Percutaneous Mitral Valve Repair With the Edge-to-Edge Technique
A Surgeon’s Perspective*
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The paper by Feldman et al. (1) in this issue of the Journal is the first published report about a new percutaneous mitral valve technology, the edge-to-edge Evalve clip (Evalve Inc., Menlo Park, California). This is an important step into a new era of catheter-based valve procedures and one that will be compared and contrasted with the ongoing excellent surgical results obtained with mitral valve repair of the myxomatous regurgitant mitral valve. The investigators, who are among the leading cardiac interventionalists in the country, have performed a carefully thought out phase I U.S. Food and Drug Administration safety trial of 27 low-risk patients with myxomatous valve disease, a group of patients for whom surgical repair of the mitral valve is safe and effective. They have clearly documented the safety of this procedure, and have also documented that there is a significant learning curve as it relates to fluoroscopy time, echocardiography time, and anesthesia time. The investigators have been careful to point out that this device and similar devices mandate multi-specialty collaboration, including cardiology, echocardiography, and cardiac anesthesia for patient safety. The interactive nature of this project is in compliance with the recent simultaneous publication of a position paper of the Society of Thoracic Surgeons, American Association for Thoracic Surgery, and the Society for Cardiovascular Angiography, endorsed by the American College of Cardiology Foundation and the American Heart Association, regarding percutaneous heart valve technology and the methods for investigation (2).

The results of this study are encouraging, but several patients did not have the Evalve device implanted when intra-procedure echocardiography failed to show reduction in mitral regurgitation (MR), there was device detachment in three patients, and open valve repair or replacement was required shortly after implantation in an additional three patients. The investigators were appropriately conservative in indicating that a significant number, but clearly not all patients, achieved reduction of MR; only 50% of the original cohort of patients reached 2+ MR or less at six months. Feasibility and safety have been answered, but additional follow-up planned for the phase II multi-center study will be important to determine whether this repair is stable over the long term.

Obviously, careful training of even the most experienced interventionalist will be required for the use of this and other similar devices. The manufacturer of this device, as well as manufacturers of other devices beginning trials, will provide careful training to limit the use of these devices to those who work in experienced valve centers (2). This will be important for public safety as well as determining, eventually, which are the best devices for a patient population.

Ultimately, the long-term efficacy of these devices will determine how widely used these devices will be. The control group has been the remarkably successful mitral valve repair of the myxomatous valve series on cardiopulmonary bypass, minimally invasive with an upper or lower mini-sternotomy (3,4), robotically (5) and thoracoscopically (6), with superb results. What practicing cardiologists may have to balance is the benefit of a percutaneous technique with residual mild or moderate MR. We do know that moderate MR, particularly with ischemic heart disease, is associated with poor long-term survival (7).

Finally, a comment about the edge-to-edge technique introduced by Alfieri et al. (8) on which the Evalve is conceptually based. This technique has been used for mitral valve repair as an adjunct technique to standard repair techniques, but when used, it has been in conjunction with a prosthetic annuloplasty ring. In most patients with myxomatous valve degeneration, the annulus is very deformed. The remodeling annuloplasty ring, developed by Carpentier (9) and Revuelta et al. (10), pioneers in this field, are equally important for successful long-term mitral valve repair as the leaflet repair techniques themselves.

This article is significant for alerting the cardiologic public that there are also a number of other new devices in development for percutaneous valve technology by several medical device companies. Different approaches for mitral valve repair include coronary sinus stenting and annular stabilization. More problematic, in this observer’s opinion, are devices for percutaneous aortic valve replacement, given the type of end-stage patient in whom this will be used for severe calcific aortic stenosis. The track record of these devices so far in European trials has been only slightly promising, with high mortality because of the patient substrate, and the inability to take away calcific debris, to protect the coronary arteries, and to prevent severe perivalvular leaks. Other interesting devices on the horizon may include operative intervention of catheter-based valves on the beating, working heart. Whatever the approach, these trials need to ensure careful scrutiny by the U.S. Food and...
Drug Administration, industry, interventionalists, and cardiac surgeons so that public safety is ensured and the best operations and devices are developed for the appropriate patient.

Although we are encouraged by the use of this truly minimally invasive non-operative treatment of myxomatous mitral valve regurgitation, we obviously need further data related to the efficacy and impact of residual MR on long-term patient prognosis, which will be studied in phase II. The investigators are to be congratulated for carrying out this unique pilot phase study carefully, safely, and objectively.

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REFERENCES


