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Percutaneous Treatment of Mitral Regurgitation: Current Status and Future Directions

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Abstract

The burgeoning field of catheter-based, percutaneous valve intervention takes an interdisciplinary approach to mitral valve regurgitation with the goal of maximizing clinical outcomes and minimizing procedure-associated morbidity. This exciting field continues to push the boundaries of technological innovation as it expands the armamentarium available to treat valvular disease. Around the world teams are working to create a catheter-based approach that is practical and durable. Several technologies are in various stages of development and clinical application.

Keywords

MitraClip; mitral regurgitation; percutaneous mitral valve; mitral valve surgery; percutaneous valve

The burgeoning field of catheter-based, percutaneous valve intervention takes an interdisciplinary approach to mitral valve regurgitation with the goal of maximizing clinical outcomes and minimizing procedure-associated morbidity. This exciting field continues to push the boundaries of technological innovation as it expands the armamentarium available to treat valvular disease. Around the world, teams are working to create a catheter-based approach that is practical and durable. Several technologies are in various stages of development and clinical application.

The MitraClip (Abbott Vascular, Menlo Park, CA) is designed to mimic Alfieri's edge-to-edge repair technique. Fluoroscopic and transesophageal echo are used to guide the device through a transseptal puncture and approximate the anterior and posterior leaflets. The target patient population for the device includes patients with mitral regurgitation (MR) who are not surgical candidates because of high operative risk. The device has also been used in lieu of early reoperation after cardiac surgery.¹ Trials in the United States^{2,3} and Europe^{4,5} have demonstrated short-term device safety, feasibility, and efficacy.

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In addition to leaflet repair, a percutaneous approach to annuloplasty has been studied. Indirect techniques capitalize on the anatomy of the coronary sinus, which parallels the posterior annulus and encircles approximately two-thirds of the mitral valve annulus. These devices indirectly transmit a constricting force on the mitral valve annulus. The designs are engineered to have an immediate effect on the mitral valve annulus as with Cardiac Dimensions Carillon System (Cardiac Dimensions, Kirkland, WA)⁶ or Viacor PTMA system (Viacor, Wilmington, MA),^{7,8} or a latent effect after suture dissolution allows for device shortening and annulus constriction as with the Edwards Monarc system (Edwards Life-sciences, Irvine, CA).⁹ The limitations of these devices include device fracture, compression of the circumflex artery or its branches resulting in ischemia, and unfavorable anatomy precluding coronary sinus access and device implantation.

Although the Endovascular Valve Edge-to-Edge Repair Study (EVEREST) trial demonstrated device safety, the EVEREST II trial showed a lower complication rate with the clip as compared with surgery.^{2,3,10} Most of this advantage was attributed to increased blood transfusion requirements in the surgical arm. Primary clinical efficacy defined as 12-month freedom from death, surgery for valve dysfunction, or the occurrence of $>2 + \text{MR}$ by intention-to-treat analysis showed that surgery was more efficacious than the clip (73% versus 55%, respectively $P = 0.007$). The 2-year results presented at the 2011 American College of Cardiology conference showed a difference in efficacy between surgery and the clip of 66.3% versus 51.7%, respectively ($P = 0.04$). At 2 years, 22% of clip patients had crossed over to surgery. There was no difference between the 2 groups with regards to left ventricle size, New York Heart Association class, or quality of life at 12 months. Studies from Germany and Italy have demonstrated short-term device efficacy in a higher-risk cohort than the EVEREST trial.^{4,5} Percutaneous mitral valve repair has shown improvement in MR severity, left ventricular volumes, and New York Heart Association class, 6-minute walk, and a decrease in brain natriuretic peptide.^{3,11} Furthermore, studies have shown improvement in hemodynamic parameters such as increased cardiac output, decreased left ventricle end diastolic volume and pressure, and decreased systemic vascular resistance.¹² As more centers perform percutaneous mitral valve intervention around the world, our understanding of the clinical outcomes of the procedure will improve. We continue to await further results from EVEREST high-risk registry as well as Real World Expanded Multicenter Study of the MitraClip System (REALISM).

Surgical mitral valve repair or replacement is possible after MitraClip placement even years after clip removal.^{13–15} The reported rate of repair is 52%–66%.^{13,16} Although some studies suggest that the decision to repair or replace is not affected by implant duration, valve injury by the clip, or difficulty removing the device, other studies have noted that clip placement followed by surgical intervention might result in a more complex surgical repair or replacement of the valve because of inability to repair.^{16–18}

The clip has several attributes including the ability to immediately evaluate the hemodynamic effect, allowing repositioning if warranted. Furthermore, the clip will allow us to offer therapy to a high-risk population ineligible for surgical intervention. However, there are several limitations. The clip requires the use of general anesthesia for transesophageal echocardiogram guidance, although the use of conscious sedation has been

described.¹⁹ The clip requires a similar procedure length and resource utilization as compared with surgery.²⁰ Because the EVEREST studies were performed at high-volume tertiary care centers, the generalizability of the study is unknown. At present, there are not enough data to support use of the device in low-risk patients or a younger cohort, because the 5- and 10-year device durability is unknown. Although surgical repair is possible after clip placement, it is unknown whether repair after device removal affects long-term outcome or survival after surgical intervention. Finally, the EVEREST trials do not have enough power to investigate differences in device outcome by etiology (degenerative versus functional), an important distinction because an emerging potential target population for this technology might include those with functional MR.

The future of mitral valve therapy necessitates an interdisciplinary approach that will allow us to tailor intervention, either surgical or catheter-based, to the patient. As the use of the percutaneous treatment increases, large, appropriately powered, prospective studies will investigate long-term outcomes. Further advancements in catheter-based therapy might include annuloplasty techniques, leaflet resection for redundant leaflets in mitral valve prolapse, left ventricular remodeling, chordal replacement, and even mitral valve replacement.

In summary, although many percutaneous technologies show promise, the device that is farthest along in development is the MitraClip system. Although short-term results have demonstrated safety and efficacy of the MitraClip, long-term results are not yet known. At this time, we should be cautious in our use of this technology in low-risk or younger patients in whom surgery has a proven record of efficacy and durability. However, the unquestionable ability of the MitraClip to reduce the severity of MR with minimal morbidity makes this an ideal option for the increasing population of high-risk and/or inoperable patients. To deliver the best care to these and all patients with mitral valve disease, our paradigm of care delivery must change, so that patients are assessed and treated by multidisciplinary teams with collective expertise with all possible treatment modalities.

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