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**Valve:** Research

# Edge-to-Edge Technique Used as a Bailout for Suboptimal Mitral Repair: Long-term Results

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## ABSTRACT

**BACKGROUND** For cases of initial suboptimal mitral valve repair, the edge-to-edge (EE) technique has been used as a bailout procedure. However the long-term durability of those rescued mitral valves is currently unknown. With this study we aim to evaluate the long-term clinical and echocardiographic results of the EE technique used to rescue patients with initial suboptimal conventional mitral valve repair.

**METHODS** A retrospective review of our institutional database was done to query for patients who had undergone mitral valve repair with the EE technique used as a bailout procedure. The cumulative incidence function using death as a competing event was used to estimate cardiac death and redo for mitral valve replacement. To describe the time course of mitral regurgitation, we performed a longitudinal analysis using generalized estimating equations with random intercept for correlated data.

**RESULTS** Eighty-one patients were selected. The median follow-up was 9.1 years (interquartile range, 6.7-12.1; maximum, 22.6 years). At 15 years the estimated Kaplan-Meier overall survival was 63.2% ± 8.69% (95% confidence interval, 43.76-77.46) and the predicted rate of moderate to severe mitral regurgitation recurrence was 16.67%. At 15 years the cumulative incidence function for redo for mitral valve replacement with death as a competing event was 2.5% (95% confidence interval, 0.48-7.84). No case of more than mild mitral stenosis was detected.

**CONCLUSIONS** The EE technique can be effectively used as a bailout procedure in patients with suboptimal conventional mitral valve repair with satisfactory long-term results.

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The absence of residual mitral regurgitation (MR) after mitral valve repair is of paramount importance for long-term durability of the repair.[1,2] Thus ideally after weaning from cardiopulmonary bypass (CPB), transesophageal echocardiography (TEE) should show no (or only trivial) residual MR, a good length of leaflet coaptation, and no iatrogenic mitral valve stenosis. However more than mild residual MR can be present in up to 4% of patients after the initial repair,[3] and a second CPB run may be necessary to improve such a suboptimal result.

Several mechanisms of residual MR have been described: Some can be defined as dynamic (systolic anterior motion [SAM], severe postoperative left ventricular dysfunction), whereas others are indeed anatomic and related to residual prolapse, cleft, and suture or ring dehiscence.[4] In most cases medical therapy can be effective in the resolution of an intraoperatively detected SAM.[5] Similarly residual clefts or suture dehiscence can be easily corrected during a second CPB run. However in other cases SAM might not be responsive to conservative maneuvers or

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the residual regurgitant jet requires complex and time-consuming techniques to be addressed; occasionally, in the worst case scenario, a replacement of the valve might become necessary. Under those circumstances in our institution the edge-to-edge (EE) technique has been used as a bailout procedure.[6]

The anatomic characteristics of the mitral valve after an initial suboptimal repair are certainly not ideal for the EE technique because of a possible significant reduction in the valve area, especially in an initial resection of the posterior leaflet or implantation of a relatively small ring. Despite this the EE technique used to rescue patients with suboptimal initial repair proved to be durable at a median follow-up of about 5 years.[7] Whether those rescued mitral valves are associated with satisfactory outcomes in the long term remains unknown. With this study we aimed to evaluate the long-term (median follow-up, 9.1 years [interquartile range, 6.7-12.1]; maximum, 22.6 years) clinical and echocardiographic results of the EE technique used to rescue patients with initial suboptimal conventional mitral valve repair.

## MATERIAL AND METHODS

**ETHICS STATEMENT.** The Ethical Committee of the San Raffaele Hospital approved the study (CE:101/INT/2021) and waived the individual informed consent for this retrospective anonymous analysis.

**STUDY POPULATION AND FOLLOW-UP.** A retrospective review of our institutional database was carried out querying for all patients who underwent a second CPB run after suboptimal initial mitral valve repair and in whom the EE technique was performed as a bailout without undoing the initial repair. For the purpose of the study we excluded all patients in whom other surgical procedures besides the rescue EE technique were used during the second pump run (cleft closure, repair of suture or ring dehiscence, or change in ring size). Similarly patients who had the primary repair undone before performing the bailout EE technique were excluded. To have a very long-term follow-up we selected patients within the time frame from 1999 to 2015. Patient charts were then analyzed to obtain details about preoperative characteristics, intraoperative variables, and in-hospital outcomes.

Survival and echocardiographic follow-ups were carried out using the informatics hospital system for outpatient clinic visits and echocardiographic examinations. Echocardiographic intervals were decided by the primary physician. If follow-up information was not present in the hospital system, patients and the referring cardiologists were reached by phone call and asked to provide all echocardiographic examinations performed. In these cases we evaluated only the echocardiographic report and not the actual DICOM image. Cause of death was determined by death certificates or information from the physician who was caring for the patient at that time.

**TABLE 1 Preoperative and Intraoperative Characteristics of the Patient Cohort (N = 81)**

| Characteristic | Values |
|---|---|
| Age, y | 57 ± 12.3 |
| Male gender | 60 (74) |
| New York Heart Association class | |
| I | 24 (30) |
| II | 35 (43) |
| III | 22 (27) |
| Median left ventricular ejection fraction, % | 60 (55-62) |
| Median end-diastolic diameter, mm | 57 (52-60) |
| Systolic pulmonary artery pressure, mm Hg | 37 ± 9 |
| Atrial fibrillation | 17 (21) |
| Redo | 1 (1) |
| Mitral regurgitation etiology | |
| Degenerative | 74 (92) |
| Fibroelastic deficiency | 18 (22) |
| Myxomatous degeneration | 56 (69) |
| Healed infective endocarditis | 6 (7) |
| Posttraumatic | 1 (1) |
| Preoperative prolapsing leaflet | |
| Posterior leaflet | 70 (86) |
| Anterior or bileaflet | 11 (14) |
| Initial technique used | |
| Ring annuloplasty | 81 (100) |
| Posterior leaflet resections ± sliding/folding plasty | 69 (85) |
| Artificial chordae implantation | 12 (15) |
| Ring characteristics | |
| Complete ring | 17 (21) |
| Band | 64 (79) |
| Median ring diameter, mm | 34 (32-38) |
| Associated procedure | |
| Aortic valve replacement | 2 (2) |
| Coronary artery bypass | 5 (6) |
| Tricuspid valve repair | 10 (12) |
| Atrial fibrillation ablation | 7 (8) |

Values are mean ± SD, n (%) or median (interquartile range).

**STATISTICAL ANALYSIS.** Continuous normal distributed variables are expressed as mean ± SD and continuous nonnormal variables median (25th percentile; 75th percentile). Categorical data are described as absolute (%). Missing data were handled by a single imputation of mean value (some data were missing for left ventricular end-diastolic diameter). The primary endpoint was MR recurrence, whereas secondary endpoints were mortality (overall and cardiac) and reoperation for severe MR. The Kaplan-Meier method was used to estimate survival during follow-up, and the log-rank test was used to make intergroup comparisons. To

identify risk factors for mortality during follow-up, a univariate and multivariable Cox regression was used.

The cumulative incidence function (CIF) using death as a competing risk was used to estimate cardiac death and reoperation for severe MR. The nonparametric Pepe-Mori test was used to make intergroup comparison between patients with central EE and para-commissural EE techniques and between patient with rescue EE technique because of SAM and residual prolapse. The Fine and Gray model for competing risk analysis was used to evaluate the predictors of cardiac death (with death for other reasons as a competing risk) and for reoperation with death for any reason as a competing risk. Covariates with a $P < .1$ at univariate analysis were included in the multivariable model. Finally, to describe the time course of MR recurrence during follow-up, we performed a longitudinal analysis using generalized estimating equations with a random intercept for correlated data. All analyses were performed with Stata software (version 15; StataCorp, College Station, TX).

**SURGICAL DETAILS AND ECHOCARDIOGRAPHIC ANALYSIS.** Most operations were performed through a conventional midline sternotomy (n = 68, 84%). The remaining 13 patients (16%) underwent minimally invasive mitral repair through a mini-thoracotomy approach. Intermittent antegrade cold blood cardioplegia or a single-dose of Custodiol crystalloid cardioplegia were used according to the preference of the operating surgeon. The water test was systematically used at the end of the initial repair. Afterward patients were weaned from CPB, and the competence of the mitral valve was systematically assessed by TEE. If SAM was detected, conservative management consisting of intravascular volume expansion, discontinuation of inotropic drugs, and eventually administration of beta-blockers was attempted.[8] If the SAM was not responsive to the medical management, surgical correction during a second pump run was considered unavoidable. When the TEE showed a residual MR more than mild that was not SAM related, a second CPB run was started to reassess the leaking mitral valve. In all patients included in this series a central or commissural rescue EE repair was performed according to the regurgitant jet location identified at the TEE or in case of residual prolapse by combining the information derived from the TEE with a careful direct intraoperative reassessment of the mitral valve.

The ring annuloplasty can cause a significant reduction of the mitral valve area, especially when resection techniques are used. Therefore extreme care was taken to keep the EE suture as short as possible to avoid iatrogenic mitral stenosis. In some patients with refractory postoperative SAM a single 4.0 polypropylene U-stitch was applied to fix the problem. The distance of the suture bites from the free edges was variable according to the anatomic findings. In patients with SAM the distance was usually around 1 cm or more to prevent the motion of the leaflets into the left ventricle outflow tract. The final valve area after the rescue EE technique was assessed by direct inspection and, in case of doubt, by the introduction of Hegar dilators. A global valve area of at least 2.5 $cm^2$ was considered satisfactory for normal-sized patients.

The valve was carefully reanalyzed by TEE after weaning from the second CPB to assess its competence and measure its final area, usually by a planimetric method using the transgastric short-axis view. According to European guidelines[9] an integrative approach considering both qualitative and quantitative parameters was used to estimate the MR grade.

**TABLE 2 Residual Defects Responsible for Suboptimal Repair and Surgical Details of the Bailout Edge-to-Edge Technique**

| Characteristic | Values |
|---|---|
| Residual mitral regurgitation due to systolic anterior motion | 20 (25) |
| Residual mitral regurgitation due to residual prolapse | 61 (75) |
| Residual posterior leaflet prolapse | 36 (44) |
| Residual anterior leaflet prolapse | 14 (17) |
| Residual bileaflet prolapse | 10 (12) |
| Malcoaptation due to postendocarditis free margin erosion | 1 (1) |
| Second cardiopulmonary bypass run time, min | 29 ± 5 |
| Second cross-clamp time | 16 ± 3 |
| Central (A2-P2) rescue edge-to-edge | 53 (65) |
| Para-commissural rescue edge-to-edge | |
| Anterolateral commissure | 8 (10) |
| Posteromedial commissure | 20 (25) |

Values are n (%) or mean ± SD.

**TABLE 3 Postoperative Data and Complications**

| Variable | Values |
|---|---|
| Median postoperative in-hospital stay, days | 5 (4-7) |
| Mean postoperative intensive care unit stay, h | 18 ± 5 |
| Low cardiac output syndrome | 3 (3.7) |
| Pericardial effusion | 2 (2.4) |
| Acute renal failure[a] | 2 (2.4) |
| Prolonged ventilatory support (>48 h) | 1 (1.2) |
| Permanent pacemaker implantation | 1 (1.2) |
| Reexploration for bleeding | 2 (2.4) |
| Transitory ischemic attack | 1 (1.2) |
| Valve area at discharge, $cm^2$ | 2.8 ± 0.6 |
| Gradient at discharge, mm Hg | 4.4 ± 1.4 |

[a]Defined as an increase in creatine values ≥ 50% of the base value. Values are mean ± SD, n (%) or median (interquartile range).

Particularly moderate MR was subcategorized as moderate to severe MR when the effective regurgitant orifice area and the regurgitant volume were within the range 30 to 39 mm$^2$ and 45 to 59 mL, respectively.[9]

## RESULTS

**PATIENTS CHARACTERISTICS, INTRAOPERATIVE VARIABLES, AND IN-HOSPITAL RESULTS.** During the study period (1999-2015) 5599 patients underwent mitral valve repair at our institution. Of these 5599 patients, 208 patients (3.4%) required a second cross-clamp. Of these 208 patients, 81 (1.4%) fulfilled the inclusion criteria and were included in the study cohort. In our center rescue EE repair was the first option when the anatomic situation was suitable. In 116 patients other techniques were used (eg, EE technique added to other surgical techniques such as cleft closure, change in the ring size, etc). Finally the remaining 11 patients underwent mitral valve replacement. Mean patient age was 57 ± 12.3 years. Table 1 describes the baseline characteristics of the study cohort.

Sixty-nine of 81 patients (85%) underwent posterior leaflet resections. Residual MR was due to SAM in 20 patients (25%) and to residual prolapse in the remaining 61 patients (75%). In some patients by revising the mitral anatomy, a new unexpected prolapse was present in a commissural region or in a segment of the valve that was not supposed to prolapse according to the initial mitral valve assessment. In other patients a residual prolapse was present at the level of the resection. Residual MR was intraoperatively graded moderate in 28 patients (34%), moderate to severe in 32 patients (40%), and severe in the remaining 21 patients (26%). Details about the mechanism of residual MR are provided in Table 2.

A central EE (A2-P2) technique was used in 53 patients (65%) and a para-commissural EE technique in 28 patients (35%). The mean time of a second cross-clamp was 16 ± 3 minutes. No left ventricular outflow track obstruction was detected in patients with initial residual MR due to SAM after the rescue EE repair. In this relatively small cohort there was no hospital mortality, and the median length of hospital stay was 5 days (interquartile range, 4-7). Table 3 summarize postoperative data and complications.

At discharge the MR was graded as absent or trivial in 61 patients and as mild (1+/4+) in 20 patients. No patient had more than mild MR or significant mitral stenosis at the transthoracic echocardiogram performed before hospital discharge. Mean area at discharge was 2.8 cm$^2$, and mean gradient at discharge was 4.4 mm Hg. No significant difference in the postoperative mean gradient and valve area was noted between patients with central and para-commissural EE repairs. Similarly, no difference in the postoperative valve area and mean gradient was noted between the EE technique due to residual prolapse or due to SAM.

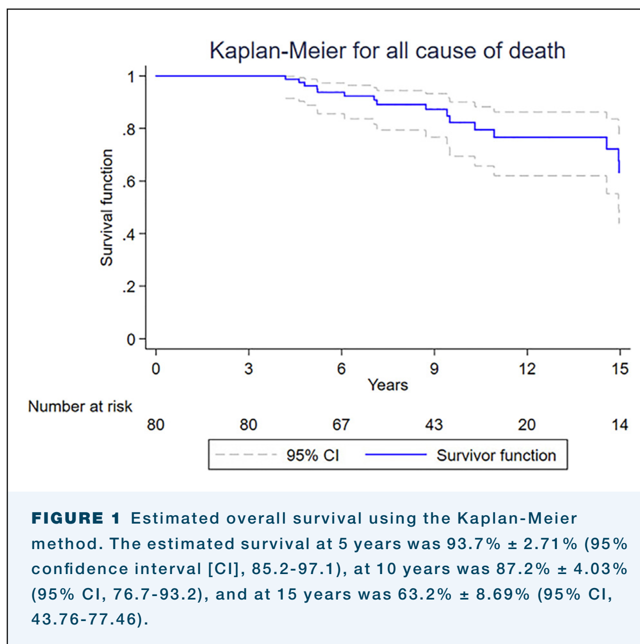


**FIGURE 1** Estimated overall survival using the Kaplan-Meier method. The estimated survival at 5 years was 93.7% ± 2.71% (95% confidence interval [CI], 85.2-97.1), at 10 years was 87.2% ± 4.03% (95% CI, 76.7-93.2), and at 15 years was 63.2% ± 8.69% (95% CI, 43.76-77.46).

**SURVIVAL ANALYSIS.** Clinical and echocardiographic follow-up were 99% complete, with a median follow-up of 9.1 years (interquartile range, 6.7-12.1; maximum, 22.6 years). The follow-up index was 0.74.

During follow-up 16 patients died (20%), for an estimated Kaplan-Meier overall survival of 63.2% ± 8.69% (95% confidence interval [CI], 43.76-77.46) at 15 years (Figure 1). Age at surgery was the only significant risk factor for mortality during follow-up in the univariate

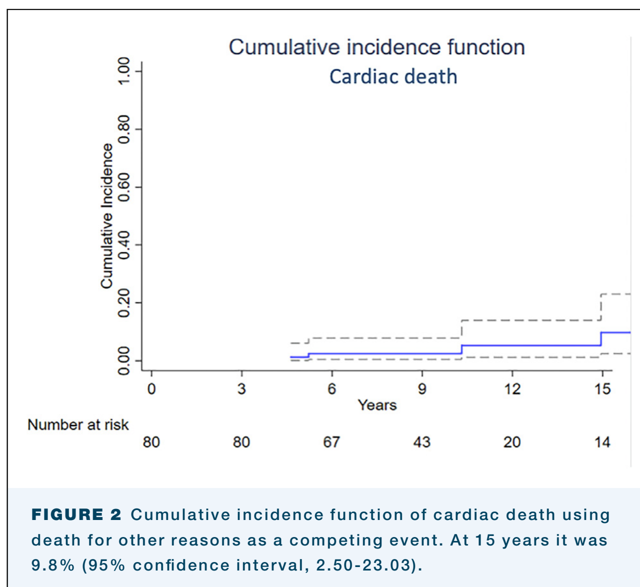


**FIGURE 2** Cumulative incidence function of cardiac death using death for other reasons as a competing event. At 15 years it was 9.8% (95% confidence interval, 2.50-23.03).

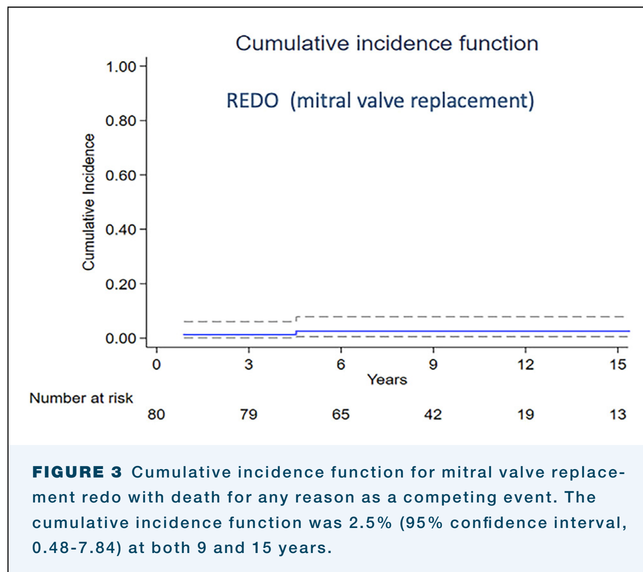


**FIGURE 3** Cumulative incidence function for mitral valve replacement redo with death for any reason as a competing event. The cumulative incidence function was 2.5% (95% confidence interval, 0.48-7.84) at both 9 and 15 years.

analysis (hazard ratio, 1.49; 95% CI, 1.24-1.78; $P < .001$). At the last outpatient visit 58 of 80 patients (72%) were in New York Heart Association class I.

Of the 16 total late deaths, only 4 were cardiac related. At 15 years the CIF for cardiac death, with noncardiac death as a competing event, was 9.8 (95% CI, 2.50-23.03) (Figure 2). Using the Fine and Gray model age at surgery was the only significant risk factor for cardiac death (hazard ratio, 1.30; 95% CI, 1.13-1.50; $P < .001$). Using the nonparametric Pepe-Mori test we found no difference in the CIF for cardiac death (with death for other reasons as a competing event) between patients with rescue EE repair due to SAM or due to residual prolapse. Similarly no difference was noted between patients with central (A2-P2) and para-commissural EE repair in the CIF for cardiac death with death for other reasons as a competing event.

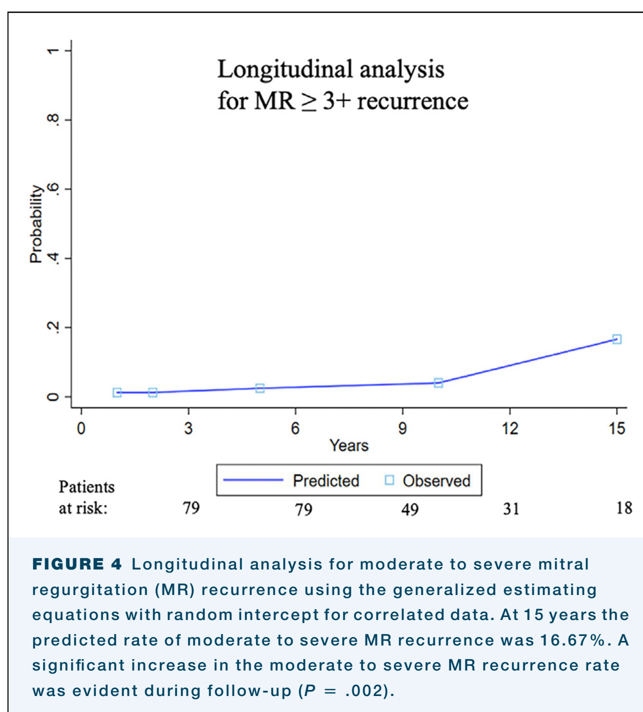


**FIGURE 4** Longitudinal analysis for moderate to severe mitral regurgitation (MR) recurrence using the generalized estimating equations with random intercept for correlated data. At 15 years the predicted rate of moderate to severe MR recurrence was 16.67%. A significant increase in the moderate to severe MR recurrence rate was evident during follow-up ($P = .002$).

**REDO RATE AND MR RECURRENCE.** During the study period mitral valve replacement for severe MR was necessary in 2 patients. At 15 years the CIF for redo for mitral valve replacement with death as a competing event was 2.5% (95% CI, 0.48-7.84) (Figure 3). Using the Fine and Gray model anterior or bileaflet prolapse emerged as a significant risk factor for reoperation (hazard ratio, 15.42; 95% CI, 1.35-17.81; $P = .028$).

The longitudinal analysis performed by means of the generalized estimating equations showed a significant increase in the rate of moderate to severe ($\geq$3+) MR during follow-up ($P = .002$) (Figure 4). At 5 years the predicted rate of MR $\geq$3+ recurrence was 5.45% and at 15 years was 16.67%. At the multivariate analysis atrial fibrillation emerged as the only significant risk factor for MR $\geq$3+ recurrence (odds ratio, 5.64; 95% CI, 1.39-22.86; $P = .015$). The actual incidence of moderate to severe recurrent MR was 8.8% (7/80). At the last follow-up 21 patients were in atrial fibrillation.

Dividing the patients into central EE and para-commissural EE repair, no difference in the recurrence rate of moderate to severe MR was noted. Similarly dividing patients into rescue EE technique due to residual prolapse and to SAM no difference in the moderate to severe MR recurrence rate was highlighted (Figure 5). Finally, no case of significant mitral stenosis was detected during follow-up. Mean area was 2.6 $\pm$ 0.7cm$^2$, and mean gradient was 5.1 $\pm$ 1.6 mm Hg. Fifty-eight of 80 patients (72%) had their echocardiography performed at our institution.

## COMMENT

The long-term durability of mitral valve repair depends on several factors, among the most important of which is absence of residual MR after the procedure.[2] However in centers with extensive expertise in mitral valve repair a second or even third CPB run may at times be necessary to achieve a perfect repair with no residual MR.[10] Sometimes the causes of the residual MR can be easily identified and corrected (residual cleft or suture dehiscence). In other cases, however, the mechanism of residual MR remains unclear or may be quite complex, thereby requiring complex and time-consuming re-repair with a significant increase in CPB and cross-clamp times, which is a known risk factor for worse in-hospital outcomes.[2]

In such situations the EE technique, because of its simplicity and versatility, can be extremely useful to

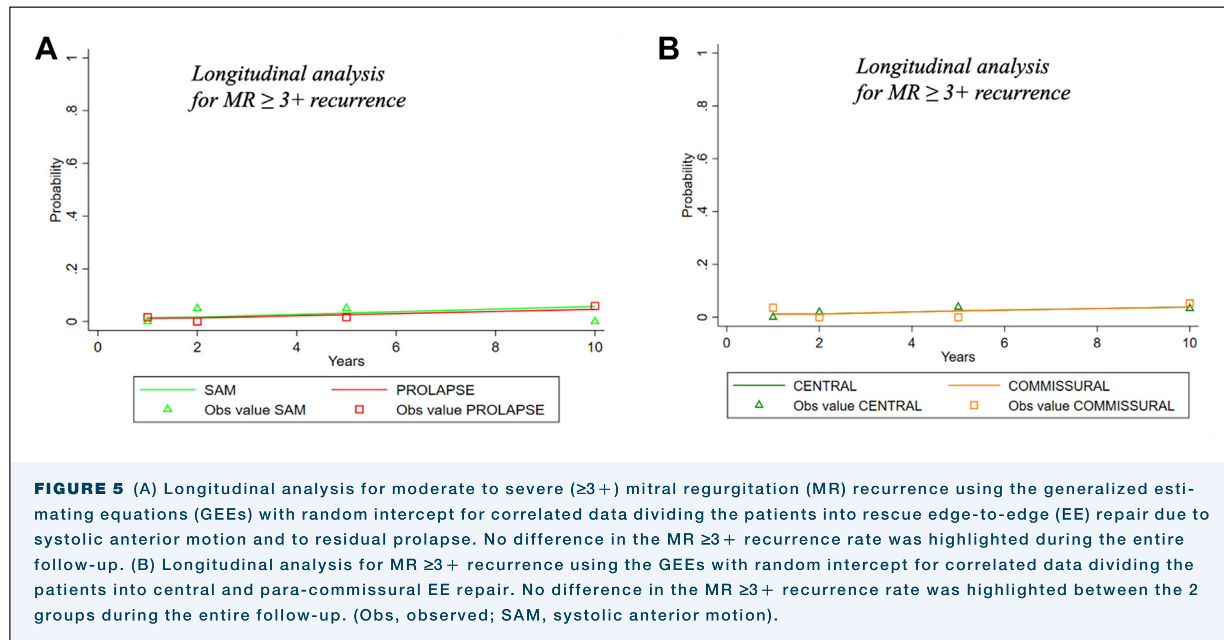


**FIGURE 5** (A) Longitudinal analysis for moderate to severe (≥3+) mitral regurgitation (MR) recurrence using the generalized estimating equations (GEEs) with random intercept for correlated data dividing the patients into rescue edge-to-edge (EE) repair due to systolic anterior motion and to residual prolapse. No difference in the MR ≥3+ recurrence rate was highlighted during the entire follow-up. (B) Longitudinal analysis for MR ≥3+ recurrence using the GEEs with random intercept for correlated data dividing the patients into central and para-commissural EE repair. No difference in the MR ≥3+ recurrence rate was highlighted between the 2 groups during the entire follow-up. (Obs, observed; SAM, systolic anterior motion).

rescue patients with suboptimal initial mitral repair with a low rate of MR recurrence at a median follow-up of 5 years.[7] Compared with a study previously published by our group,[7] the present study corroborates those results with a significantly longer median follow-up and also adds some important information such as the absence of significant differences in the MR recurrence rates between central and para-commissural rescue EE repair and between patients in whom the failure of the initial repair was due to SAM or residual prolapse. Moreover, compared with our previous study, in the present study the cohort size was considerably bigger, the median follow-up was doubled, and much more echocardiographic details were collected (including also the analysis of the time course of MR recurrence). Thus this more detailed information supported the good result of the EE technique used as a bailout for initial suboptimal repair.

As expected we observed that postoperative SAM was significantly more common in the early phase of the study period, when surgical techniques aimed at decreasing more effectively the height of the posterior leaflet (sliding, folding, butterfly) were not extensively adopted. On the other hand residual prolapse can be the result of misinterpretation of the initial MR mechanism, and that consequential imperfect surgical decision and its rate remained substantially constant during the study period. In both situations undoing of the initial repair with or without the addition of other techniques may be necessary to restore mitral valve competence. This might lead to a significant increase in the cross-clamp time with related deleterious effects.[2] Moreover in small centers with low expertise in mitral valve repair, the presence of significant residual MR after the initial repair could be treated with mitral valve replacement with an even worse in-hospital and long-term outcome. In our opinion the EE technique used as a bailout represents a very useful surgical tool to avoid these 2 deleterious situations (valve replacement in a valve amenable for repair and long cross-clamp times).

However it is important to emphasize that the anatomic situation of a mitral valve after an initial suboptimal repair is certainly not ideal for an EE technique. Indeed the presence of a small ring and the adoption of resection techniques for the posterior leaflet can cause a significant reduction of the mitral valve area. Thus extreme care must be taken to maintain the EE repair as short as possible to avoid iatrogenic mitral valve stenosis. In our cohort most patients were discharged from the hospital with a mitral valve area > 2.5 $cm^2$ and very few with a valve area between 2 and 2.5 $cm^2$. During follow-up no case of significant mitral valve stenosis was detected.

Because of the limited size of the study cohort, the analysis of the risk factors for MR recurrence and redo must be interpreted cautiously. However our results are in line with the literature showing an increased risk of MR recurrence and redo for patients with anterior and bileaflet prolapse and atrial fibrillation.[1,2]

Nevertheless, regardless of the initial technique adopted, mitral valve repair does not cure the underlying degenerative process, and late recurrent MR remains a potential problem, especially in the very long term.[11] In the past freedom from reoperation was largely

considered the best indicator for mitral valve repair success. In the recent years this assumption has been heavily questioned, and currently it is a common view that the MR recurrence rate should be considered the gold standard to evaluate the success of mitral valve repair.[10] In our cohort we noticed a moderate to severe MR recurrence rate of 2.53% at 5 years and of 16.67% at 15 years. These results are in line with the most recent report from a tertiary center with extensive expertise in mitral valve repair,[10] and thus we are relatively confident in stating that the EE technique used to rescue patients with suboptimal initial mitral repair can provide very good results without compromising the durability of the repair in the long term.

Finally during the last years the use of transcatheter EE repair for MR recurrence after surgical mitral valve repair has significantly increased, although only scant data are available in the literature. Although our surgical rescue EE technique is inevitably different from the transcatheter EE repair, the results of this report may confirm and reinforce the role of transcatheter EE repair as the application to treat selected patients with failed surgical mitral repair.

**LIMITATIONS.** The main limitations of our study are related to its retrospective nature and to the limited size of the study cohort. Moreover not all the echocardiograms were performed in our institution. Nevertheless the echocardiographic follow-ups were consciously collected, being aware of the aforementioned limit, and are complete enough to provide solid and comprehensive conclusions about the rate of MR recurrence. Also the inclusion of only 1 patient with MR because of blunt chest trauma may be debatable, but the inclusion of this single patient does not alter the results and may provide an awareness to also consider EE repair in such an acute and rare condition.

**CONCLUSION.** The EE technique can be effectively used as a bailout procedure in patients with suboptimal mitral repair with good results also when the follow-up is extended up to 15 years. The rate of moderate to severe MR recurrence and the redo rate were equally low. The location of the EE repair (central vs paracommissural) and the reason for the EE repair (SAM vs residual prolapses) do not seem to influence the durability of the repair. Because of its simplicity, versatility, and durability in our center the EE technique represents the first option to rescue patients with suboptimal initial mitral repair.

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### DISCLOSURES

The authors have no conflicts of interest to disclose.

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