removal. In the past 20 years at Mayo Clinic in Rochester, 97.3% of all leads have been completely removed. Approximately 1% of leads have been incompletely removed, leaving a very small segment firmly attached to the endocardium. In 1.5% of patients, leads could not be removed transvenously and required surgical intervention. "Virtually all leads that have been in place for less than 5 years have been completely removed successfully," says Dr Osborn. "For leads that have been in place for more than 5 years, the success rate for complete lead removal is approximately 92%."

The rate of potentially life-threatening complications, however, remains between 2% and 3%. These include innominate vein or superior vena cava laceration, cardiac perforation, requirement for emergent (rescue) surgery, pericardial effusion requiring intervention, blood loss requiring transfusion, deep venous thrombosis, tricuspid valve damage resulting in significant regurgitation, ventricular arrhythmias requiring intervention, pulmonary embolism, cerebrovascular accident, transient respiratory failure, transient renal failure, and axillary or subclavian venous bleeding requiring surgical intervention. Laceration of the superior vena cava accounts for more than 60% of procedural mortality. Cardiac perforation and consequent emergent surgery accounts for the majority of the other deaths.

## RECOGNITION



Win-Kuang Shen, MD (center), chair of the Division of Cardiovascular Diseases at Mayo Clinic in Arizona, received the 2013 Medal of Honor from the Alumni Association of New York Medical College for his extraordinary achievements as an internationally recognized teacher, researcher, and clinician. The award was presented in New York City by John Cosgrove, MD (left), representing the Board of Governors of New York Medical College, and Henry Saphier, MD (right), president of the Alumni Association.



# Mechanical Circulatory Assist Device Program at Mayo Clinic in Rochester

## Lessons Learned From the First 200 LVAD Implants and Beyond

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The Mechanical Circulatory Assist Device Program at Mayo Clinic in Rochester was formally established in 2007 to address the needs of an advanced heart failure population demonstrated to benefit from such support even in the absence of proceeding to transplant. Until then, no more than 10 left ventricular assist devices (LVADs) had been implanted in any single year at Mayo Clinic in Rochester. This year, the program celebrated the 200th continuous-flow LVAD implant since 2007; to date, a total of 223 long-term continuous-flow LVADs have been implanted, and 4 patients with biventricular heart failure have

received total artificial hearts with subsequent heart transplantation.

### A Unique Patient Population

LVAD therapy can be offered to patients with advanced heart failure either as a bridge to transplant or destination therapy (in patients who are not transplant candidates). Bridge-to-transplant patients will remain on device therapy until a donor heart becomes available and they undergo transplantation. Destination therapy patients receive the device and remain on device support for the rest of their lives. Patients who are bridge-to-transplant candidates tend to be

younger and without serious comorbid conditions; patients who are destination therapy candidates tend to be older and often possess various comorbid conditions that preclude them from being considered for transplant. In some cases, LVAD therapy can modify a comorbid condition such that a patient can become suitable for transplant, such as in the reversal of severe pulmonary hypertension. This is referred to as the bridge-to-decision strategy.

The majority of centers implant LVADs for patients as a bridge to transplant. In contrast, the majority of patients at Mayo Clinic receive LVAD therapy as destination therapy. "Subsequently, compared to all the clinical trials reporting results for device therapy, our patients on average are 5 to 10 years older at the time of implant and have more comorbidities, such as compromised pulmonary and renal function," according to John M. Stulak, MD, transplant surgeon at Mayo Clinic in Rochester. Nevertheless, outcomes parallel and often exceed those reported in clinical trials (Figure).

The etiology of heart failure in the majority of patients is either ischemic or idiopathic dilated; however, there is an increased frequency of patients with end-stage congenital heart disease, restrictive and hypertrophic cardiomyopathy, and senile amyloidosis. These diagnoses are quite challenging when it comes to considering device therapy, and the patient selection process is continually refined when considering device therapy in these patients.

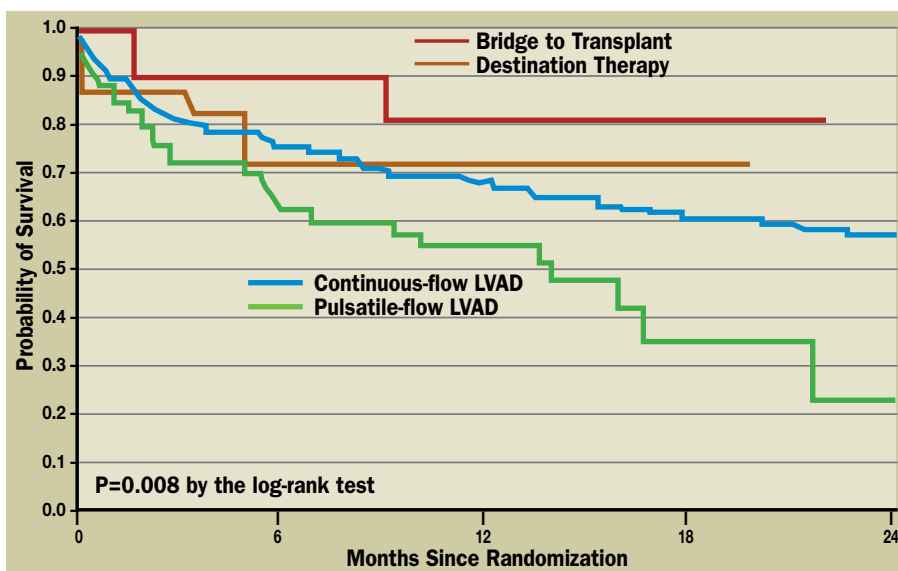


Figure. Survival for patients following continuous-flow implantation as bridge to transplant and destination therapy at Mayo Clinic in Rochester are shown superimposed upon historical survival curves for pulsatile- and continuous-flow pumps from the landmark trials (labeled accordingly).

### Patient Selection for LVAD Therapy

"In general, selecting the appropriate patients

for LVAD therapy is critical, as patient condition at the time of presentation is very closely tied to early and late outcomes," says John A. Schirger, MD, transplant cardiologist at Mayo Clinic in Rochester. "When referral is very late in the disease process, patients are at significantly higher risk of early mortality and prolonged hospitalization." Identifying a patient who has a poor prognosis and poor functional capacity with or without recent hospitalizations allows for patients to undergo implantation with lower early risk. End-organ derangements are adverse predictors of outcome, as is poor nutritional status manifested as cardiac cachexia. Device therapy is best instituted electively, and early referral with close follow-up allows for optimizing timing of LVAD implantation.

In the case of a significantly decompensated patient with more severe end-organ dysfunction, temporary mechanical support can be utilized to ascertain whether long-term LVAD therapy is appropriate. LVAD therapy should not be viewed simply as an alternative to death, but rather as a bridge to life and indeed an improved quality of life. Early referral and appropriate timing of implant helps in the attainment of these goals.

A team of cardiologists, surgeons, coordinators, nurses, and social workers are involved in the preoperative evaluation of patients with advanced heart failure; team members are available 24/7 for evaluation of potential LVAD patients. Additionally, potential LVAD recipients meet with a palliative care team prior to implantation. Traditionally, palliative care teams have been engaged during end of life for comfort care, but Mayo Clinic has been at the forefront of utilizing these skill sets preoperatively to review and discuss goals of care and methods of enhancing quality of life after LVAD implant.

### **Follow-up, Lifestyle Modifications, and LVAD-related Complications**

Close collaboration with local physicians is required in caring for patients following LVAD implantation. Team members at Mayo Clinic in Rochester have provided training at facilities in the care area regarding the special needs of these patients. Additionally, a standardized protocol has been developed to ensure appropriate scheduling of follow-up tests and visits. In between visits at Mayo Clinic, the team maintains very close contact with local physicians to coordinate the LVAD patient's care.

After LVAD implantation, patients have normal postsurgical activity restrictions with some particular additions unique to the LVAD. Patients are counseled to avoid static electricity, soaking and submerging in water (due to the infection risk of the percutaneous driveline), sleeping in a prone position, and driving. While there are no specific laws regarding driving, it is recommended that

patients not drive after LVAD implantation due to uncertain liability in the event of a motor vehicle accident. Travel, especially internationally, also poses problems. Issues of power conversion, medical letters, airline notification, security clearance, and notification of local LVAD centers in proximity to the patient's destination need to be resolved prior to travel abroad.

While on device support, patients can experience an array of LVAD-related medical issues that may require attention. These include bleeding (most commonly gastrointestinal), arrhythmias, hemolysis, thromboembolic events (stroke or pump thrombosis), right ventricular failure (manifested by fluid retention and renal insufficiency), and "suction events" (rapid drops in pump speed followed by an increase to the set value).

Despite these challenges, patients report an improved quality of life in addition to clearly demonstrable improvements in survival and exercise capacity.

### **Future Directions**

Advances in the field of mechanical circulatory support are focused in 2 areas: device innovation and refinement in patient selection. In terms of device innovation, there is continued miniaturization of pumps and improvements in design such that enhanced biocompatibility will hopefully translate into increased durability. The team at Mayo Clinic in Rochester has been active in all major device trials to date and is participating in upcoming device trials. In terms of patient selection, there is current research focusing on the application of LVAD therapy in less-ill individuals. Currently, patients are considered candidates for LVAD therapy when in NYHA Functional Class IV (and select patients in late NYHA Functional Class IIIB). Both the ROADMAP and REVIVE-IT clinical trials focus on rigorously evaluating LVAD therapy in more functional individuals.

### **The VAD Generation**

With the dramatic increase in the application of LVAD therapy worldwide, there will be unmet clinical needs for these patients. In order to adequately care for these patients, more rehabilitation units, dialysis units, care facilities dealing with senility, wound centers, and nutrition centers (just to name a few) will need to have specialty training to effectively care for LVAD patients. The "VAD generation" is a group of patients who are no longer facing death as a result of heart failure and are subsequently aggregating into a considerable subset of geriatric medicine. They have special needs and circumstances that are not necessarily understood by the general public, medical society, or even family members. Awareness of these many issues is crucial to ensure that their needs are able to be met.

# Mayo Clinic Leads Multinational Study Establishing Benefit of Early Surgical Correction of Mitral Valve Regurgitation

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Rakesh M. Suri, MD, DPhil; Maurice E. Sarano, MD

Degenerative mitral regurgitation due to leaflet prolapse is common and can be surgically repaired in the vast majority of patients, thus improving symptoms and restoring normal life expectancy. Despite the safety and efficacy of contemporary mitral valve repair, an ongoing international debate persists regarding the need for early intervention in patients without class I indications (that is, individuals with no or minimal symptoms and normal left ventricular function).

This debate is in part propagated by conflicting views of the prognostic consequences of uncorrected severe mitral regurgitation—considered as benign by those supporting medical "watchful waiting" (until a distinct event occurs) versus conveying excess mortality and morbidity (including heart failure and atrial fibrillation) by those advocating early surgical intervention. The controversy is further reflected in current consensus statements, which classify early mitral valve repair as a Class IIa recommendation (preponderance of evidence in favor) in North America and Class IIb (not favored) in Europe.

Watchful waiting has recently come under renewed scrutiny, however, due to emerging evidence that a growing number of centers can now achieve high (> 90%) mitral valve repair rates with very low operative risk (< 0.5%), and increasing recognition that awaiting incipient symptoms or ventricular dysfunction prior to intervention may be associated with excess long-term mortality and heart failure despite eventual "rescue surgery." Although single-center data have suggested that early surgery is beneficial, the long-term consequences of currently interpreted and applied guidelines in diverse "real-world" tertiary care practices are unknown.

To understand the comparative effectiveness of early surgery versus initial conservative management strategies, Rakesh M. Suri, MD, DPhil, cardiovascular surgeon at Mayo Clinic in Rochester, Maurice E. Sarano, MD, cardiologist at Mayo Clinic in Rochester, and coauthors from 5 other international centers analyzed data from the Mitral Regurgitation International Database (MIDA). This database is a multicenter, multinational registry of echocardiographically diagnosed mitral regurgitation due to flail leaflets. They tested the null hypothesis that these therapeutic approaches are associated with similar late outcomes.

"The results showed that mitral valve surgery provided significant benefits over watchful waiting once patients have severe regurgitation as documented by a reliable surrogate, the identification of a flail leaflet," says Dr Suri, the lead author. "This is perhaps counter-intuitive to patients because they often assume that they should be more severely affected before they need surgery. Actually, the opposite is true. Once

## RECOGNITION



Stephen L. Kopecky, MD (center), cardiologist at Mayo Clinic in Rochester, received the Jan J. Kellermann Memorial Award for distinguished work in the field of cardiovascular disease prevention. Presenting the award at the annual meeting of the International Academy of Cardiology were Asher Kimchi, MD (left), clinical chief of the Division of Cardiology and medical director of the Preventive and Consultative Heart Center of Excellence at the Cedars-Sinai Heart Institute in Los Angeles, California, and founder and chairman of the International Academy of Cardiology, and John A. Elefteriades, MD (right), director of the Yale Center for Thoracic Aortic Disease and chief of cardiothoracic surgery at Yale University and Yale-New Haven Hospital.

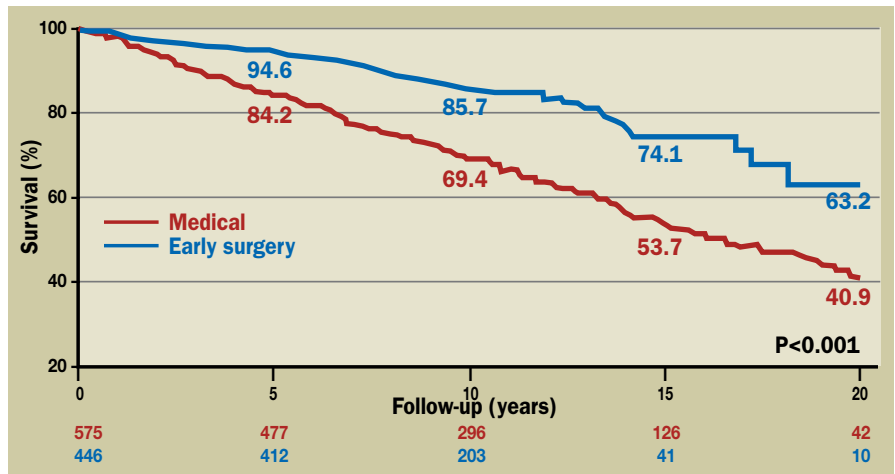


a patient with severe mitral regurgitation due to flail leaflet has surgery, even without symptoms, long-term benefits are observed with only a very low upfront risk. In other words, surgery is protective in that it increases long-term survival and decreases the risk of heart failure if performed promptly following diagnosis."

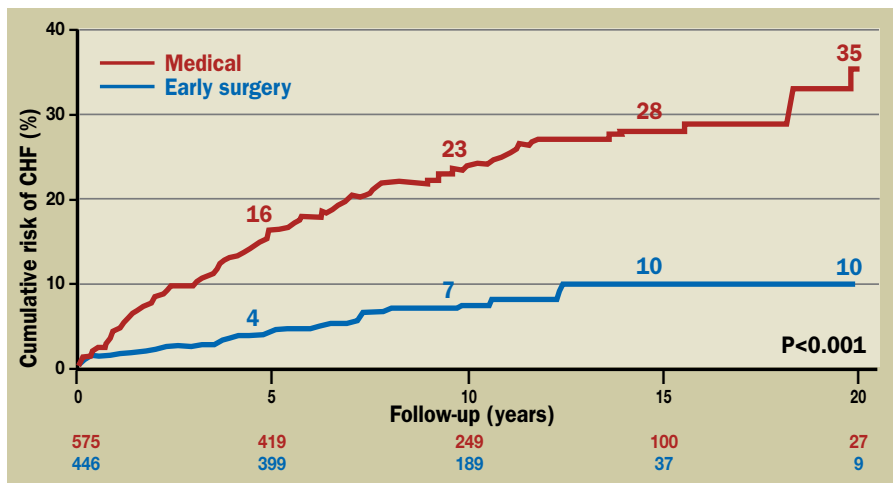
In the study of 1,021 patients with severe mitral valve regurgitation without symptoms or other classical indications for surgery (heart failure or left ventricular dysfunction), 446 underwent mitral valve repair surgery within 3 months of diagnosis, while 575 had an initial medical monitoring while surgery remained a possible later option. Participants were followed for an average of 10 years, the longest of any previous study examining the question of when to operate.

Long-term survival rates were higher (Figure 1) for patients who had surgery within 3 months of diagnosis compared with those who were medically managed for the initial 3 months following diagnosis (86% versus 69% at 10-year follow-up). In addition, long-term heart failure risk was lower (Figure 2) for patients who had surgery early (7% versus 23% at 10-year follow up). There was not a difference between the 2 groups for late-onset atrial fibrillation, which is another concern for patients with severe mitral valve regurgitation.

"In the past, the risk of surgery and complications was greater, and watchful waiting made more sense," says Dr Sarano. But today, referent valve centers have a greater than 95% success rate for mitral valve repair. In addition, the operative risk of death today is less than 0.1%, while it was more than 10 times higher in the 1980s. "The results were of a magnitude greater than expected and were strikingly consistent using 3 robust statistical methods," reports Dr Suri.



**Figure 1.** Survival curves of individuals treated with early mitral valve repair versus those with medical management. Absolute survival numbers listed below the graph. Improved survival was observed in those treated with early surgical intervention throughout the study period.



**Figure 2.** The cumulative risk of developing congestive heart failure with early mitral valve repair was vastly lower than the risk in those individuals initially treated with medical management. Absolute numbers of affected individuals listed below the graph.

## RECOGNITION



From left, Niti R. Aggarwal, MD; Dawn C. Scantlebury, MBBS; LaPrincess C. Brewer, MD; and Mothilal Sonia Jain, MBBS, fellows in the cardiovascular training program at Mayo Clinic in Rochester, received the American Heart Association's Women in Cardiology Trainee Awards for Excellence. This award encourages and recognizes outstanding academic and clinical performance in women cardiology fellows during cardiovascular-related specialty training.

## RECOGNITION



Clifford D. Folmes, PhD, received the 2013 Edward C. Kendall Mayo Clinic Alumni Association Award for Meritorious Research. The Kendall Award recognizes outstanding research conducted by an individual in training whose primary appointment is in research.

Dr. Folmes is a senior research fellow in the Division of Cardiovascular Diseases at Mayo Clinic in Rochester, and his discoveries shed light on how energy metabolism fuels stem cell identity. This new knowledge is critical for translation of stem cell technologies into repair solutions. Dr. Folmes' work has been conducted in association with Andre Terzic, MD, PhD, director of the Mayo Clinic Center for Regenerative Medicine.

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Feb 24-28, 2014, Cancun, Mexico

### British Cardiovascular Society: Cases, Controversies and Updates

Mar 3-7, 2014, Royal College of Physicians, London, England  
[www.bcs.com](http://www.bcs.com)

### Mayo Clinic International Vascular Symposium

Mar 27-29, 2014, Buenos Aires, Argentina  
[www.mayo.edu/cme/internationalvascular2014](http://www.mayo.edu/cme/internationalvascular2014)

## CARDIOVASCULAR SELF-STUDY

<https://cardiovascular.education-registration.com/selfstudy>