Adverse events during reoperative cardiac surgery: Frequency, characterization, and rescue

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Objectives: To (1) determine frequency of occurrence and risk factors for intraoperative adverse events (IAE) during reoperative cardiac surgery, (2) characterize them with respect to structure injured, timing, and use of preventive strategies, and (3) identify the impact on outcome in terms of successful and unsuccessful rescue and cost.

Methods: Operative notes of 1847 patients undergoing reoperative cardiac surgery were reviewed to identify and characterize documented intraoperative adverse events. Logistic regression modeling was used to identify risk factors for intraoperative adverse events and outcomes. Expected versus observed poor outcomes (stroke, myocardial infarction, death) was used to measure rescue.

Results: Among 127 patients, 145 (7%) intraoperative adverse events occurred. These included injuries to bypass grafts (n = 47), heart (n = 38), and great vessels (n = 28) and ischemia without graft injury (n = 22). Most occurred on opening (n = 34, 23%) and during prebypass dissection (n = 57, 39%). Risk incremented as reoperations increased. Seventy-seven patients experienced 1 or more lapses in preventive strategies. Patients with intraoperative adverse events had a greater number of poor outcomes (n = 24 [19%] vs n = 107 [6.2%]; $P < .0001$) and incurred higher direct technical intraoperative and postoperative costs (ratio 1.3). Twelve patients with intraoperative adverse events were predicted to have poor outcomes versus 24 who did ($P < .0001$), indicating 12 "failures to rescue."

Conclusions: Adverse events still occur regularly during cardiac reoperation, are related to complexity of the procedure, and occur particularly during dissection and often when preventive strategies have not been used. Compensatory rescue measures are not always successful. Adverse events lead to poor patient outcome and higher cost.

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Mishaps still regularly occur during cardiac reoperations. Most of these events can be anticipated, and they occur despite utmost efforts to avoid them. Recently, it has been shown that reoperation per se in select groups of patients no longer appears to be a major risk factor for poor outcome.[1,2] This seems in part related to the implementation of strategies to prevent mishaps and to compensate for them when they occur to avoid poor patient outcome.

Purposes of this study were to (1) determine frequency of occurrence of reported intraoperative adverse events (IAE) and their risk factors, (2) characterize them with respect to structure injured, timing of their occurrence, and lapses of preventive strategies, and (3) identify the impact on outcome in terms of successful and unsuccessful rescue and cost.

Patients and Methods

Patients

Between July 2002 and July 2004, 1985 consecutive cardiac reoperations were performed at Cleveland Clinic; 65 patients undergoing heart transplantation and 73 with repairs of the descending aorta via thoracotomy were excluded, leaving 1819 who underwent 1847 reoperations. During the subsequent 18 months, July 2004 to January 2006, prospective IAE data

Abbreviations and Acronyms

CPB = cardiopulmonary bypass
CL = confidence limits
CT = computed tomography
IAE = intraoperative adverse event
ITA = internal thoracic artery
MRI = magnetic resonance imaging
SD = standard deviation

were recorded on 245 patients undergoing reoperation by one surgeon (G.B.P.) to validate reporting of events.

Data Collection

Operative notes were reviewed to identify recorded IAEs. A data collection tool was created to capture perioperative details (Appendix E1) not gathered prospectively for the Cardiovascular Information Registry. For each IAE, conditional statements were used to determine whether imaging, circulatory support, or technical preventive strategies had been used (Appendix E2).

The Institutional Review Board of the Cleveland Clinic approved use of these data and databases for research.

Characterization of IAEs

IAEs were categorized on the basis of (1) injured structures, (2) timing of the IAE during surgery, and (3) lapse of preventive strategies. A more elaborate description of reoperative strategies and surgical challenges is presented in Appendix E3.

Injured structures included those to bypass grafts, heart, great vessels, and other (new intraoperative ischemia not associated with direct injury and documented by electrocardiographic changes, ventricular fibrillation, or bradycardia requiring change in surgical progress, as well as severe lung injury).

Lapses in *preventive strategies* attributed to *imaging* included the following:

- Injury to bypass grafts, native coronary vessels, right ventricle, or brachiocephalic vein on opening when the patient did not have preoperative computed tomography (CT) or magnetic resonance imaging (MRI)
- Internal thoracic artery (ITA) or vein graft injury when it was immobile on preoperative angiography
- Requirement for additional revascularization without preoperative mapping of conduit availability

Lapses attributed to *circulatory support* because extrathoracic cannulation site was not exposed or used included the following:

- Injury on opening despite a preoperative cardiac catheterization, CT, or MRI identifying structure at immediate risk
- Injury to an ITA crossing the midline or to an immobile graft

Lapses attributed to *surgical technique* included the following:

- Injury during sternotomy after wires removed
- Failure to first mobilize the right sternal border and injury requiring cannulation occurred
- Tearing of right ventricle or atrium caused by traction
- Ventricular fibrillation triggered by cautery
- Ischemia triggered by manipulating or cauterizing vein graft or arteriosclerotic aorta

Patient outcome. Poor outcome was the composite end point of stroke, myocardial infarction, or hospital death as defined for The Society of Thoracic Surgeons national database. (For details, see http://www.ctsnet.org/file/rptDataSpecifications252_1_ForVendorsPGS.pdf.)

Rescue and failure to rescue. Once injury or ischemia occurs, primary objectives of a rescue strategy are to establish and maintain perfusion to protect brain and heart. Efficiency of compensatory strategies to accomplish this was assessed by ability to prevent stroke, myocardial infarction, and death.

Cost. Detailed operative and postoperative direct technical costs were extracted for each patient from the hospital's cost-accounting system. Direct technical costs included anesthesia, surgery, pathology, nursing (operating room, intensive care unit, hospital, rehabilitation), pharmacy, respiratory therapy, radiology, laboratory, pain management, and miscellaneous. (For details, see http://www.eclipsys.com/Solutions/executives.asp). Indirect costs and professional fees were not included.

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Data Analysis

Categorical variables are summarized by frequencies and percentages and continuous variables by means ± 1 standard deviation. Group comparisons were made with the χ^2 or Wilcoxon rank sum tests.

Risk factors. Risk factors associated with IAEs and with poor outcomes (stroke, myocardial infarction, hospital death) in all patients and in the subset of patients with IAEs were identified by bootstrap bagging[3,4] using the variables listed in Appendix E4, with automated stepwise analysis of 1000 bootstrap resamplings and a P value for variable retention of .05. Thereafter, these analyses were aggregated and variables or closely correlated clusters of variables appearing in 50% of analyses or more were retained in the final multivariable model.

Rescue and failure to rescue. To determine whether poor outcomes were more common in the IAE group, we used logistic regression analysis to model the composite end point occurring in the non-IAE group (Appendix E5). Variable selection used bagging, with resampling of 1000 bootstrap samples and retention of variables $P < .05$. The resulting model was used to predict expected number of events in the IAE group. This was compared with number of observed events by a χ^2 test. The difference between expected and observed poor outcomes was designated "failure to rescue."

Risk factors found were only univariably evaluated in the IAE group, because a reliable, robust multivariable model could not be formed with so few events (n = 24 in the IAE group).

Cost. The unadjusted direct technical cost ratio of IAE and the non-IAE groups was calculated from median cost. To make a fair comparison, we developed a propensity model[5,6] by augmenting the logistic regression model of predictors for IAE with other preoperative and intraoperative factors (Appendix E4). This propensity model was used to compute a propensity score for each patient, and the scores were used to obtain pairs of matched patients from the two groups. Distribution of median cost ratios from 10,000 bootstrap runs of the matched pairs was evaluated to approximate the adjusted cost ratio and provide confidence intervals around the estimate.

Presentation. Mean values are accompanied by ±1 standard deviation (SD) and regression coefficients by ±1 standard error. Proportions are accompanied by 68% confidence limits (CL, equivalent