Quality control in a training course of off-pump coronary artery bypass grafting surgery

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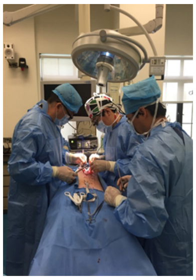
ABSTRACT

Objectives: Off-pump coronary artery bypass grafting (OPCAB) surgery is controversial in part because of the surgeon's experience, which correlates with how the surgeon is trained. Because the training model of OPCAB is not uniform, the quality control in the training process seems to be more important and needs to be further discussed.

Methods: Nine surgeons accepted and completed an OPCAB training course at a single center to become independent surgeons. This training program is characterized by 6 progressive levels supervised by experienced trainers. In total, 2307 consecutive cases of OPCAB performed by the 9 trainee surgeons were analyzed for monitoring and evaluation in quality control. The funnel plots and cumulative summation (CUSUM) analysis method were used to evaluate the performance of each surgeon.

Results: The mortality and complications of each surgeon were all within the 95% confidence interval of funnel plots. The CUSUM learning curves of first 3 trainees was analyzed and showed that the trainees need to complete approximately 65 cases to cross the CUSUM learning curve to reach a steady state.

Conclusions: The trainees can directly receive the OPCAB training course under the guidance of experienced surgeons with a rigorous schedule. It is feasible to perform quality control by funnel plots and CUSUM method in OPCAB surgery to ensure the safety of the training course. (JTCVS Open 2023;14:252-60)



Live off-pump animal experiment.

CENTRAL MESSAGE

A rigorous training program for off-pump coronary artery bypass was designed. Quality control can be measured using funnel plots and the cumulative summation method.

PERSPECTIVE

This study describes an off-pump coronary artery bypass grafting (OPCAB) training program at our center. We demonstrate that quality of the surgery and safety of the training course can be monitored with funnel plot and cumulative summation.

▶ Video clip is available online.

Since Robert Goetz first published his experience with coronary artery bypass grafting (CABG) in 1961, CABG has become an important revascularization method of coronary artery disease.[1] In efforts to avoid complications that may be attributable to aortic manipulation, global myocardial ischemia, and the systemic inflammatory response associated with cardiopulmonary bypass, some surgeons have embraced off-pump coronary artery bypass grafting (OPCAB), especially in high-risk groups of patients.[2,3] For the first generation of OPCAB surgeons, mastering the relevant techniques was achieved through their own learning and exploration. They had extensive experience with on-pump CABG surgery. Through the improvement of technology and the development of surgical instruments, they repeatedly explored and practiced, and gradually transitioned from on-pump to off-pump. Second-generation OPCAB surgeons can be trained in high-volume cardiac centers and advance in OPCAB

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Abbreviations and Acronyms

CABG	= coronary artery bypass grafting
CUSUM	= cumulative summation
CVVH	= continuous venovenous hemofiltration
MI	= myocardial infarction
OPCAB	= off-pump coronary artery bypass grafting
SPC	= statistical process control

techniques under the guidance of experienced surgeons. These types of training are generally considered safe and feasible. However, compared with on-pump CABG, OPCAB training has more uncertainties in terms of selection criteria, training process, training cycle, and evaluation methods. For different centers or different surgical teams, the training methods of OPCAB surgery are not uniform. How to evaluate the efficacy of quality control, especially the early warning mechanism of abnormal results, should be a problem to which every trainer needs to pay attention.

The proportion of off-pump bypass surgery in China is greater than that in Europe and America.[4] A considerable number of surgeons have been exposed to this technology, and their proportion of OPCAB surgery has reached more than 90%. OPCAB training in some centers is for young doctors without experience in coronary surgery, which has greater requirements for quality control. In our center, a training course of off-pump bypass has existed for many years. Senior operators have served as direct trainers, designed a set of advanced training programs, paid attention to the study of learning curve, and actively carried out risk control and early warning of training quality to improve the training quality.[5]

METHODS

Training Program

The OPCAB training program at our center is geared toward cardiac specialists who have received general surgery training but have no experience performing cardiac surgery independently. This training course is divided into 6 levels, from level B to Level G, and each level corresponds to the relevant training content and evaluation indicators (Table 1). Trainees must complete each level of training in order to achieve the training objectives and meet the evaluation criteria before entering the next level. From grade B to grade E, trainees are supervised and monitored by mature surgeons. After reaching Grade F, they become relatively independent doctors and are monitored by the quality control system. After completing Grade F, they are reviewed by the committee and finally enter Grade G to become independent doctors. All animals received humane care in compliance with the Guide for the Care and Use of Laboratory Animals (Video 1).

Surgical Technique

The operations were all performed through a median sternotomy. After the pericardium was opened, deep pericardial stitches were used to help elevate the heart and expose the target vessels. Stabilization of the target coronary arteries was accomplished with a tissue stabilizer, and an intracoronary shunt was used during distal anastomosis. The left internal mammary artery, right internal mammary artery, radial artery, and great saphenous veins were harvested as conduits material beforehand as needed. The left internal mammary artery was usually used to reconstruct the left anterior descending branch. The great saphenous vein, right internal mammary artery, or the radial artery were used to reconstruct the right coronary or the circumflex territories.

Case Inclusion Criteria

Nine trained physicians were enrolled in the study, and the data of these physicians who performed surgery independently after attaining Grade F training were analyzed. The data were obtained from Peking University People's Hospital database from 2007 to 2016. A total of 2739 patients undergoing CABG, including 162 (5.9%) on-pump CABG surgery, 2307 (84.2%) median sternotomy OPCAB surgery, and 270 (9.9%) minimally invasive direct CABG. This study was approved by our institutional review board/ethics committee (2023PHB072-001, 2/16/2023). Consent for individual use of data was waived because of the nature of the study and previous approval for use of such data at the time of operative consent.

Definitions of Complications and Major Parameters

We used the American Association for Thoracic Surgery definitions for perioperative myocardial infarction (MI).[6] The other definitions are as follows: (1) perioperative death: death caused by any reason during the period of intraoperative or postoperative hospitalization; if the patient has been discharged from hospital, it refers to death within 30 days after surgery; (2) emergency conversion: converting from off-pump to on-pump because of hemodynamic instability or unsatisfactory exposure to finish the anastomosis; (3) acute renal failure: patients with normal preoperative renal function need continuous venovenous hemofiltration (CVVH) therapy postoperatively; (4) resternotomy: reopen for bleeding, acute pericardial tamponade, hemodynamic instability, or other reasons; (5) postoperative stroke: any new permanent global or focal neurologic deficit that could not be attributed to preexisting neurologic and/or non-neurologic pathophysiologic abnormalities; and (6) malignant ventricular arrhythmia: an arrhythmia that causes hemodynamic disorder within a short time and needs urgent treatment.

Statistical Analysis

In this study, perioperative death, perioperative MI, postoperative renal failure, postoperative stroke, emergency conversion, resternotomy, and malignant ventricular arrhythmia were defined as the evaluation indicators of cumulative summation (CUSUM). CUSUM was defined as $Sn = \Sigma(Xi-Po)$, where $Xi = 1$ for a "failure" to achieve the target value of the evaluation indicators and $Xi = 0$ for a "success" (avoidance of the 4 major complication), whereas Po is the reference value that is the possibility of evaluation indicators cannot reach the target value. Referring to previous literature and our own experience, we set the Po for emergency conversion, perioperative MI, and resternotomy as 5%, 5%, and 2%, respectively. Continuous variables are expressed as means $\pm$ standard deviation; if the data conformed to a normal distribution, the 2 groups were compared using an independent samples *t* test, and multiple groups were compared using variance analysis. For nonnormal distribution data, the Wilcoxon rank sum test was used for comparison between the 2 groups, and Kruskal–Wallis H test was used for comparison between multiple groups. Categorical variables are described as percentages (rate), the comparison between the 2 groups using the χ^2 test, and the comparison between multiple groups using crosstabulation analysis. All the analysis was performed with SPSS, version 23.0 (IBM Corp) and R, version 3.5.1 (R Foundation for Statistical Computing).

RESULTS

Baseline Characteristics and Perioperative Variables of the Patients

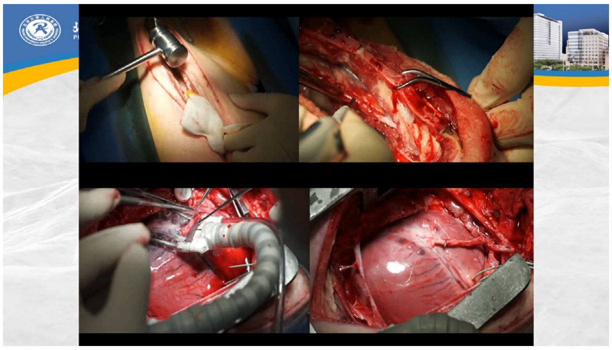
In total, 2307 cases of OPCAB operations were performed by 9 surgeons who completed Level E in the OPCAB training course at our center. The operative (including

TABLE 1. OPCAB training process and level identification

Level	Stage	Task	Volume	Evaluation
Basic level	B1	Patient care	Null	Supervisor's approval
	B2	Vein grafts harvest	20	Consecutive 10 good veins
Comprehensive level	C1	Chest open and IMA harvest	50	Consecutive 20 good IMAs
	C2	CPB skills	30	Supervisor's approval
Devoted level	D1	In vitro animal heart	50	Supervisor's approval
	D2	Proximal anastomosis	50	Consecutive 20 successful anastomosis
Encouraging level	E1	On-pump anastomosis	50	Consecutive 20 successful anastomosis
	E2	Live off-pump animal	5	Supervisor's approval
	E3	Off-pump anastomosis	50	Consecutive 20 successful anastomosis
	E4	Composite grafts or sequential grafts	10	Consecutive 10 successful anastomosis
Free level	F1	Protected operator	30	Consecutive 30 successful cases
	F2	MIDCAB	10	Consecutive 10 successful cases
Graduated level	G	Independent surgeon	null	Committee's approval

IMA, Internal mammary artery; *CPB*, cardiopulmonary bypass; *MIDCAB*, minimally invasive direct coronary artery bypass.

30-day) mortality was 1.6% (37 patients). The mean number of distal anastomoses was 3.1 ± 0.85 per patient. Perioperative intra-aortic balloon pump using was 4.5% (104 patients). Conversion to cardiopulmonary bypass was 1.7% (39 patients). Perioperative MI was 3.8% (87 patients), and early stroke was 0.6% (14 patients). In total, 45 patients (2.0%) underwent resternotomy as the result of bleeding or pericardial tamponade. The baseline characteristic variables and perioperative outcomes of all the patients who underwent OPCAB are summarized in Table E1 and Table E2. The perioperative data of operations performed by each surgeon (surgeons A-I) are shown in Table 2. The mortality rate ranged from 0% to 2.7%, of which 4 surgeons had a mortality rate of less than 1% and 2 surgeons had a mortality rate of more than 2%. There was no difference about the incidence of major complications including perioperative MI, resternotomy, acute renal failure, and early stroke. The 9 surgeons were divided into 3 groups by the number of operations they completed: the exploration group, with fewer than 65 cases (surgeons G, H, and I), and the stable group, with more than



VIDEO 1. Training scenarios of OPCAB. Video available at: https://www.jtcvs.org/article/S2666-2736(23)00087-6/fulltext.

65 cases but fewer than 200 cases (surgeons D, E, and F). Surgeons A, B, and C, who completed more than 200 operations, were defined as the mature group. The results showed that there was no significant difference in the perioperative outcomes of the 3 groups, but it could be seen that the exploration group had relatively better performance, which may be associated with fewer cases performed and more strict patient selection (Table 3).

Quality Assessment Using the Funnel Method

Perioperative mortality and complications of each surgeon were monitored by a funnel plot. Take Figure 1 as an example, the X-axis represents the number of operations, and the Y-axis represents mortality and incidence of complications. The black solid line represents the mean line of evaluation indicators incidence. The dashed blue line represents the 95% confidence interval, which was set as a typical monitoring line. Although the number of surgeries performed by each trainee was different, the mortality rate of each trainee was within the 95% confidence interval. Similarly, the 4 curves of Figure 2 show that incidence of major complications including perioperative MI, resternotomy, CVVH, and early stroke were all within 95% confidence interval. For physicians in training with a small number of cases, the results were freer above and below the mean line, suggesting that the impact of individual case results was more significant. Some data points were closer to the warning value of the 95% confidence interval, and special attention should be paid to the warning value. For doctors in training with a larger number of cases, the results were closer to the mean line, suggesting that the clinical results were more stable. The result of these funnel plots indicated that the surgical risk was controllable and the training results were acceptable (Figures 1 and 2, *A-D*).

TABLE 2. Perioperative data of different surgeons

Item	A	B	C	D	E	F	G	H	I	Total
Number of operations	353	729	704	199	105	147	22	25	23	2307
Mortality rate	2.3	1.8	0.9	2.0	1.9	2.7	0	0	0	1.6
Perioperative myocardial infarction	4.5	3.8	3.3	4.0	4.8	3.4	4.5	0	4.3	3.8
Emergency conversion	1.1	2.3	1.7	2.5	0	0.7	4.5	0	0	1.7
Resternotomy	0.8	2.3	1.6	2.0	2.9	3.4	4.5	0	4.3	2.0
Renal failure	2.0	1.6	1.1	2.5	1.9	2.0	0	0	4.3	1.6
Early stroke	0.3	0.5	0.7	0.5	0	1.4	0	4.0	0	0.6
Postoperative hospital stay, d	12.1 ± 7.2	11.5 ± 7.4	11.1 ± 8.1	12.3 ± 9.8	10.2 ± 4.1	12.6 ± 9.5	12.6 ± 6.4	8.7 ± 3.3	12.6 ± 8.4	11.5 ± 7.8
EuroSCORE II	1.4 ± 0.9	1.4 ± 1.0	1.1 ± 0.6	1.4 ± 0.9	1.4 ± 0.9	1.3 ± 1.0	1.2 ± 0.6	1.2 ± 0.5	1.2 ± 0.4	1.3 ± 0.8

EuroSCORE, European System for Cardiac Operative Risk Evaluation.

Quality Assessment Using CUSUM Method

The cases of OPCAB surgery independently performed by the 6 surgeons (surgeon A-F) in the mature and stable groups were retrospectively collected, and the learning curve was plotted by CUSUM method. In the mature group, the CUSUM curve of the recent 50 cases performed by surgeon A showed an upward trend, indicating that the operation failure rate increased, mainly due to the increase in the perioperative MI. In addition to the increased risk factors of patients, the department has been more active in monitoring perioperative MI in recent years, but the overall perioperative MI rate has not increased. Approximately 62% of the operations in this study were performed by surgeons B and C, who have performed more than 700 operations total. The performance of these 2 surgeons was stable, and performance of surgeon C was slightly better than surgeon B, which may be related to the lower European System for Cardiac Operative Risk Evaluation II score (Figure 3, *A*). In the stable group, the results showed that the CUSUM values of the 3 surgeons were all below the 80% warning line (Figure 3, *B*), indicating that the operation quality of the 3 surgeons was controllable.

The first 90 cases of OPCAB surgery independently performed by the 3 surgeons in the mature group were analyzed to evaluate the number of cases required to cross the curve. The learning curve from surgeon A is divided into 2 phases, the ascending phase and the descending phase; the peak of the curve was reached between the 60th and 70th cases. The slope k value of the curve became negative after the 65th case of surgery, indicating that surgeon A successfully crossed the learning curve after the 65th case of OPCAB surgery (Figure 4, *A*).The learning curve from surgeon B is also divided into 2 phases, the rising phase and the falling phase. After the 59th operation, the slope of the curve k became negative, indicating that he successfully crossed the learning curve after the 59th OPCAB surgery (Figure 4, *B*). The learning curve from surgeon C was different from the first 2 surgeons, which have a rapid rising phased (the first 12 cases), a slow rising phase (13th to 28th cases), the plateau phase (the 29th to 66th cases), and the descending phase (after the 67th case).The third surgeon successfully crossed the learning curve after 66 OPCAB operations (Figure 4, *C*). The cases required to cross the exploring phase entering stable state were 65, 59, and 66 respectively. All the 3 surgeons had an obvious OPCAB learning curve; the trainees need to complete approximately 65 cases to cross the CUSUM learning curve to reach a steady state.

TABLE 3. Comparison of perioperative data of the 3 surgeon groups divided by the number of operations they performed

Item	Exploration group (n = 70)	Stable group (n = 451)	Mature group (n = 1786)	*P* value
Mortality rate	0 (0)	10 (2.2%)	27 (1.5%)	.315
Perioperative myocardial infarction	2 (2.9%)	18 (4.0%)	67 (3.8%)	.894
Emergency conversion	1 (1.4%)	6 (1.3%)	33 (1.8%)	.739
Resternotomy	2 (2.9%)	12 (2.7%)	31 (1.7%)	.383
Renal failure	1 (1.4%)	10 (2.2%)	27 (1.5%)	.569
Early stroke	1 (1.4%)	3 (0.7%)	10 (0.6%)	.720
Postoperative hospital stay, d	11.2 ± 6.5	11.9 ± 8.8	11.4 ± 7.6	.531
EuroSCORE II	1.1 ± 0.4	1.3 ± 0.8	1.3 ± 0.8	.195

EuroSCORE, European System for Cardiac Operative Risk Evaluation.

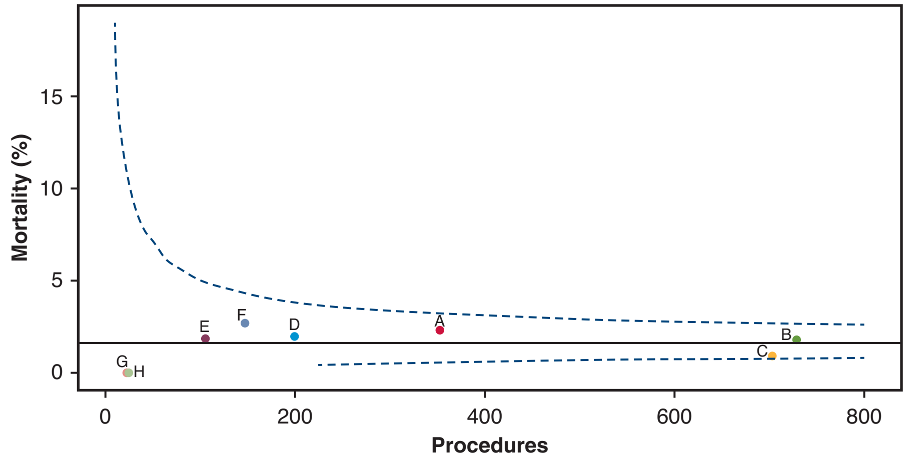


FIGURE 1. Funnel plot showing the operative mortality of different surgeons.

Comment

OPCAB requires fine anastomosis of target vessels under heart-beating conditions, which requires high technical abilities for surgeons. The surgical experience is often an important determinant of operative efficiency and long-term survival.[7,8] In China, the development of coronary artery surgery progressed in the 1990s, later than congenital heart surgery and valve surgery, resulting in many cardiac surgeons still lacking coronary surgical experience despite years of professional service. However, currently most institutions had several sophisticated OPCAB surgeons who adopted OPCAB as a routine procedure for patients undergoing isolated CABG. This situation made it feasible for us to pursue a study that explores the feasibility and safety of conducting OPCAB training in surgeons lack of coronary surgical experience. To train more qualified OPCAB surgeons in a relatively short period, it is necessary to create a standardized training course and strengthen the quality monitoring of surgery. Through the training course in our center, the resident can begin the

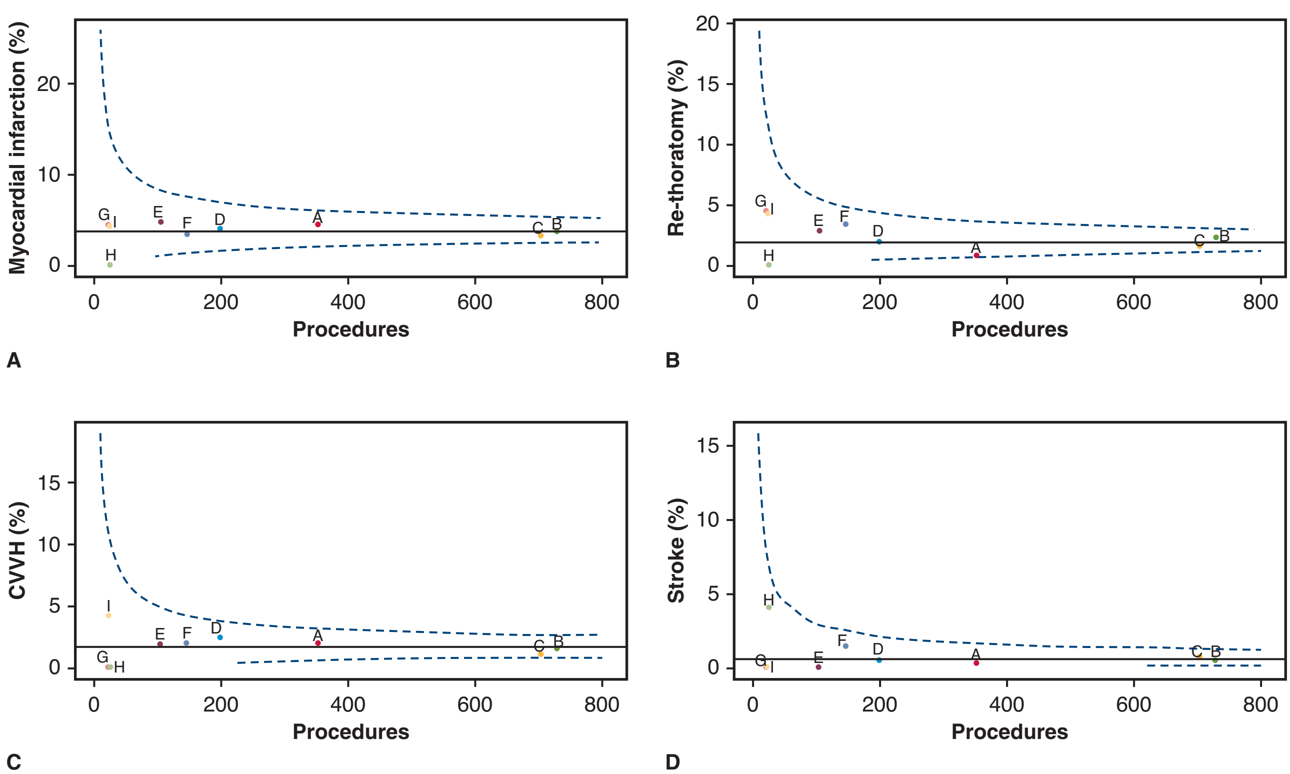


FIGURE 2. A-D, funnel plots showing the major operative complications of different surgeons. *CVVH*, Continuous venovenous hemofiltration.

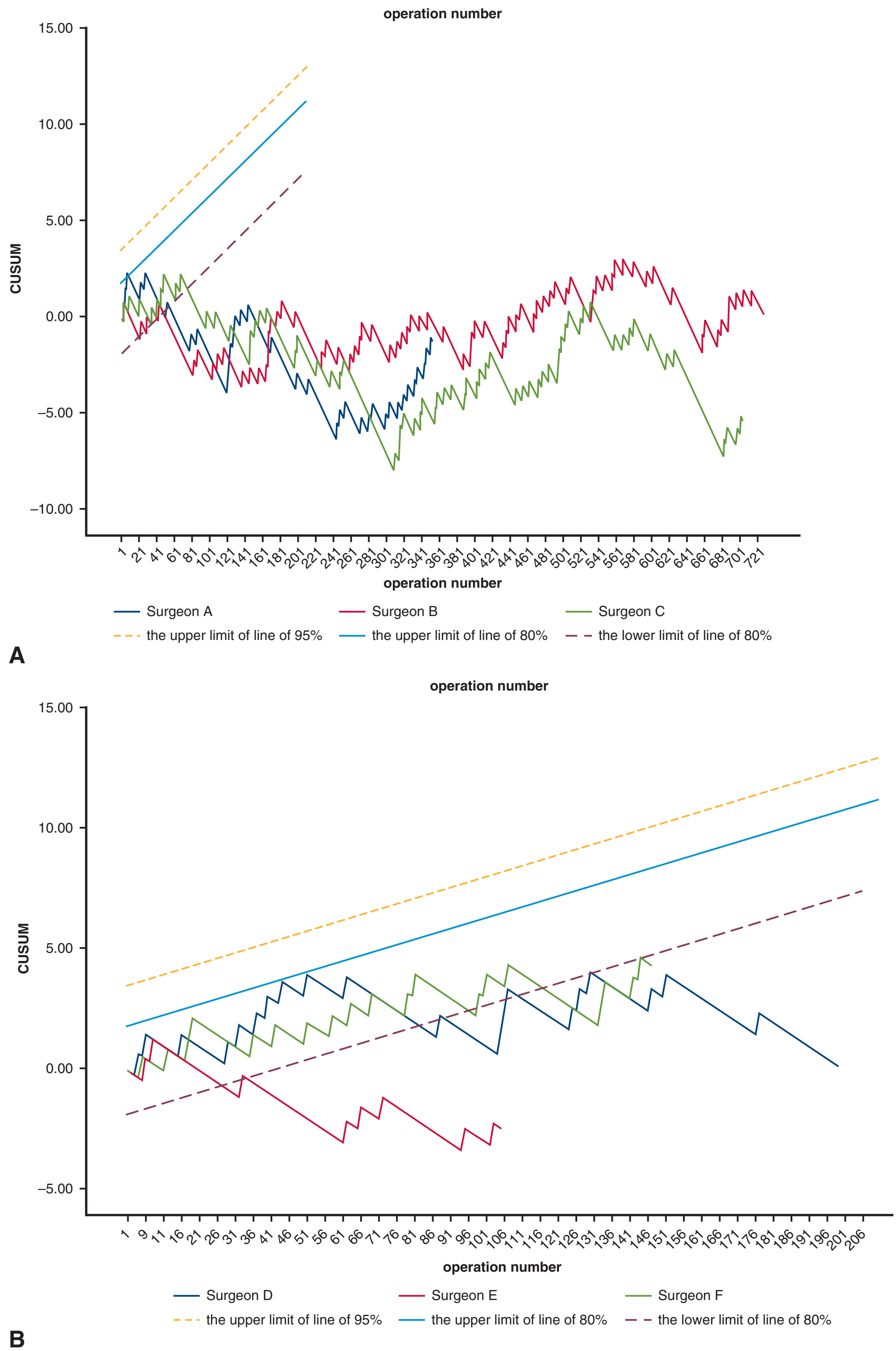
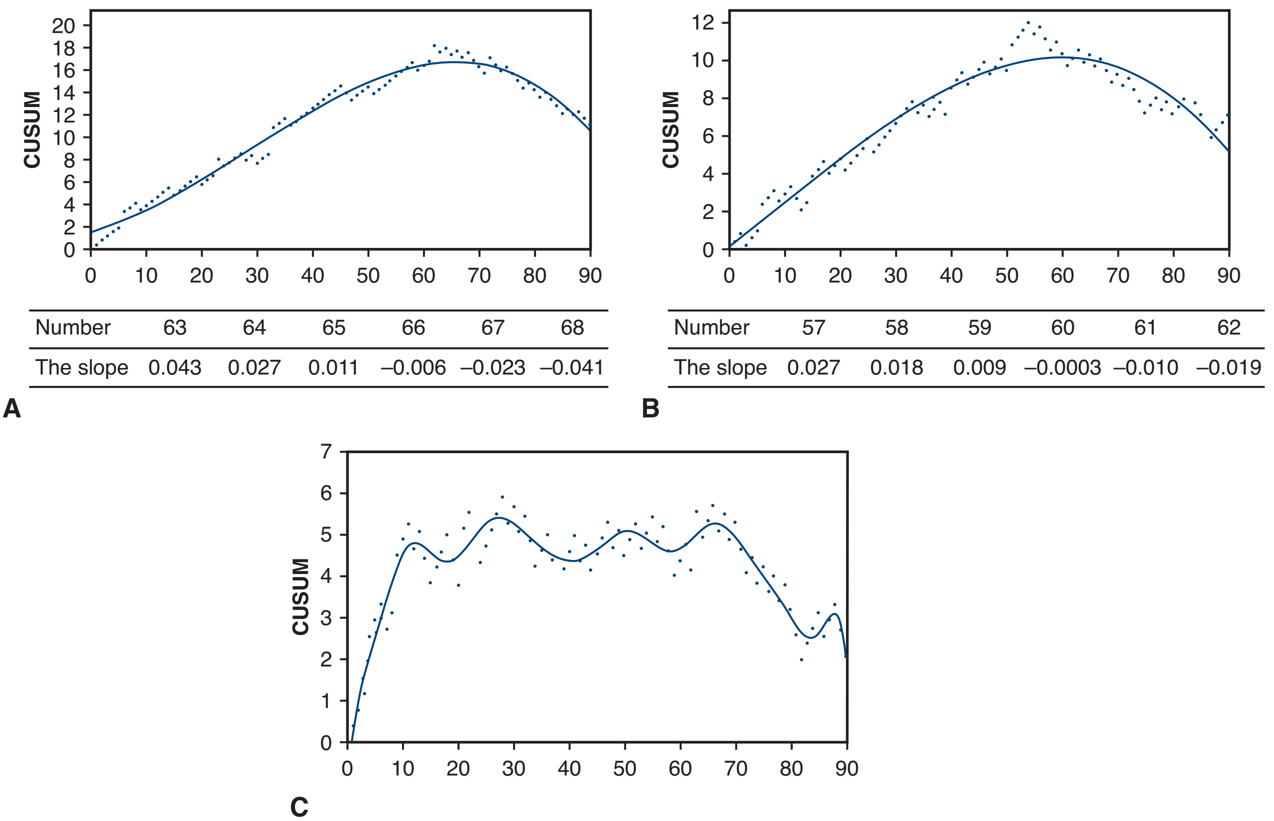


FIGURE 3. A, B, The quality assessment by CUSUM method in mature and stable group. *CUSUM*, Cumulative summation.



Number	63	64	65	66	67	68
The slope	0.043	0.027	0.011	−0.006	−0.023	−0.041

Number	57	58	59	60	61	62
The slope	0.027	0.018	0.009	−0.0003	−0.010	−0.019

FIGURE 4. A-C, The CUSUM learning curve of surgeons A-C. *CUSUM*, Cumulative summation.

training once they enter cardiac surgery to be an independent OPCAB surgeon. This study mainly discusses the quality control method of the OPCAB training course at our center. To make certain the mortality and morbidity of operations performed by trainees is in an acceptable range can help to ensure the safety of surgery and indicate whether there is need for adjustment and improvement during the clinical process.[9]

There have been many methods of quality control. Statistical process control (SPC), developed in the 1920s by the physicist Walter Shewhart to improve industrial manufacturing, has been widely implemented. The commonly used methods of SPC include the funnel plots and CUSUM method, which has been used in the medical field Since the 1970s, mainly for public health monitoring, surgical quality control, and learning curve analysis.[10,11] Funnel plots based on SPC can be used for medical quality control and meta-analyses.[12,13] The results are easy to understand and unaffected by sample size differences and confounding factors between groups. The results from Noyez,[14] who compared several commonly used quality control methods in cardiac surgery, suggest that CUSUM is the most useful one, and a funnel plot is more suitable for quality control for different institutions or surgeons.

In this study, a funnel plot was used to monitor the outcomes of OPCAB operations performed by different trainee surgeons in different years. The average perioperative mortality of OPCAB in our center was 1.6%, which was consistent with the mortality rate in the Randomized On/Off Cardiopulmonary Bypass (ROOBY) study (1.6%) and lower than that of the CABG Off or On Pump Revascularization Study (CORONARY) study (2.5%).[15,16] The incidence of perioperative MI, resternotomy, early stroke, and renal failure requiring CVVH was similar to the reported results.[15-17] Generally, the study learning curve before entering the descending phase includes 2 phases, the rising phase and plateau phase. The fewer number of cases required to complete the rising phase and cross the curve, the better effect the training receives. In this study, the learning curve of surgeon C was different from surgeon A and B; although with the similar cases required to cross the learning curve, he has successfully completed the rising phase with the fewest cases (28 cases). To compare this surgeon with the other two, we found that there was no difference in baseline data of cases, nor the surgical backgrounds and training process they received, only due to the highest surgical frequency by the surgeon. Thus, we deduced that a better learning curve will be obtained by increasing the surgery frequency appropriately.[18,19]

The core of operation quality control is to evaluate the performance of the surgeon who is the specific implementer of the entire medical process. As the number of operations increases, the technical ability and experience will gradually improve and finally reach a relatively stable state. However, the stability may sometimes be influenced by high-risk patients, resulting in fluctuations in the quality result of the surgery, so individualized diagnosis and treatment strategies for high-risk cases are needed to ensure the OPCAB quality control. In this study, funnel plots and the CUSUM method were used to evaluate the quality of the operations performed by different surgeons. Funnel plots can intuitively reflect the number of operation cases, mortality, and complication rates of different trainee surgeons, and the operation quality can be monitored by an 80% warning line. Once the cumulative value reaches the line, we will pay more attention to the clinical strategy including the case selection and take adjustment measures in time. The CUSUM method has superiority for monitoring the changes in a continuous process, which can directly reflect the overall trend and periodic gradient changes of operation quality. According to the gradient change, problems can be found in time and adjustments can be actively made, so the quality control of subsequent operations can be guaranteed. However, the CUSUM method is not suitable for comparisons among multiple groups because too many interference factors in a graph will affect the intuition of the method; also, too small a sample size is not suitable for the CUSUM method. In summary, both the funnel plots and the CUSUM method are recommended to be used for quality control in OPCAB operations, and the results suggested that the performance of all the surgeons trained by the OPCAB training course at our center was satisfactory.

Limitations

Although our study is an innovative attempt at introduction of a OPCAB training course and evaluation of the quality control enterprise, several limitations of our study should be recognized. The first and most important limitation of this study was its descriptive nature. Second, only perioperative death and major complications were analyzed; the results of patency of graft and the long-term outcomes were not obtained.

CONCLUSIONS

The trainees without coronary surgical experience can directly receive OPCAB training under the guidance of experienced surgeons with a rigorous schedule. It is feasible to perform quality control for OPCAB operations performed by trainees using funnel plots and the CUSUM method.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: off-pump coronary artery bypass grafting, quality control, funnel plots, CUSUM failure analysis

TABLE E1. Baseline characteristic variables of the patients

Item	Study population (n = 2307)
Age, y	63.03 ± 8.95
Female	605 (26.2%)
BMI	25.37 ± 3.13
AMI	452 (19.6%)
LM disease	522 (22.6%)
Diseased vessels	2.87 ± 0.39
NYHA ≥III	398 (17.3%)
Hypertension	1417 (61.4%)
Diabetes	837 (36.3%)
COPD	37 (1.6%)
PVD	282 (12.2%)
Previous cerebral infarction	306 (13.3%)
Chronic renal insufficiency	130 (5.6%)
Smoking	1080 (46.8%)
LVEF	60.82 ± 11.03
EuroSCORE II	1.28 ± 0.83

BMI, Body mass index; *AMI*, acute myocardial infarction; *LM*, left main; *NYHA*, New York Heart Association; *COPD*, chronic obstructive pulmonary disease; *PVD*, peripheral vascular diseases; *LVEF*, left ventricular ejection fraction; *EuroSCORE*, European System for Cardiac Operative Risk Evaluation.

TABLE E2. Perioperative variables of the patients

Item	Study population (n = 2307)
Number of distal anastomoses	3.10 ± 0.85
Preoperative IABP use	13 (0.6%)
Postoperative IABP use	91 (3.9%)
Postoperative hospital-stay time, d	11.52 ± 7.84
In-hospital mortality	37 (1.6%)
Perioperative myocardial infarction	87 (3.8%)
Emergency conversion	40 (1.7%)
Resternotomy	45 (2%)
Renal failure	38 (1.6%)
Early stroke	14 (0.6%)
Wound problem	42 (1.8%)
Malignant arrhythmia	40 (1.7%)
Postoperative atrial fibrillation	199 (8.6%)

IABP, Intra-aortic balloon pump.