Mitral regurgitation (MR) is today the second most frequent native valve disease in Western countries after aortic stenosis, which justifies the interest in its treatment. Mitral valve surgery, especially valve repair, is the gold standard for treatment of patients with severe symptomatic MR and/or objective signs of left ventricular dysfunction. However, surgery may be high risk or even contraindicated in a substantial group of patients due to the presence of severe comorbidities and/or very severe left ventricular dysfunction. These findings set the stage for the new percutaneous techniques.

**PERCUTANEOUS CORONARY SINUS ANNULOPLASTY**

Prosthetic ring annuloplasty is key in most cases of surgical valve repair because there is always some degree of annular dilation in severe chronic MR. Surgical mitral annuloplasty is used to treat chronic MR, either in isolation or, most often, in combination with other techniques.

The proximity between the coronary sinus and the mitral annulus is exploited on the basis of the theory that a device with foreshortening capacities placed in the former may reduce the size of the latter and increase leaflet coaptation. However, several studies based on anatomy and/or imaging using computed tomography have shown several potential limitations of this approach. First, the ring inserted into the coronary sinus is necessarily incomplete and localized to the posterior half of the annulus covering only 120° or 140° of the circumference of the mitral annulus, leaving the commissures and the anterior half of the annulus unsupported. Thus, efficacy is a concern in cases in which surgeons usually use undersized and complete rings. Second, the coronary sinus is 1 or 2 cm away from

WITH DEVICE DESIGN IMPROVEMENTS, PROPER PATIENT SELECTION, AND CAREFUL TECHNIQUE, PERCUTANEOUS CORONARY SINUS ANNULOPLASTY MAY BE A Viable TREATMENT OPTION FOR MITRAL REGURGITATION.

**BY ALEC VAHANIAN, MD**

"Mitral regurgitation is today the second most frequent native valve disease in Western countries after aortic stenosis..."
the atrioventricular groove on the atrial side. These two factors may well limit the efficacy of this approach. Third, there is a potential risk of cinching the circumflex artery while crossing the coronary sinus because in 40% to 70% of cases, the former passes between the latter and the mitral annulus. These anatomic factors are highly variable from one patient to another.

The technical issues here are finding the most effective proximal and distal fixation for stabilization and a material with sufficient constraining force to obtain a sufficient reduction of diameter. Several experimental studies have been performed in animals with acute and chronic models of moderate functional regurgitation and have shown potential to reduce the size of the mitral annulus and the degree of MR.

CURRENT DATA

To date, more than 100 cases of coronary sinus annuloplasty have been performed in man with three different devices: the Monarc device, the Carillon Mitral Contour System, and the Percutaneous Transvenous Mitral Annuloplasty system (Viacor, Inc., Wilmington, MA).

The Monarc device (Figure 1) is composed of two self-expanding stents (one proximal, one distal) connected by a bridge element, which has a delayed foreshortening capacity (after 3 to 6 weeks) due to presence of absorbable material.

The Carillon Mitral Contour System (Figure 2) also has a proximal and a distal anchor, which are joined by a nitinol wire element. This latter device is retrievable and allows for immediate assessment of efficacy and risk of compression of the circumflex artery. The Percutaneous Transvenous Mitral Annuloplasty system (Figure 3) consists of a polytetrafluoroethylene catheter in which different stiffness rods are introduced, putting pressure on the posterior annulus at the P2 seg-

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ment of the mitral valve. After testing to find the appropriate combination of rigid elements, permanent implantation is performed. Here again, the device is retrievable in cases of absence of efficacy or circumflex cinching.

The procedures are performed after venous approach through the jugular or subclavian veins followed by catheterization of the distal part of the coronary sinus. Overall, this approach is much simpler than percutaneous edge-to-edge mitral valve repair.

The only published report concerns a very limited number of patients with the Monarc device. Unfortunately, bridge fractures appeared in three fourths of patients in initial testing. The Viacor device has been initially used in a temporary intraoperative setting, pending permanent implantation. Similarly, the first generation of the Carillon system had technical failures leading to slippage of the distal anchor and was redesigned.

Clinical experience with second-generation devices has only been reported orally in a limited number of patients (approximately 100), and not, as yet, in peer-reviewed journals.

All patients in these preliminary studies had functional MR either of ischemic origin or in cardiomyopathy. The overall 30-day implantation success rates range from 31% with the Viacor device to 80% with the Monarc device. Complications, such as tamponade, may occur, mostly due to perforation of the coronary sinus by the guidewires (3%–4%), or due to coronary sinus dissections (up to 8% with the Viacor device).

Systematic coronary angiography performed either immediately after implantation of the device or within the following weeks showed that up to 30% of patients present with some degree of coronary vessel compression, which could lead to clinical complications in rare circumstances. No cases of coronary sinus thrombosis or erosion have been reported.

Data on efficacy are very limited at the present stage and reported only with the Monarc and the Carillon devices in which a reduction of the degree of MR ≥1+ was observed in 50% to 60% of cases, either immediately (Carillon) or after 6 months (Monarc). Finally, four cases of asymptomatic silent device separation were observed in the first 50 patients implanted with the Monarc system.

Currently, all three systems are being redesigned to improve stability, tractability and durability before new clinical studies can begin.

**DISCUSSION**

There are several issues regarding percutaneous coronary sinus angioplasty that should be resolved. First, technical improvements need to be made to reduce the occurrence of device failure and improve procedural success. Second, efficacy should be evaluated using properly designed trials with core laboratory analysis and randomized design. Third, the detection of patients at risk of coronary cinching is also crucial. Screening using multislice computed tomography could achieve this.

The potential candidates are patients with functional MR, that is to say, dilated cardiomyopathy or ischemic MR. These patients are numerous, and they are often at high surgical risk due to their cardiac condition, as well as the presence of comorbidity. However, the data avail-
able on the results of mitral valve repair alone in functional MR are quite limited and even conflicting. Furthermore, the efficacy in regard to survival has yet to be proven in randomized trials and large retrospective series have shown that, partly due to the high incidence of recurrence of MR, this procedure has no effect on mortality, even if symptoms may improve temporarily.

Thus, it may well be necessary in the future to combine the coronary sinus approach with procedures addressing left ventricular chamber remodeling, and/or edge-to-edge repair, even if the efficacy of the edge-to-edge repair is debated in the context of functional MR. Percutaneous annuloplasty could also be a useful adjunct to edge-to-edge repair in cases of degenerative MR.

Case reports when using the Monarc device have suggested that it was possible to combine coronary sinus annuloplasty with percutaneous edge-to-edge mitral valve repair, as well as with the implantation of pacing leads for resynchronization. In addition, surgical annuloplasty has shown to be feasible in case of failure.

DIRECT ANNULOPLASTY

To avoid the limitations of the coronary sinus approach, a number of devices have been developed to perform direct annuloplasty. They are at an even more preliminary stage than their coronary sinus counterparts because most are still experimental.

The Mitralign device (Figure 4) enables a direct suture plication of the posterior part of the mitral annulus. A catheter is placed retrograde into the left ventricle and positioned behind the posterior mitral leaflet. Anchors are placed in the annulus and connected in order to apply tension, and, therefore, plicate the annulus. Experimentally, such suture plication has been shown to reduce annular circumference by approximately 20%, resulting in a decrease in the degree of MR. The surgical comparator is seldom used and has acceptable clinical efficacy in association with other mitral valve repair techniques. The first in-man cases using the percutaneous approach have been performed.

The QuantumCor device (QuantumCor, Bothell, WA), used only experimentally as yet, remodels the posterior annulus by application of radiofrequency energy. The MiCardia variable size rings (MiCardia Corporation, Irvine, CA) use a dynamic, prosthetic, annuloplasty ring, which is implanted surgically and can be secondarily reshaped and remodeled using an energy source introduced via transseptal catheterization and directed to the area to be reshaped. These two latter approaches have not been used in man.

In the future, percutaneous mitral annuloplasty will probably be used in combination with other approaches acting on left ventricular remodeling and/or resynchronization, which have proven to be effective in many patients with functional MR.

CONCLUSION

Experience today shows that percutaneous coronary sinus annuloplasty is feasible; however, these techniques are at an early phase and should be very carefully compared to the gold standard, which is surgical and/or medical therapy, to evaluate both safety and efficacy.

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