Impact of Failed Mitral Clipping on Subsequent Mitral Valve Operations

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Background. This study analyzed the effect of failed percutaneous mitral intervention with the MitraClip device (Abbott Laboratories, Abbott Park, IL) on subsequent mitral valve (MV) operations.

Methods. Nineteen patients (74 ± 9 years) with treatment failure after implantation of 37 MitraClips (mean, 1.9 ± 0.8; range, 1 to 4) for functional or degenerative MV disease underwent operations a median of 12 days later (range, 0 to 546 days). All patients were studied before and after the operation by clinical investigation and echocardiographic analysis. Intraoperative findings and the effect on the operation were analyzed and described in detail. Data before clipping and at the time of operation were compared, and the surgical outcome was recorded.

Results. There was a significant increase in risk between that at the time of clipping and that at subsequent operations, noted as a rise of the European System for Cardiac Operative Risk Evaluation II from a median 12.74% to 26.87%, respectively (p < 0.0001, Wilcoxon signed rank test). Severe clip implantation-induced tissue damage was found in most patients. Surgical MV repair could be performed in 5 of 6 patients (83%) with a 1-clip implant and in only 3 of 13 patients (23%) when 2 or more clips had been inserted (p = 0.0188, Wilcoxon–Mann–Whitney test). All patients required other associated procedures: closure of an artificial atrial septal defect that was caused by the clipping procedure (100%), tricuspid valve repair (37%), atrial fibrillation ablation operations (37%), coronary artery bypass grafting (16%), and aortic valve replacement (11%). Two early cardiac deaths (<30 days) occurred. Survival at 1 year was 68%.

Conclusions. There is a remarkable impact of failed clipping procedures on MV operations. We observed a severely aggravated cardiac pathology in parallel with a reduced preoperative clinical state compared with the original condition. Moreover, the likelihood of an optimal surgical solution with valve reconstruction was reduced thereafter. However, operations in the critical situation of an unsuccessful mitral clipping procedure should be discussed immediately, because it still seems to be an option compared with conservative therapy.


For the treatment of relevant mitral regurgitation (MR), the MitraClip device (Abbott Laboratories, Abbott Park, IL) has been described as an alternative to operations or medical therapy and was outlined as an option for high-risk patients in the 2012 European Society of Cardiology/European Association for Cardio-thoracic Surgery Guidelines [1–5]. However, long-term data of larger patient cohorts after mitral clipping are nonexistent. In addition, little is known about surgical options after failed, insufficient, or unsuccessful MitraClip implantation, and the effects on subsequent operations are unknown. We report our clinical experience with 19 patients who underwent MV operations after failed mitral clipping procedures. Patient characteristics, intraoperative findings, and the effect on surgical strategy are analyzed and described in detail.

Patients and Methods

The Hamburg General Medical Council Ethics Committee approved the protocol for this study.

Preoperative State

We investigated 19 consecutive patients who underwent open heart operations between October 2009 and July 2012. All patients had undergone a mean of 1.9 ± 0.8 MitraClip procedures (total, 37; range, 1 to 4) for MV disease that was functional or degenerative, or both, from September 2009 to June 2012. They were presented for surgical repair by the authorized cardiologists who had performed the clip implantations, consisting of two very experienced groups of interventional cardiologists who had started with mitral clipping in 2009 (together these groups perform, at the present time, about 150 to 200 clipping procedures per annum). After intensive discussion, we accepted all patients for surgical intervention. We had no general exclusion criteria except severe sepsis or on-going cardiopulmonary resuscitation; these exclusion criteria did not apply. The operations were performed a median of 12 days after clip

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imputation (range, 0 to 546 days). Ten patients underwent procedures within 30 days after clip implantation, and 9 were operated on more than 30 days later (4 of them at >1 year). The primary indication for percutaneous MV therapy had been assessment of high surgical risk (European System for Cardiac Operative Risk Evaluation [EuroSCORE II] >10%; median, 12.74% [lower quartile, 5.83%; upper quartile, 18.36%]; n = 13), for example, because of prior open heart surgery in 7, advanced age exceeding 75 years in 7, or reduced left ventricular ejection fraction of 0.39 or less in 12. The EuroSCORE II uses 17 patient-related and cardiac-related factors.

Three patients with a lower risk profile had initially refused an open heart operation and definitely wanted an interventional approach instead. All patients now suffered from severe recurrent or persistent MV disease after clipping, despite adequate medical therapy. Before and after their operations, they received standard heart failure medications. Before their operations, 12 patients were in sinus rhythm, and 7 had atrial fibrillation. Two patients were accepted for operations in an emergency situation. Detailed data of patient characteristics are given in Table 1.

### Surgical Strategy

Our explicit aim was to perform surgical mitral repair, if possible; therefore, the operations were performed by an experienced team specializing in reconstructive mitral operations. Clip explantation training had been performed before and was repeated after the first four operations. The operations were done on cardiopulmonary bypass with antegrade Bretschneider cardioplegia. After sternotomy and initiation of cardiopulmonary bypass, the distal anastomoses for conventional coronary artery bypass grafting were performed when indications of revascularization were apparent.

The left atrium (LA) was opened by standard left atriotomy, and the MV was exposed using the Cosgrove retractor. Etiologic, functional, and segmental MV analyses were applied according to the criteria formulated by Carpentier [6]. The characteristics of clip implantation failure and the degree of tissue damage were assessed.

### Table 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Variablea</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>74 ± 9</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8</td>
</tr>
<tr>
<td>Male</td>
<td>11</td>
</tr>
<tr>
<td>NYHA class</td>
<td>3.6 ± 0.5</td>
</tr>
<tr>
<td>Etiology of mitral disease</td>
<td></td>
</tr>
<tr>
<td>Chronic ischemic</td>
<td>8 (42)</td>
</tr>
<tr>
<td>Degenerative</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Dilated cardiomyopathy</td>
<td>3 (16)</td>
</tr>
<tr>
<td>Combined</td>
<td>3 (16)</td>
</tr>
<tr>
<td>Implantable MitraClips, No.</td>
<td>1.9 ± 0.8</td>
</tr>
<tr>
<td>Time since clipping, d</td>
<td>12 (0–546)</td>
</tr>
<tr>
<td>Mitral regurgitation grade</td>
<td>2.8 ± 0.2</td>
</tr>
<tr>
<td>Left atrium diameter, mm</td>
<td>54 ± 7 (40–69)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction</td>
<td>0.36 ± 0.11 (0.19–0.60)</td>
</tr>
<tr>
<td>Prior open heart operation</td>
<td>7 (37)</td>
</tr>
<tr>
<td>Prior intervention</td>
<td>16 (84)</td>
</tr>
<tr>
<td>Percutaneous coronary intervention</td>
<td>11 (58)</td>
</tr>
<tr>
<td>Implantable cardioverter-defibrillator</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Percutaneous MV interventionb</td>
<td>2 (11)</td>
</tr>
<tr>
<td>TAVI</td>
<td>1 (5)</td>
</tr>
<tr>
<td>ASD occluder implantation</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Ventricular tachycardia ablation</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Artificial ASD</td>
<td>19 (100)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>7 (37)</td>
</tr>
<tr>
<td>Relevant functional tricuspid valve diseasec</td>
<td>7 (37)</td>
</tr>
<tr>
<td>Relevant coronary artery disease</td>
<td>3 (16)</td>
</tr>
<tr>
<td>Aortic valve disease</td>
<td>2 (11)</td>
</tr>
<tr>
<td>Emergency operation</td>
<td>2 (11)</td>
</tr>
<tr>
<td>EuroSCORE II, %</td>
<td>26.87 (3.31–89.03)</td>
</tr>
</tbody>
</table>

| Lower quartile, upper quartile | 17.08, 42.20 |

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**Table 1.** Patient Characteristics

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Clips were explanted as follows: the lock harness and a conventional small suction tube were passed with a 4-0 Gore-Tex suture (W.L. Gore and Associates, Flagstaff, AZ; Fig 1). By pulling the suture and pushing the tube toward the clip, the surgeon carefully attempted to open the arms and the grippers of the clip without damaging the leaflet tissue. If that was not successful, the clips were cut out with scissors.

After clip explantation, we determined whether mitral repair was feasible. Before mitral repair or replacement,
closure of the left atrial appendage and standardized ablation were performed in patients with atrial fibrillation [7]. After repair, precise evaluation of preserved valve symmetry and proper leaflet coaptation was done, including ventricular filling with saline solution. When the MV could not be repaired, replacement using a conventional bioprosthesis was performed. Afterwards, the artificial atrial septal defect (ASD) that was caused by the transseptal approach for clipping (Fig 2) was closed with a suture from the LA side. Eventually, all other procedures, including tricuspid valve repair or aortic valve replacement, were performed.

Postoperative Status and Data Analysis
Functional status was assessed according to the New York Heart Association (NYHA) criteria, and transthoracic echocardiography (1 week postoperatively) and transesophageal echocardiography (intraoperatively) were performed for valve analysis by an experienced cardiologist (transthoracic echocardiography) or an experienced anesthesiologist/cardiologist (transesophageal echocardiography). Left ventricular and LA dimensions were determined from parasternal M-mode acquisitions, and the severity of MR was graded from color-flow Doppler in the parasternal long-axis and apical 4-chamber view.
Mitral insufficiency was quantified by vena contracta and the maximal jet area/left atrial area. A residual regurgitation of grade 1 or less, leaflet coaptation of 5 mm or more, and MV area (MVA) of 2.0 cm² or more was assessed as an acceptable result for MV repair in that situation. According to the protocol, preoperative and postoperative cardiac rhythm, the need for intraaortic balloon pump (IABP) support, and the following complications were noted: cardiac and noncardiac death, perioperative myocardial infarction, reoperation for bleeding, cerebrovascular events, pneumonia, and wound infection. At 1-year follow-up, the following events were noted: cardiac and noncardiac death and reoperation for recurrent MR.

Continuous data are shown as median, first (lower) and third (upper) quartile, and minimum and maximum, or are described by arithmetic means and standard deviations, if appropriate. Differences in continuous data between EuroSCORE II values at the time of clipping and at the time of the operation were tested by the Wilcoxon signed rank test. Differences in the number of clips and the duration of the procedure between patients with repaired and replaced MVs were proved with the Wilcoxon–Mann-Whitney test. All p-values were two-sided, and a value of less than 0.05 was deemed significant. All calculations were performed with SAS 9.3 software (SAS Institute Inc, Cary, NC).

Results

Preoperative State
At the time of their operations, 7 patients were in NYHA class III (27%) and 12 were in class IV (63%). All patients had moderately severe (27%) or severe (63%) MR (mean grade 2.8 ± 0.2). The MVA was 2.6 ± 0.8 cm² (range, 1.8 to 3.8 cm²). A mean gradient of 6.2 ± 1.3 mm Hg (range, 5 to 8 mm Hg) was found in 5 of 19 patients, and the MVA in these 5 patients was 2.1 ± 0.2 cm² (range, 1.8 to 2.4 cm²). There was a significantly increased risk, calculated using the EuroSCORE II, between the time of clipping and at the subsequent operation; the EuroSCORE II had changed from a median of 12.74% (lower quartile, 5.83%; upper quartile, 18.36%; range, 0.98% to 40.59%) to 26.87% (lower quartile, 17.08%; upper quartile, 42.20%; range, 3.31% to 89.03%), respectively (p < 0.0001, Wilcoxon signed rank test). The increase was caused by changes in renal impairment, deterioration in the preoperative state, NYHA class, pulmonary hypertension, weight of the intervention, urgency, and age (up to five factors in 1 patient). At the time of the operation, 13 patients (68%) had a score of more than 20% compared with only 3 patients (16%) before the clipping procedure.

Intraoperative Findings
No patient showed signs of acute, subacute, or chronic endocarditis. Severe tissue damage caused by the clipping procedure was found in all patients, however. There was a relevant reduction in MVA when multiple segments were connected with clip material (Fig 2) or there was still severe MR with artificial lesions (Fig 3) or acute leaflet perforation combined with visible tissue inflammation (Fig 4, on the left), or both. In patients with clip implantation that was more than 2 months old, (chronic) perforation in one or more segments without visible inflammation was found (Fig 4, on the right). Also found were chordal ruptures caused by the clipping procedures (Figs 4, 5) and inadequate long-term reduction in the dimensions of the anterior/posterior annulus (Figs 3–5). No visible significant progression of the original functional or degenerative MV disease was noted. All deteriorations were associated with clip implantation. Other findings were technical problems, including “loss” of a clip, which occurred in a 73-year-old patient undergoing an emergency redo operation in the hybrid operating room, in which the clip was still connected to the clip delivery system with a nitinol wire (Fig 1), or ASD occluder migration into the right ventricle.

Operation
The number of implanted MitraClips had an effect on the probability of successful mitral repair: surgical repair could be performed in 5 of 6 patients with only 1 clip implant (83%) and in 3 of 9 patients when 2 clips had been inserted (33%). After 3 or more clip implantations, only valve replacement could be performed; our repair rate was only 23% when 2 or more clips had been inserted (3 of 13 patients; p=0.0188, Wilcoxon-Mann-Whitney test;
Fig 6). There was no significant influence of the time between clipping and the surgical repair on the repair rate ($p > 0.99$, Wilcoxon–Mann–Whitney test). We tried to perform the clip explantation as outlined above. However, in all cases, we did not find clip opening to be easy without aggravating tissue damage. Clip explantation was always difficult, even if the implant had been in place for only a very short time.

Various associated procedures had to be performed in all patients: closure of an artificial ASD that was caused by the clipping procedure (100%), tricuspid valve repair (37%), atrial fibrillation ablative operation (37%), coronary artery bypass grafting (16%), and aortic valve replacement (11%). Mitral repair techniques followed standardized procedures, including closure of perforations using 5-0 Cardionyl sutures (Peters Surgical, Bobigny, France), posterior sliding plasty, commissural plasty, chordal replacement with Gore-Tex sutures, and annuloplasty with implantation of conventional 2-dimensional ($n = 5$) or 3-dimensional ($n = 3$) ring material. The latter depended on the etiology and type of ventricular remodelling (mean ring size, $30 \pm 4$ mm; range, 26 to 38 mm). We decided to leave intensely in-grown clip material in place in 3 patients to prevent tissue damage by clip explantation. In 11 patients, the size of the implanted bioprosthesis was $31 \pm 1$ mm (range, 29 to 33 mm). Intraaortic balloon pump implantation was necessary in 3 patients (16%).

Survival and Follow-Up
There were 2 early cardiac deaths (<30 days) in patients at very high surgical risk. They had severe functional MR and left ventricular ejection fractions of only 0.19 and 0.29 (both NYHA class IV), both already had implantable cardioverter defibrillators, and their EuroSCORE IIs were 43.59% and 20.36%. In these patients, we did a precise mitral repair with a sufficient echocardiographic result. The patient with EuroSCORE II of 43.59% was implanted with an intraaortic balloon pump but died of low cardiac output on the first postoperative day. The other patient, with a score of 20.36%, died of sepsis, multiorgan failure, and low cardiac output after 8 days.

In general, echocardiographic control (intraoperative transesophageal echocardiogram) and transthoracic echocardiogram at 1 week demonstrated the absence of significant MR in all patients (grade 0.5 ± 0.7). LA size had decreased to $50 \pm 3$ mm, and the mean left ventricular ejection fraction was $0.35 \pm 0.12$. MVA was calculated as $2.9 \pm 0.6$ cm² (range, 2.2 to 3.8 cm²). There were no perioperative myocardial infarctions, no reoperations for bleeding, and no wound infections. A cerebrovascular event occurred in 1 patient, and pneumonia developed in 3 patients. The 1-year-survival was 68% (6 deaths: 2 noncardiac, 4 cardiac). Four of these were late deaths (2 after repair, 2 after replacement) for cardiac and noncardiac reasons. At 1 year, the 13 survivors were in NYHA class 1.5 ± 0.5. No reoperations occurred during the follow-up period due to recurrent MR.

Comment
Based on the principles of MV repair published by Carpentier 3 decades ago [6], mitral reconstruction has become a reliable strategy for patients with significant MR. Particularly in patients with degenerative or chronic ischemic etiology, or both, excellent clinical results have been documented [8–13]. In patients with degenerative (repair: leafllet/chordal-reconstruction plus annuloplasty) or functional (repair: only restricted annuloplasty) MR, almost all valves can be successfully
preserved and only in a smaller number is valve replacement necessary. With development of mitral repair, and as an alternative to complex reconstruction, the Alfi\'eri group published the double-orifice technique (suture adaption of the middle of the posterior/anterior leaflet) and recommended this concept as a “simple solution for complex problems” [14]. However, this technique, which is normally combined with prosthetic ring annuloplasty, is still seen as controversial, and many surgeons prefer an intervention that preserves the full mitral opening.

The MitraClip strategy is an interventional variation of the Alfi\'eri technique; instead of a mitral leaflet suture in the middle of the valve, performed during an open heart operation, a “simple” percutaneous clipping, without cardiopulmonary bypass, should minimize the patient’s burden. From that point of view, the technique is at least less invasive than an open surgical repair. However, whether the results are really equal to or better than a standardized surgical approach in long-term morbidity and mortality (even in patients with high surgical risk) cannot be fully answered as long as these data remain unavailable.

Therefore, the 2012 European Society of Cardiology/European Association for Cardio-thoracic Surgery Guidelines state that, mitral clipping must be regarded as an option in a situation of inoperability or for “high-risk” patients only [4]. For this reason, research data that help us to understand more of the effects of the clipping procedure itself are of great interest. Our analysis of 19 patients shows that with an unsuccessful clipping, the patient’s condition deteriorates dramatically in tissue damage and increased risk. Because the risk increases with time, early operation seems to be an advantage.

In our investigation, the clips generally did not open easily. Therefore, after the first 4 patients, and to exclude a fault in our explantation technique, we performed a training clip explantation. We were able to demonstrate that after implantation failure of only 1 clip, mitral repair
could still be completed in 83% of patients. This confirms our earlier experience, published in 2010, where we reported complex surgical repair after unsuccessful implantation of 1 clip [15]. In contrast to this, replacement had to be performed in 77% of patients with 2 or more clip implants. Other experiences also emphasize that there might be a need for valve replacement after failed clipping [16–18]. However, because of severely aggravated cardiac pathology and a reduced preoperative state after failed MitraClip intervention, the surgical procedure is really complex and requires the full spectrum of valvular repair techniques.

Our data demonstrate that the chance of an optimal surgical solution with highest clinical benefit from a MV operation is reduced by the failure of a prior clipping procedure. We observed that cardiac pathology, and the mitral tissues in particular, had deteriorated significantly due to the clipping procedure itself, leading to additional severe lesions such as chordal rupture or leaflet perforation. The question of whether a satisfactory MV repair can be achieved in most patients must therefore be viewed negatively.

Nevertheless, particularly because of the encouraging early results of the Endovascular Valve Edge-to-Edge Repair Study (EVEREST) trials, and from observational studies [1–3, 5], it must be anticipated that an increasing number of clipping procedures will be performed and more cases of failed intervention will occur. We therefore believe that cardiac surgeons should immediately adjust their strategies to accommodate that situation. Although an open heart operation after leaflet clipping represents a challenge, we have demonstrated that it can be completed successfully by an experienced team, even in complex situations. However, the indication for percutaneous mitral intervention should be discussed carefully with the patient in a competent heart team, because the likelihood of a perfect surgical repair is low and the patient’s prognosis may dramatically worsen afterward. Valve pathology can severely deteriorate after a preceding percutaneous MV intervention, thereby reducing the chance for a successful surgical repair. However, recent research has shown that multiple clips are commonly used for intervention [19].

At present, every effort should be made to prevent treatment failure after MitraClip implantation, particularly in low-risk patients. Mitral clipping must therefore not be performed in patients who can be operated on with an acceptable risk, because the risk of the operation dramatically increases after failure of clip implantation and the chance of a satisfactory MV repair decreases. From our point of view, there is still a need to discuss the term “inoperable patient” because many “inoperable” patients were successfully operated on after failed MitraClip implants. We believe it is advisable to perform operations after unsuccessful mitral clipping in centers that have developed some expertise in this kind of operation.

Our study has some limitations. This analysis was not undertaken to evaluate the results of mitral clipping in general; therefore, multicenter studies of larger patient cohorts and long-term follow-ups are required. Instead, in our institution, we focused on patients with clip implantation failure that were scheduled for open heart operations so we could learn about effects on the clinical situation, the mitral tissues, and on surgical proceedings after clipping. However, the number of patients we dealt with was small and our experience relates only to a single center, thereby limiting the data set and breadth of conclusions.

The patients were very heterogeneous regarding their risk profiles and cardiac and extracardiac comorbidities. Patients were presented for surgical interventions done by two groups of interventional cardiologists. Considering the number of clip implants performed annually by these two groups, the 19 patients obviously represent a minority of MitraClip patients (low monadic percent range). A greater number of patients may show at least early success, as others have published [1–3, 5].

Our strategy was to perform reconstructive MV operations whenever possible. Our analysis was not undertaken to compare the technique of mitral repair with mitral replacement. Whether repair or replacement is the better strategy after clip implantation failure should be the subject of further research. Associated procedures had to be performed in most patients, and this may have influenced the results. The long-term prognosis of the patients is still unknown and should be studied further. Investigations by other centers are required to confirm these early results over a longer period with larger patient populations.

In conclusion, there is a remarkable impact of failed or unsuccessful clipping procedures on MV operations. In a heterogeneous group of 19 patients, we observed a severely aggravated cardiac pathology in parallel with a reduced preoperative clinical state compared with the situation before clipping. Moreover, the likelihood of an optimal surgical solution with valve reconstruction was reduced thereafter. However, surgical intervention in the critical situation of a failed mitral clipping procedure should be discussed immediately because it still seems to be an option compared with conservative therapy. The long-term prognosis of patients with or without satisfactory mitral clipping is still unknown and should be the subject of further research.

References


INVITED COMMENTARY

Drs Geidel and Schmoeckel [1] report their experience with mitral valve surgery after failed mitral clipping in 19 patients. The median time for surgery to 12 days. The median European System for Cardiac Operative Risk Evaluation (EuroSCORE II) significantly increased from 12.74% at the time of mitral clipping to 26.87% at the time of surgery in this elderly group of patients. Complex mitral valve repair was performed on 8 of 19 patients and the rest required mitral valve replacement with a bioprosthesis. Thirty-day mortality was 20%, and survival at 1 year was 68%. The researchers conclude, and rightly so, that failed mitral clipping is associated with very high risk, with a likely repair being untenable and very complex when attempted.

This report raises two very important questions. The first question relates to offering conventional open heart surgery to a very sick group of patients who were deemed inoperable in the first place when their initial EuroSCORE II was significantly lower. Data from the Endovascular Valve Edge-to-Edge Repair Study II presented at the American Association for Thoracic Surgery Mitral Conclave 2013 (Dr Paul A. Grayburn, Baylor Heart and Vascular Institute, Dallas, TX) showed that for patients with residual grade 3 or 4 mitral regurgitation, survival at 1 year was 58%, which is comparable to the survival of surgical patients in this report. Of 351 patients, none required surgical intervention because of being deemed inoperable.

The second question relates to the wisdom of performing mitral valve repairs in this very sick and elderly group of patients. By the investigators’ admission, clip explantation was always difficult even when the clip was in place for only a short time. Other daunting complications were the presence of multiple perforations, chordal ruptures, and intense inflammation. It is worth noting that 4 of 6 deaths at 1 year were patients who had a repair. Geidel and Schmoeckel [1] do not provide any information about ischemia time and cardiopulmonary bypass time in repair patients versus replacement patients. It is not hard to guess that these times for valve replacements will be significantly less than for the repairs.

I really enjoyed reading this very important study. Important lessons are learned. Mainly, these are extremely sick patients with dismal survival. A discussion of the high risk among cardiac surgeons, cardiologists, anesthesiologist, and intensivists would be the right thing to do. Failure of medical treatment should not be an automatic indication for surgery. Finally, complex repairs should be avoided as it no doubt prolongs the procedure. In my opinion, the agreed upon rationales for repair do not apply to these patients.

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Reference