Universal definition of perioperative bleeding in adult cardiac surgery

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Objectives: Perioperative bleeding is common among patients undergoing cardiac surgery; however, the definition of perioperative bleeding is variable and lacks standardization. We propose a universal definition for perioperative bleeding (UDPB) in adult cardiac surgery in an attempt to precisely describe and quantify bleeding and to facilitate future investigation into this difficult clinical problem.

Methods: The multidisciplinary International Initiative on Haemostasis Management in Cardiac Surgery identified a common definition of perioperative bleeding as an unmet need. The functionality and usefulness of the UDPB for clinical research was then tested using a large single-center, nonselected, cardiac surgical database.

Results: A multistaged definition for perioperative bleeding was created based on easily measured clinical end points, including total blood loss from chest tubes within 12 hours, allogeneic blood products transfused, surgical reexploration including cardiac tamponade, delayed sternal closure, and the need for salvage treatment.

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Depending on these components, bleeding is graded as insignificant, mild, moderate, severe, or massive. When applied to an established cardiac surgery dataset, the UDPB provided insight into the incidence and outcome of bleeding after cardiac surgery.

Conclusions: The proposed UDPB in adult cardiac surgery provides a precise classification of bleeding that is useful in everyday practice as well as in clinical research. Once fully validated, the UDPB may be useful as an institutional quality measure and serve as an important end point in future cardiac surgical research. (J Thorac Cardiovasc Surg 2014;147:1458-63)

Supplemental material is available online.

Perioperative bleeding in patients undergoing cardiac surgery is common. Bleeding may be insignificant and not require treatment or may be serious and life threatening. Bleeding is frequently treated with allogeneic blood product transfusion (packed red blood cells [PRBCs], fresh frozen plasma [FFP], or platelet concentrates [PLT]). Although transfusion is recognized to adversely affect early and late outcomes,[1-4] it remains common after cardiac surgery despite improvements in transfusion medicine and system-based protocols.[5-8]

Periprocedural bleeding has become an important outcome measure in cardiology practice and frequently serves as a component of combined end points in randomized clinical trials (RCTs).[9-11] Although precise definitions for complications such as renal failure, acute myocardial infarction, and neurologic complications after cardiac surgery exist,[12-16] no standardized definition for perioperative bleeding has been established, making the interpretation of clinical trials more difficult and hindering attempts to study patient blood management. We propose that a more precise definition of perioperative bleeding based on easily measurable clinical variables would improve analysis of this clinical problem and be useful as a measure of clinical quality. A universal definition of perioperative bleeding (UDPB) in adult cardiac surgery would standardize nomenclature, improve outcome definitions, and be useful in future clinical trials. The UDPB may also serve as a measure for institutional quality improvement and a tool to propose, test, and implement solutions to reduce bleeding and transfusion.

MATERIALS AND METHODS

The authors are involved in the International Initiative for Haemostasis Management in Cardiac Surgery, an international, multidisciplinary collaboration with interest and expertise in the perioperative management of bleeding associated with cardiac surgery, patient blood management, and transfusion avoidance. The group recently published an editorial document addressing current areas in which solid data are lacking to guide blood management in adult cardiac surgery patients.[17]

The UDPB was conceived and defined through a series of face-to-face and interpersonal meetings and represents the consensus opinion of the group (Table E1). The UDPB was tested using a large, clinical, cardiac, surgical database (IRCCS Policlinico San Donato, Milan, Italy), which prospectively included all patients undergoing cardiac surgery since 2000. A retrospective analysis of patients who underwent surgery in 2011 was performed in a post hoc analysis of a recently published study[18] that was approved by the local ethics committee with a waiver of written informed consent. Data routinely included in the database were supplemented with additional data from patient files as needed. To verify the clinical impact of this stratification, operative (30-day) mortality rates were analyzed and statistically compared for between-group differences. Multivariate analyses (linear, logistic regression) were applied to assess determinants of UDPB class and the impact of this classification on operative mortality. A computerized statistical package (SPSS 13.0, Chicago, Ill) was used.

RESULTS

UDPB

The UDPB is based on 9 events occurring during surgery or within the first postoperative day: (1) delayed sternal closure, (2) postoperative chest tube output, (3) PRBC transfusion, (4) FFP transfusion, (5) PLT transfusion, (6) cryoprecipitate transfusion, (7) use of factor concentrates, (8) use of recombinant activated factor VII (rFVIIa), and (9) surgical reexploration. The UDPB defines 5 perioperative bleeding classes, which are designed to characterize the severity of bleeding, regardless of its source. The contribution of each of these events to the UDPB is presented in Table 1.

Rationale

The presence of the worst, single, predefined attribute is sufficient to place a patient in a particular bleeding class; the presence of all attributes within a class is not necessary. Chest tube output or magnitude of transfusion are not the sole criteria for the classification. This approach is conservative and ensures the capture of significant bleeding events. For example, early surgical reexploration may limit total transfusion or total chest tube output, yet our classification identifies the patient as experiencing a severe or class 3 bleeding event. We recognize that the decision to reexplore is surgeon dependent and subjective, however reexploration is associated with recognized adverse consequence,[19] and the categorization as severe attempts to reflect this. This worst-parameter principle was applied throughout the bleeding classification system.

1. Delayed sternal closure

Delayed sternal closure in clinical practice identifies patients who experience severe, refractory, intraoperative