Transcatheter therapies for mitral regurgitation: A surgeon's perspective

Marc R. Moon, MD

The American College of Cardiology, American Association for Thoracic Surgery, Society of Thoracic Surgeons (STS), and Society of Cardiovascular Angiography and Interventions collaborated to write an overview of transcatheter therapies for mitral regurgitation (MR), which has been published in the March 2014 issue of *The Journal of Thoracic and Cardiovascular Surgery*.¹ The multisocietal document included a summary of the current results of standard mitral valve (MV) surgery and a summary of clinical trials of transcatheter MR therapies and identified critical components for a successful program. The document was developed to address critical issues for implementation of innovative transcatheter MR therapies for selected patients and to help frame future discussions as the technology continues to evolve while “maintaining the best interests of the patients” as the driving force behind the initiative. The present brief synopsis summarizes the aspects of the multisocietal document that are of most interest to surgeons.

The results with standard MV surgery for MR have generally been outstanding for most patients at experienced centers. Degenerative MR secondary to isolated posterior leaflet pathologic features can be successfully repaired in >95% of patients, with a mortality rate of <1% to 2%. Less invasive approaches have become attractive because of the potential to diminish postoperative discomfort and complications and hasten the return to normal activities; however, such approaches should not be endorsed without ensuring a reasonable likelihood of a durable result. Of the numerous devices currently under investigation, the edge-to-edge MitraClip device (Abbott Vascular, Santa Clara, Calif) has undergone the most extensive human testing in the United States.²⁻⁴ The MitraClip was modeled after the Alfieri double-orifice technique, which has been used successfully as an adjunct for complex MV repair and to decrease the risk of systolic anterior motion in selected cases.^{5,6}

The MitraClip was approved in October 2013 by the Food and Drug Administration for significant,

symptomatic, degenerative MR in highly anatomically selected patients determined to be at prohibitive risk of open surgery by an experienced heart team.¹ Approval was based, to a large degree, on the results from the Endovascular Valve Edge-to-Edge Repair Study (EVEREST) II trial, which randomized 279 patients with severe MR in a 2:1 ratio to the transcatheter MitraClip (n = 184) or open surgery (n = 95).⁴ As expected, the transfusion rates (45% vs 13%) and incidence of major morbidity (9% vs 2%), as defined by the STS, were greater with open surgery; however, the mortality rate was similar (1%-2%), and surgery for MV dysfunction was more common after transcatheter repair (20% vs 2%). In the original intention-to-treat analysis, 21 patients who refused treatment after randomization (6 transcatheter, 15 open surgery) were assumed to have persistent MR for the primary efficacy analysis (freedom from death, surgery for MV dysfunction, or 3+ or 4+ MR). Thus, for all 279 patients, the primary efficacy at 12 months had been reached for 55% of the transcatheter and 73% of the open surgery patients ($P = .007$). Excluding those patients who had refused treatment after randomization increased the primary efficacy to 57% for the transcatheter group and 88% for the open surgery group. Subgroup analysis demonstrated that the efficacy was better with open surgery for younger patients (<70 years old), degenerative MR, and ejection fraction 60%. At 4 years, survival was similar but late MR was less common after open surgery ($P < .001$, Figure 1).⁷

As with most innovative procedures, the results seemed to improve with increased experience⁸ and patient selection, specifically high-risk surgical patients.⁹⁻¹² Whitlow and associates⁹ studied transcatheter MitraClip use in 78 patients with an STS surgical risk of 12%. Mortality at 30 days was 7.7% compared with 8.3% in a comparator group of open surgery patients who had been screened for, but not enrolled in, the EVEREST II trial. At 1 year, 24% of the transcatheter patients had died. However, among the survivors, 78% had MR grade 2+ and most had experienced improved symptoms, quality of life, left ventricular reverse remodeling, and decreased readmissions for heart failure. Several other studies have corroborated the satisfactory results in high-risk subsets,¹⁰⁻¹² in particular, those with functional MR,^{13,14} which is being evaluated in 2 current trials (Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for Extremely High-Surgical-Risk Patients [COAPT] and A Randomized Study of the MitraClip Device in Heart Failure Patients With Clinically Significant Functional Mitral Regurgitation [RESHAPE-HF]).^{15,16}

From the Division of Cardiothoracic Surgery, Washington University School of Medicine, St Louis, Mo.

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Address for reprints: Marc R. Moon, MD, Division of Cardiothoracic Surgery, Washington University School of Medicine, 660 S Euclid Ave, Box 8234, St Louis, Mo 63110-1013 (E-mail: moonm@wustl.edu).

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FIGURE 1. Mitral regurgitation grade at 4 years in the Endovascular Valve Edge-to-Edge Repair Study (EVEREST) II trial for patients randomized to transcatheter mitral regurgitation (MR) therapy with the MitraClip device or open surgery (based on data from Mauri and colleagues⁷).

SURGICAL INTERVENTION AFTER FAILED TRANSCATHETER MR REPAIR

Geidel and Schmoeckel¹⁷ reported 19 patients who had undergone open MV surgery 12 days (median) after failed transcatheter MitraClip placement. The EuroSCORE had increased from 13% at MitraClip implantation to 27% at open surgery. MV repair was possible in 83% of patients who had had only 1 clip implanted; however, replacement was necessary in 77% of the patients who had had 2 clips implanted. Glower and colleagues¹⁸ also noted leaflet damage in 30% of patients after failed transcatheter repair, with fibrosis and leaflet scarring most common after 30 days. MV replacement was necessary in 17 of 37 patients (46%) with a failed transcatheter procedure compared with only 13 of 80 patients (16%) initially randomized to open surgery.

GUIDELINES FOR OPERATOR TRAINING, CARE PROTOCOLS, AND OUTCOMES ASSESSMENT

The challenges of evaluating and treating patients with complex cardiac disease and significant comorbidities requires a multidisciplinary team at a high-volume center. The model established during release of transcatheter aortic valve replacement, including the heart team paradigm, should pertain to the dissemination of transcatheter MV therapies.^{1,19,20} The clinical cardiologist will most often determine the timing of referral for intervention and then works with the interventional cardiologist and cardiac surgeon to determine the best course of therapy. Imaging specialists are essential to delineate the anatomic limitations to the various treatment options and to provide imaging capabilities during interventions. (The current relative technical limitations to transcatheter MitraClip implantation include pathologic findings isolated to the A2-P2 area, a

coaptation length of 2 mm, a coaptation depth of 11 mm, a flail gap <10 mm, a flail width <15 mm, an MV orifice area >4 cm², and a mobile leaflet length >1 cm.) The interventional cardiologist must be skilled in all aspects of transcatheter structural procedures, and the cardiac surgeon must be competent in catheter-based and surgical approaches to MR, including repair and replacement options. The multisocietal document¹ has specified: “The cardiac surgeon and interventional cardiologist will collaborate during the performance of transcatheter mitral procedures and will designate primary and secondary operator as appropriate for the specific findings and challenges encountered in any individual patient,” noting that “Procedural teams function best with both disciplines represented and working collaboratively.”

Protocols outlining the roles of the individual heart team members and establishing a collaborative process for shared decision making with the patient are important. A detailed outline of the facilities, personnel experience, care protocols, and complication management strategies must be developed. The preoperative evaluation should include a complete assessment of the comorbidities, cardiac function, valvular anatomy and mechanics, and the need for coronary revascularization. A hybrid operating suite with capability for cardiopulmonary bypass is not strictly necessary for current transcatheter MV therapies but will become necessary if transcatheter MV replacement options materialize and could add a level of security if complications occur rapidly during transcatheter repair. Laminar air flow is mandatory to provide operating room level sterility. The specific competency requirements for individual and institutional experience with transcatheter and open surgical procedures and the specific criteria for training and performance metrics will be outlined in a forthcoming multisocietal consensus statement. The addition of transcatheter MR therapies to the STS/American College of Cardiology Transcatheter Valve Therapy registry with reporting of postprocedural 30-day and 1-year outcomes will be essential to monitor the safety and efficacy of these new technologies.²¹ The multisocietal document¹ concluded with the following recommendations:

1. Heart valve centers of excellence are defined by the competence of the individual members and the presence of a multidisciplinary heart team that works collaboratively in the best interest of patients. All aspects of patient evaluation, care, and follow-up, including mandatory participation in the Transcatheter Valve Therapy registry, must be addressed with dedicated pathways.
2. Availability and reimbursement for new devices should be limited to heart valve centers of excellence that meet national criteria.
3. Operator training and credentialing criteria must be established by a multisocietal group.

4. Guidelines for transcatheter MV interventions should be substantiated and developed, with performance measures and appropriate use criteria for expanded indications based on rigorous trials and registry assessment.

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