Mitral valve surgery after failed MitraClip—Operation for the inoperable?

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Abstract

Background: Percutaneous edge-to-edge mitral valve repair technique (MitraClip) is a widely used treatment for mitral regurgitation (MR) in patients assessed with high surgical risk or inoperability. Only limited experiences with this highest-risk patient population exist. Procedural failure for MitraClip or recurrent MR is a strong predictor of 1-year mortality. Open mitral valve surgery constitutes the last bailout for patients within this cohort.

Methods: This retrospective single-center cohort study analyzed 17 mitral valve surgery patients after failed MitraClip. We, therefore, analyzed a high-risk patient population (EuroSCORE II = 10 ± 2.0) with persistent mitral valve regurgitation, which was mainly caused by detachment or dislocation of the MitraClip.

Results: Symptomatic patients with failed MitraClip need a convenient operation (mean time to mitral valve surgery = 23 ± 44 days). The patient's collective showed many complex reoperations with the need for concomitant surgery. Considering the high-risk patient population, we showed an average 30-day all-cause mortality (18%, n = 3) accompanied by typical postoperative complications related to prolonged mechanical ventilation (44 ± 48 h) and ICU stay (11 ± 11 days), reflecting high-risk patients. Further, excellent valve-related outcomes were shown regarding adverse cardiac events (valve-related mortality 6%, n = 1) and postoperative echocardiographic results (moderate or severe paravalvular leak 6%, n = 1).

Conclusion: Failure of MitraClip represents a challenging situation limited by high-risk profiles of patients and limits the possibility of surgical valve repair, shown by a high rate of mitral valve replacement (94%, n = 16). Secondary surgery was associated with moderate 30-day and postdischarge outcomes. Therefore, a careful evaluation of patients undergoing MitraClip is of paramount importance.
INTRODUCTION

Mitrval valve repair with the percutaneous edge-to-edge mitral valve repair technique (MitraClip) became a widely used intervention for mitral regurgitation (MR) in patients assessed with high surgical risk or inoperability. Failure of MitraClip and higher-grade recurrent MR strongly predicts increased 1-year mortality.\(^1,2\) In most cases of failed MitraClip, the open mitral valve surgery constitutes the last bailout for this patient cohort.\(^3\) Indication for operation is mostly driven by a recurrent MR (>88% of cases), sometimes accompanied by mitral stenosis.\(^2\) Still, only limited experiences with this highest risk patient population exist. A careful evaluation of patients undergoing MitraClip by the heart team and comprehensive preoperative evaluation is of paramount importance. Our study aims to contribute to further exploration and refinement of patient selection criteria and predictors for MitraClip failure.

METHODS

2.1 Study population

This study retrospectively analyzed a cohort of 17 patients with failed MitraClip concerning pre-MitraClip characteristics, peri-interventional and intraoperative variables, and postoperative outcomes after reoperation for failed MitraClip. All perioperative data were extracted from our institutional database. The manuscript was submitted to the local ethics committee, which stated that we are exempted from applying for ethical approval under German law. No separate ethics application or statement of ethical approval by the local ethics committee is required to perform purely retrospective clinical studies.

2.2 Variables of interest

First, we analyzed patients’ preoperative characteristics before MitraClip intervention, as shown in Table 1. Therefore, we extracted data regarding the patient’s age, body mass index, sex, medical history about the cardio-vascular disease, NYHA functional class, echocardiographic evaluation of the mitral and tricuspid valve, and the EuroSCORE II for risk assessment.

Second, peri-interventional characteristics (Table 2) of patients undergoing MitraClip were collected, analyzing the number of implanted clips, the potential cause of failed clip implantation, echocardiographic assessment, and short-term clinical outcomes.

Third, the perioperative characteristics of patients undergoing open mitral valve surgery are displayed in Table 3. Data concerning time to mitral valve surgery after MitraClip, the urgency of operation, complexity, and type of mitral valve operation were analyzed retrospectively.

Table 4 shows postoperative outcomes after open mitral valve surgery due to failed MitraClip. The 30-day all-cause mortality and mortality in the follow-up period, adverse cerebro-cardiac events, and postoperative echocardiography characteristics were collected.

2.3 Statistical analysis

The statistical analysis was performed with SPSS-Statistics-25 (IBM Corporation). The data tables show that all data are given as mean and standard deviation (SD) for continuous variables. Categorical variables are expressed as a percentage (number of the sample).

TABLE 1 Preoperative characteristics of patients undergoing MitraClip

| Patient’s characteristics before MitraClip | Value (n = 17) |
|------------------------------------------|-------------|
| Age, years                               | 76 ± 6      |
| Body mass index (kg/m²)                  | 26 ± 5      |
| Men, % (n)                               | 47 (8)      |
| Chronic lung disease, % (n)              | 12 (2)      |
| Renal insufficiency, % (n)               | 65 (11)     |
| Hypertension, % (n)                      | 100 (17)    |
| Diabetes mellitus, % (n)                 | 47 (8)      |
| Previous stroke, % (n)                   | 24 (4)      |
| Peripheral vascular disease, % (n)       | 12 (2)      |
| Pulmonary hypertension, % (n)            | 71 (12)     |
| Atrial fibrillation, % (n)               | 47 (8)      |
| Coronary artery disease, % (n)           | 59 (10)     |
| Previous PCI                             | 24 (4)      |
| Previous heart surgery, % (n)            | 47 (8)      |
| Previous CABG                            | 29 (5)      |
| NYHA functional Classes III–IV, % (n)    | 94 (16)     |
| Decompensation, % (n)                    | 65 (11)     |
| Mitral insufficiency, severe, % (n)      | 82 (14)     |
| Tricuspid insufficiency, severe, % (n)   | 35 (6)      |
| EuroSCORE II                             | 10 ± 2.0    |

Note: Data are expressed as mean ± standard deviation (SD) or percentage (counts) as indicated.

Abbreviations: CABG, coronary artery bypass grafting; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.
Abbreviation: NYHA, New York Heart Association.

Note: Data are expressed as mean ± standard deviation (SD) or percentage (counts) as indicated.

Abbreviation: NYHA, New York Heart Association.

TABLE 2 Periinterventional characteristics of patients undergoing MitraClip

| Periinterventional MitraClip characteristics | Value (n = 17) |
|---------------------------------------------|---------------|
| Number of clips                              | 1.5 ± 0.9     |
| Subjective clinical improvement, % (n)       | 24 (4)        |
| Detachment/dislocation of clip, % (n)        | 29 (5)        |
| Reclinking, % (n)                            | 0 (0)         |
| Perforation of mitral valve, % (n)           | 6 (1)         |
| Periprocedural pericardial tamponade, % (n)  | 6 (1)         |
| Moderate or severe mitral regurgitation, % (n)| 88 (15)       |
| Eccentrical mitral jet, % (n)                | 29 (5)        |
| Moderate or severe mitral stenosis, % (n)    | 12 (2)        |
| Persistent NYHA functional classes III–IV,% (n)| 35 (6)       |
| Persistent peripheral oedema, % (n)          | 35 (6)        |
| Endocarditis, % (n)                          | 12 (2)        |

Note: Data are expressed as mean ± standard deviation (SD) or percentage (counts) as indicated.

Abbreviation: NYHA, New York Heart Association.

TABLE 3 Perioperative characteristics of patients undergoing reoperation after MitraClip

| Perioperative reoperation characteristics | Value (n = 17) |
|------------------------------------------|---------------|
| Time to mitral valve surgery (days)      | 23 ± 44       |
| Urgent operation, % (n)                  | 53 (9)        |
| Emergency operation, % (n)               | 12 (2)        |
| Reoperation, % (n)                       | 47 (8)        |
| Mitral valve replacement, biological, % (n)| 88 (15)      |
| Mitral valve replacement, mechanical, % (n)| 6 (1)        |
| Mitral valve reconstruction, % (n)       | 6 (1)         |
| Concomitant procedures, % (n)            | 47 (8)        |
| Concomitant CABG, % (n)                  | 18 (3)        |
| Concomitant tricuspid valve surgery, % (n)| 47 (8)        |
| Cardiopulmonary bypass time (min)        | 153 ± 54      |
| Aortic cross-clamp time (min)            | 82 ± 26       |
| Operation time (min)                     | 251 ± 75      |

Note: Data are expressed as mean ± standard deviation (SD) or percentage (counts) as indicated.

Abbreviation: CABG, coronary artery bypass grafting.

TABLE 4 Postoperative outcomes of patients after reoperation

| Postoperative outcomes | Value (n = 17) |
|------------------------|---------------|
| Thirty-day all-cause mortality, % (n) | 18 (3)        |
| In hospital mortality, % (n)            | 12 (2)        |
| Valve-related mortality, % (n)          | 6 (1)         |
| Moderate or severe paravalvular leak, mitral % (n) | 6 (1) |
| Permanent new pacemaker implantation, % (n) | 0 (0) |
| Rethoracotomy for bleeding, % (n)       | 12 (2)        |
| Cerebrovascular events, % (n)           | 0 (0)         |
| Perioperative myocardial infarction, % (n) | 0 (0) |
| Acute respiratory syndrome, % (n)       | 24 (4)        |
| Pneumonia, % (n)                        | 12 (2)        |
| Renal failure with new dialysis, % (n)   | 12 (2)        |
| Mechanical ventilation, (h)             | 44 ± 48       |
| Length of ICU stay (days)               | 11 ± 11       |
| Length of hospital stay (days)          | 18 ± 11       |
| Mean pressure gradients (mmHg)          | 5 ± 2         |
| Left ventricular ejection fraction <30 mmHg, % (n) | 18 (3) |
| Mean follow-up after discharge (months)  | 15.8          |
| Death within follow-up, % (n)           | 17 (1)        |

Note: Data are expressed as mean ± standard deviation (SD) or percentage (counts) as indicated.

Abbreviation: ICU, intensive care unit.

3 | RESULTS

3.1 Characteristics of patients undergoing MitraClip

Baseline characteristics of patients (n = 17) before MitraClip (Table 1) were as follows: age = 76 ± 6 years, body mass index = 26 ± 5 kg/m².

3.2 Peri-interventional characteristics of patients undergoing MitraClip

Underlying mitral valve disease was functional MR in 88% (n = 15) and degenerative MR in 18% (n = 3) of cases. The most common indication for surgery was persistent or recurrent MR (Grade > 2) in 88% of cases, whereas in 12% it was mitral stenosis. Etiologies associated with the second mechanism (leaflet perforation) include endocarditis (n = 2).
The mean number of implanted MitraClips was 1.5 ± 0.9, of which 29% (n = 5) showed a detachment or dislocation after application. No case of re-clipping was registered in the reported collective. Other periprocedural complications included perforation of the mitral valve (n = 1) and pericardial tamponade (n = 1). One-fourth (24%, n = 4) of patients reported a subjective clinical improvement within the in-hospital stay, and 35% (n = 6) showed a persistent NYHA functional class III-IV and peripheral edema. Twelve percent (n = 2) of patients developed endocarditis shortly after MitraClip.

3.3 | Perioperative characteristics of patients undergoing secondary mitral valve surgery

The mean time after MitraClip to secondary mitral valve surgery was 23 ± 44 days, of which 53% (n = 9) of patients required an urgent operation and 12% (n = 2) were emergency cases. Almost half of the patients (47%, n = 8) were re-do cases. In 88% (n = 15) of cases, patients received a biological mitral prosthesis, in 6% (n = 1) a mechanical mitral valve and in 6% (n = 1) a mitral valve reconstruction was realized. In 47% (n = 8) of cases, concomitant surgery was reported, with coronary artery bypass grafting (18%, n = 3) and tricuspid valve surgery (47%, n = 8). The mean cardiopulmonary bypass time was 153 ± 54, aortic cross-clamp time was 82 ± 26 min, and the mean operation time was 251 ± 75 min.

3.4 | Postoperative outcomes after secondary mitral valve surgery

The 30-day all-cause mortality after secondary mitral valve surgery was 18% (n = 3), 12% (n = 2) of patients died in hospital. Valve related mortality was 6% (n = 1). A moderate to severe paravalvular leak was reported in 6% (n = 1). No patient needed new pacemaker implantation. A rethoracotomy due to postoperative bleeding occurred in 12% (n = 2) of cases. No cerebrovascular events or periprocedural myocardial infarction were reported. Patients stayed for 11 ± 11 days in the intensive care unit, with a total of 18 ± 11 days in-hospital. Within this time, 24% (n = 4) of patients suffered from an acute respiratory syndrome, and 12% (n = 2) had pneumonia, time of mechanical ventilation reported with 44 ± 48 h. With the need for new dialysis, renal failure occurred in 12% (n = 2). Echocardiography parameters before discharge showed a mean pressure gradient of 5 ± 2 mmHg for the mitral valve. 18% (n = 3) of patients showed a left ventricular ejection below 30%. Within the mean follow-up of 15.8 months, one patient died after being discharged from the hospital. The total mortality was 18% (n = 3).

4 | DISCUSSION

In our study, the 17 patients who underwent mitral valve surgery after performing the MitraClip procedure were initially classified as high surgical risk and, therefore, inoperable regarding conventional mitral valve surgery. The baseline characteristics of patients undergoing MitraClip were comparable with recent literature. The majority of the patients who underwent mitral valve replacements showed a very complex mitral pathology, as shown in Figures 1 and 2. Nevertheless, the in-hospital mortality was acceptable as only two patients died (12%). Our outcome is consistent with recent publications on post-MitraClip failure—surgical treatment as an ultima ratio strategy, in which the feasibility of surgery with acceptable outcomes has been demonstrated. Depending on the operative risk, the indication for surgical therapy after the MitraClip procedure should be made jointly by cardiologists and cardiac surgeons on an interdisciplinary basis. If coronary artery bypass surgery is indicated simultaneously, the indication for surgical treatment of the mitral valve can be given since it is associated with improved survival.

Two large clinical trials, the MITRA-FR and COAPT result in conflicting results about percutaneous repair of secondary severe MR. As shown by the MITRA-FR investigators, patients who underwent MitraClip in addition to medical therapy showed comparable rates of death or hospitalization as patients with medical therapy alone after 12 months. In contrast, the COAPT study...
resulted in a lower rate of hospitalization driven by heart failure and lower all-cause mortality after 24 months in patients undergoing MitraClip in addition to medical therapy when compared to the maximal dose of guideline medical therapy.\(^8\)

Further, randomized trials were performed, allowing a direct comparison between MitraClip and mitral valve surgery in different patient populations.\(^9\) At this moment, mitral valve surgery is slightly superior to MitraClip therapy in terms of safety and efficacy, provided that the risk of cardiac surgery is acceptable. However, transcatheter mitral valve repair failure using a MitraClip device demonstrates a demanding condition with surgical strategies restricted by the high-risk profiles of the patients.\(^10\) Nevertheless, in the hands of experienced surgeons, surgical treatment of the mitral valve disease after the MitraClip procedure is feasible and safe.\(^5\) In the present study, in-hospital mortality was 12% (\(n = 2\)), in the range between 9% and 32% previously published by different authors.\(^2,11–13\) After 1 year, the mortality rate was significantly lower than the other studies published between 2016 and 2019.\(^11,12,14\) When mortality is restricted to valvular causes, the result decreases from 18% to 6%. This trend continues throughout the entire observation period of the study, namely that 1/3 of the deaths occurring in this study did not have a cardiovascular cause.

The definition of treatment success for MitraClip therapy dates back to the EVEREST-1 trial and includes implantation of at least one clip and achievement of a residual mitral insufficiency \(\leq 2^+\).\(^15\) In surgical therapy, on the other hand, treatment success is only considered to have been achieved when the residual mitral insufficiency does not exceed severity level 1+.\(^16\)

According to the study's data on which this paper is based, one of the patients had a mitral insufficiency severity \(\geq 2^+\) postoperatively. These outcomes are slightly better in contrast to Mellillo et al.\(^2\). Nevertheless, data from large registry studies showed that the treatment goal of residual mitral insufficiency \(\leq 1^+\) can be achieved in most cases.\(^17\) It is known from recent studies on mitral valve surgery that residual mitral insufficiency is an important negative prognostic factor.\(^18,19\) This can also be assumed for patients after MitraClip procedures are supported by the previous study results.\(^20\) However, even achieving a residual mitral insufficiency \(\leq 1^+\) during MitraClip treatment is no guarantee that the treatment outcome will remain stable over time. Progress of the underlying disease or detachment of the clip from either sail may increase the severity of residual mitral insufficiency.\(^21\) In this regard, the highest rate of progression is expected within the first 6 months.\(^9\) The postsurgical outcome seems to show both good durability and improvement in clinical symptoms, according to available data.\(^2\) Careful patient selection is essential for this. Furthermore, the anatomical complexity of the pathology probably plays a crucial role. However, previous MitraClip implantation endangered the possibility of surgical valve repair, presented by the high rate (94%) of patients requiring mitral valve replacement. Geidel et al. reported on a case series of \(n = 22\) patients with surgical heart revision after failed MitraClip. Within this collective, the authors also reported a high rate of mitral valve replacement of 86%. The cardiac-related mortality of 4.5% at 30 days was quite low, and after a median follow-up of 4.7 years, 68% of patients were still alive.\(^22\) These data also suggest that surgical revision after failed MitraClip is a safe option concerning the high-risk patient population.

Nevertheless, a randomized controlled study between surgical mitral valve repair and mitral replacement after failed MitraClip is missing regarding long-term survival and quality of the repair. A careful evaluation of patients undergoing MitraClip by the heart team and extensive preoperative evaluation is of prime importance—patients with a failed MitraClip procedure miss out on future surgical valve repair and might have a poor outcome. In this respect, all patients with highly symptomatic mitral insufficiency and complex valve pathology should be referred to specialized centers. There, a case-specific evaluation of therapeutic options can be performed, and the best possible strategy for rehabilitation of the mitral insufficiency can be developed and finally recommended by the interdisciplinary heart team.

### 5 | STUDY LIMITATIONS

Our study has several limitations beyond the retrospective and single-center design, reporting a relatively small cohort of patients. All studies in our extensive literature research were retrospective, and inclusion criteria varied across different studies. However, it remains unclear in which interval surgical revision should be performed. In this regard, Geidel et al. favored a short interval between failed MitraClip therapy and mitral valve surgery to avert a recurrence of cardiac decompensation. Due to the small number of patients, this was not examined in detail in our study. Therefore, the presented data have to be taken with caution.

### 6 | CONCLUSION

Failure of MitraClip represents a challenging situation limited by the high-risk profiles of patients. Previous MitraClip implantation jeopardizes the possibility of surgical valve repair, as shown by the high rate (94%) of patients requiring mitral valve replacement. Mitral valve surgery after failed MitraClip was associated with moderate 30-day and postdischarge outcomes. A careful evaluation of patients undergoing MitraClip by the heart team and comprehensive preoperative evaluation is of paramount importance—patients with a failed MitraClip intervention miss out on future surgical valve repair and might have a poor outcome.

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### CONFLICT OF INTEREST

None declared.

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