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ORIGINAL ARTICLE

Analysis of the Learning Curve in Mitral Valve Replacement Through the Right Anterolateral Minithoracotomy Approach: A Surgeon's Experience with the First 100 Patients

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Background To apply the cumulative sum (CUSUM) failure analysis to assess the performance of a single surgeon during mitral valve replacement via the right anterolateral minithoracotomy (RAMT) approach and to analyse the learning curve for the procedure.

Methods A total of 100 mitral valve replacements were performed using the RAMT approach from June 2011 to April 2013 by a single surgeon with no prior experience of this technique. Patients were divided into five blocks according to the operation date. The perioperative data were collected prospectively and analysed using descriptive statistics and CUSUM failure analysis.

Results No significant differences in the background factors among the five periods were observed, except for a small increase in patient age from periods 1 to 5 ($p = 0.004$). The surgeon's performance improved with time; a decrease in the cross-clamp time, operative time, and blood loss was observed ($p < 0.001$). However, no significant difference in the number of failed cases was observed among the periods. All failure cases were evaluated by the CUSUM failure analysis and the CUSUM curve reflected a learning curve associated with this new procedure. The surgeon crossed the lower 80% boundary after about 33 operations, which indicates that better results can be obtained after this point.

Conclusions Minimally invasive mitral valve surgery using the RAMT approach can be performed by a new surgeon. Furthermore, CUSUM curve analysis is a simple statistical method to implement continuous individual performance monitoring.

Keywords Mitral valve replacement • Anterolateral minithoracotomy • Cumulative sum analysis • Learning curve • Quality control

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Introduction

Since the right anterolateral minithoracotomy (RAMT) approach was described in the mid-1990s [1–3], many publications have demonstrated that the short-term results of this technique are at least as good as, if not better than, conventional mitral valve replacement (MVR) performed through the standard median sternotomy (SMVR). The theoretical advantages of this approach include the avoidance of a sternotomy, therefore, reducing pain and surgical trauma, decreasing bleeding, promoting an earlier functional recovery and shorter hospital stay, and reducing costs [4–8]. Despite these benefits, many surgeons are still reluctant to perform MVR through the new RAMT approach. This could be due to apprehension of deleterious patient outcomes, especially during the early stages of applying the new technique. Therefore, it is necessary to assess the quality of the surgeon's performance when beginning to apply the new technique in practice. Unfortunately, to our knowledge, few studies have focussed on this issue. The current methods of technology assessment are subjective or implicit; thus more objective methods of assessment based on the statistical process controlling technique, such as cumulative sum (CUSUM) analysis, may be helpful [9–12].

In 2011, after a period of observation and training by experimenting on animals, the RAMT approach for MVR was introduced in our institute. To evaluate the performance quality of a single cardiac surgeon starting to use RAMT for MVR, we designed the present prospective study using the CUSUM analysis.

Material and Methods

Patient Selection

Between June 2011 and April 2013, 100 patients consecutively underwent MVR surgery using the RAMT approach performed by a single surgeon at our institute. In this series, the inclusion criterion was a pure mitral valve lesion. The exclusion criteria included age over 70 years, severe peripheral vascular disease, history of a previous right-sided thoracotomy/irradiation, concomitant coronary artery disease requiring surgical revascularisation, or concomitant aortic valvular disease requiring surgery. All data presented in this study was prospectively collected. The study was approved by the clinical audit committee of the fourth affiliated hospital of Guangxi Medical University to meet ethical and legal requirements. Individual informed consent was obtained.

Operative Technique

All surgical procedures were carried out by the same surgeon, who had significant prior experience with mitral valve surgery performed through a sternotomy. Patients were submitted to surgical interventions under general anaesthesia with a double lumen endotracheal intubation. The patient was then placed in the supine position with an air sack under the right scapula to elevate the right side and for adduction of the right arm. Cardiopulmonary bypass (CPB) was established through cannulation of the right femoral artery and vein using the Seldinger technique. The chest was opened and an anterolateral skin incision, 5 to 7 cm in length, was made at the fourth intercostal space to allow access to the chest cavity. The right lung was retracted posteriorly, and the right lobe of the thymus gland was resected. The pericardium was opened 2 cm anteriorly parallel to the phrenic nerve before inserting a Chitwood transthoracic aortic cross-clamp (Scanlan International Inc, Minneapolis, MN, USA) through the third intercostal space at the mid-axillary line. After initiating extracorporeal circulation, while maintaining the oesophageal temperature at 28–32 °C, the ascending aorta was cross-clamped and myocardial protection was achieved by infusion of antegrade cardioplegic solution through the root cannula at the ascending aorta. Before cardiac opening, carbon dioxide (CO_2) insufflation was performed by the direct insertion of the 16-gauge angiocatheter connected to the CO_2 tank. The MVR procedure was then completed via the interatrial groove approach and a continuous suture was applied to fix the prosthesis.

Definitions of Surgical Failure

As perioperative death is rare after elective or urgent isolated mitral operations, it is unsuitable for assessing performance. Therefore, we defined surgical failure as the occurrence of one or more of the following events: (i) perioperative death (all deaths within 30 days of operation irrespective of where the death occurred, and all hospital deaths after 30 days among patients who had not been discharged after the operation); (ii) intraoperative conversion to median sternotomy; (iii) perivalvular leakage; (iv) postoperative femoral artery dissection; (v) stroke; (vi) in-hospital reoperation for any cause; and (vii) surgical wound infection.

Statistical Analysis

To facilitate statistical analyses and interpretation of results, the patients were grouped into five blocks (periods 1–5; 20 patients in each) according to the operation date. The operative variables were measured; statistical differences among groups were assessed using Fisher's exact tests for categorical outcomes and an analysis of variance (ANOVA) for continuous outcomes. Furthermore, the learning curve was evaluated using the CUSUM method, which has been used often in recent learning curve studies [10–12]. Herein, we followed Novick's methods [13]; CUSUM was defined as $Sn = \sum(Xi - p0)$, where $Xi = 0$ for success and 1 for failure and p0 is the reference or target value. In our study, p0 was set at 0.1, indicating that the ''target failure rate'' (i.e., combined death and/or complication rate) was 10%; this assumption was supported by the data published in many other studies [14,15]. Finally, 80% alert and 95% alarm boundary lines were calculated and constructed for the CUSUM curves according to the Novick's methods [13].

For all analyses, a p-value of 0.05 or less was used to determine statistical significance. All reported p-values are two-sided. All statistical analyses were performed using SPSS 17.0 (SPSS, Inc., Chicago, Il, USA).

Results

All 100 patients underwent elective minimally invasive cardiac surgery (MICS) via the RAMT approach. The baseline demographic data are listed in Table 1, which shows that there were no significant changes in preoperative factors such as sex, left ventricular ejection fraction (LVEF), body mass index (BMI), and the cardiac function as classified by the New York Heart Association (NYHA) class, among all five periods, except for a small increase in patient age from periods 1 to 5 ($p = 0.003$). As shown in Table 2, the surgeon's performance improved with time, along with a decrease in the cross-clamp time, operative time, and blood loss ($p < 0.001$) (Figure 1). Although there was a reduction in the number of failures, it was not significantly different among the five periods (Figure 2).

Furthermore, all failures evaluated by the CUSUM failure analysis are listed in Table 3. One patient (1%) died in hospital and another 10 patients (10%) incurred one of the seven surgical failure events listed above. The CUSUM curve (Figure 3) reflects a ''learning curve'' associated with this new procedure, which showed that at least 33 cases were required to reach the plateau of this type of operation for this surgeon.

Discussion

Over the past decade, minimally invasive mitral valve surgery, especially through the RAMT approach, has been increasingly employed due to its excellent short- and long-term results [1–3]. However, when a novel technique is introduced, the surgeon must gain proficiency and experience by performing the procedure on suitable patients, termed a ''learning curve.'' Despite the extensive body of literature on outcome analysis in minimally invasive mitral valve surgery, few studies have focussed on the learning curve of this new technique in the past decade. The purpose of our study was to statistically analyse the learning curve of a single cardiac surgeon over a 2-year period, from the onset of independent practice to completion of 100 cases of minimally invasive mitral valve surgery using the RAMT approach.

The results of our study showed that there is a definite surgical learning curve, which is characterised by a decrease in the cross-clamp time, operation time, and blood loss from periods 1 to 5, despite a significant increase in the patient's age. The fact that no significant differences in the other preoperative patient variables were found from periods 1 to 5 indicates that the improved results were not due to the avoidance of special cases with increasing experience.

Because the learning curve truly exists, applying suitable valuation tools is essential in the accurate evaluation of a single surgeon's performance, especially when a novel technique is introduced. Unfortunately, the traditional way of auditing surgical performance is by retrospective analysis of

Table 1 Preoperative factors of the patients ($\bar{x} \pm s$).

Variables	P1	P2	P3	P4	P5	p
Gender						0.876
Male	11	12	9	11	12	
Female	9	8	11	9	8	
Age (years)	32.4 ± 5.7	35.5 ± 7.2	36.3 ± 3.9	36.7 ± 5.8	40.0 ± 6.3	0.004*
LVEF (%)	54.3 ± 6.4	53.7 ± 4.8	53.9 ± 4.1	52.9 ± 5.1	53.6 ± 5.4	0.956
BMI (kg/m^2)	21.7 ± 1.6	22.4 ± 1.9	21.8 ± 1.7	22.6 ± 2.1	22.8 ± 1.3	0.206
Diagnosis						0.522
MI	11	6	5	4	6	
MS	6	10	11	13	10	
MI + MS	3	4	4	3	4	
Aetiology						0.739
Rheumatic	15	13	11	15	16	
Degenerative	4	6	7	5	3	
Others	1	1	2	0	1	
NYHA Class						0.942
I	6	6	7	7	5	
II	12	10	10	11	10	
III	2	4	3	2	5	

Abbreviations: LVEF, left ventricular ejection fraction; BMI, body mass index; NYHA, New York Heart Association; MS, mitral stenosis; MI, mitral insufficiency.
*$p < 0.01$.

Table 2 Operative data of the patients.

Variables	P1	P2	P3	P4	P5	*p*
Cross-clamp time (min)	38.7 ± 8.2	29.0 ± 2.4	28.1 ± 2.7	27.5 ± 3.1	26.8 ± 2.3	0.000*
Operation time (min)	177.1 ± 35.8	131.2 ± 9.4	126.1 ± 11.0	122.8 ± 13.5	120.4 ± 9.1	0.000*
Blood loss (ml)	365.3 ± 55.4	284.5 ± 32.7	229.5 ± 41.7	183.0 ± 16.7	172.5 ± 27.9	0.000*
Total failure number	5	2	2	1	1	0.238
Reoperation for bleeding	2	1	1	0	1	
Conversion to median sternotomy	2	1	0	1	0	
Death for any causes	1	0	0	0	0	
Wound infection	0	0	1	0	0	

*$p < 0.01$.

the outcome data and statistical testing to assess the learning curve. In the present study, we decided to take Novick's lead in using the CUSUM method to evaluate the quality of the surgeon's performance during the first 100 surgeries using the minimally invasive approach.

The CUSUM, initially developed by Page in an industrial context in 1954, has been shown to be the most suited for detecting small, persistent process changes [16]. In 1992, Williams first proposed its use in a medical context [17], and in 1994, de Leval and associates illustrated its ability to detect a cluster of deaths after arterial switch repair for transposition of the great arteries [18]. The CUSUM technique allows monitoring of changes in perioperative mortality and morbidity, which provides an almost real-time monitoring of the surgical performance. Nowadays, the CUSUM test is favoured by care providers owing to its simple formulation and intuitive representation. Several studies have confirmed utility of the CUSUM method to assess cardiac surgery results, especially the off-pump coronary artery bypass surgery performed by beginners [12,13,19–21]. However, the CUSUM method is not often used for monitoring performance in minimally invasive valvular procedures.

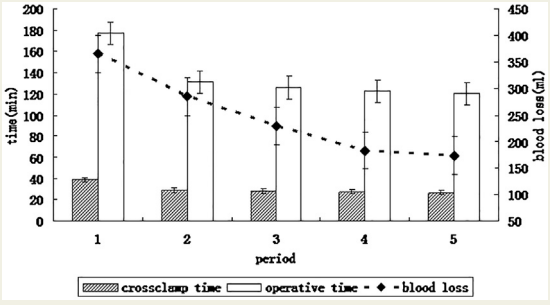

Figure 1 Cross-clamp time/operative time/blood loss in periods 1 to 5.

Table 3 Analysis of all failure cases.

Case No.	Failure cause
1	Conversion to median sternotomy
6	Reoperation for bleeding
9	Death from rupture of the left ventricular
16	Reoperation for bleeding
20	Conversion to median sternotomy
26	Reoperation for bleeding
39	Conversion to median sternotomy
48	Surgical wound infection.
55	Reoperation for bleeding
67	Conversion to median sternotomy
97	Reoperation for bleeding

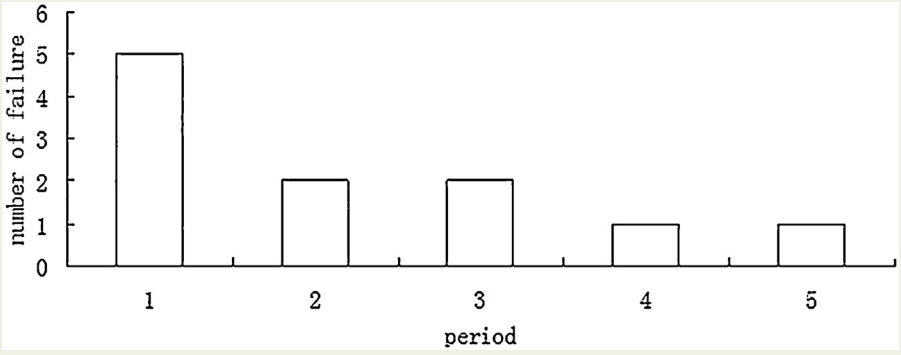

Figure 2 Number of failure according the period of operation.

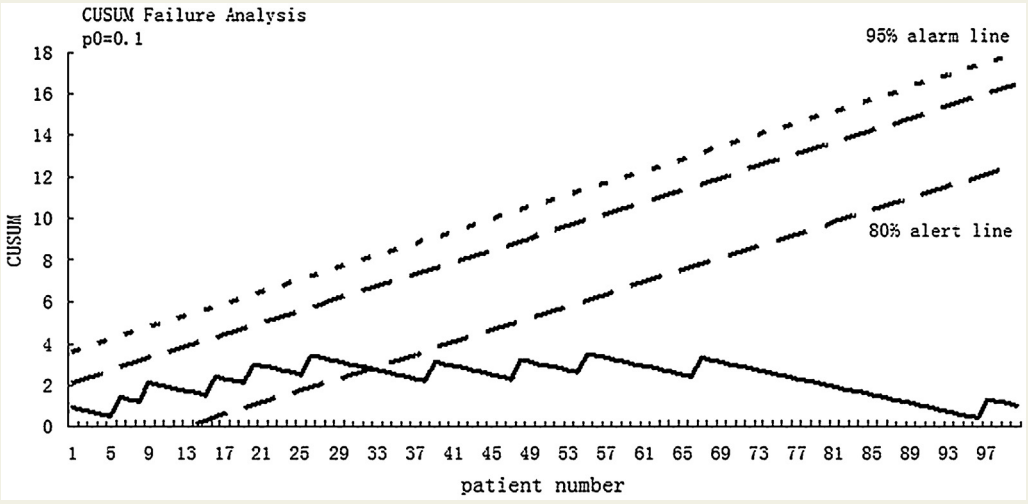

Figure 3 CUSUM analysis of the clinical outcomes.

In 2012, Michele Murzi and colleagues demonstrated that aortic valve replacement (AVR) and MVR could both be safely performed through the RAMT approach without exposing the patient to an increased operative risk, even during the surgeon's initial experience, although a learning curve does indeed exist [22,23]. After quality evaluation of the surgeon's performance using the CUSUM method, they concluded that CUSUM analysis is a valuable tool for assessing the learning curve of new surgical techniques and to implement continuous performance monitoring. The same results were provided by Holzhey and colleagues [24], who concluded that 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 does exist between individual surgeons.

Our study provided similar results, which indicates that the CUSUM analysis can allow the implementation of control charts for continuous individual performance monitoring. Consistent with the clinical results, the CUSUM curve presented a very small ascent stage, suggesting that the surgeon faced an elevated incidence of failures at the beginning. As the entire operative field could not be directly visualised, reoperation for bleeding made up approximately 45% (5/11) of all complications, whereas conversion to a median sternotomy made up 36% (4/11), leading us to modify the surgical technique to minimise the chance of these complications occurring. In our experience, bleeding most frequently occurred at the inner thoracic wall. As a result, before closing the incision, we routinely use the thoracoscope to thoroughly inspect the inner thoracic wall. Although it is difficult to account for the role played by the change in the outcomes, by doing this we have observed a decline in the complications mentioned above, which was also reflected in the CUSUM curve; the surgeon had accumulated sufficient experience to achieve a reduction in the complications after approximately 33 cases.

However, the primary driver of operative efficiency in the procedure is the collaborative experience of the operative team, rather than the individual experience of the single surgeon [25]. Therefore, the learning curve of the entire operative team may be more meaningful, which is the direction of our future research.

Limitation

The present study is aimed to report a single surgeon's first 100 cases' experience in China, and the number of cases that have undergone this type of surgery is still quite limited, and as it is not a comparative study, we can not make definitive inferences about its real advantages and disadvantages.

Conclusion

Mitral valve replacement through the RAMT approach can be performed by a surgeon with no prior experience of this technique; however, the surgeon's performance should be monitored closely. The CUSUM curve analysis is a simple statistical method to implement continuous individual performance monitoring, especially at the beginning of the surgeon's training process.

Conflicts of Interest

The authors declare no conflict of interest.

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