Commentary: Transcatheter edge-to-edge repair strategy: Time to evolve, not to fail

Patrick M. McCarthy, MD

For degenerative mitral regurgitation (DMR), repair is a Class I indication over replacement and is the standard of care. Repair has better early and late survival, less thromboembolic risk, less subacute bacterial endocarditis, no need for anticoagulation therapy, and returns survival to an age- and sex-matched population.1 Late durability is excellent.2,3 It can be challenging and is closely tied to surgeon volume.4 But repair use is rising, and recently was reported at 82.5% in the United States.5 Transcatheter edge-to-edge repair (TEER) is increasing in effectiveness. There are now approximately 150,000 MitraClip (Abbott) implants worldwide. In this report by Kaneko and colleagues,6 there were 11,396 TEER implants and of these 548 (4.8%) had reintervention, including 254 who had surgery. For the subset needing reintervention, the peri-operative risk was high. After TEER, only 2% of patients had mitral repair. But, Food and Drug Administration approval for TEER in DMR is only for prohibitive and high-risk surgery cases as determined by a heart team using the Society of Thoracic Surgeons predicted risk of mortality score (>6 for repair), frailty, and so on. The high procedural risk for reintervention is expected. At that age and risk strata, patients want no stroke and to feel better. They accept a low risk of failure because TEER is safer. In this sense they are like high-risk transcatheter aortic valve replacement (TAVR) patients studied in randomized trials.

What does this mean for the field of mitral surgery? Many of us think the time is right for a randomized surgery versus TEER trial in moderate-risk and elderly patients (MitraClip REPAIR MR study [ClinicalTrials.gov identifier: NCT04198870]). Moderate-risk TAVR trials followed successful completion of the high-risk trials. But others note low risk patients ask about TEER, and sometimes push for that less-invasive therapy (like some low-risk patients pushed for TAVR after the high-risk trials were published). Response to that patient is easy: Just say no. TEER for low-risk patients is not studied, not Food and Drug Administration or Medicare approved, and potentially Medicare fraud. In part due to patient pressure, we have another randomized trial (Percutaneous or Surgical Mitral Valve Repair study [ClinicalTrials.gov identifier: NCT05051033]) that includes low-risk patients intended to show superiority of surgery over TEER. Surgical repair is the standard of care, so why do we need to show superiority to TEER? Even industry is not suggesting that TEER should be studied in this population at this time. Moreover, whereas the TAVR trials studied many thousands of patients in high-, medium-, and low-risk patients, this small trial (450 patients) will study all risk categories with 2 TEER devices. What if there aren’t enough patients to

From the Division of Cardiac Surgery, Northwestern University Feinberg School of Medicine, Chicago, Ill.

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Address for reprints: Patrick M. McCarthy, MD, Division of Cardiac Surgery, Northwestern University Feinberg School of Medicine, 676 N Saint Clair St, Arkes Family Pavilion, Suite 730, Chicago, IL 60611-2908 (E-mail: Patrick.McCarthy@nm.org).

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prove surgery is superior in low-risk patients? If the concern is that some low-risk patients demand TEER today, then wait till a small underpowered study is published showing statistically insignificant differences to surgery. Mitral repair for DMR is much less risky, and much more successful, than surgical aortic valve replacement in many ways. The stepwise approach of the TAVR trials gave important and credible information that addressed many questions. Before we confuse the approach to DMR surgery, we should follow a similar thoughtful and stepwise approach.

References