The influence of a percutaneous mitral repair program on surgical mitral valve volume

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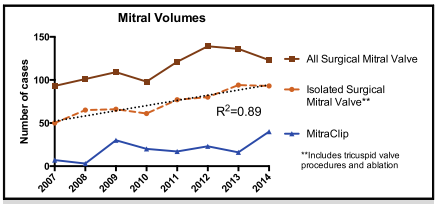
ABSTRACT

Objectives: Percutaneous mitral repair with the MitraClip system (Abbott Vascular, Santa Clara, Calif) has been available in trials since 2006 and is currently approved for patients with degenerative mitral valve disease at prohibitive risk for surgery. There has been concern that novel transcatheter approaches may detract from mitral valve surgical volumes. We sought to evaluate the influence of our MitraClip program on our surgical mitral valve volumes and outcomes.

Methods: All patients referred for MitraClip underwent evaluation by a multidisciplinary team. Patients were screened for surgical candidacy and suitable valve anatomy for transcatheter repair. The fate of patients referred for MitraClip as well as the overall surgical mitral volumes and outcomes were evaluated.

Results: From July 2007 to December 2014, 468 patients were referred for the MitraClip procedure at our institution. Of these, 156 patients (33.3%) received a MitraClip (including 45 implanted by surgeons), whereas 82 patients (17.5%) underwent surgical interventions. During this timeframe, the volume of isolated mitral valve operations increased from 50 procedures in 2007 to 93 in 2014 (80% increase; $R^2 = 0.89$). Importantly, operative mortality for all patients undergoing isolated mitral surgery from 2008 to 2014 was 2.6%, with an observed to expected ratio of 0.64.

Conclusions: The availability of MitraClip resulted in an increase in our mitral valve referrals. Despite seeing an increase in higher risk referrals, operative mortality for mitral surgery remained excellent. Multidisciplinary evaluation, including input from experienced mitral surgeons, is necessary to have a successful percutaneous and surgical mitral valve program. (J Thorac Cardiovasc Surg 2015;150:1093-7)



MitraClip and mitral surgery volumes, 2007 to 2014.

Central Message

MitraClip availability is associated with increasing surgical volumes and excellent outcomes despite high-risk referrals.

Perspective

Percutaneous mitral valve repair has sustained slow adoption by surgeons amid concerns including influence on surgical volumes. It is our perception that a valve center inclusive of transcatheter therapies is in itself beneficial to surgical volumes and allows a center to offer the full range of percutaneous, minimally invasive, and full sternotomy complex mitral repair and high-risk mitral replacement.

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Traditional therapy for severe mitral regurgitation (MR) has relied on surgical correction of the mitral valve. One repair technique, the Alfieri stitch, provided the foundation for MitraClip (Abbott Vascular, Santa Clara, Calif) transcatheter valve repair.[1] The MitraClip device has been available through clinical trials since 2006, and our institution began performing this type of transcatheter mitral repair in 2007.

MitraClip provides an appealing alternative to surgery for properly selected patients. One-year results from the Endovascular Valve Edge-to-Edge Repair Study (EVEREST II) high-risk registry and the Real World Expanded Multicenter Study of the MitraClip System (REALISM) continued access high-risk arm demonstrated that 84% of patients had MR $\leq 2+$ at 1 year with few device-related complications and a 4.8% 30-day mortality.[2] Recent 5-year data from the EVEREST II trial demonstrated that improvement in MR remains durable with associated decreases in left ventricular end diastolic volumes.[3] Moreover, patients at high surgical risk with degenerative MR experienced fewer hospitalizations with improved functional status at 1 year, reflecting the improvement in patient quality of life with this percutaneous option.[4] These encouraging data

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Abbreviations and Acronyms
MR = mitral regurgitation
PROM = predicted risk of mortality
STS = Society of Thoracic Surgeons

resulted in Food and Drug Administration approval of the MitraClip device for symptomatic patients with 3+ to 4+ primary leaflet disease (degenerative MR) at prohibitive risk for surgery. With functional MR, European studies have shown promising results for MitraClip, with 86% of patients demonstrating New York Heart Association functional class I to II symptoms at 1 year.[5] In the United States, the ongoing Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) trial is evaluating the efficacy of MitraClip in patients with functional MR.

Performance and acceptance of the MitraClip procedure has experienced slow adoption by surgeons. The reduction in MR with MitraClip is inferior to the reduction obtained with surgery, and many surgeons are concerned that performing the MitraClip procedure will detract from surgical volumes. In this context, we sought to analyze patients referred for MitraClip to determine what risk profiles these patients present and to describe which therapies they eventually received, including MitraClip, surgery, or medical management. We also examined our surgical volumes over the timeframe during which MitraClip has been used at our institution. We hypothesized that MitraClip patient referrals encompass a relatively high-risk group of patients, and that surgical volumes were not detrimentally affected by the availability of the MitraClip procedure at our institution.

METHODS

MitraClip Evaluation Process

Patients who were referred for MitraClip were initially screened. Potential candidates went on to a full evaluation process consisting of transthoracic echocardiography to assess MR severity as well as mitral valve area and coexisting valvular abnormalities, followed by transesophageal echocardiography to identify mitral pathology and to determine if the MitraClip would be efficacious. In many cases where high-risk surgery was considered an option, chest computed tomography was obtained to evaluate for mitral annular calcification and ascending aortic calcium burden, and right and left heart catheterization was performed to evaluate pulmonary hemodynamic parameters and coronary artery disease, respectively. Pulmonary function testing was obtained to rule out intrinsic pulmonary disease.

MitraClip placement was considered feasible in patients with an effective orifice area >4 cm^2, a single dominant jet, and leaflets without edge calcification. A weekly valve conference consisting of surgeons, interventional cardiologists, heart failure specialists, nurse practitioners, imaging specialists, and selected medical specialists (eg, pulmonologists, nephrologists, oncologists, geriatricians, and hepatologists) discussed each case to determine candidacy for MitraClip procedure versus surgery or optimal medical management. During much of the time period analyzed, selection criteria were specific to available MitraClip trials and registries.

Patients

Approval for this retrospective study was obtained through the University of Virginia Institutional Review Board, with a waiver of individual patient consent. All patients referred for consideration of MitraClip repair from July 2007 through December 2014 were included in our analysis. Internal valve clinic databases were used to identify patients referred for MitraClip evaluation. Patient records were then reviewed to identify the results of the evaluation process and eventual therapy received. For patients who underwent MitraClip procedure or any surgical procedure (ie, patients with a completed preprocedural/preoperative evaluation), the preoperative risk status and outcomes were evaluated. Outcomes included 30-day mortality, renal failure, stroke, and postoperative length of stay.

Statistical Analyses

Surgical volumes were assessed with linear regression to determine the strength of growth trends over time. Continuous variables for patient demographic characteristics and outcomes were compared using Student *t* test or Wilcoxon rank-sum tests as appropriate. Categorical variables were compared using Fisher exact test. Means are presented with standard deviations, and medians are presented with interquartile ranges.

RESULTS

Referrals for MitraClip and Therapy Decisions

From July 2007 through December 2014, 468 patients were referred to our facility for consideration of MitraClip therapy (Figure 1). After evaluation by the multidisciplinary team, 156 patients (33.3%) received a MitraClip. A total of 82 patients (17.5%) underwent surgical interventions, including 52 isolated mitral operations, 12 concomitant mitral surgeries with tricuspid repairs, and 7 concomitant mitral surgeries with coronary artery bypass grafting. Seven patients referred for MitraClip underwent left ventricular assist device placement, and 2 underwent epicardial left ventricular lead placement for chronic resynchronization therapy. A total of 132 patients (28.2%) received medical management, and 6.6% died during the evaluation process.

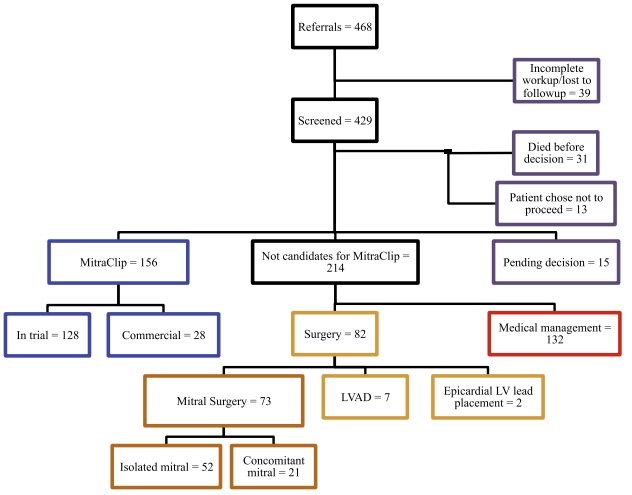

FIGURE 1. Patients referred for MitraClip procedure and eventual therapies received. *LVAD*, Left ventricular assist device; *LV*, left ventricular.