

Argument for Prophylactic, Catheter-Based Repair of Mitral Regurgitation

A 62-year-old asymptomatic man presents with severe mitral regurgitation (MR) caused by a flail P2 segment. Should this patient be considered for catheter-based repair?

Surgical repair is the gold standard for degenerative MR. With modern techniques, prophylactic surgery may be considered when there is a high likelihood of successful repair (>95%) and a low mortality (<1%), particularly when performed in referent centers.¹ This approach may stave off adverse ventricular remodeling and has been associated with improved survival, although the procedural risk and potential complications are being immediately undertaken.²

Over the past decade, transcatheter mitral repair has emerged as an alternative. Several devices are available, with the predominant technology being MitraClip (Abbott Vascular, Santa Clara, CA), which is currently the only device approved in the United States. Although MitraClip has been found to have favorable safety (procedural mortality, 1%–2%), its efficacy is known to be less than that of surgery, with ≈40% of patients having moderate or worse residual MR.³ Thus, it is not surprising that the lower clinical efficacy observed with transcatheter repair has led to a relatively narrow indication, with the intended use restricted to symptomatic patients and prohibitive surgical risk.¹

Data from clinical trials such as those that examined MitraClip therapy are appropriately held in high regard because of the scientific rigor associated with randomization that reduces study bias. Nonetheless, the catheter-based techniques have continued to evolve. These changes have included advances in procedural imaging (eg, 3-dimensional echocardiography), device design (eg, nitinol grippers), and leaflet grasping techniques (eg, slow engagement); insight into predictors of success (eg, A2-P2 pathology, procedural frequency); and the growing expertise of those who perform the procedure. As an example, the rates of single leaflet device attachment have decreased from ≈8% in preapproval studies to ≈1% in commercial practice.⁴

With surgery, the determination of valve reparability is governed by the pathology and the surgical expertise. Certainly, these determinants have variability, are subject to local interpretation, and can be challenged by confounding factors such as clinical experience, operator enthusiasm, and patient desire. These challenges are magnified when “prophylactic” mitral surgery is considered. Nonetheless, the issues surrounding the prophylactic approach have been actively addressed for decades, with practice guidelines now established. If these same conditions could be met by rigorous study of catheter-based repair, should such therapy be offered in a fashion similar to surgery?

There is reasonable optimism that transcatheter repair could approach the effectiveness of surgery when there is a high level of diligence (Figure). Currently, ≈60% of treated patients have mild or no residual MR, attaining reduction defined as optimal. These results, which may be encouraging to some and dis-

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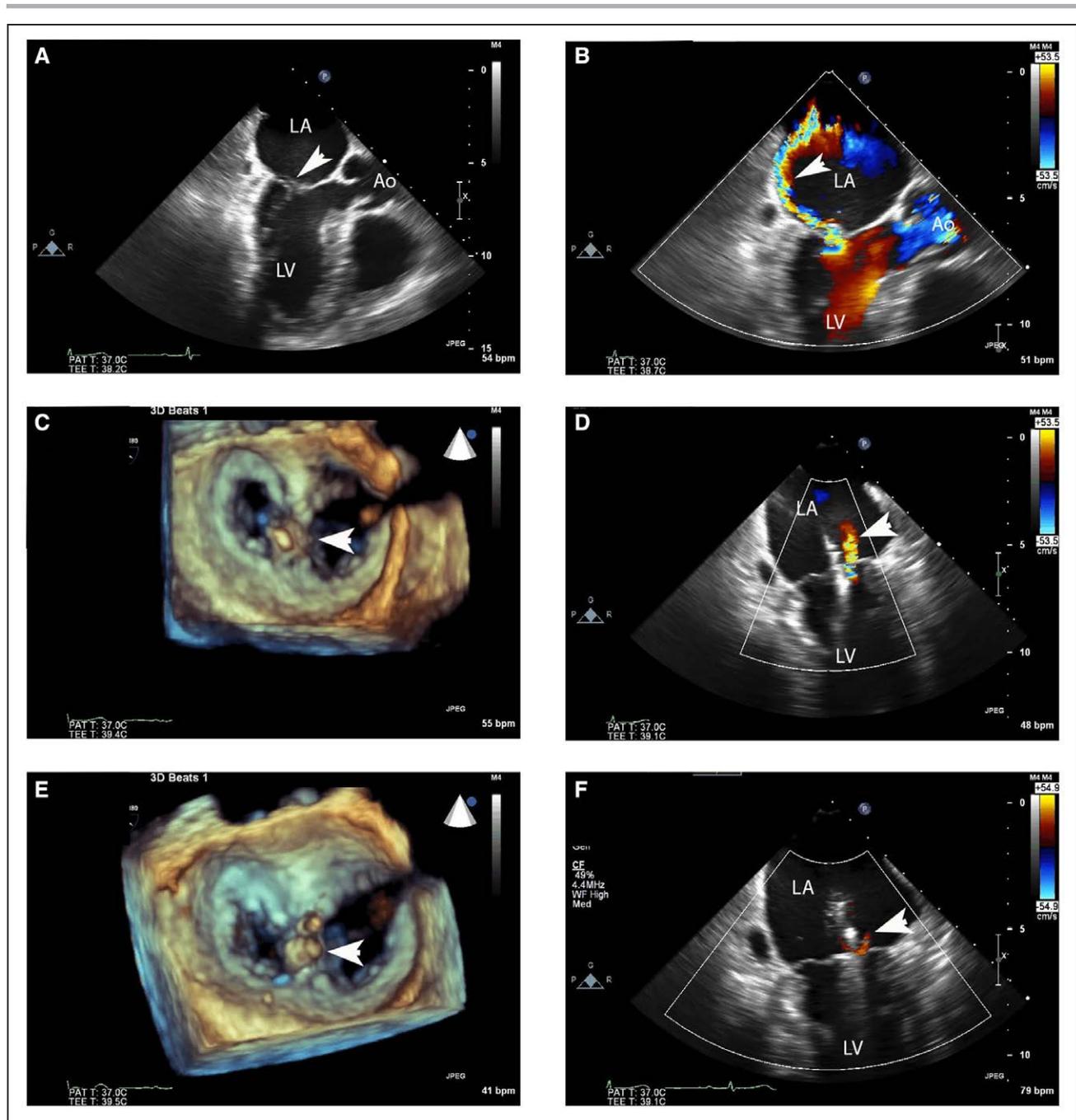


Figure. Optimization of reduction of mitral regurgitation with transcatheter mitral valve repair.

A, Baseline transesophageal echocardiography (TEE) shows flail posterior mitral valve leaflet (arrowhead). **B**, Color-flow imaging demonstrates severe mitral regurgitation (MR; arrowhead). **C**, After standard techniques for placement of a MitraClip, the flail segment is treated, and 3-dimensional TEE shows creation of a tissue bridge (arrowhead). **D**, After this initial grasp, there is significant improvement with mild to moderate residual MR (arrowhead). With comprehensive imaging, the flail segment is no longer evident. **E**, Despite this improvement, however, the heart team elects to optimize the MR reduction further. The MitraClip is repositioned ≈ 1 mm lateral in a position that is almost imperceptibly different from the first grasp (arrowhead). **F**, After this repositioning, complete elimination of MR is achieved (arrowhead). Ao indicates aorta; LA, left atrium; and LV, left ventricle.

couraging to others, have been observed in relatively unselected cohorts with variable anatomy such as stenosis ($\approx 21\%$), annular calcification ($\approx 37\%$), leaflet calcification ($\approx 18\%$), secondary MR ($\approx 18\%$), and even prior surgical repair ($\approx 2\%$). In addition, although transcatheter repair is a complex procedure, $\approx 70\%$ of the centers in 1 registry had no experience before commercial approval.⁴

More work is needed to further improve the outcomes of transcatheter repair and to define populations in whom and centers where surgery-like results can be achieved. The anatomic criteria that would lead to surgery-like results are not known. This effort would include examination of procedural techniques for optimizing MR reduction and criteria for heart team experience, with attention to both operators and imagers.

These scientific inquiries could occur with registries targeted to achieve optimal MR reduction with transcatheter repair or randomized trials that incorporate modern techniques and device iterations. Durability would need to be addressed, particularly given the known rates of residual MR and concerns that annuloplasty is not performed at the time of leaflet therapy. A distinct advantage of surgical therapy is the availability of an array of tools and techniques with known clinical benefit. Studies of transcatheter therapy need to examine the roles of other tools that may improve outcomes such as percutaneous annuloplasty devices used either alone or in concert with current techniques.

Although compelling data have demonstrated the potential benefit of mitral referent centers for surgery, the boundaries for what should be treated with catheter-based therapy remain wholly unstudied and require further investigation. Notably, these initiatives of further inquiry would be intended to broaden, not constrict, the availability and clinical indications of transcatheter mitral valve repair, which is currently limited to patients who cannot have surgery. Patients would potentially benefit from public outcome reporting, with details on pathogenesis and success of repair or replacement. Such accountability would be important given the widespread availability of catheter-based therapy. It has been established that, with professional training, broad adoption of catheter-based therapies for valvular disease and beneficial outcomes is possible.^{4,5} Further extension of such efforts is necessary for catheter-based therapy to have surgery-like indications, which would necessarily stem from surgery-like results in terms of efficacy, safety, and durability. Even in the present state and without such efforts, operators who perform transcatheter mitral valve repair should not settle for moderate residual MR because such residual MR may have a negative clinical impact, similar to what is known to occur after open surgery.⁴

As with many procedures, there is an ongoing evolution of transcatheter repair. Achievement of surgery-like results with catheter-based therapy is already known to be possible in some patients. Accordingly, this appeal may lead to speculation for how catheter-based approaches can be applied more broadly for patient benefit, including those with traditional indications for MR intervention and those who may benefit from prophylactic relief. More randomized trials with modern techniques are needed to determine whether comparable efficacy could exist for transcatheter approaches. Moreover, this understanding may expand the number of patients appropriately treated for MR in

a timely fashion, through either the appeal of a less invasive option or the halo effect on surgical practice that can come from the adoption of such therapies. Early intervention in asymptomatic MR patients has been associated with improved outcomes, and such an effect could be expected to occur with catheter-based therapy if the efficacy is demonstrated to be comparable to that of surgery in selected patients.

ARTICLE INFORMATION

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