Cumulative sum failure analysis for eight surgeons performing minimally invasive direct coronary artery bypass

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Supplemental material is available online.

Objective: Analysis of average and individual surgical performance for minimally invasive direct coronary artery bypass was used to enhance quality control for that operation.

Methods: A total of 1441 standard minimally invasive direct coronary artery bypass procedures performed from August 1996 to January 2006 were analyzed for mortality and 10 other major perioperative complications. Learning curves and assessment of perioperative outcome were calculated using descriptive statistics and cumulative sum observed minus expected failure analysis for 8 involved surgeons with a personal experience ranging from 27 to 443 procedures.

Results: The incidence of in-hospital mortality was 0.9% and compared favorably with the predicted mortality calculated by the logistic EuroSCORE (3.6%, $P < .01$). Cumulative sum analysis revealed that 2 surgeons crossed the 95% reassurance boundary after 50 operations and that 2 surgeons crossed the 95% reassurance boundary after 100 operations. There were significant differences between surgeons with regard to the learning curves and perioperative complications (3.6%–29.6%, $P < .01$). Two surgeons crossed the 95% alarm-line indicating unacceptably high failure rates.

Conclusions: Minimally invasive direct coronary artery bypass has become a procedure with low mortality and low complication rates, but results are case-load and surgeon dependent. Cumulative sum analysis is a valuable method allowing for a breakdown of complication rates over time displaying individual surgeons' strengths.

ACD

For several years, quality assurance has become increasingly important in cardiac surgery. De Leval and colleagues[1] and Carthey and colleagues[2] outlined the importance of analysis of human factors in cardiac surgery and individual failure analysis. Minimally invasive direct coronary artery bypass (MIDCAB) grafting has been performed since 1996 in a standardized way at our institution. With the high number of MIDCAB procedures performed under similar conditions, it is not only possible to describe the outcome and complication rate of the procedure but also possible to compare individual surgeons' performances and learning curves.

The usefulness of the sequential probability cumulative sum (CUSUM) technique to analyze surgical performance has been shown in recent publications.[3-6] It allows for detection of changes in perioperative mortality and morbidity during the patient care process. It provides almost real-time monitoring of surgical performance if updated after each procedure.[3] CUSUM analysis acknowledges the importance of individual experience in monitoring performance and allows for easy charting of a learning curve with regard to the incidence of perioperative complications. The charts are intuitively readable, but care is needed to avoid misinterpretation.[7] The CUSUM method is able to demonstrate changes in the patient care process as a whole regardless of where these

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Abbreviations and Acronyms
CUSUM = cumulative sum
MIDCAB = minimally invasive direct coronary artery bypass

changes originate. Comparing results between different surgeons often fails because of the case mix and the variety of variables influencing patient outcome. Several risk-adjusted methods have been suggested for this scenario. In this study, no risk adaptation was used for the reasons outlined in the discussion.

With the quantity of MIDCAB operations at our institution performed under a standardized protocol (equal patient origin and patient selection, standardized surgical technique, identical postoperative management and medication), we found the non–risk-adjusted methods most practical and sufficient to evaluate and compare individual surgical performance over time.

Materials and Methods

From August 1996 to January 2006, 1441 patients underwent MIDCAB at our institution following a standardized protocol. The surgical technique has been described.[8] Eight surgeons were involved in the MIDCAB program, achieving a different level of experience ranging from 27 to 443 operations. Five surgeons performed more than 100 operations. Written and electronic files of all patients were screened for demographic data, risk factors, intraoperative parameters, and postoperative short-term and long-term complications and outcome. All data were entered into a database, and standard descriptive statistical and CUSUM analyses were conducted using Microsoft Office Excel (Microsoft Corp, Redmond, Wash) and SPSS 10.0 (SPSS Inc, Chicago, Ill).

CUSUM Analysis

Cumulative failure charts and their use have been described.[3-6] In this study, non–risk-adjusted cumulative observed minus expected failure charts were used. The statistical principles were adapted from the comprehensive tutorial by Rogers and colleagues.[3] CUSUM was defined as S_n = where $X_i = 1$ for a "failure" (intraoperative conversion, death, or any major complication as defined in Table 1) and as $X_i = 0$ for a complete "success" (none of the above complications). The target value p_0 was set to 0.1, indicative of an "acceptable failure rate" of 10% according to previous publications[4,5] and our own experiences with off-pump coronary artery bypass surgery.

CUSUM curves, together with control boundaries, were calculated and drawn according to the formulas shown in the Appendix. The crossing of an upper boundary was interpreted as an increase of the failure rate to an unacceptably high level of $p_1 = 0.2$, whereby crossing the upper 80% boundary set off a mild alarm to the surgeon and crossing the upper 95% boundary gave reason for more thorough investigation. Crossing the lower 95% boundary led to the conclusion that the complication rate of the particular surgeon was equal to or below the accepted rate of p_0. The curve moving in between the boundary lines indicated lack of statistic significance and triggered merely further monitoring (Figures E1, E2, and E3).

Whereas crossing the boundary lines is equivalent to a significant result in statistical testing, the comparison between surgeons is merely visual.

TABLE 1. Definition of major complication

Major Complication	Definition
Conversion	Necessity for any intraoperative conversion to sternotomy or use of CPB
Mortality	Death in hospital or within 30 d after the date of operation
Myocardial infarction	Postoperative myocardial infarction as confirmed by ECG findings or significantly high levels of CK/CKMB
Reintervention	Necessity for postoperative reintervention on the target vessel
IABP/ECMO	Necessity for use of IABP and/or ECMO in low cardiac output
Rhythm disorder	New onset of atrial fibrillation, need for pacemaker implantation, ventricular tachycardia, or ventricular fibrillation
Stroke	Permanent neurologic impairment caused by stroke or intracerebral hemorrhage
Bleeding	Reoperation for bleeding usually indicated when chest tube output exceeded 1000 mL or x-ray indicated hematothorax
Renal	Acute renal failure requiring temporary hemofiltration
Pulmonary	Prolonged ventilation (>24 h), reintubation, and/or severe pneumonia that prolonged hospital stay
Sepsis	Occurrence of sepsis or intestinal ischemia

CPB, Cardiopulmonary bypass; *ECG,* electrocardiogram; *CK,* creatine kinase; *IABP,* intra-aortic balloon pump; *ECMO,* extracorporeal membrane oxygenation.

Results

Operation Times

Median operation times were between 100 and 138 minutes. One surgeon (surgeon E) reached a median operation time of 61 minutes. There was a wide range from 40 to 350