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Valvular Heart Disease Clinic

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Toward a New PARTNERship for the Treatment of Aortic Stenosis



Charanjit S. Rihal, MD, Thoralf M. Sundt III, MD, and Maurice E. Sarano, MD

Case Presentation

An 87-year-old man presented to his local hospital with severe exertional dyspnea (New York Heart Association [NYHA] class III) that had been progressive during the preceding 6 months. He had a long history of a systolic heart murmur. Additional medical history included coronary artery bypass graft surgery 12 years previously, diet-controlled diabetes mellitus, hypertension, chronic renal insufficiency, and atrial fibrillation, and he was taking warfarin. On examination his blood pressure was 96/60 mm Hg, and his heart rate was 60 beats per minute. There was jugular venous distention, and the carotid pulsations were low volume and delayed. Cardiopulmonary examination revealed a single second heart sound, a grade 3/6 late peaking systolic ejection murmur, and a softer grade 2/6 holosystolic murmur at the apex. Bilateral crackles were present over the lower halves of the lungs, and bilateral edema to the knees was present. The chest x-ray revealed cardiomegaly and pulmonary venous hypertension. A 2-dimensional and Doppler echocardiogram showed severe aortic stenosis with a mean gradient of 70 mm Hg and a calculated aortic valve area of 0.58 cm²; the ejection fraction was 25%. Moderate mitral regurgitation and moderate tricuspid regurgitation were also present, with a right ventricular systolic pressure of 65 mm Hg.

Treatment Options

Aortic valve replacement has been the “gold standard” for treatment of aortic stenosis and is associated with low morbidity, low mortality, and good long-term results. Various valves, both mechanical and tissue bioprosthetic, are available. However, the increasing prevalence of severe calcific aortic stenosis in an aging population has resulted in a greater number of high-risk patients with severe symptomatic aortic stenosis. These patients have higher operative risks, often in the range of 10% to 20%. Complications such as renal failure, prolonged ventilator dependence, and wound-healing problems occur with higher frequency in these high-risk patients.

Mayo Clinic in Rochester, Minnesota, is participating in a randomized clinical trial—the Placement of Aortic Transcatheter Valve Trial (PARTNER)—to evaluate a new cardiac valve designed to be placed

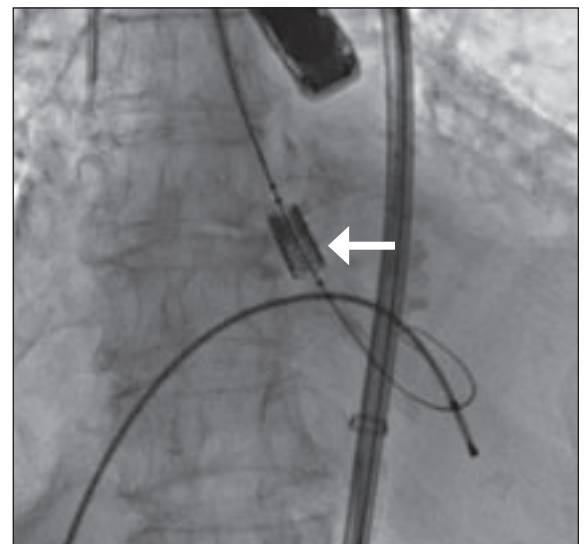


Figure 1. Deployment of percutaneous aortic valve bioprosthesis. Arrow indicates investigational valve mounted on a balloon catheter.

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without the need for a median sternotomy. This valve is a balloon-expandable, stented bioprosthesis designed to be delivered through either the transfemoral or the transapical route. It has been approved in some European countries and has been placed in almost 4,000 patients worldwide. This trial seeks to compare morbidity and mortality of transfemoral (or transapical) prosthesis implantation with the morbidity and mortality associated with standard aortic valve replacement via median sternotomy.

PARTNER enrollment is an option that can be considered for high-risk subsets of patients with aortic stenosis. PARTNER will enroll more than 1,000 patients into 1 of 2 cohorts: cohort A will directly compare the prosthesis vs standard aortic valve replacement; cohort B will compare transfemoral prosthesis implantation vs standard medical management (which can include balloon valvuloplasty if clinically indicated) in patients whose condition is deemed inoperable. At Mayo Clinic in Rochester, these investigative implantations are performed by a multidisciplinary team of cardiac interventionalists, surgeons, valve and imaging specialists, and anesthesiologists specifically trained in these procedures.

The entry criteria include the presence of symptomatic severe aortic stenosis (defined as aortic valve area <0.8 cm² or mean gradient >40 mm Hg) and a minimum Society of Thoracic Surgeons (STS) score of at least 10 (<http://www.sts.org/sections/stsnation/aldatabase/riskcalculator/>). Aortic stenosis must be the dominant valvular lesion and the only cardiac condition necessitating therapy. Certain circumstances, such as severe calcification of the aorta (“porcelain aorta”), may qualify a patient for the trial even if the STS score is less than 10. A CT angiogram of the aorta and iliac and femoral arteries is required to as-

sess the adequacy of the peripheral vessels for transfemoral access. The primary end point to be assessed will be mortality at 1 year, with various secondary end points, including NYHA functional classification and noninvasive valve hemodynamic measurements.

Patient Outcome

The patient presented in the case study met all inclusion and exclusion criteria, was enrolled in PARTNER, and randomly assigned to implantation of the investigative valve. A successful procedure was performed under general anesthesia by the transfemoral route. The valve gradient was reduced from 75 mm Hg to 9 mm Hg, and the calculated aortic valve area increased from 0.5 cm² to 2.1 cm² (Figures 1, 2, and 3). The patient was extubated later the same day and eventually discharged home on the fourth day after the procedure.

PARTNER is a resource for high-risk patients with aortic stenosis in whom standard therapeutic options are often limited. Potential candidates may be referred directly to the Mayo Clinic Valvular Heart Disease or Interventional Clinics (507-284-3994 or 800-471-1727). The Mayo Clinic trial coordinator can be reached at 507-255-7100.



Figure 2. Investigational aortic valve (arrow) after deployment.

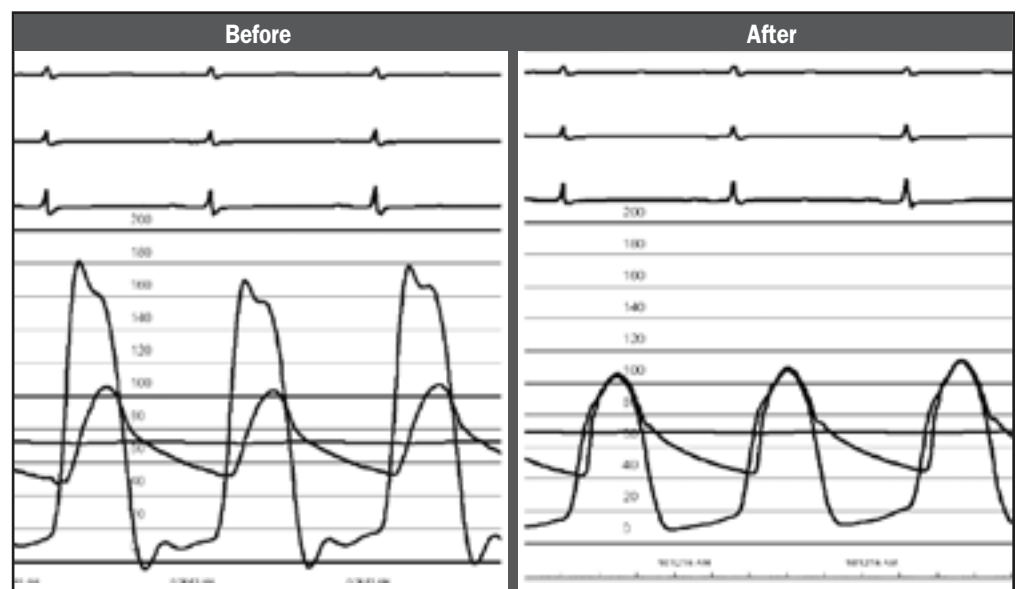


Figure 3. Invasive hemodynamics before and after investigational aortic valve replacement.



Sumil V. Mankad, MD

The Role of 3D Echocardiography in the Assessment of Valvular Heart Disease

Three-dimensional (3D) echocardiography is one of several emerging modalities that expand the ability to delineate cardiac anatomy and function. Although still in evolution, 3D echocardiography has now clearly demonstrated that it can complement current 2D echocardiographic techniques in the assessment of valvular heart disease by providing a better understanding of the topographic aspects of pathology, refining the nonplanar spatial relationships of intracardiac structures, and providing new indices not described by 2D echocardiography. Specifically, 3D echocardiography allows for an en face view of valvular structures that previously was not possible using 2D echocardiography. Image resolution remains a concern for transthoracic 3D imaging, but the recent development of 3D transesophageal echocardiography (TEE) (either real-time or reconstructed) has made this less of an issue.

“Development of 3D echocardiography has

made significant contributions to our understanding of mitral valve function and its functional relationship to other anatomic structures,” according to Sunil V. Mankad, MD, a cardiologist in the Echocardiography Laboratory at Mayo Clinic in Rochester, Minnesota. “Although in the vast majority of patients with mitral stenosis, comprehensive 2D and Doppler echocardiography is sufficient; 3D echocardiography has been demonstrated in several clinical trials to provide better correlation with invasively determined mitral valve area.” The technique involves capturing a 3D data set with either transthoracic or TEE imaging and performing mitral valve planimetry. The great advantage of 3D over 2D in this setting is its ability for adjustment of the “cut-planes” of interrogation to be certain that the mitral valve is being interrogated “on-plane,” and tangential cuts through the orifice can be avoided. 3D echocardiography increases the diagnostic confidence that the true smallest mitral valve area is being measured. An example of this technique using 3D transthoracic imaging is shown in Figure 1. The Echocardiography Laboratory at Mayo Clinic in Rochester has also demonstrated that 3D planimetry of the

aortic valve in aortic stenosis is feasible, although highly accurate data are not always available because of heavy leaflet calcification interference with image resolution.

With the advent of real-time 3D TEE, rapidly obtainable en face views of the mitral valve either from the left atrial perspective (“surgeon’s view”) or from the left ventricular perspective are now possible with intraoperative TEE during mitral valve surgery. Cardiologists at Mayo Clinic in Rochester have demonstrated the incremental value of 3D TEE in the recognition of mitral valve surgical pathology during operative repair. This is especially the case with respect to mitral valve anterior leaflet pathology and with commissural disease. Examples of typical 2D and corresponding 3D TEE pathology are shown in Figures 2,

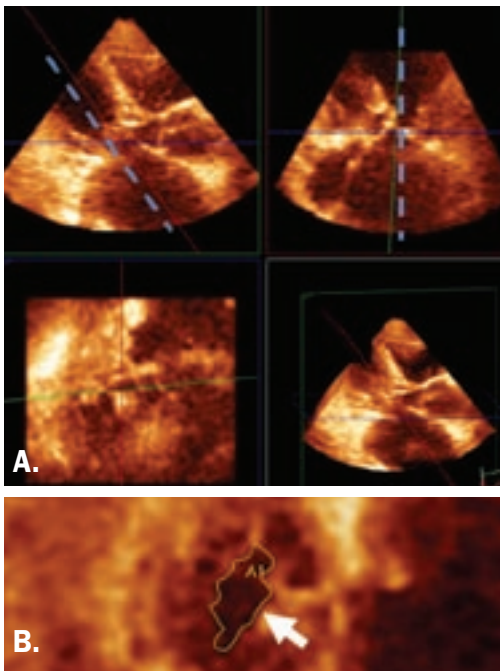


Figure 1. 3D Planimetry for Mitral Stenosis. A, Multiplanar reconstruction views are used to manipulate the cutplanes (blue dashed lines) so that the mitral orifice can be visualized en face at its smallest point (B). B, The white arrow indicates the mitral valve area trace that is performed on a reconstructed image guided by the 3D echo images shown in A.

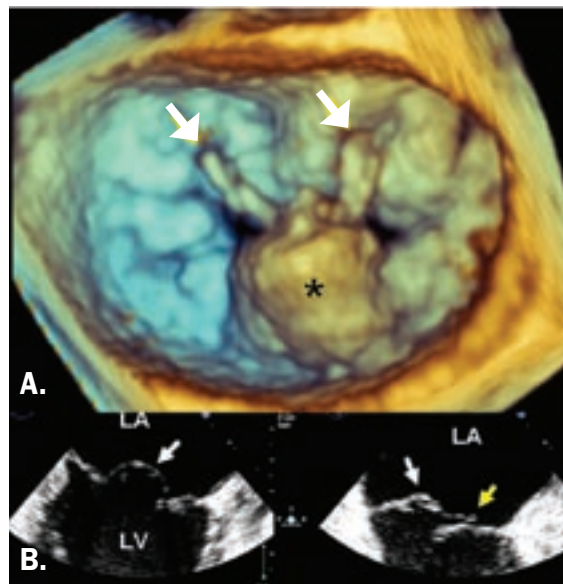


Figure 2. Flail Mitral Valve Posterior Leaflet (Middle Scallop, P2). A, Live 3D TEE en face view of the mitral valve at end systole from the left atrial perspective demonstrates the flail P2 scallop (asterisk) and clearly shows multiple torn chordae tendineae (arrows). B, 2D TEE end-systolic views demonstrate a flail middle scallop of the posterior mitral leaflet (P2). The flail P2 scallop is highlighted by the white arrows in the commissural 60° view on the left and a long-axis 110° view on the right; torn chordae tendineae are noted on the long-axis view (yellow arrow). LA, left atrium; LV, left ventricle.

Echocardiography

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3, and 4. Although 2D TEE remains an excellent method for the assessment of mitral valve disease, 3D TEE allows for a more rapid assessment of surgical pathology and can increase diagnostic confidence.

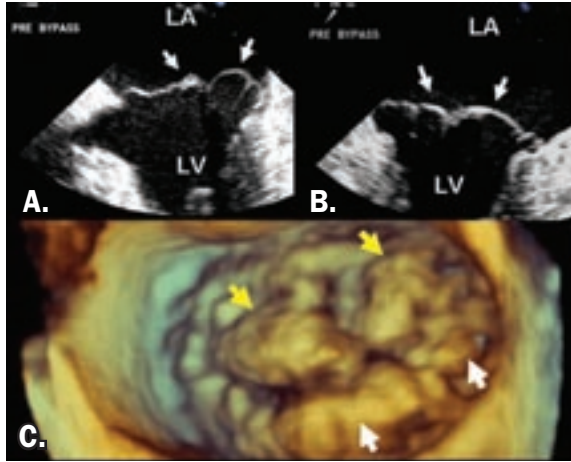


Figure 3. Barlow Mitral Valve. A and B, End-systolic 2D TEE views at 0° and 56° (commissural view), respectively. Severe bileaflet prolapse (Barlow disease) involves both the anterior and posterior middle scallops of the mitral valve (A2 and P2, arrows). C, Live 3D TEE en face view of the mitral valve at end systole from the left atrial perspective demonstrates severe bileaflet prolapse. The severe redundancy of leaflet tissue and more prominent prolapse of A2 and A3 (yellow arrows) as well as P2 and P3 (white arrows) are clearly evident. LA, left atrium; LV, left ventricle.

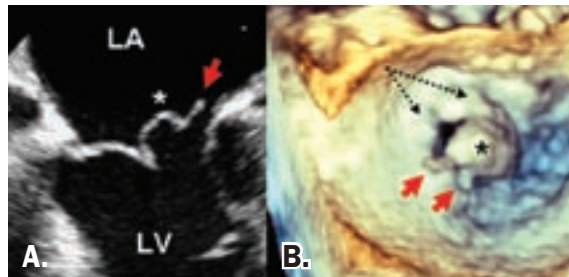


Figure 4. Flail Anterior Mitral Valve Leaflet (Middle Scallop, A2). A, 2D TEE end-systolic view demonstrating a flail middle scallop of the anterior mitral leaflet (A2). The flail A2 scallop is noted by the white asterisk and torn chordae tendineae are noted by the red arrow. B, Live 3D TEE en face view of the mitral valve at end systole from the left atrial perspective demonstrates not only the flail A2 scallop (asterisk) but also delineated is an unsupported lateral scallop (A1) noted by the dotted black arrows and multiple torn chordae tendineae (red arrows). The unsupported A1 segment was also diagnosed by 2D TEE, but with less certainty and after imaging from multiple planes. LA, left atrium; LV, left ventricle.

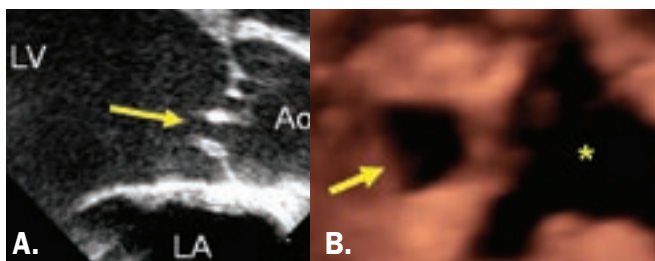


Figure 6. Aortic Valve Perforation. A, This long-axis 2D TEE view in a patient with healed aortic valve endocarditis shows the aortic valve with multiple echobright echodensities most consistent with healed vegetations. A large region of “echo dropout” (arrow) is consistent with a perforation. B, The true aortic valve orifice (asterisk) is well seen, as is the en face view of the perforation (arrow). The size of the perforation as well as leaflet location is better identified using 3D TEE. Ao, aorta; LV, left ventricle; LA, left atrium.

Offline analysis of mitral anular geometry as well as anular conformational changes during the cardiac cycle is possible with 3D echocardiography and may provide further understanding of the mechanisms underlying mitral regurgitation (Figure 5).

The Echocardiography Laboratory at Mayo Clinic in Rochester was among the first to report on the superiority of 2D TEE over transthoracic echocardiography for the diagnosis of complications of endocarditis. “3D TEE may also be useful in this setting by allowing for better visualization of leaflet perforations as well as a clearer description of adjacent cardiac structures,” says Dr Mankad. An example of an aortic valve leaflet perforation complicating a case of aortic valve endocarditis is shown in Figure 6. Finally, again because of its ability to provide en face views of valvular structures, 3D echocardiography can be helpful in identifying whether pacemaker or intracardiac defibrillator leads are implicated in cases of tricuspid regurgitation, something that can be dif-

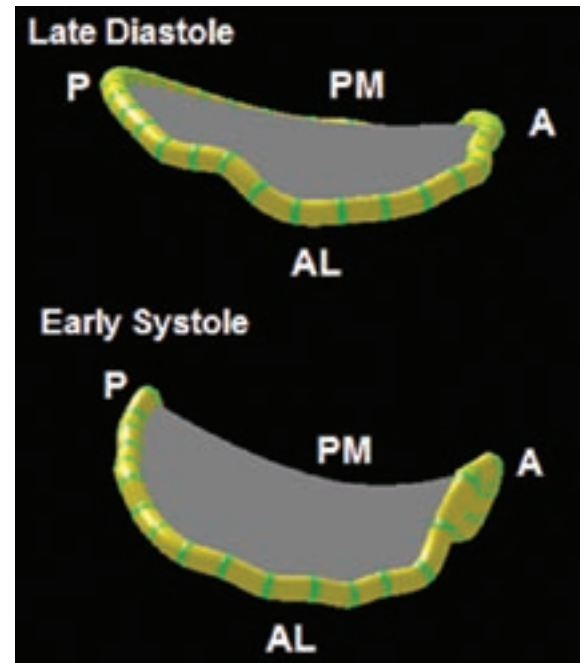
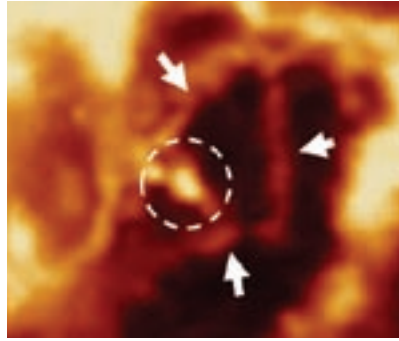


Figure 5. 3D Echocardiographic Reconstruction of the Mitral Anulus. The reconstructed images demonstrate the extensive mitral anular shape change that occurs under normal circumstances during the cardiac cycle in a patient without severe mitral valve disease. P, posterior; A, anterior; AL, anterolateral; PM, posteromedial.

Figure 7. 3D Echocardiography of Tricuspid Valve. A short-axis en face view of the tricuspid valve in a patient with severe tricuspid regurgitation; the spatial relationship between the tricuspid valve leaflets (arrows) as well as a pacemaker lead (circle) are well seen by 3D echo, thus allowing for better differentiation as to whether pacemaker lead interference with tricuspid valve leaflet coaptation is the cause of the patient's tricuspid regurgitation. Although difficult to see on this still frame image, the pacemaker lead was seen to be interfering with leaflet mobility on the motion images (image courtesy of Grace Lin, MD).



difficult to do using 2D echocardiography (Figure 7). Ongoing investigations will also clarify whether 3D color Doppler imaging provides further clarification of regurgitant severity and whether 3D imaging can be of value during interventional procedures.

“3D echocardiography is an emerging modality with a diverse array of clinical applications, including assessment of valvular heart disease,” says Dr Mankad. “It complements current 2D echocardiographic techniques and its use continues to evolve as technologic advances are developed.”



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Ebstein Anomaly: Update on Surgical Management

Ebstein anomaly is a rare congenital heart malformation with a seemingly infinite range of anatomic variability. In addition, the clinical presentation is also widely variable, ranging from the need for urgent surgical intervention in a symptomatic neonate to an incidental finding in an asymptomatic adult patient on a routine medical examination.

“The rarity of this anomaly and the numerous repair techniques described in the literature have resulted in uncertainty as to the best approach—operative technique or optimal timing of operation—even among those centers with a large

experience in the condition,” says Joseph A. Dearani, MD, a cardiovascular surgeon at Mayo Clinic in Rochester, Minnesota. “Consequently, it can be challenging for the cardiologist to know when to refer for operation and for the surgeon to develop a consistent method with reproducible and reliable results.”

Echocardiography confirms the diagnosis, determines the degree of tricuspid regurgitation, allows accurate evaluation of the tricuspid leaflets and subvalvar apparatus (displacement, tethering, dysplasia), determines the size and function of the atrialized right ventricle and the left ventricle, and the presence or absence of atrial septal defect (Figure). Magnetic resonance imaging (MRI) is being used increasingly in patients with all types of cardiac disease, including those with Ebstein anomaly. At present, physicians at Mayo Clinic in Rochester use both 2- and 3-dimensional echocardiography for evaluation of tricuspid

valve anatomy and MRI for assessment of right ventricular size and function.

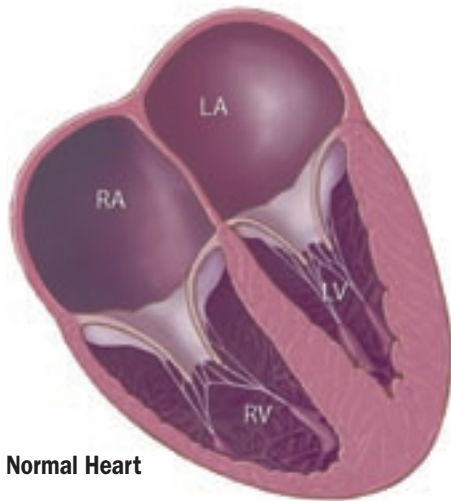
In general, different management strategies are applied to 3 groups of patients with Ebstein anomaly: symptomatic neonates; children, adolescents, and young adults; and older adults.

Neonates

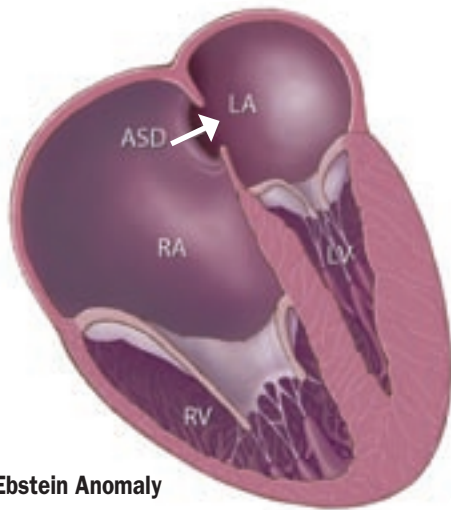
Surgical intervention is indicated for neonates who remain in congestive heart failure or are profoundly cyanotic despite intensive medical therapy. Medical management should be optimized; intubation with mechanical ventilation and intravenous inotropic support are used as needed. Two main surgical pathways can be considered: the biventricular repair and the single ventricle pathway, ie, the right ventricular exclusion technique.

The biventricular strategy includes tricuspid valve repair and subtotal closure of the atrial septal defect. Successful repair typically depends on the presence of a large, “sail-like” anterior leaflet since the repair is generally of the monocuspid type. Right atrial reduction is performed routinely to diminish the size of the markedly enlarged heart and allow room for the compressed lungs.

Alternatively, the right ventricular exclusion approach involves fenestrated patch closure of the tricuspid valve orifice, atrial septectomy, and a systemic artery-to-pulmonary artery shunt. This approach is particularly useful when there is concomitant anatomic right ventricular outflow tract obstruction (RVOTO) or pulmonary stenosis (PS). Right atrial reduction is also routinely performed to allow space for the lungs. As with other patients with shunt-dependent pulmonary circulation, early postoperative management can be challenging, and careful surveil-



Normal Heart



Ebstein Anomaly

Figure. Normal cardiac anatomy (top) and anatomic abnormalities typical of Ebstein anomaly. The tricuspid valve is displaced downward from its normal position. Ebstein anomaly is frequently associated with atrial septal defect (ASD).

lance is required between the first operation and the second-stage procedure (bidirectional cavopulmonary shunt), which is usually performed at 3 to 6 months of age. The modified Fontan procedure is then performed at 2 to 4 years of age.

“In the current era, both surgical strategies continue to have high early mortality (10%-30%), even in the most experienced hands, when compared with outcomes to treat the majority of other complex congenital heart anomalies operated on in the first month of life, where the early mortality has been uniformly reduced to less than 5% (for example, an arterial switch procedure),” says Dr Dearani. The intermediate-term results for each pathway appear promising.

Children and Young Adults

While medical management, including diuretic and antiarrhythmic drugs, may be used to control some of the symptoms of heart failure and arrhythmias, most patients eventually require surgery. Observation alone may be advised for asymptomatic patients with no right-to-left shunting, mild cardiomegaly, and normal exercise tolerance. Surgery is offered when a patient has symptoms or cyanosis, decreased exercise tolerance, progressive cardiomegaly on chest

radiography, progressive right ventricular dilation or reduction of right ventricular systolic function by echocardiography, or the appearance of atrial or ventricular arrhythmias. If it is likely by echo appearance that the valve can be repaired, surgery is done earlier than if it is clear that the valve is not repairable and will need to be replaced. If the valve clearly needs to be replaced, surgery is postponed as long as possible.

“There is general agreement that management of children, adolescents, and young adults should focus on tricuspid valve repair, as opposed to valve replacement,” says Dr Dearani. “Almost always this operation is elective, and early mortality is low, as it should be.” While there is no general agreement as to the ideal method of valve repair, “cone reconstruction” provides the most anatomic repair and should be applied when the anatomy allows.

Older Adults

Management of older adults (>50 years) with Ebstein anomaly has its own set of technical challenges—often markedly enlarged hearts with concomitant atrial tachyarrhythmias, possible atherosclerotic coronary artery disease, or other acquired valve abnormalities. The presence of medical comorbid conditions such as diabetes or hypertension is also common, making perioperative management more difficult. The durability of the porcine bioprosthesis in older patients makes tricuspid valve replacement a good alternative when valve repair is not possible, since durability and freedom from reoperation have been shown to be very good. The need for concomitant procedures such as the maze procedure and coronary artery bypass grafting is more common and also needs to be considered.

Tricuspid Valve Repair

To increase the number of successful tricuspid valve repairs, particularly in children, cardiovascular surgeons at Mayo Clinic in Rochester have been using cone reconstruction, which is different than previous valvuloplasty techniques in that it is a near-anatomic repair and can be applied to a wide range of anatomic variations. The end result of the cone reconstruction includes 360° of tricuspid leaflet tissue surrounding the right atrioventricular junction. This allows leaflet tissue to coapt with leaflet tissue, similar to what occurs with normal tricuspid valve anatomy. In addition, the reconstructed tricuspid valve is reattached at the true tricuspid valve annulus (atrioventricular junction) so the hinge point of the valve is in a normal anatomic location. The thinned, transparent, atrialized right ventricle is plicated so areas of right ventricular dyskinesia are reduced or eliminated.

The cone reconstruction restores the appearance of near-normal tricuspid valve anatomy and function more than any previously described technique. Relative contraindications to the cone reconstruction include older age (>45-50 years), moderate pulmonary hypertension, severe left ventricular dysfunction (ejection fraction <30%), complete failure of delamination of septal and inferior leaflets with poor delamination of the anterior leaflet (ie, <50% delamination of the anterior leaflet), muscularized tricuspid leaflets, severe right ventricular enlargement, and severe dilation of the right atrioventricular junction (true tricuspid annulus).

Tricuspid Valve Replacement

Prosthetic tricuspid valve replacement remains a good alternative for the treatment of Ebstein anomaly when valve repair is not feasible. Porcine bioprosthetic valve replacement, as opposed to mechanical valve replacement, is generally preferred because of

relative good durability of the porcine bioprosthesis in the tricuspid position and the lack of need for chronic warfarin anticoagulation. Mechanical tricuspid valve replacement in Ebstein anomaly may be associated with a higher frequency of prosthetic valve dysfunction than mechanical valves in other cardiac positions, particularly when right ventricular function is poor. In general, postoperative management includes short-term (3 months) warfarin anticoagulation for porcine bioprostheses and lifelong aspirin, 81

mg daily. When a mechanical valve is used, the target international normalized ratio is 3.0 to 3.5 in addition to aspirin, 81 mg daily.

The Role of the Bidirectional Cavopulmonary (Glenn) Shunt

“We use the bidirectional cavopulmonary shunt selectively but more frequently in the current era since we and others have shown improved early results,” says Dr Dearani. The bidirectional cavopulmonary shunt is helpful when the right ventricle is severely dilated and/or functioning poorly, or when a successful tricuspid valve repair has resulted in an effective valve orifice that has mild to moderate stenosis (mean gradient >6 mm Hg). The bidirectional Glenn shunt decreases the volume load on the dysfunctional right ventricle by 35% to 45%, depending on patient age, and provides preload to the left ventricle. Even in the presence of moderate left ventricular dysfunction (ejection fraction of 35%-40%), it is usually feasible to perform a bidirectional Glenn shunt.

Potential disadvantages of the bidirectional Glenn shunt include pulsations of the head and neck veins, facial swelling, and the development of arteriovenous fistulas in the pulmonary vasculature. In addition, access to the heart from the internal jugular approach is compromised for electrophysiologic studies and for pacemaker lead placement, if needed in the future.

Outcomes

Since the first patient underwent successful tricuspid valve repair at Mayo Clinic, performed by Dr Gordon Danielson in 1972, the Mayo Clinic experience now exceeds approximately 800 patients undergoing operation for Ebstein anomaly. Early mortality has been reduced to less than 2%; the only independent risk factor for early death is severe preoperative right ventricular dysfunction. Independent predictors of poor late outcomes include increased hematocrit, male sex, mitral regurgitation requiring intervention, RVOTO or PS, left ventricular dysfunction, and renal insufficiency. Predictors of the need for reoperation include young age at operation (<12 years), decreased left or right ventricular function, RVOTO or PS, any arrhythmia procedure, and ventricular tachycardia.

Quality of life remains an important consideration for clinicians and surgeons when counseling patients with Ebstein anomaly. Functional outcomes after operation for Ebstein anomaly have demonstrated improved exercise tolerance. The need for late reoperation and rehospitalization (usually because of atrial tachyarrhythmias) continues to present a challenge, emphasizing the importance of lifelong surveillance by cardiologists and surgeons experienced in treating patients with congenital disorders.

LEADERSHIP



Randall J. Thomas, MD, MS, of the Division of Cardiovascular Diseases at Mayo Clinic in Rochester, is the 2010 president of the American Association of Cardiovascular and Pulmonary Rehabilitation, a multidisciplinary specialty organization that is aimed at reducing the morbidity, mortality, and disability from cardiovascular and pulmonary diseases through education, prevention, rehabilitation, research, and disease management.

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Jan 25-29, 2010, Big Island, HI

Phone: 919-297-7162; e-mail: jtraynor@asecho.org

23rd Annual State-of-the-Art Echocardiography

Feb 7-11, 2010, Scottsdale, AZ

Phone: 919-297-7157; e-mail: abuff@asecho.org

OTHER EDUCATION OPPORTUNITIES

Resuscitation Science Symposium

Nov 14-15, 2009, Orlando, FL

Phone: 800-748-3583 or 508-743-8517

American Heart Association Scientific Sessions

Nov 14-18, 2009, Orlando, FL

Phone: 800-748-3583 or 508-743-8517

International Stroke Conference

Feb 24-26, 2010, San Antonio, TX

Web: strokeconference.americanheart.org

ACC.10: 59th Annual Scientific Session

Mar 14-16, 2010, Atlanta, GA

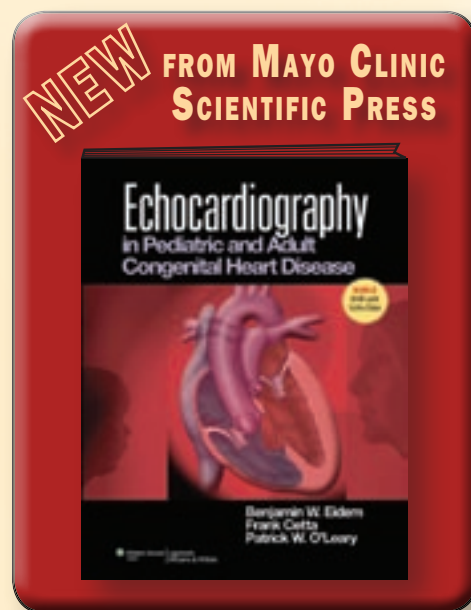
Web: ACC10.acc.org

ASE 21st Annual Scientific Sessions:
Practical Applications of Cardiovascular
Ultrasound in the 21st Century

Jun 12-15, 2010, San Diego, CA

Phone: 919-297-7157;

e-mail: abuff@asecho.org



Mayo Clinic Cardiovascular Update

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RECOGNITION



Nanette K. Wegner, MD, professor of medicine in the Division of Cardiology at Emory University, was the speaker at the 15th annual Robert L. Frye lecture on August 26, 2009.



Sheldon G. Sheps, MD, professor of medicine (emeritus) in the Division of Nephrology and Hypertension at Mayo Clinic in Rochester, has received the 2009 Mayo Clinic Distinguished Alumni Award.



W. Bruce Fye, MD, of the Division of Cardiovascular Diseases at Mayo Clinic in Rochester, has received the Lifetime Achievement Award from the American Osler Society. Dr Fye is also president of the American Association for the History of Medicine.