

## Are intraoperative precursor events associated with postoperative major adverse events?

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**Objectives:** Precursor events are undesirable events that can lead to a subsequent adverse event and have been associated with postoperative mortality. The purpose of the present study was to determine whether precursor events are associated with a composite endpoint of major adverse cardiac events (MACE) (death, acute renal failure, stroke, infection) in a low- to medium-risk coronary artery bypass grafting, valve, and valve plus coronary artery bypass grafting population. These events might be targets for strategies aimed at quality improvement.

**Methods:** The present study was a retrospective cohort design performed at the Queen Elizabeth Health Science Centre. Low- to medium-risk patients who had experienced postoperative MACE were matched 1:1 with patients who had not experienced postoperative MACE. The operative notes, for both groups, were scored by 5 surgeons to determine the frequency of 4 precursor events: bleeding, difficulty weaning from cardiopulmonary bypass, repair or regrafting, and incomplete revascularization or repair. A univariate comparison of  $\geq 1$  precursor events in the matched groups was performed.

**Results:** A total of 311 MACE patients (98.4%) were matched. The primary outcome occurred more frequently in the MACE group than in the non-MACE group (33% vs 24%;  $P = .015$ ). The incidence of the individual events of bleeding and difficulty weaning from cardiopulmonary bypass was significantly higher in the MACE group. Those patients with a precursor event in the absence of MACE also appeared to have a greater prevalence of other important postoperative outcomes.

**Conclusions:** Patients undergoing cardiac surgery who are exposed to intraoperative precursor events were more likely to experience a postoperative MACE. Quality improvement techniques aimed at mitigating the consequences of precursor events might improve the surgical outcomes for cardiac surgical patients. (*J Thorac Cardiovasc Surg* 2014;147:1499-504)

An important component of quality improvement in cardiac surgery is an impartial evaluation of death and major morbidity in patients undergoing cardiac surgery. These metrics serve as quality indicators for outcomes, process, and structure of care.<sup>1,2</sup> Specifically, preventable death and morbidity are logical targets for quality improvement strategies, because they are potentially avoidable. Unavoidable injury, however, is thought to occur unexpectedly, with the temporal sequence of the inciting event to the injury very short. The published data have suggested that 56% to 87% of deaths in cardiac patients are nonpreventable,<sup>3,4</sup> potentially altering the success of quality improvement efforts.

It is possible that the causal pathway of these “unavoidable” injuries begins long before any overt warning signs are present. Upstream events, such as precursor events, have received recent attention as a focus for alterability. Precursor events are events that precede an adverse event such as death.<sup>5</sup> They are undesirable events that can lead to a subsequent adverse event. Intraoperative precursor events have been reported to occur in 73.3% of cardiac cases, with a mean of 3.5 precursor events per case.<sup>6</sup> Also, precursor events occurred more frequently in patients experiencing “death or near miss.” Intraoperative near misses and major complications have also been associated with increased postoperative death,<sup>7,8</sup> especially if the event went uncompensated.

Because compensation or appropriate responses to critical intraoperative events are important to prevent a potential adverse event from subsequently developing,<sup>9</sup> a surgical team might believe that a precursor event, if compensated for, would negate this potential. However, it might be, rather, that these “forgotten” events, whether compensated for or not, are the nidus in which begins the propagation of the precursor event toward an adverse event. Usually, such propagation is prevented through system safeguards<sup>10</sup>;

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### Abbreviations and Acronyms

CABG	= coronary artery bypass grafting
CPB	= cardiopulmonary bypass
MACE	= major adverse cardiac events
OR	= operating room

however, failure to recognize the importance of the precursor event could act as a “hole” in this layer of defense. As such, even nominal events could pose a potential risk to the patient and could account for death or major injury, regardless of the perceived “preventability.”

The goal of the present study was to determine whether intraoperative precursor events, regardless of the compensation or seriousness, contribute to postoperative death or major morbidity. In the present study, we chose to emphasize the coronary artery bypass grafting (CABG), valve, and CABG plus valve patient population, because this patient group encompasses most of current cardiac surgery clinical practice. Also, we limited the risk profile to low to medium preoperative predicted risk, because high-risk patients represent a small proportion of clinical practice, and their acuity might overwhelm any effect precursor events would have on subsequent outcomes.

## METHODS

### Data Source

The present study was a retrospective cohort design. The Maritime Heart Center Cardiac Surgery Registry is a detailed clinical database housed at the Queen Elizabeth II Health Science Center (Halifax, Nova Scotia, Canada). It includes pre-, intra-, and postoperative data prospectively collected for all cardiac surgical cases performed at the Queen Elizabeth II Health Science Center from 1995 to the present. The data are collected by trained abstractors, and a database administrator maintains the registry. The database is audited annually.

### Study Population

A patient cohort from 2004 to 2009 that included consecutive CABG, aortic valve replacement, mitral valve repair, and mitral valve replacement with or without CABG was used to develop a nonparsimonious logistic regression model that described the composite outcome of major adverse cardiac events (MACE). MACE was defined as in-hospital death, stroke (permanent or transient), acute renal failure (>176 mmol or a 50% increase from baseline if chronic renal failure), or infection (sepsis, pneumonia, or deep sternal wound infection). The predictor variables included in the model were important preoperative variables that might influence the probability of experiencing postoperative MACE. A detailed description of the model development can be found in the [Appendix](#).

The predicted probability of MACE was calculated for each patient in the model cohort. To define a study cohort of patients with low to medium risk of MACE, the model cohort was truncated at the 75th percentile. Using the predicted probability of MACE, each patient with postoperative MACE was matched 1:1 with a patient without postoperative MACE. A greedy matched algorithm that proceeded from a 5-digit to a 1-digit match on risk was used.

### Precursor Events

Precursor events were defined as undesirable incidents that occurred proximally in the causal pathway of an adverse event. They are required

for the adverse event to occur but do not always result in said event. As such, precursor events will occur with more frequency than will adverse events.<sup>5</sup> In general, precursor events are easily compensated for by the care team and are seldom recognized as a critical event in the causal pathway of an adverse event. Four intraoperative precursor events of interest were identified through quality assessment exercises at our institution: (1) bleeding, (2) failure to wean from cardiopulmonary bypass (CPB), (3) regrafting or repair of conduit or valve, and (4) incomplete revascularization or repair.

Bleeding was defined as any instance of surgical bleeding (other than related to the grafts) or coagulopathy requiring intervention such as repair, a return to CPB for repair, administration of blood products, or a delay in the termination of surgery. Failure to wean from CPB included any instance in which the patient did not wean or struggled to wean, requiring a return to CPB, insertion of an intra-aortic balloon pump, additional inotropic support, insertion of a ventricular assist device, and pacing or prewean pacing required to wean in the specific instance of valve surgery. Regrafting or repair of the conduit or valve included any instance in which regrafting or repair was undertaken because of issues with conduit length, lie, poor flow reading, wall motion abnormality on transesophageal echocardiogram, bleeding, perivalvular leakage, and persistent stenosis or regurgitation despite repair or replacement. Incomplete revascularization or repair occurred when not all critically diseased territories had undergone grafting or persistent stenosis or regurgitation or perivalvular leakage considered significant by best standard of care practices was not corrected. This could have been because of an inadequate size of the target vessel, a paucity of conduit, or other patient or technical factors.

The primary outcome was having  $\geq 1$  intraoperative precursor events.

The operative notes were used to identify the precursor events according to the surgeons' description of the events in the operating room (OR). These operative notes were dictated immediately after the operation before a MACE occurred, allowing for an unbiased measure of the prevalence of the precursor events. Patient and surgeon identifiers were removed from the operative notes for the matched groups, and the anonymous operative notes were distributed to 5 surgeons for review and identification of the precursor events. No surgeon received their own operative notes. Any operative note that reported a death in the OR or that was reported as a late dictation was removed from the review, along with the matched partner note. Inter-rater reliability was assessed.

A secondary analysis was planned to examine whether the precursor events were associated with other secondary outcomes, including pump time, clamp time, intraoperative inotropic use, postoperative blood product use, low cardiac output syndrome, and ventilator and intensive care unit length of stay. This was achieved by excluding the MACE events from the matched groups and then comparing all patients with a precursor event with those who did not. This was a hypothesis-generating analysis only.

### Statistical Analysis

Previous research from our institution examining precursor events and death in a low-risk CABG population revealed that patients who died postoperatively had had 30% more precursor events than those who did not die. For the study to achieve 80% power with an alpha of 0.05, the required sample size per group for a 50%, 40%, and 30% relative risk difference was 48, 112, and 243, respectively. Because the present study had a mixed population with an unknown risk difference, the largest sample size was used.

Continuous variables were compared using a 2-tailed *t* test or Wilcoxon rank sum test, and categorical variables were analyzed using a chi-square or Fisher's exact test, as appropriate. The prevalence of precursor events was compared between the matched groups (those with MACE vs those without MACE). The outcomes were analyzed using the chi-square test or Fisher's exact test, as appropriate.

All statistical analysis was performed using Statistical Analysis Systems software, version 9.2 (SAS Institute, Cary, NC).

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