The Wishful Thinking of Indirect Mitral Annuloplasty
Will It Ever Become a Reality?

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During the past 3 decades, there have been major advances in our understanding of mitral valve function and its pathophysiology. This has led to the development of very creative and effective surgical techniques for the repair of the mitral valve.

A variety of novel percutaneous approaches based on proven surgical technologies to repair mitral valves are being developed. The ultimate goal of percutaneous indirect mitral annuloplasty techniques is to reduce the mitral annulus septal-to-lateral distance by exerting force through a device deployed in the coronary sinus (CS)/great cardiac vein. Although initial preclinical and clinical studies have shown the feasibility of these techniques, anatomic studies describing the spatial relations of the CS/great cardiac vein have raised concerns regarding their potential clinical efficacy and risk of complications. The anatomic proximity of the CS to the mitral annulus has motivated a great deal of interest in using the natural course of the CS to reshape the mitral annulus. In this issue of Circulation: Cardiovascular Interventions, Sack et al report on the initial human experience of the PTMA coronary sinus device (Viacor Inc, Wilmington, Mass) permanent implant in patients with functional mitral regurgitation ≥2+, New York Heart Association Functional class ≥II, and an ejection fraction between 20% to 50%. Patients with an organic mitral valve disease, a previous stenting of the proximal left circumflex artery, and a dominant left system were excluded. The study group included 27 patients (with intention to implant); however, only one third of these actually underwent successful permanent implantation. The reasons for failure to implant included diagnostic failure, minor complications, unsuccessful acute reduction of mitral regurgitation, device instability, and technical difficulties. Of the 9 patients who underwent permanent implantation, 1 patient required device removal at 1 week because it fractured, and 1 patient died 3 months postimplant from progressive congestive heart failure. Of the 7 remaining implant patients, 3 underwent surgical annuloplasty because of worsening mitral regurgitation 3 months to almost a year after implantation. Only 4 patients (17%) remain with the device anywhere from 2.5 to 17 months after implantation.

The purpose of this study was to assess the safety and feasibility of the permanent implantation of the device. Indeed, the diagnostic and the implantation procedures were relatively safe, and the most severe complications were not lethal (1 patient had transient ischemia in the circumflex artery distribution, which led to coronary stenting, and 1 patient developed acute pericardial effusion, which required drainage).

The authors nicely describe the experience and the learning curve associated with using the equipment and its components. However, the small number of patients who finally underwent a successful implantation of a long-term device is disappointing. This small number obviously reflects the very steep learning curve not only of the new device but also,
perhaps more importantly, of the patients selected for this approach.

The limited success may have other explanations. Of course the effect of these devices will depend on their individual mechanism of action, but more importantly, this effect may be difficult to predict in each specific case due to the nonplanar, 3-dimensional anatomy of the mitral annulus and because in most cases the CS does not lie directly on the atrioventricular groove.14–18 Furthermore, it is well known that the mitral annulus has a rotational and translational motion with changes in its surface area throughout the cardiac cycle19 and also that the posterior distance between the CS and the annulus increases in patients with congestive heart failure. In addition, coronary arteries very frequently traverse between the coronary sinus/great cardiac vein and the mitral annulus, which can be compressed extrinsically by the device in the coronary sinus.14,16,18–19 Finally, the effective amount of septal-lateral annular reduction is significantly smaller than what has been suggested by the surgical literature.20,21 Thus, it seems that this technology will be applicable to only a very small number of patients with functional mitral regurgitation. Certainly, the long-term benefits are uncertain from this early and small study. Nonetheless, the procedure may have some benefit as a bridge technology, or in combination with other percutaneous mitral valve repair technologies. In any case, a study with larger number of patients and longer follow-up will be needed to determine the device safety. Once safety is established, a randomized clinical trial to confirm efficacy will be required. Finally, we should not forget the important lesson learned from the history of prosthetic valves. The initial attempts of surgical valve replacement in humans in the 1950s were disappointing.22–24 However, research, technical improvements, persistence, experience, and courage led to the development of a product that eventually worked and saved the lives of thousands. This may well be the case with percutaneous repair of the mitral valve in patients with functional mitral regurgitation.

Disclosures
Dr Kronzon is a stockholder in Guided Delivery Systems.

References

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