ORIGINAL RESEARCH

# Impact of the Commercial Introduction of Transcatheter Mitral Valve Repair on Mitral Surgical Practice

Hiroki Niikura, MD; Mario Gössl, MD; Richard Bae, MD; Benjamin Sun, MD; Judah Askew, MD; Kevin Harris, MD; Karol Mudy, MD; Craig Strauss, MD; Larissa Stanberry, PhD; Andrea Sweeney, MBA; Paul Sorajja, MD

***Background*—**There has been uncertainty regarding the effect of transcatheter mitral valve repair (TMVr) with MitraClip on cardiac surgical practice. Our aim was to examine the impact of the commercial introduction of TMVr to a comprehensive mitral program.

***Methods and Results*—**We evaluated 875 patients (aged 69±14 years; 58% men) who underwent transcatheter or mitral surgical procedures over a 6-year period at our institution. Main outcomes were changes in surgical procedural volume after TMVr introduction and short-term mortality for surgical and TMVr procedures. The numbers of patients treated with MitraClip, isolated mitral repair, and any mitral surgery were 249, 292, and 626 patients, respectively. Compared with surgery, patients with MitraClip were older (aged 82±8 versus 64±12 years; $P<0.001$) and had more severe morbidity. Following the introduction of MitraClip, surgical volumes steadily increased to a rate of 10 (95% CI, 3–7) procedures per year for isolated mitral procedures and 17 (95% CI, 13–20) procedures per year for all mitral surgeries. Both MitraClip and surgical volumes increased at the same rate ($P$=0.42). In-hospital mortality was 3.2% for MitraClip and 2.1% for all mitral surgeries ($P$=0.33). At 30 days, survival free of all mortality ($P$=0.17) and freedom from heart failure rehospitalization ($P$=0.75) were similar for transcatheter and surgical procedures.

***Conclusions*—**The commercial introduction of TMVr may be associated with growth in cardiac surgery, without detracting from other therapies, and favorable clinical outcomes for all treated mitral regurgitation patients. These findings demonstrate the potential benefits of complementary therapies in the treatment of patients with mitral regurgitation. **(*J Am Heart Assoc*. 2020;9:e014874. DOI: 10.1161/JAHA.119.014874.)**

**Key Words:** halo effect • MitraClip • mitral regurgitation • mitral surgery • transcatheter mitral valve repair

Mitral regurgitation (MR) is the most common valvular lesion in the Western countries, occurring in >6% of people aged >65 years.[1,2] Surgical treatment, with either mitral repair or chordal-sparing valve replacement, is the standard of care for patients with symptomatic severe MR. With modern techniques, surgery can be accomplished through a variety of approaches with high rates of MR relief (>95%) and low operative mortality (1–3%).[3–10] For many MR patients, surgery is a life-saving therapy and can be associated with restoration of normal longevity.[11,12] Therefore, consideration of surgery is recommended for all patients with symptomatic severe MR.[13,14]

Over the past decade, transcatheter approaches for MR treatment have emerged.[2,15–21]

Such approaches have been designed to potentially address unmet clinical needs, with the appeal of a relatively less invasive alternative to open surgery. In 2013, transcatheter mitral valve repair with MitraClip (Abbott Vascular) was approved for clinical use in the United States.[16,18,21] From 2013 to 2017 in the United States, the commercial indications of MitraClip were that it was used to treat severe symptomatic degenerative MR in patients who had prohibitive surgical risk, and a multidisciplinary heart-team evaluation was required for coverage determination by the Centers for Medicare and Medicaid Services. Although this indication is focused on patients who cannot undergo surgery, there has been concern about the impact of this introduction on traditional mitral surgical practice.[22] These concerns entail the effects of transcatheter approaches on surgical volumes, including the potential for cannibalization within a referral

*From the Valve Science Center, Minneapolis Heart Institute Foundation, Abbott Northwestern Hospital, Minneapolis, MN.*

Accompanying Tables S1, S2 and Figures S1 through S3 are available at https://www.ahajournals.org/doi/suppl/10.1161/JAHA.119.014874

**Correspondence to:** Paul Sorajja, MD, Roger L. and Lynn C. Headrick Chair, Valve Science Center, Minneapolis Heart Institute Foundation, Abbott Northwestern Hospital, 800 East 28th Street, Minneapolis, MN 55407. E-mail: paul.sorajja@allina.com

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## Clinical Perspective

### What Is New?

- There has been uncertainty regarding the effect of transcatheter mitral valve repair on cardiac surgical practice.
- We examined the impact of transcatheter mitral valve repair introduction in a comprehensive valve program.
- There were significant increases in cardiac surgical procedures that coincided with the commercial introduction of transcatheter mitral valve repair with MitraClip.

### What Are the Clinical Implications?

- This investigation demonstrates that introduction of commercial transcatheter mitral valve repair may be associated with growth in cardiac surgery and beneficial clinical outcomes for patients with a broad range of surgical risk (ie, halo effect).
- Our findings support the notion that complementary transcatheter and surgical therapies can be implemented successfully, without detracting from each other; thus, they should be considered essential components of a state-of-the-art valve center.

center, and the impact on clinical outcomes among patients who require procedural therapy for MR.

In this study, we examined the impact of the commercial introduction of transcatheter mitral valve repair with MitraClip on mitral surgical practice in a tertiary referral center.

## Methods

The data that support the findings of this study are available from the corresponding author on reasonable request.

### Study Population

We examined all patients who underwent surgical or commercial transcatheter therapy for MR at Abbott Northwestern Hospital (Minneapolis, MN) from January 1, 2012, through December 31, 2017. This time period was chosen to examine surgical practice before and after the commercial introduction of MitraClip, which was approved for commercial use on October 24, 2013. Elective, urgent, and emergent cases of commercial therapy, including open repair, valve replacement, and transcatheter mitral valve repair with MitraClip, were included for analysis. Patients who underwent therapy as part of a research protocol or a noncommercial compassionate use treatment were excluded. All study patients provided informed consent for use of their medical records for research purposes, in accordance with Minnesota statutes. This study was conducted in accordance with the Declaration of Helsinki and was approved by the Allina institutional review board.

### Data Collection and Definitions

In this retrospective cohort study, the medical records were manually reviewed by trained doctors and staffs in their entirety for patient demographics, symptom status, morbidities, procedural therapy types, and clinical outcomes. For each patient, the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) for mitral repair and mitral replacement was calculated using the online tool (available at http://riskcalc.sts.org/STSWebRiskCalc273) at the time of the multidisciplinary heart-team conference.[23] The major adverse clinical events as defined by the Mitral Valve Academic Research Consortium criteria included the occurrence of all-cause death, cardiac death, rehospitalization for heart failure, myocardial infarction, stroke, major bleeding (updated Valve Academic Research Consortium [VARC-2] criteria), major vascular complication, and subsequent or repeated surgical/transcatheter procedure.[24,25] Occurrence of death was confirmed through review of the electronic medical records or examination of Minnesota Department of Health records. Isolated mitral surgical procedures were defined as those that occurred without concomitant coronary artery bypass grafting or other valvular therapy (repair or replacement). For financial analyses, data on hospitalization costs were obtained from the Allina Health electronic data warehouse. In this study, hospitalization cost included costs of medication, laboratory, room, radiation, respiratory, supply, and procedure.

### Statistical Analysis

Procedural data were grouped according to transcatheter or surgical treatment for comparisons. Clinical outcomes during the procedure, hospitalization and at 30-day and 12-month follow-up were examined. The main outcomes of interest were changes in surgical procedural volume after the commercial introduction of MitraClip and mortality for surgical and MitraClip procedures at discharge and 30-day follow-up. Secondary end points were mortality, hospitalization for heart failure, and reintervention for recurrence of MR at 12-month follow-up. Categorical variables were expressed as frequencies and percentages. Continuous, symmetrically distributed variables were summarized by mean±SD. Skewed, continuous variables were summarized by their medians with interquartile ranges (IQRs; 25th, 75th percentiles). Categorical variables were compared using either the $\chi^2$ test of association or Fisher exact tests (in case of small counts). Independent *t* tests for normally distributed variables and nonparametric Wilcoxon rank sum tests for skewed continuous data were used to assess group differences in each year or before (ie, from 2012 to 2013) and after (from 2014 to 2017) introduction of MitraClip.

The annual proportions of surgical cases performed for MR over the study period were compared using a test for equal proportions. Annual volumes for open surgical cases were calculated, and changes in procedural volumes were estimated using a linear regression approach; estimates and their corresponding 95% CIs are reported. The Kaplan–Meier method was used to calculate survival estimates for the end points of all-cause mortality and the combined end point of death and heart failure rehospitalization, with comparisons performed using the log-rank test. Patients who were lost to follow-up were censored at the time of the last clinical encounter. One patient converted to emergent mitral valve replacement. The follow-up of this patient as a MitraClip patients was terminated at the time of surgery; therefore, this patient was followed up as a surgical patient. The unadjusted and adjusted hazard risks of 1-year all-cause mortality were assessed using the Cox proportional hazards regression model. In the multivariable Cox proportional hazards regression model, covariates with $P<0.05$ and clinically relevant variables were selected. To evaluate 1-year all-cause mortality and the combined end point of death and heart failure rehospitalization at 1-year follow-up and to estimate hazard ratios of 1-year all-cause mortality for both MitraClip and surgery patients in 4 different time periods (ie, 2014, 2015, 2016, and 2017), post hoc subanalyses were performed for the theses subgroups.

In cost analyses, only the financial data related to the first hospitalization were considered for patients who underwent multiple admissions within the period 2013–2017. The hospitalization, procedural, and medication costs for MitraClip and surgical procedures were summarized using medians (interquartile ranges [IQRs]) and were compared using Wilcoxon rank sum tests. The variances of the cost components between MitraClip and surgical procedures were compared using *F* tests for variances applied to log-transformed data; estimated variance ratios, 95% CIs, and *P* values are reported. Records with missing data were excluded from the analyses. The results are reported as percentage change in costs with corresponding 95% CI. All statistical analyses were performed with the statistical package R v3.0.1 (R Core Team) and SPSS v25 (IBM Corp).

# Results

## Patient Characteristics

During the study period, 875 patients (509 [58.2%] were male, with a mean age of 69.4±13.8 years) underwent open surgery (n=626) or transcatheter mitral valve repair with MitraClip (n=249). Among the surgical patients, 373 had repair, whereas 253 had chordal-sparing valve replacement. In comparison to surgical patients, those who underwent MitraClip were older (82.0±7.8 versus 64.3±12.4 years; $P<0.001$), less commonly male (48.6% versus 62.0%; $P<0.001$), and had a higher frequency of severe heart failure and morbidities. The median STS-PROM for patients with MitraClip repair was significantly greater than for those who had surgery (5.4% [IQR: 3.7–8.3] versus 1.3% [IQR: 0.6–2.8]); $P<0.001$). The frequency of primary MR as the pathology treated was similar for the 2 treatment groups, although patients who had surgery had less severe MR, higher rates of underlying mitral stenosis, and lower right ventricular systolic pressures on echocardiography at baseline. Among patients with degenerative MR, 484 patients (55.4%) showed leaflet prolapse, and 178 (20.3%) showed flail leaflet. The leaflet prolapse was significantly more frequent in the surgical patients (44.2% versus 59.9%, $P<0.001$), and the flail leaflet was significantly more frequent in the MitraClip patients (32.1% versus 15.7%, $P<0.001$; Table 1).

## Surgical Volumes

Following the commercial introduction of MitraClip, the number of surgical cases for isolated mitral therapy and all mitral surgeries both increased during the study period (Figure 1). Overall, the volume of patients increased by 17 (95% CI, 13–21) procedures per year, with no difference between the rates of change of the MitraClip and surgical procedures ($P=0.42$ for the interaction term). The rate of increase for isolated mitral surgery was 10 (95% CI, 3–17) procedures per year ($P=0.02$). For all mitral surgeries, the rate of increase was 17 (95% CI, 13–20) procedures per year ($P=0.01$).

For surgical procedures, there were no changes in the distributions of age ($P=0.62$), sex ($P=0.31$), body mass index ($P=0.58$), and STS-PROM ($P=0.26$ for mitral repair and $P=0.27$ for mitral replacement; Figure 2A, Table S1). Among the surgical patients, comparisons of the median of STS-PROM for repair, STS-PROM for replacement, age, and body mass index before (ie, 2012–2013) and after (ie, 2014–2017) the commercial introduction of MitraClip showed no significant difference between those time periods (STS-PROM for repair, $P=0.82$; STS-PROM for replacement, $P=0.59$; age, $P=0.24$; body mass index, $P=0.70$; Figures S1A–S1D). The proportion of surgical cases performed for primary MR over the study period varied from 71% to 81% ($P=0.35$; Figure 2B).

## Clinical Outcomes

Surgical treatment was associated with lower rates of residual MR, higher postprocedural mitral gradients, and longer length of hospital stay (Table 2). Among the surgical patients, 104 patients underwent concomitant coronary artery bypass graft, 27 underwent concomitant aortic valve replacement, and 43 had concomitant tricuspid repair or replacement. Among the patients with MitraClip, the number of deployed clips for each

**Table 1.** Baseline Clinical and Echocardiographic Characteristics

| Variable | All | MitraClip | Surgical Therapy | *P* Value |
|---|---|---|---|---|
| All patients, n | 875 | 249 | 626 | . . . |
| Age, y, mean (SD) | 69.4 (13.8) | 82.0 (7.8) | 64.3 (12.4) | <0.001 |
| Male sex | 509 (58.2) | 121 (48.6) | 388 (62.0) | <0.001 |
| Body mass index, kg/m$^2$, mean (SD) | 27.4 (5.7) | 26.3 (5.7) | 28.0 (5.6) | <0.001 |
| NYHA class III or IV | 461 (52.7) | 236 (94.8) | 225 (35.9) | <0.001 |
| Medical history | | | | |
| Coronary artery disease | 315 (36.0) | 120 (48.2) | 195 (31.2) | <0.001 |
| Peripheral vascular disease | 80 (9.1) | 39 (15.7) | 41 (6.5) | <0.001 |
| Hypertension | 533 (60.9) | 187 (75.1) | 346 (55.3) | <0.001 |
| Diabetes mellitus | 153 (17.5) | 56 (22.5) | 97 (15.5) | 0.02 |
| Atrial fibrillation | 348 (39.8) | 167 (67.1) | 181 (28.9) | <0.001 |
| Chronic obstructive pulmonary disease | 141 (16.1) | 70 (28.1) | 71 (11.3) | <0.001 |
| Prior myocardial infarction | 98 (11.2) | 38 (15.3) | 60 (9.6) | 0.02 |
| Prior stroke | 96 (11.0) | 42 (16.9) | 54 (8.6) | 0.001 |
| Hemoglobin, mean (SD), mg/dL | 13.0 (1.9) | 12.4 (1.7) | 13.2 (1.9) | <0.001 |
| Creatine, mean (SD), mg/dL | 1.1 (0.8) | 1.3 (0.5) | 1.1 (0.9) | 0.002 |
| Prior procedure | | | | |
| Prior sternotomy | 172 (19.7) | 87 (34.9) | 85 (13.6) | <0.001 |
| History of PCI | 129 (14.7) | 61 (24.5) | 68 (10.9) | <0.001 |
| History of CABG | 91 (10.4) | 62 (24.9) | 29 (4.6) | <0.001 |
| Permanent pacemaker or ICD | 106 (12.1) | 56 (22.5) | 50 (8.0) | <0.001 |
| Medications | | | | |
| Aspirin | 498 (56.9) | 150 (60.2) | 348 (55.6) | 0.24 |
| Warfarin or Xa inhibitor | 249 (28.5) | 121 (48.6) | 128 (20.4) | <0.001 |
| β-Receptor antagonist | 438 (50.1) | 169 (67.9) | 269 (43.0) | <0.001 |
| ACEI or ARB | 336 (38.4) | 104 (41.8) | 232 (37.1) | 0.23 |
| Diuretic | 359 (41.0) | 175 (70.3) | 184 (29.4) | <0.001 |
| STS-PROM for repair, %, median (IQR) | 2.1 (0.8, 4.6) | 5.4 (3.7, 8.3) | 1.3 (0.6, 2.8) | <0.001 |
| STS-PROM for replace, %, median (IQR) | 3.5 (1.6, 6.9) | 7.9 (5.6, 11.6) | 2.3 (1.3, 4.5) | <0.001 |
| Grade 3 or 4 mitral regurgitation | 805 (92.0) | 247 (99.2) | 558 (89.1) | <0.001 |
| ERO, mean (SD), cm$^2$ | 0.48 (0.3) | 0.46 (0.3) | 0.49 (0.3) | 0.35 |
| Regurgitant volume, mL | 73.6 (42.7) | 71.0 (42.6) | 74.9 (42.7) | 0.37 |
| Mean mitral gradient >5 mm Hg | 78 (8.9) | 2 (0.8) | 76 (12.1) | <0.001 |
| LVEF, mean (SD), % | 58.6 (9.8) | 57.5 (9.9) | 59.1 (9.6) | 0.03 |
| LVDd, mean (SD), cm | 5.1 (0.8) | 4.9 (0.8) | 5.1 (0.8) | <0.001 |
| LVDs, mean (SD), cm | 3.4 (0.8) | 3.4 (0.9) | 3.4 (0.8) | 0.43 |
| RVSP, mean (SD), mm Hg | 36.5 (14.1) | 41.7 (13.9) | 34.1 (13.5) | <0.001 |
| Mitral regurgitation cause | | | | |
| Degenerative | 663 (75.8) | 190 (76.3) | 473 (75.6) | 0.86 |
| Leaflet prolapse | 485 (55.4) | 110 (44.2) | 375 (59.9) | <0.001 |
| Anterior | 69 (7.9) | 21 (8.4) | 48 (7.7) | 0.68 |

Continued

**Table 1.** Continued

| Variable | All | MitraClip | Surgical Therapy | *P* Value |
|---|---|---|---|---|
| Posterior | 305 (34.9) | 65 (26.1) | 240 (38.3) | <0.001 |
| Bileaflet | 111 (12.7) | 24 (9.6) | 87 (13.9) | 0.092 |
| Flail leaflet | 178 (20.3) | 80 (32.1) | 98 (15.7) | <0.001 |
| Anterior | 98 (11.2) | 21 (8.4) | 27 (4.3) | 0.021 |
| Posterior | 106 (12.1) | 52 (20.9) | 54 (8.6) | <0.001 |
| Bileaflet | 24 (2.7) | 7 (2.8) | 17 (2.7) | 1 |
| Function | 69 (7.9) | 12 (4.8) | 57 (9.1) | 0.04 |
| Mixed | 14 (1.6) | 8 (3.2) | 6 (1.0) | 0.03 |
| Other | 129 (14.7) | 39 (15.7) | 90 (14.4) | 0.67 |
| Obstructive HCM | 12 (1.4) | 10 (4.0) | 2 (0.3) | <0.001 |
| Postsurgical repair | 34 (3.9) | 9 (3.9) | 25 (4.0) | 0.79 |
| Rheumatic disease | 34 (3.9) | 0 | 34 (5.4) | <0.001 |
| Endocarditis | 7 (0.8) | 0 | 7 (1.1) | 0.09 |
| Leaflet thrombus | 1 (0.1) | 0 | 1 (0.2) | 0.53 |

Data are shown as No. (%) except as noted. ACEI indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; CABG, coronary artery bypass grafting; ERO, effective regurgitant orifice; HCM, hypertrophic cardiomyopathy; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; LVDd, left ventricular end-diastolic diameter; LVDs, left ventricular end-systolic diameter; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RVSP, right ventricular systolic pressure; STS-PROM, Society of Thoracic Surgeons Predicted Risk of Operative Mortality.

procedure was 1.4±0.5, and the most frequent location of clip implantation was the A2-P2 segments of the mitral valve (85.9% of cases). In addition, 3 patients required in-hospital conversion to open cardiac surgery. Of those patients, 1 patient was converted to emergent mitral valve replacement. In-hospital mortality for the overall population was 2.4%, and it was not

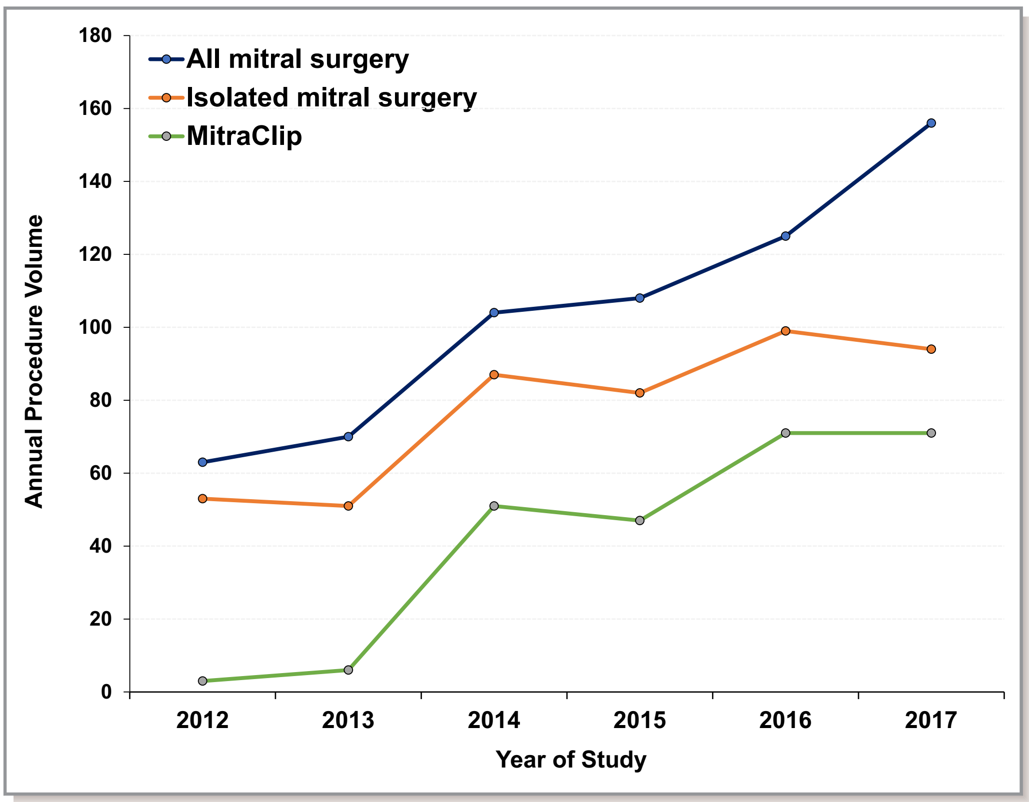


**Figure 1.** Annual volumes per calendar year for transcatheter and surgical mitral procedures during the study period.

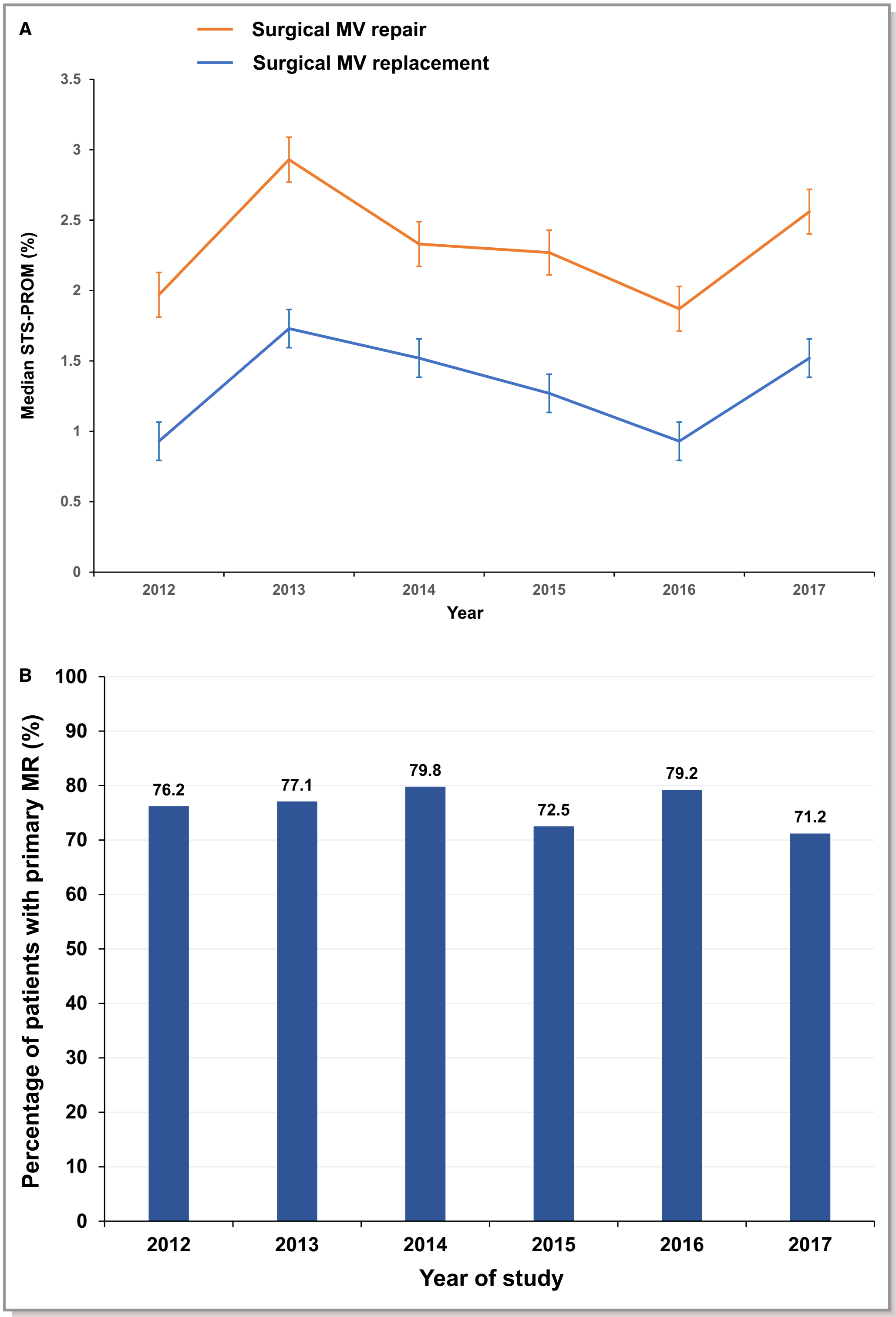


**Figure 2.** Surgical risk and pathology for patients who had mitral surgery during the study period. **A**, Society of Thoracic Surgery Predicted Risk of Mortality (STS-PROM) for mitral repair and replacement. **B**, Proportion of patients with primary mitral regurgitation (MR). MV indicates mitral valve.

different between the 2 treatment groups (3.2% for MitraClip versus 2.1% for surgery; $P$=0.33). After 30 days, all-cause mortality was similar for both transcatheter and surgical procedures (4.0% versus 2.2%; $P$=0.17; Table 3). At 1 year, repeat surgical interventions were higher for patients with MitraClip (8.8% versus 1.8%; $P$<0.001). All-cause mortality at 1 year for the overall study population was 9.6%, and it was significantly higher in MitraClip patients than in surgical

**Table 2.** Procedural and In-Hospital Clinical Outcomes

| Variable | All | MitraClip | Surgical Therapy | *P* Value |
|---|---|---|---|---|
| All patients, n | 875 | 249 | 626 | . . . |
| Procedure success | 854 (97.5) | 233 (93.6) | 621 (99.2) | <0.001 |
| Residual regurgitation grade ≤2 | 807 (92.2) | 201 (80.7) | 606 (96.8) | <0.001 |
| MG after procedure, mm Hg, mean (SD) | 4.6 (2.2) | 4.1 (2.1) | 4.8 (2.1) | <0.001 |
| LOS after procedure, d, median (IQR) | 6 (4, 8) | 2 (1, 3) | 7 (6, 9) | <0.001 |
| Major vascular complication | 10 (1.1) | 3 (1.2) | 7 (1.1) | 1 |
| Myocardial infarction | 13 (1.5) | 1 (0.4) | 12 (1.9) | 0.12 |
| Stroke | 19 (2.2) | 6 (2.4) | 13 (2.1) | 0.80 |
| New PPM and ICD implantation | 49 (5.6) | 0 | 49 (7.8) | <0.001 |
| In-hospital mortality | 21 (2.4) | 8 (3.2) | 13 (2.1) | 0.33 |

Data are shown as No. (%) except as noted. ICD indicates implantable cardioverter-defibrillator; IQR, interquartile range; LOS, length of hospital stays; MG, mean gradient; PPM, permanent pacemaker.

patients (18.9% versus 5.9%; *P*<0.001; Table 3, Figure 3A). For the combined end point of death and heart failure rehospitalization, survival at 1 year was 11.8% in the overall study population and higher for MitraClip patients (22.1% versus 7.7%; *P*<0.001; Table 3, Figure 3B).

Among the surgical patients, significant differences were observed in all-cause mortality and the combined end point of death and heart failure rehospitalization at 1-year follow-up between the surgical repair group and surgical replacement group (all-cause mortality, *P*<0.001; death and heart

**Table 3.** Clinical Outcomes at 30-Day and 1-Year Follow-Up

| Variable | All | MitraClip | Surgical therapy | *P* Value |
|---|---|---|---|---|
| All patients, n | 875 | 249 | 626 | |
| At 30 d | | | | |
| All-cause mortality | 24 (2.7) | 10 (4) | 14 (2.2) | 0.17 |
| Cardiac death | 14 (1.6) | 7 (2.8) | 7 (1.1) | 0.08 |
| Rehospitalization for heart failure | 12 (1.4) | 4 (1.6) | 8 (1.3) | 0.75 |
| Death or rehospitalization for heart failure | 30 (3.4) | 14 (5.6) | 16 (2.6) | 0.04 |
| Myocardial infarction | 15 (1.7) | 2 (0.8) | 13 (2.1) | 0.26 |
| Stroke | 20 (2.3) | 6 (2.4) | 14 (2.2) | 0.81 |
| Major bleeding (VARC-2 criteria) | 42 (4.8) | 6 (2.4) | 36 (5.8) | 0.04 |
| At 1 y | | | | |
| All-cause mortality | 84 (9.6) | 47 (18.9) | 37 (5.9) | <0.001 |
| Cardiac death | 34 (3.9) | 19 (7.6) | 15 (2.4) | <0.001 |
| Rehospitalization for heart failure | 42 (4.8) | 19 (7.6) | 23 (3.7) | 0.02 |
| Death or rehospitalization for heart failure | 103 (11.8) | 55 (22.1) | 48 (7.7) | <0.001 |
| Myocardial infarction | 19 (2.2) | 5 (2.0) | 14 (2.2) | 1 |
| Stroke | 40 (4.6) | 9 (3.6) | 31 (5.0) | 0.48 |
| Reintervention | 33 (3.8) | 22 (8.8) | 11 (1.8) | <0.001 |
| Surgical mitral valve replacement | 12 (1.4) | 7 (2.8) | 5 (0.8) | 0.046 |
| Surgical mitral valve repair | 4 (0.5) | 0 | 4 (0.6) | 0.21 |
| Transcatheter mitral repair with MitraClip | 17 (1.9) | 15 (6.0) | 2 (0.3) | <0.001 |

VARC indicates Valve Academic Research Consortium.

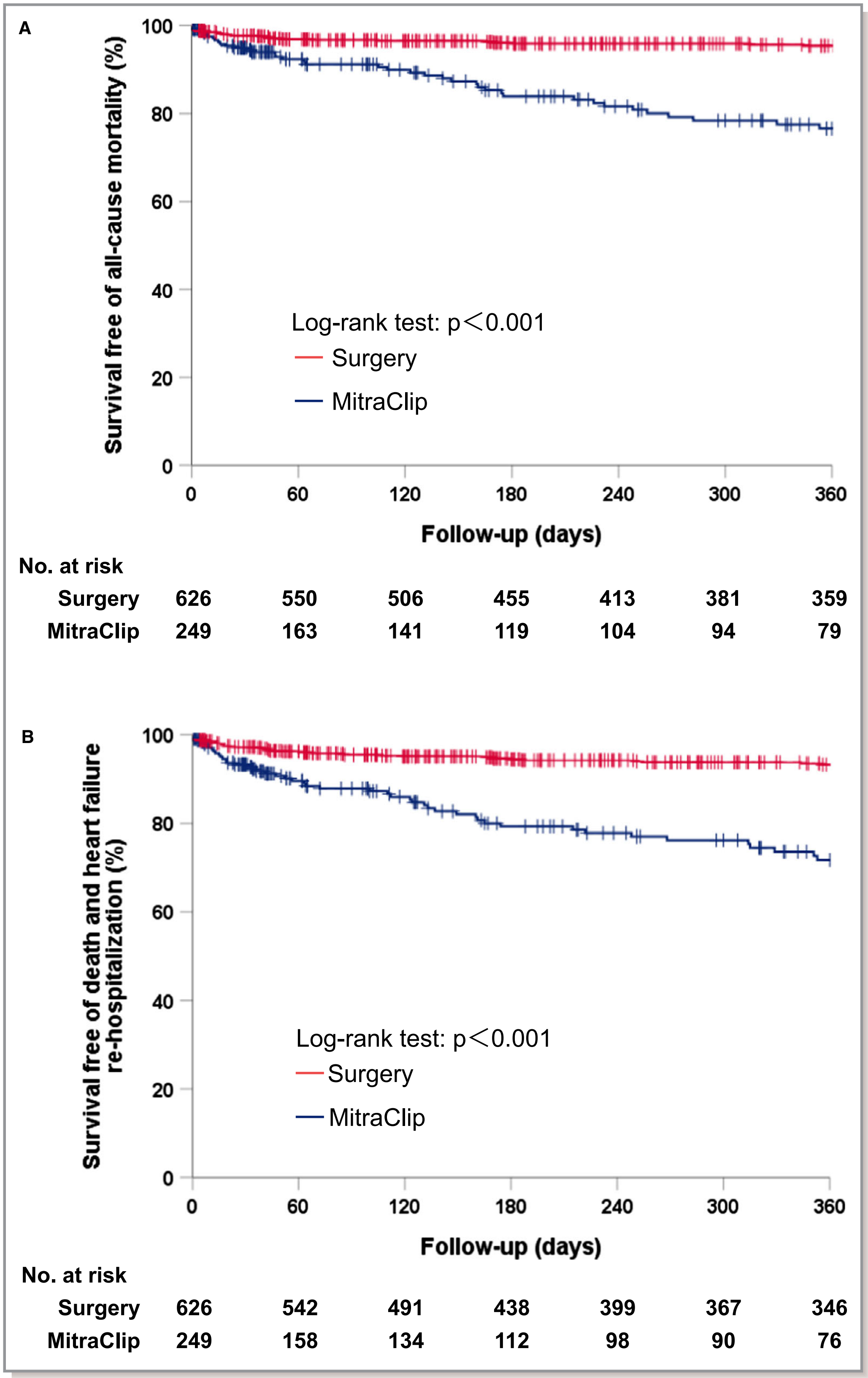


**Figure 3.** Survival according to treatment type. **A**, Survival free of all-cause mortality. **B**, Survival free of the combined end point of all-cause mortality or heart failure rehospitalization.

failure rehospitalization, *P*=0.002; Figures S2A and S2B; Table S2).

The MitraClip procedure was significantly associated with the risk of 1-year all-cause mortality (hazard ratio: 5.15; 95% CI, 3.28–8.07; *P* <0.001). After multivariable adjustment, the MitraClip procedure was not associated with 1-year all-cause mortality (adjusted hazard ratio: 1.55; 95% CI, 0.85–2.84; *P*=0.15; Table 4). In addition, comparing 4 time periods (ie, 2014, 2015, 2016, and 2017), both 1-year all-cause mortality and the combined end point of death and heart failure rehospitalization showed no significant difference between the MitraClip and surgery groups in 2017 (all-cause mortality, *P*=0.35; death and heart failure rehospitalization, *P*=0.13). In contrast, the surgery group showed significantly better results in both 1-year clinical outcomes than the MitraClip group in the other time periods. Furthermore, for the MitraClip group, the risk of all-cause death was higher but not statistically different compared with that for the surgery group in 2017 (*P*=0.36; Figure S3).

## Financial Analyses

Cost data were available for 736 hospital admissions, including 220 MitraClip procedures and 516 mitral surgeries. The median length of hospital stay for MitraClip patients and surgery patients were 2 (IQR: 1–3) and 7 (IQR: 6–9) days, respectively. The length of hospital stay for MitraClip patients decreased by 12% (95% CI, 6–17%) during the study period, whereas that for surgical patients remained virtually unchanged, with an annual percentage change of 0.6% (95% CI, −3% to 4%).

Median in-hospital costs were higher for MitraClip than for mitral surgery ($37 700 [IQR: $36 500–$40 200] versus $25 400 [IQR: $19 600–$35 200]; *P*<0.001). This difference was largely attributable to higher procedural costs for MitraClip ($35 100 [IQR: $34 400–$36 100] versus $13 500 [IQR: $10 700–$17 200]; *P*<0.001), although medical costs were higher for surgery ($1764 [IQR: $1392–$2637] versus $361 [$272–$591]; *P*<0.001; Figure 4, Table 5). In MitraClip patients, 94% (IQR: 88–95%) of the total hospitalization costs were attributed to procedural costs, whereas 1% (IQR: 0.7–1.5%) were attributed to medical costs. Conversely, the allocations of procedural and medical costs for mitral surgery were 54%, (IQR: 45–60%) and 7% (IQR: 6–9%) of the total hospitalization costs, respectively. The variability of hospitalization and procedural costs was higher for surgical procedures than for MitraClip procedures. The estimated ratios of variance of surgical to MitraClip costs were 3.2 (IQR: 2.5–4.0; *P*<0.001) for hospitalization costs and 2.7 (IQR: 2.2–3.4; *P*<0.001) for procedural costs. For medical

**Table 4.** Uni- and Multivariable Cox Proportional Hazards Regression Analysis for 1-Year All-Cause Mortality

| | Univariable | | Multivariable | |
|---|---|---|---|---|
| | Unadjusted HR (95% CI) | *P* Value | Adjusted HR (95% CI) | *P* Value |
| Age | 1.07 (1.04–1.09) | <0.001 | 1.02 (0.99–1.04) | 0.24 |
| Sex (male) | 1.27 (0.83–1.95) | 0.27 | | |
| Body mass index | 1.01 (0.97–1.05) | 0.56 | | |
| NYHA class ≥3 | 9.88 (4.94–19.75) | <0.001 | 4.93 (2.31–10.5) | <0.001 |
| Atrial fibrillation | 1.83 (1.19–2.81) | 0.006 | 0.95 (0.59–1.51) | 0.81 |
| COPD | 2.56 (1.60–4.09) | <0.001 | 1.43 (0.88–2.33) | 0.14 |
| Prior stroke | 1.45 (0.79–2.68) | 0.23 | | |
| Prior CABG | 4.24 (2.62–6.86) | <0.001 | 2.15 (1.29–3.59) | 0.003 |
| STS-PROM for repair | 1.08 (1.06–1.10) | <0.001 | 1.04 (1.01–1.08) | 0.006 |
| STS-PROM for replace | 1.08 (1.06–1.09) | <0.001 | | |
| Preprocedural MR grade ≥3 | 0.56 (0.30–1.06) | 0.076 | | |
| Preprocedural severe TR | 2.42 (1.16–5.04) | 0.018 | 1.05 (0.50–2.22) | 0.90 |
| LVEF (for every 1% increase) | 0.98 (0.96–1.00) | 0.051 | | |
| Isolated mitral repair or replacement | 0.22 (0.14–0.36) | <0.001 | | |
| Isolated mitral repair | 0.084 (0.031–0.23) | <0.001 | | |
| MitraClip procedure | 5.15 (3.28–8.07) | <0.001 | 1.55 (0.85–2.84) | 0.15 |

CABG indicates coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; HR, hazard ratio; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; MR, mitral regurgitation; STS-PROM, Society of Thoracic Surgeons Predicted Risk of Operative Mortality; TR, tricuspid regurgitation.

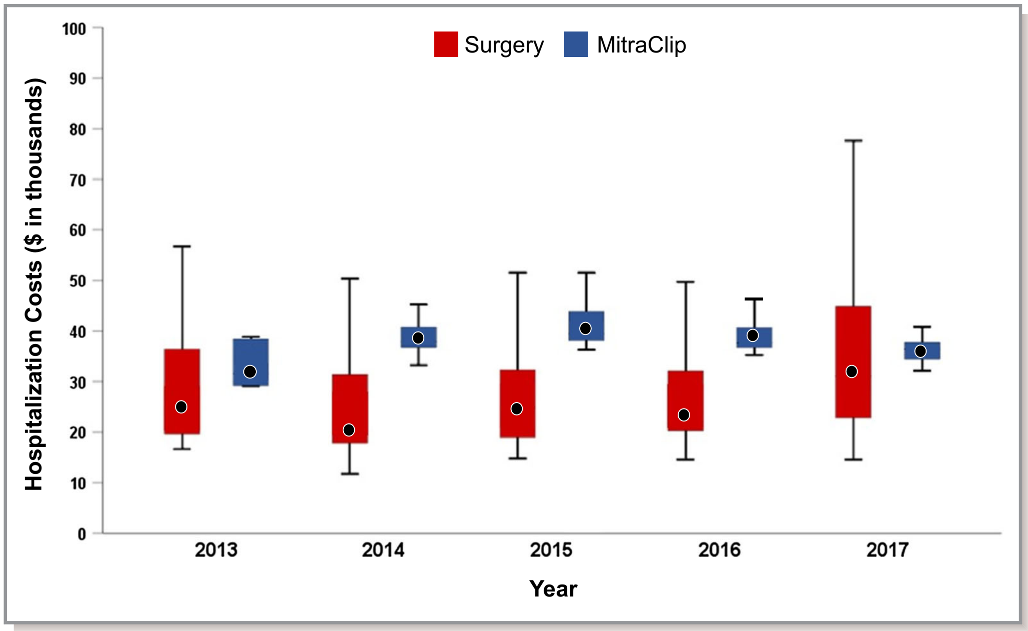


**Figure 4.** Hospitalization costs per calendar year for transcatheter and surgical therapy. Medians (dots), 25th to 75th quartiles (boxes), and ranges (lines) are shown.

costs, variability was higher for MitraClip than for surgical procedures with the estimated ratio of cost variances being 1.4 (IQR: 1.1–1.7; $P$=0.007).

## Discussion

In this investigation of 875 patients treated for MR, there were significant increases in cardiac surgical procedures that coincided with the commercial introduction of transcatheter mitral valve repair with MitraClip. Clinical success rates were high and procedural mortality was low for both surgical and transcatheter groups, affording effective and safe therapy for a spectrum of patients with MR. These findings demonstrate the potential benefits of complementary procedures in a comprehensive mitral referral center.

When cardiac surgical and transcatheter approaches are both options, there is the potential for these therapies to detract from each other or to be competitive in their undertaking. Such observations have been noted in the treatment of cardiovascular diseases where the intended clinical indications overlap, such as patients in need of coronary revascularization (percutaneous coronary intervention versus coronary artery bypass grafting) or those with symptomatic severe aortic stenosis (transcatheter aortic valve replacement versus surgical aortic valve replacement). In this study, transcatheter repair with MitraClip was introduced into our practice and utilized in patients with high or prohibitive surgical risk (STS-PROM for repair, median: 5.4 [IQR: 3.7–8.3]) and in patients with predominantly primary or degenerative MR (76.3% of patients), consistent with the commercial indication for the therapy in the United States. We found that the commercial introduction of transcatheter repair was associated with a positive impact on cardiac surgery, with growth that occurred for all types of mitral surgeries during the study period.

Growth in service lines besides the applied care or therapy has been described as a “halo effect.” The benefits of such an effect are multidisciplinary growth and sustainability in a given healthcare center, which in turn can better serve patients, particularly when the care is complex or novel. Although our study is a single-center investigation, similar findings on

**Table 5.** Median (Interquartile Range) Costs by Procedure Type (in US Dollars)

| Costs | All (N=802) | MitraClip (n=223) | Surgical Therapy (n=579) | $P$ Value |
|---|---|---|---|---|
| Hospitalization* | 30 900 (21 400–38 800) | 37 700 (36 400–40 200) | 25 400 (19 600–35 200) | <0.001 |
| Procedure | 16 200 (11 700–34 100) | 35 100 (34 400–36 100) | 13 500 (10 700–17 200) | <0.001 |
| Medication | 1504 (843–2182) | 361 (272–591) | 1764 (1392–2637) | <0.001 |

*Hospitalization costs included costs of medication, laboratory, room, radiation, respiratory support, supply, and procedure.

transcatheter repair of MR have been described previously in reports from Germany and the University of Virginia.[22,26] Notably, the halo effect can extend beyond clinical outcomes and can be associated with financial health of a multidisciplinary program, as observed in our investigation. Compared with those for surgical patients, procedural costs were higher, but length of hospital stay and cost variability were both lower for MitraClip patients.

Although our center was an active participant in preclinical evaluations of MitraClip, the commercial introduction was performed with ongoing training and dedication of the staff, and a close collaboration between surgeons and cardiologists in the evaluation and treatment of patients with mitral disease. In our practice, each patient being considered for transcatheter valve therapy is discussed in a weekly, multidisciplinary conference. The conference also serves as an open forum and a resource for practitioners of all specialties in our healthcare system who seek assistance in the management of any patient with valvular or structural heart disease. In our multidisciplinary conference, a quorum is required, and the comprehensive clinical history, surgical risk assessment, and imaging studies are reviewed, followed by discussion for a consensus on the most appropriate surgical or transcatheter treatment plan. As a focal point for discussion in our practice, transcatheter therapy with MitraClip likely enabled broad awareness of the multidisciplinary methods of care that are available to our patients, and this awareness helped to spur growth in cardiac surgery. For 30 patients, referral was specifically for MitraClip, but after multidisciplinary evaluation, cardiac surgery was undertaken.

It is important to note the distinct clinical characteristics of the transcatheter patients, who were considerably older and more commonly affected with significant comorbidities and had more severe heart failure in comparison to those who had surgery (STS-PROM, median: 5.4% [IQR: 3.7–8.3%) for repair versus 1.3% [IQR: 0.6–2.8%) for transcatheter versus surgery; $P<0.001$ in both cases). Importantly, the procedural mortality for all therapies was low (<2.5%) across the spectrum of predicted surgical risks for our patients. Although residual MR was more common with MitraClip, symptom improvement and survival at 30 day were similar for transcatheter and surgical therapies. Furthermore, after multiple adjustment, MitraClip therapy was not associated with 1-year all-cause death. In addition, in 2017, no difference in 1-year mortality was observed between the 2 therapies. These observations reflect the successful application of transcatheter therapy in a fashion that was complementary to modern surgical practice, enabling our center to treat patients with a broad range of surgical risks. MR is a complex disease with a myriad of potential therapies. Broad surgical expertise is required for treatment of a broad range of patients and may not be available in some centers. Nonetheless, our findings demonstrate that commercial introduction of complementary therapy can be beneficial for multidisciplinary growth.

Characteristics of state-of-the art valve centers include the availability of both surgical and transcatheter therapies. Practice guidelines for valvular heart disease advise a heart team approach whenever any procedural therapy is being considered.[13,14] We believe that our positive findings reflect the availability of these therapies and the success of our collaborative multidisciplinary approaches. Although our center is a tertiary care center, these processes have the potential to be implemented universally.

## Limitations

Our study has several limitations. First, we presented data of patients who underwent surgical or transcatheter mitral therapy from 2012 through 2017 in this study. Our cohort data included only surgical patients enrolled for about 1.5 years before the introduction of MitraClip. Thus, our results may limit the number of surgical patients for the period before the introduction of MitraClip. However, we chose this period before the introduction of transcatheter mitral valve repair so that we could have insight into practice immediately before the procedure was made available. Second, the present investigation is a retrospective study, and the effects of unknown confounding factors cannot be excluded. Our findings reflect performance in a single-center tertiary care facility and thus may be locally and institutionally specific; therefore, challenges in generalizability may exist.

## Conclusions

This investigation demonstrates that introduction of commercial transcatheter mitral valve repair may be associated with growth in cardiac surgery and beneficial clinical outcomes for a cohort of patients with a broad range of surgical risks. These findings support the notion that complementary transcatheter and surgical therapies can be implemented successfully without these therapies detracting from each other; thus, they should be considered essential components of a state-of-the-art valve center.

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# SUPPLEMENTAL MATERIAL

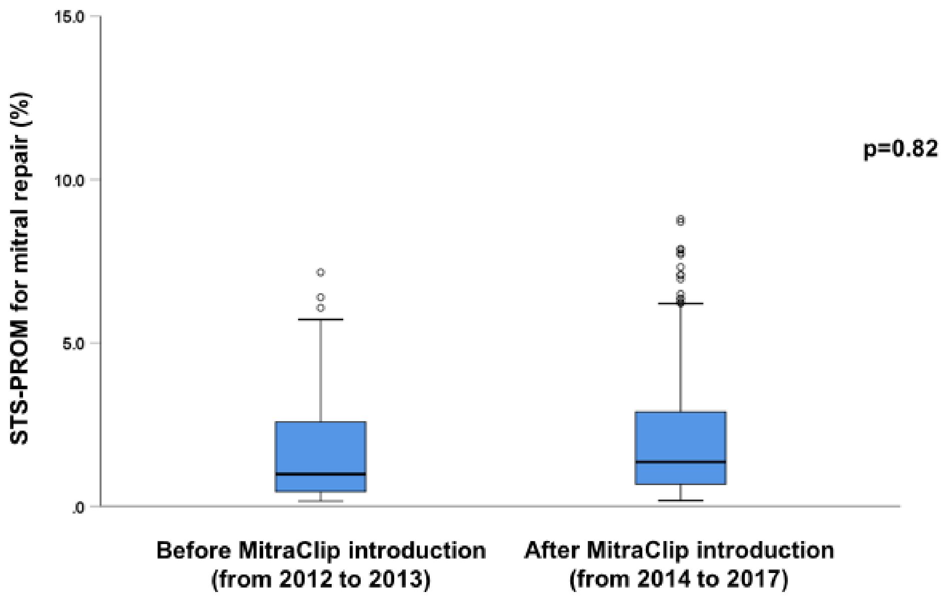
**Table S1. Temporal change in age, sex and BMI in the surgical patients.**

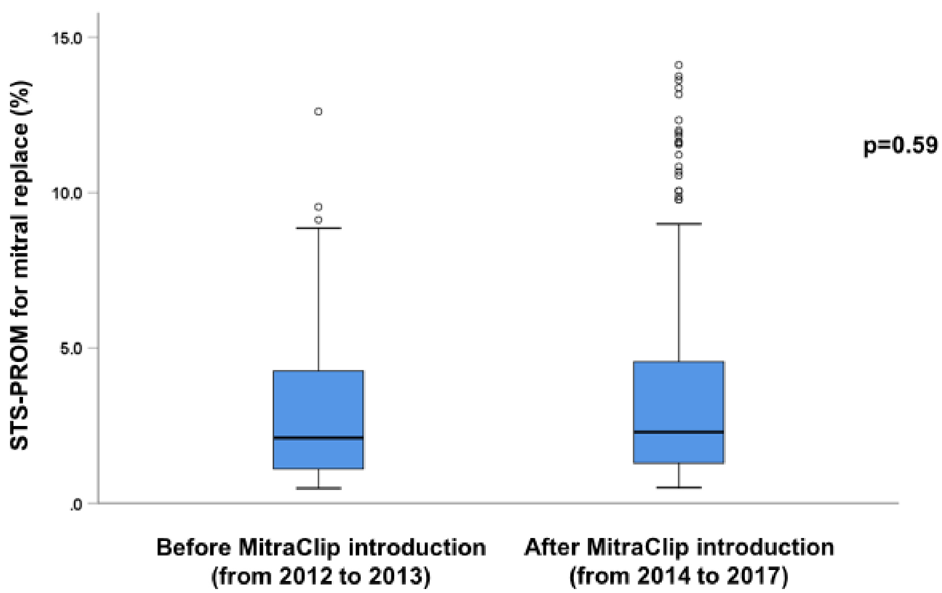
| | 2012 (n=63) | 2013 (n=70) | 2014 (n=104) | 2015 (n=108) | 2016 (n=125) | 2017 (n=156) | p value |
|---|---|---|---|---|---|---|---|
| Age, mean (SD), yrs | 62.6 (11.2) | 64.5 (12.6) | 65.0 (12.9) | 64.6 (13.0) | 63.1 (12.2) | 65.2 (12.3) | 0.62 |
| Male, n (%) | 33 (52.4) | 47 (67.1) | 69 (66.3) | 72 (66.7) | 73 (58.4) | 94 (60.3) | 0.31 |
| BMI, mean (SD), kg/m$^2$ | 28.1 (5.6) | 28.1 (6.1) | 27.1 (5.2) | 28.0 (5.9) | 27.9 (5.3) | 28.3 (5.8) | 0.58 |

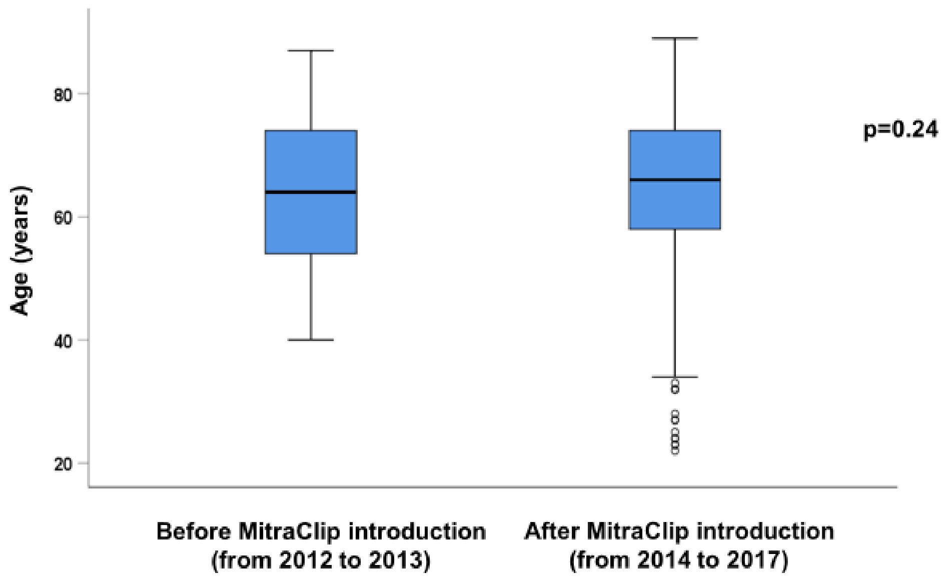
**Table S2. One-year clinical outcomes according to procedural types.**

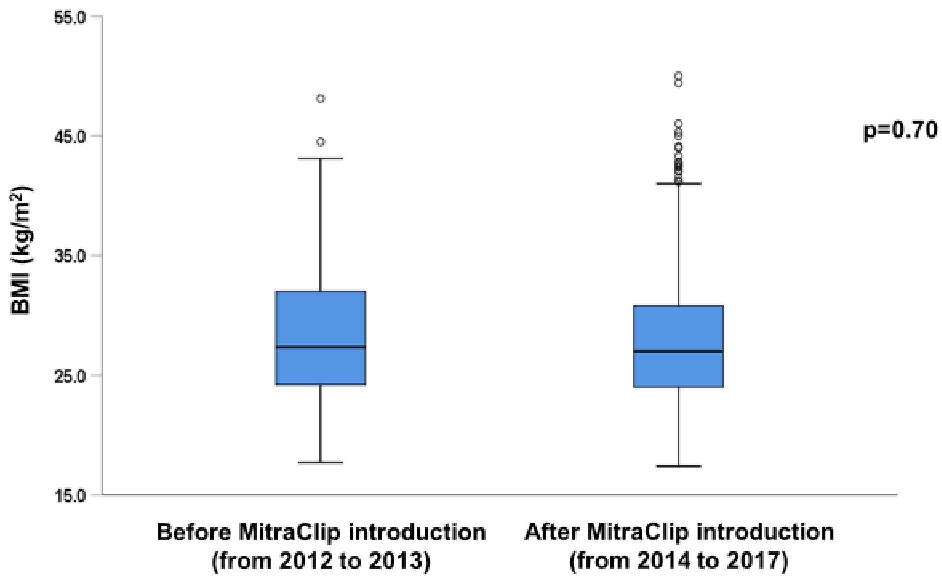
| | No. (%) | | | | |
|---|---|---|---|---|---|
| **Variable** | **All** | **MitraClip** | **Surgical repair** | **Surgical replacement** | **P value** |
| All patients | 875 | 249 | 373 | 253 | |
| All-cause mortality | 84 (9.6) | 47 (18.9) | 10 (2.7) | 27 (10.7) | <0.001 |
| Cardiac death | 34 (3.9) | 19 (7.6) | 4 (1.1) | 11 (4.3) | <0.001 |
| Rehospitalization for heart failure | 42 (4.8) | 19 (7.6) | 6 (1.6) | 17 (6.7) | 0.001 |
| Death or rehospitalization for heart failure | 103 (11.8) | 55 (22.1) | 19 (5.1) | 29 (11.5) | <0.001 |
| Reintervention | 33 (3.8) | 22 (8.8) | 9 (2.4) | 2 (0.8) | <0.001 |
| Surgical replacement | 12 (1.4) | 7 (2.8) | 3 (0.8) | 2 (0.8) | 0.10 |
| Surgical repair | 4 (0.5) | 0 | 4 (1.1) | 0 | 0.10 |
| Transcatheter mitral repair with MitraClip | 17 (1.9) | 15 (6.0) | 2 (0.5) | 0 | <0.001 |

**Figure S1. Comparison of baseline characteristics between before and after commercial introduction of MitraClip in the surgery patients.**



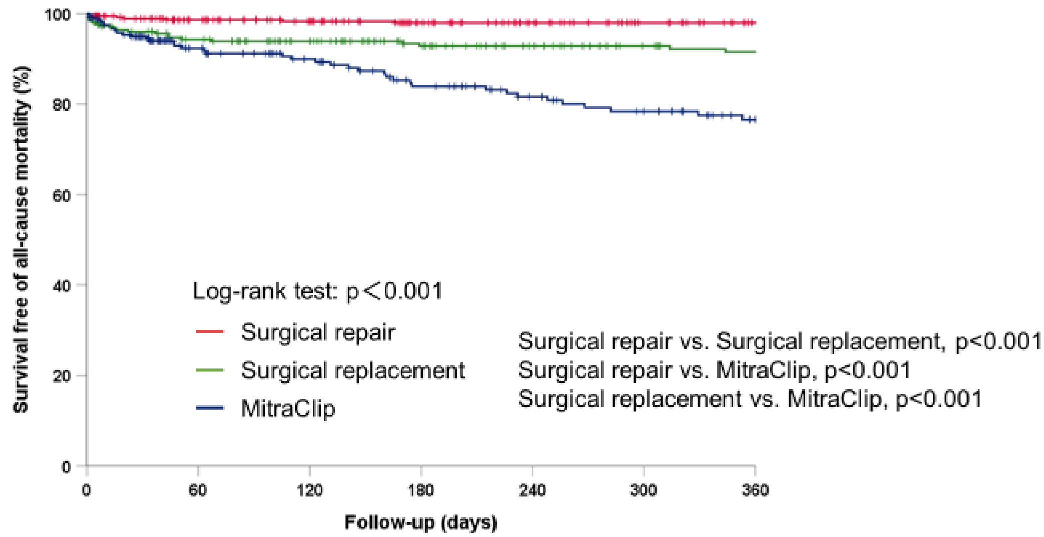





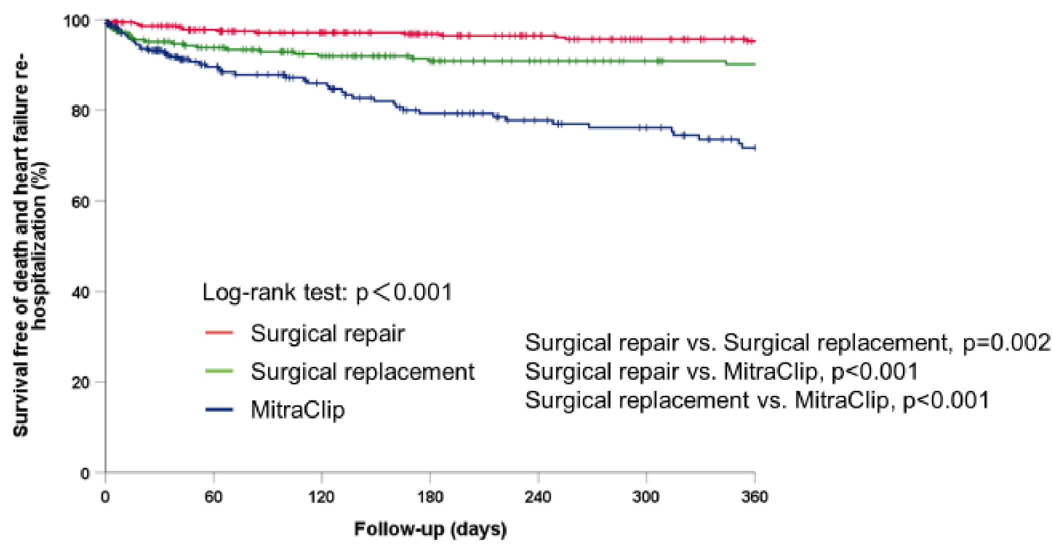

A, Society of Thoracic Surgery Predicted Risk of Mortality (STS-PROM) for mitral repair. B, STS-PROM for mitral replacement. C, Age. D, Body mass index (BMI).

**Figure S2. Survival according to procedure types.**




No. at risk

| | 0 | 60 | 120 | 180 | 240 | 300 | 360 |
|---|---|---|---|---|---|---|---|
| Surgical repair | 373 | 331 | 306 | 280 | 257 | 238 | 222 |
| Surgical replacement | 253 | 220 | 199 | 176 | 157 | 144 | 138 |
| MitraClip | 249 | 163 | 141 | 119 | 104 | 94 | 79 |




No. at risk

| | 0 | 60 | 120 | 180 | 240 | 300 | 360 |
|---|---|---|---|---|---|---|---|
| Surgical repair | 373 | 330 | 304 | 276 | 253 | 233 | 217 |
| Surgical replacement | 253 | 211 | 186 | 162 | 147 | 135 | 130 |
| MitraClip | 249 | 163 | 141 | 119 | 104 | 94 | 79 |

A, Survival free of all-cause mortality. B, Survival free of the combined endpoint of all-cause mortality or heart failure re-hospitalization.

**Figure S3. Comparison of hazard ration of one-year all-cause mortality between surgery and MitraClip groups per calendar year.**