Learning Minimally Invasive Mitral Valve Surgery

A Cumulative Sum Sequential Probability Analysis of 3895 Operations
From a Single High-Volume Center

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Background—Learning curves are vigorously discussed and viewed as a negative aspect of adopting new procedures. However, very few publications have methodically examined learning curves in cardiac surgery, which could lead to a better understanding and a more meaningful discussion of their consequences. The purpose of this study was to assess the learning process involved in the performance of minimally invasive surgery of the mitral valve using data from a large, single-center experience.

Methods and Results—All mitral (including tricuspid, or atrial fibrillation ablation) operations performed over a 17-year period through a right lateral mini-thoracotomy with peripheral cannulation for cardiopulmonary bypass (n=3907) were analyzed. Data were obtained from a prospective database. Individual learning curves for operation time and complication rates (using sequential probability cumulative sum failure analysis) and average results were calculated. A total of 3895 operations by 17 surgeons performing their first minimally invasive surgery of the mitral valve operation at our institution could be evaluated. The typical number of operations to overcome the learning curve was between 75 and 125. Furthermore, >1 such operation per week was necessary to maintain good results. Individual learning curves varied markedly, proving the need for good monitoring or mentoring in the initial phase.

Conclusions—A true learning curve exists for minimally invasive surgery of the mitral valve. Although the number of operations required to overcome the learning curve is substantial, marked variation exists between individual surgeons. Such information could be very helpful in structuring future training and maintenance of competence programs for this kind of surgery. (Circulation. 2013;128:483–491.)

Key Words: learning curve ◼ mitral valve ◼ surgery

Minimally invasive surgery of the mitral valve (MIS-MV) has become the routine approach to mitral valve disease in some centers, particularly in Europe, with excellent short- and long-term results. However, most reports come from high-volume centers with extensive experience in these techniques. Surgeons at other centers might be reluctant to adopt the minimally invasive approach because of the initial learning curve involved. Although several publications have discussed the learning curve associated with MIS-MV operations, such publications are expert opinion only with few supportive data.

Clinical Perspective on p 491

For many operators, it remains a question whether the potential benefits of MIS-MV, such as reduced respiratory support, less pain, improved cosmetics, and lower risk of wound infections can outweigh the potential drawbacks of an initially higher complication rate when a new approach is adopted. In fact, some experts have argued that the learning curve for minimally invasive procedures should prevent its widespread implementation. To the best of our knowledge, however, no study to date has methodically examined the true learning curve for MIS-MV.

Therefore, the purpose of our study was to analyze and compare the learning curves of surgeons who have started performing MIS-MV operations at our institution, to calculate average trends, and to provide recommendations on the necessary experience to achieve and retain high-quality outcomes in this field.

Methods

Patients

A total of 5287 patients who underwent mitral valve or tricuspid valve surgery or atrial fibrillation ablation therapy between 1994 and 2011 at our institution were analyzed. Patients undergoing other concomitant procedures such as coronary bypass surgery, aortic valve replacement, or aortic surgery were excluded. Nine patients undergoing robotic mitral valve surgery by both staff and guest surgeons were also excluded. Such procedures were never performed on a routine basis at our center because of time and resource use. Of the 5287 patients, 3907 (74%) were operated on with an MIS-MV technique. The percentage of MIS-MV varied over time and is shown in Table 1. The 3907 operations were performed by a total of 21
Table 1. Percentage of MIS-MV Procedures Over Time

<table>
<thead>
<tr>
<th>Year</th>
<th>Total MV Operations, n</th>
<th>MIS-MV n</th>
<th>%</th>
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</tr>
<tr>
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<td>80</td>
</tr>
<tr>
<td>Total</td>
<td>5287</td>
<td>3907</td>
<td>74</td>
</tr>
</tbody>
</table>

MIS-MV indicates minimally invasive surgery of the mitral valve; and MV, mitral valve.

Data were drawn from a prospectively gathered database for MIS-MV housed at our institution. The study was approved for anonymous analysis by the institutional review board, with additional patient consent waived.

Patient Selection and Surgical Technique

It is the policy at our institution to use the MIS-MV approach whenever possible. The main reasons for not using minimally invasive procedures were previous right thoracotomy with expected lung adhesions, difficulties with femoral vessel cannulation, and in the case or urgent or emergent surgery, the unavailability of a surgeon versed in the MIS-MV approach. Other possible reasons for preferring the sternotomy approach were a very low ejection fraction (to achieve the shortest possible cross-clamp time) and expected difficulties with valve replacement because of extremely severe annular calcification or deep annular abscess. Such decisions were made at the surgeon’s discretion.

In all patients who underwent an MIS-MV, a right-lateral mini-thoracotomy and femoral cannulation for cardiopulmonary bypass with mild to moderate hypothermia were performed. In the vast majority of patients, a transthoracic aortic clamp as introduced by Chitwood et al was used. Details on the MIS-MV operative approach are described more thoroughly elsewhere. Patients who underwent robotic mitral valve surgery were excluded.

Data Analysis

Categorical variables are expressed as proportions and continuous variables as means±SD throughout this study. Patients were divided into groups of 50 consecutive operations to evaluate the influence of growing surgical experience on adverse outcomes. Testing for differences between these groups was done with the χ² test.

The primary outcome was a composite end point consisting of all important adverse events, including intraoperative conversion to sternotomy, re-exploration for bleeding, valve-related reoperation within the same hospital stay, new renal failure requiring dialysis, stroke, perioperative myocardial infarction, low-cardiac-output syndrome with necessity for intra-aortic balloon pump or extracorporeal membrane oxygenation support, or death. Patients in whom >1 of the above complications occurred were considered to have experienced only 1 primary outcome. The primary outcome had to occur within 30 days after the index procedure or until the first discharge from hospital, whichever was longer.

The learning process was first assessed by compiling the average complication rates (ie, the occurrence of the primary outcome) over all surgeons in blocks of 50 operations. Furthermore, an analysis of the influence of the operation frequency (ie, number of operations per week) on the principal outcome occurrence was performed.

Learning curves were then determined for each individual surgeon with regard to total operation time, aortic cross-clamp time, and primary outcome rates. The learning curves for complication rates were calculated for both the whole institution and the individual performance of each surgeon.

To generate learning curves, we used the sequential probability cumulative sum (CUSUM) failure analysis, which has been described in detail elsewhere. In brief, the actual minus expected failure rate is plotted against the number of operations. The resulting chart runs parallel to the x axis when the complication rate is as expected, turns upward when more complications than expected occur, and turns downward when a favorably low complication rate is observed. Additionally, boundary lines are calculated to mark the borders for statistical significance.

Results

As stated, surgeons with <20 MIS-MV operations were excluded. Thus, 3895 operations performed by 17 surgeons could be analyzed in detail. The mean number of operations per surgeon was 189 with a range from 21 to 1385. Table 2 provides a summary of important patient characteristics and postoperative complications for the entire group. Table 3 summarizes important intraoperative parameters and outcome variables.

Average Learning Curves

The learning curves with regard to selected adverse events according to the total number of operations performed per surgeon are depicted in Figure 1. Despite the wide variation, a clear tendency toward better results with growing experience was observed. Although an adverse event (ie, conversion to sternotomy, re-exploration for bleeding, valve-related reoperation during hospitalization, new dialysis, stroke, myocardial infarction, low-cardiac-output syndrome, or death) was observed in almost every fourth patient at the beginning of the surgeon’s experience, this rate fell to a normal range of ~10% after 250 operations (P=0.124). A large proportion of this observed trend was attributable to the falling rate of reexplorations for bleeding, reduced from 8.2% to 1.9% after 300 operations (P=0.085). In addition, the conversion rates to sternotomy and the necessity for cardiac reoperations showed...
Institutional Learning Curve

Figure 2 depicts the learning curve of the entire institution. After a slight accumulation of failures in the early years, the learning curve became consistently downward (ie, fewer complications than expected) after the fourth year of implementation of the MIS-MV program. From 2008 on, however, the complication rate started to rise again. This time point is congruent with a number of new surgeons joining the MIS-MV program. The early phases of their learning curves added up to a higher overall complication rate for the entire institution (see Figure 3). Only in 2011 did the curve start to improve again. It is important to note that an increase in the learning curve did not translate into a worse operative mortality. That is, the 30-day mortality rate remained stable throughout the last 7 years of the study, consistently remaining between 1% and 2%.

For a closer analysis of which event had the highest impact on the rising institutional learning curve, we calculated exclusion learning curves by sequentially eliminating each single complication from the analysis and comparing the resulting calculated curves. This analysis revealed that re-exploration for bleeding played a dominant role. If it was excluded from the failure analysis, the learning curve continued to decline as expected after so many years of institutional experience (see Figure 4).

Individual Surgeon Learning Curves: Complications

Of the 17 surgeons who were available for analysis, 8 operators showed a classic learning curve with a turning point toward a lower complication rate typically after 75 to 125 operations (see Figure 5A). Five surgeons could be marked as outperformers (Figure 5B) with a very low rate of adverse events from the beginning of their experience, whereas 4 surgeons were identified to have too many complications breaking the line of statistical significance (underperformers; see Figure 5C).

Individual Learning Curves: Operative Times

We also analyzed operative times for potential learning curves. We failed to identify typical learning curve patterns with regard to aortic cross-clamp and total operative times (Figure 6). The operative times were quite stable from the beginning of each surgeon’s experience, with only a little improvement over time (Figure 6).

Influence of Operation Frequency

We also examined the influence of MIS-MV frequency (ie, number of operations per week per surgeon) on the adverse event rate probability. As Figure 7 shows, a clear tendency for better results was observed if the surgeon performed MIS-MV at least twice per week. A higher frequency than 2 operations per week brought only minor further improvement in outcomes. A more detailed analysis including the absolute experience of a surgeon revealed that the above-described relation is particularly evident after the initial learning phase of 50 operations (see Figure 8).
Discussion

No prospective, randomized studies comparing MIS-MV surgery with a conventional sternotomy approach exist to date. Given the strong attitudes of surgeons on both sides of the issue and the relative infrequency of mitral valve surgery, it is unlikely that such a randomized trial will ever be performed. Propensity-matched comparisons of the 2 techniques observed similarly excellent outcomes for both types of operations, with no apparent drawbacks of the MIS-MV approach.\textsuperscript{11,12} In addition, our study reveals an overall mitral valve repair rate (82.4%), a rate of intraoperative repair failure (1.4%), and a rate of early valve-related reoperation...
(3.1%) comparable to those described for sternotomy mitral valve surgery in the literature. The percentage of patients who required mitral valve reoperation during follow-up has been described in detail in previous publications from our institution, with reoperation rates that are within the range of results published for full sternotomy mitral valve surgery.\textsuperscript{2,3,13} However, these studies come from high-volume centers with vast experience in MIS-MV surgery.

The MIS-MV approach has gained increasing acceptance during the last decade, now being performed in 34\% of patients undergoing isolated mitral valve surgery in Germany.\textsuperscript{14} Increased acceptance of MIS-MV is probably attributable to a combination of the following factors: improved instruments for surgical access with good visualization of the mitral valve, preservation of the integrity of the osseous thoracic wall, faster patient recovery, very good short- and long-term results with high rates of mitral valve repair, and increasing patient demand.\textsuperscript{15} Patient demand is likely to increase as knowledge of percutaneous mitral valve repair methods becomes increasingly widespread, which may lead to more surgeons adopting the MIS-MV technique.

Several concerns have been raised arguing against the widespread adoption of MIS-MV surgery, however. An increased stroke rate possibly resulting from retrograde systemic perfusion has been observed in a large registry and has been discussed in detail.\textsuperscript{16} Pertaining to another concern that has been discussed in detail, we recorded 10 aortic dissections (0.26\%) that we attributed to peripheral cannulation, cardioplegia

\begin{figure}
\centering
\includegraphics[width=\textwidth]{learning_curves}
\caption{Individual learning curves of all surgeons listed according to the year they started performing minimally invasive mitral valve surgery.}
\end{figure}
needle insertion, cross-clamping of the ascending aorta, or injury from an endoaortic balloon clamp. These complications were not related to the stage of training of the surgeon.

Other potential drawbacks include prolonged cardiopulmonary bypass and ischemic times, the associated learning curve, exposure difficulties in patients with challenging anatomy, suboptimal deairing techniques, and complex methods of cardioplegia administration.

The purpose of our study was to formally assess a potential drawback of MIS-MV surgery: the learning curve. The consistency in patient selection, surgical techniques, and perioperative management over the study period allowed us a unique opportunity to assess the MIS-MV learning curve in our institution. In addition, the large number of operations performed by a relatively large number of surgeons allowed us to compare learning curves between surgeons and to assess the importance of operation frequency on adverse outcomes.

CUSUM analysis has been previously used to examine learning curve associated with off-pump coronary bypass surgery and minimally invasive direct coronary artery bypass, but it has not been applied in the area of MIS-MV surgery. The CUSUM technique allows monitoring of changes in perioperative mortality and morbidity during the patient care process. It can be repeated as often as desired, even after each operation, providing an almost real-time monitoring of surgical performance. We observed a large degree of variability in CUSUM failure curves according to individual surgeons. Such information may be critically important to those centers that are planning to adopt an MIS-MV program and may be helpful in structuring training and maintenance of competence programs.

In the present study, the calculation of average learning curves for the entire group of surgeons supplied a general impression of the learning process of this operative technique. The large standard deviation of some values indicates that
average numbers should serve as only a general impression, which may lead to a more thorough analysis of individual adverse outcome failure curves.

Interestingly, we did not observe an obvious learning curve with regard to operative times, probably because surgeons were assigned less complex patients during their initial MIS-MV experience. Operative times do not usually play a decisive role in patient outcomes, however, as long as they are not excessively long.

The results of our analysis for adverse outcomes support the hypothesis that MIS-MV surgery has a prolonged learning curve, even in a center performing a large volume of MIS-MV operations. The learning curve is particularly noteworthy given that all surgeons in the present study had significant prior experience with mitral valve surgery performed through a sternotomy (at least 40 operations). Although substantial intersurgeon variability existed, a higher complication rate during the beginning phase of MIS-MV adoption was the rule rather than the exception. In addition, we found that the performance of >1 MIS-MV operations per week was associated with the best outcomes.

It should be stressed, however, that the predominant driving factor behind our observed learning curve was the requirement for rethoracotomy for bleeding. Removal of this complication from our composite adverse event outcome resulted in a much more favorable view of the learning curve for the entire group of surgeons (Figure 4). Our observed rethoracotomy for bleeding rate (7.2%) appears higher than
observed resternotomy rates for full sternotomy mitral valve repair surgery (0.9%–4.4%). Reoperation for bleeding may represent a drawback of MIS-MV surgery, probably because the entire operative field cannot be directly visualized. Our elevated rethoracotomy rate led us to incorporate other methods to minimize the chance of this complication occurring (eg, using the thoracoscope to inspect the inner thoracic wall thoroughly before closing the incision).

Throughout the years, the MIS-MV program has always been confined to a relatively small number of surgeons (ie, ≈3–5). A new surgeon was trained only if it was foreseeable that another would leave the clinic. In 2011, for instance, 367 procedures were performed by 5 surgeons (96, 86, 43, 70, and 72 procedures per surgeon), whereas a beginner in this field performed 13 procedures. One of the major questions of the analysis was whether this restriction to so few surgeons is a reasonable strategy because the right lateral approach is not the exception but the rule for mitral valve surgery at our center. We can conclude from the results of the present study that this strategy was correct, and it will remain unchanged in the future.

Our observed numbers of operations to overcome the learning curve (≈75–125) and to maintain optimal results (>50 per year) are somewhat sobering given that the average number of mitral valve operations performed per surgeon per year is 6 in the United States. One can conclude from our observations that MIS-MV surgery should probably be restricted to high-volume centers with a relatively large and stable number of mitral valve operations and that the number of surgeons performing these procedures should be limited within these centers.

Despite our observations, we strongly believe that MIS-MV surgery is beneficial for patients and that surgeons should not be completely discouraged from adopting these procedures. Technical tips can be learned from programs with established MIS-MV programs. Exposure to MIS-MV techniques as a resident (particularly to patient setup, femoral cannulation, and mitral valve exposure) and further postfellowship training after becoming familiar with mitral valve repair techniques via a full sternotomy should lead to minimization of the learning curve. In addition, careful patient selection should be implemented during the initial phase of the program. For example, initial MIS-MV operations should be restricted to preferably male patients who are nonobese and have a simple mitral valve pathology (eg, isolated P2 prolapse). Finally, institutional factors such as volume of mitral valve operations, dedicated cardiac anesthesia, and familiarity with minimally invasive cardiopulmonary bypass methods should also be considered. With these caveats in mind, we believe that the establishment of an MIS-MV program is feasible and beneficial.

Once an MIS-MV institutional program is established, our experience suggests that a close monitoring system for patient outcomes with appropriate statistical methods should be performed. If excess complications are observed or if a statistical underperformer is identified, further action may be required. In our institution, for example, our CUSUM analysis led to a higher awareness for the most frequent complication (ie, rethoracotomy for bleeding) and focused our attention on methods to minimize its occurrence.

In our opinion, a surgeon who has been trained for MIS-MV surgery is still a valuable operator even in the face of temporary underperformance. Oftentimes, minor changes in the operative strategy can lead to significant improvements in outcome. Our policy is to therefore give MIS-MV surgeons who are underperforming a chance to benefit from a relatively short period of supervision by a very experienced senior surgeon. At our institution, 2 surgeons went through such a retraining phase after a thorough data analysis.

Limitations
The present study is retrospective in nature and therefore is subject to the inherent weaknesses of a retrospective analysis. In addition, it depicts only a single-center experience, which may limit its generalizability to other centers.

Conclusions
MIS-MV surgery is associated with a prolonged learning curve. Although intersurgeon variability was observed, a relatively large number of MIS-MV operations was required to overcome the learning curve. Training and maintenance of competence programs may need to be adjusted to reflect these realities. In addition, our results suggest that the adoption of MIS-MV surgery be restricted to centers with a large volume of mitral valve procedures.

Disclosures
None.
Minimally invasive operations have gained wider acceptance in the field of cardiac surgery during the last decade. Despite the obvious advantages, these operations have been challenged for delivering the same results as conventional surgery. Particular concerns have been raised because an additional learning phase is required. However, the often cited learning curves have barely been examined methodically. The purpose of this study was to assess the learning process involved in the performance of minimally invasive surgery of the mitral valve.

Minimally invasive mitral valve operations have gained wider acceptance in the field of cardiac surgery during the last decade. Despite the obvious advantages, these operations have been challenged for delivering the same results as conventional surgery. Particularly, concerns have been raised because an additional learning phase is required. However, the often cited learning curves have barely been examined methodically. The purpose of this study was to assess the learning process involved in the performance of minimally invasive surgery of the mitral valve.


CLINICAL PERSPECTIVE

Minimally invasive operations have gained wider acceptance in the field of cardiac surgery during the last decade. Despite the obvious advantages, these operations have been challenged for delivering the same results as conventional surgery. Particular concerns have been raised because an additional learning phase is required. However, the often cited learning curves have barely been examined methodically. The purpose of this study was to assess the learning process involved in the performance of minimally invasive surgery of the mitral valve. It comprises a frank analysis of the past and delivers insight in the current training program and its monitoring. It also shows the usefulness of the sequential probability cumulative sum failure analysis as an easy tool for early detection of systemic problems. We found that a true learning curve exists for minimally invasive surgery of the mitral valve operations. Although the number of operations required to overcome the minimally invasive surgery of the mitral valve learning curve is substantial, marked variation exists between individual surgeons. For some surgeons, the analysis even resulted in retraining under supervision. Such information could be very helpful in structuring future training and maintenance of competence programs for this kind of surgery.

References


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