EDITORIAL COMMENT

Percutaneous Valve Replacement and Repair

Fiction or Reality?*

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Greater advances in the use of percutaneous techniques for the treatment of coronary artery disease and cardiac non-coronary interventions have occurred during the last few years. Among them, percutaneous techniques for the treatment of stenotic valvular lesions were developed, and their benefits were demonstrated in the treatment of most patients with pulmonary stenosis, rheumatic mitral stenosis, and tricuspid stenosis and in some patients with non-calcific aortic stenosis (1,2). Even as percutaneous catheter approaches may be the procedure of choice for most patients with rheumatic mitral stenosis, they certainly are not for most elderly patients with calcific aortic stenosis (1,2). Although percutaneous techniques are the procedure of choice for the treatment of most stenotic valvular lesions, open heart surgery with valve replacement or repair is the only therapeutic alternative for the treatment of patients with symptomatic regurgitant valve lesions and for patients with calcific aortic stenosis (1–3).

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Hundreds of thousands of patients in the U.S., including a large share of patients with congestive heart failure, might benefit from heart valve repair or replacement. To date, the surgical approach is the only option available for cardiac valve replacement. It is expected that >300,000 patients will undergo heart valve surgery in 2004 despite its invasiveness, risk, and cost. However, valve replacement has limitations, such as surgical mortality, high-risk patient subgroups, chronic anticoagulation, postoperative recovery, and late failure of bioprosthetic valves.

The future of percutaneous valve repair and replacement depends on the development of collapsible and compressible valve prostheses, transcatheter valve repair technologies, anti-calcification treatment, and innovative valve suturing technologies. An integration of known technologies, including balloon-expandable technology, balloon technology for predilation and deployment, and bi- or tri-leaflet heart valve designs made from polymer or biologic material have the potential to help in the development of percutaneous techniques for the treatment of regurgitant lesions. We can dream of an ideal valve for percutaneous placement. This valve should be available at variable sizes, should be biocompatible, and should have excellent intrinsic properties and low profile. Finally, this valve should be able to be sutured into an expandable stent without losing its properties after crimping and re-expansion. Recently, percutaneous transcatheter replacement of the pulmonic valve was introduced by Bonhoeffer et al. (4,5), and percutaneous valve replacement of calcific aortic stenosis was introduced by Cribier et al. (6,7). This pioneering work by these two investigators represents a milestone that opens a new era of interventional cardiology (4–7).

Mitral regurgitation is a common disease that is clinically significant because of its detrimental effect on left ventricular function. Mitral regurgitation causes volume overload of the left ventricle and results in a vicious cycle. Volume overload leads to remodeling, with left ventricular dilation and consequent left ventricular dysfunction. Left ventricular dilation also produces abnormalities of mitral valve support and enlargement of the mitral annulus, which by themselves lead to progressive worsening of mitral regurgitation. The mitral valve apparatus is a complex structure composed of the mitral annulus, the mitral valve leaflets, the chordae tendineae, the papillary muscles, and the supporting of the left ventricular wall, the aorta, and the left atrium walls. Disease processes affecting any one of these components may result in dysfunction of the mitral valve apparatus, prolapsing leaflets, and mitral regurgitation. Whatever the etiology of mitral regurgitation is, surgical mitral valve repair currently is the procedure of choice (3). Initial attempts at percutaneous mitral valve repair have recently been reported. Two procedures dealing with different components of the mitral valve apparatus have been reported; the edge-to-edge repair and mitral valve anuloplasty using a coronary sinus device (8,9). The surgical edge-to-edge repair has been shown to be an effective method for repairing either structurally or functionally deficient mitral valves. The catheter-based Evalve Cardiovascular Valve Repair System (CVRS; Evalve Inc., Redwood City, California) is the first successful percutaneous endovascular adaptation of this repair technique. The early clinical results with the Evalve CVRS are compelling. The phase I study of the Evalve cardiovascular repair system, Endovascular Valve Edge-to-Edge Repair Study (EVEREST I), is currently underway in the U.S. and will provide initial information on safety and feasibility of the procedure. Enrollment in the trial is ongoing, with the results for the first 10 patients presented at the American College of Cardiology's late-breaking clinical trial session (New Orleans, Louisiana, March 2004). The clip was safely deployed in all 10 patients without complications. A reduction in mitral regurgitation to ≤2 grades was achieved in seven patients. The clip was not released in the other three patients, who underwent elective surgery. Ongoing studies with this technology will help to refine the technique and

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establish what will most likely be an increasing clinical applicability (9).

Future studies also are indicated to evaluate the potential for adjunctive catheter-based annuloplasty systems. Minimally invasive or even percutaneous valve repair has gained more momentum in recent months. Several companies are working on attractive instrumentation and devices to achieve this goal. The knowledge of the anatomy and pathophysiology of the coronary sinus is an important prerequisite of such devices. Multiple endovascular indirect annuloplasty (“sinoplasty”) systems as the one described by Maniu et al. (10) in this issue of the Journal are in preclinical development and also may offer adjunctive technology in the treatment of patients with significant mitral regurgitation. In this paper, the authors reported on the placement of a percutaneous mitral annuloplasty device that results in a significant reduction in the severity of functional mitral regurgitation associated with severe left ventricular dysfunction in a canine animal model of rapid pacing-induced heart failure with functional mitral regurgitation. Cinching of the device in the coronary sinus resulted in significant decrease in mitral annulus diameter, mitral regurgitation jet area, and mitral regurgitation jet area-to-left atrium area ratio. This technique capitalizes on the relationship of the coronary sinus to the mitral annulus.

Nevertheless, there are some limitations in this study, such as the use of a single model of functional mitral regurgitation. Also, the severity of mitral regurgitation was only modest. There is a need to apply this technique to other models of mitral regurgitation, such as those of ischemic mitral regurgitation. Furthermore, this device is placed in the coronary sinus, and the circumflex artery is an important surrounded structure of the coronary sinus. Therefore, it is important to determine whether this device could interfere with coronary blood flow, particularly in the circumflex artery. As described by the authors, the relationship between the circumflex and the coronary sinus varies, and there is potential for device-induced compression of the circumflex artery.

A dramatic change is expected to occur during the next decade as the emergence of transcatheter heart valve repair techniques significantly reduces the risk and cost associated with heart valve procedures. Animal and early human studies indicate that nonsurgical techniques to valve replacement and repair are feasible. These techniques already have been applied safely to humans with artificial pulmonary artery trunks. More recently results from the approach to aortic valve replacement and mitral valve repair in animals and humans are encouraging. Pulmonary valve replacement, aortic valve replacement, and emerging techniques for percutaneous mitral valve repair recently have opened new perspectives on transcatheter replacement and repair of cardiac valves. Thus, percutaneous valve replacement and repair is not fiction—it is a reality.

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