Management of Massive Post-Bypass Related Hemorrhage: A Rational Approach

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Associate Professor of Anesthesiology
Case Western Reserve University School of Medicine
Educational Objectives:

- Identify patients at risk for massive post-bypass bleeding
- Apply sound treatment strategies to severely hemorrhaging patients post-bypass
- Successfully integrate the administration of banked blood products and pharmacologic adjuncts to control severe bleeding
Disclosures:

Covidien: consultant, speaker’s bureau, funded research

CSL Behring: funded research
Please visit the Case Cardiac Anesthesia Group website

www.casecag.com

for media related to this presentation
Echo Clip Of The Week

Click on the image below to download the new echo of the week.

Detail any apparent aortic root and/or ascending aortic pathology in this series of clips.

Manuscript of the Month

Real Time Continuous Monitoring of Cerebral Blood Flow Autoregulation Using Near-Infrared Spectroscopy in Patients Undergoing Cardiopulmonary Bypass

Submitted by
Scott T. Leffler, M.D.
CASECAG Lectures

University Hospitals Case Medical Center

**Speaker:** Edwin G. Avery, IV, M.D.

**Title:** Constrictive Pericarditis vs. Restrictive Cardiomyopathy: Sorting It All Out

**Location:** Society of Cardiovascular Anesthesiologists Annual Meeting 2014, New Orleans, LA - Sheraton Hotel

**Date:** March 3, 2014

**Title:** Acute Blood Pressure Management: A Clinical Update

**Location:** University Hospitals Case Medical Center Anesthesiology Grand Rounds Case Western Reserve University School of Medicine - BES-105

**Date:** December 11, 2013

**Title:** Management of Massive Bypass Related Hemorrhage: A Rational Approach

**Location:** 2012 American Society of Anesthesiologists Annual Meeting - Washington, D.C.

**Date:** October 14, 2012
Overview:

- Cardiac surgical bleeding – definition & prevalence
- Etiology of cardiac surgical bleeding
- Assessment of cardiac surgical related bleeding
- Rational treatment of cardiac surgical bleeding – Laboratory algorithm based approach
- Clinical case presentation
Cardiac Surgical Bleeding
Definition & Prevalence
Excessive Cardiac Surgical Bleeding:

**Definition**

- Loosely defined as “I know it when I see it…”
- Formally defined as the following:
  - > 300 mLs of chest tube drainage in 1st hour after chest closure
  - ≥ 8 mLs/kg in any 2 successive hours
  - 20 mLs/kg in first 4 hours post-CPB
- Usually accompanied by a volume requirement

† 2006 Speiss B, Harrow J, Kaplan J. Kaplan’s Cardiac Anesthesia. Chap. 29, p 974
Semin Thorac Cardiovasc Surg 2000;12:326
Cardiac Surgical Bleeding: Prevalence

Approximately **5%** of cardiac surgical patients develop *excessive hemorrhage†*

Factors that have been observed to be associated with a need for transfusion include‡ (in contrast to massive bleeding):

- Antecedent antiplatelet/antithrombotic therapies
- Noncardiac comorbidities (hepatic & renal dysfunction)
- Redosternotomy or complex surgery
- Advanced age
- Emergency surgery
- Deep hypothermic circulatory arrest (antiplatelet effect)
- Low preoperative red cell mass
- Length of extracorporeal circulation time (especially > 2.5 hrs)

† 2006 Speiss B, Harrow J, Kaplan J. Kaplan’s Cardiac Anesthesia. Chap. 29, p 974
‡ 2011 Ann Thorac Surg;91: 944-82
Massive Hemorrhage ↔ Massive Transfusion
Massive Transfusion: Definition

- Administration of 8-10 units of RBCs < 24 hrs
- Acute administration of 4-5 units of RBCs in < 1 hr
- Transfusion equivalent to a patient’s entire blood volume in < 24 hrs

Cardiac Surgical Bleeding: Etiology
Cardiac Surgical Bleeding: Etiology

- Preoperative antiplatelet or irreversible antithrombotic agents†
  - ADP antagonists ± arachidonic acid inhibitors
  - GP IIbIIIa antagonists
  - Low molecular weight heparin
  - Direct thrombin inhibitors
  - Unfractionated heparin (reversible)
  - Warfarin (reversible)
  - Factor Xa inhibitors (reversible)

†Klick JC. Avery EG. Anesthesiology 2nd ed. 2012; Chap 16; 196-217
Noncardiac comorbidities (hepatic dysfunction)

Laboratory evidence of coagulopathy
(minor abnormalities [e.g., INR 1.3 or PTT 38 sec] may represent major coagulation protein deficiencies)†

Drug/Toxin related hepatocellular dysfunction

Cardiac related hepatic dysfunction

Right heart based congestive heart failure can result in impeded blood flow to the liver → hepatic synthetic dysfunction

†Schmaier AH. Hematology: Principles & Practice 6th ed Chap 131, 2013
Avery EG, Klick JC. Intraoperative Patient Blood Management, AABB 2014 (In Press)
Cardiac Surgical Bleeding: Etiology

- Noncardiac comorbidities (renal dysfunction)
- Preoperative **renal insufficiency**
  - Lower erythropoietin levels
  - Inability to clear biochemical mediators that beget inflammation and bleeding)
    - Bradykinin
    - Interleukin-1
    - Interleukin-6
    - Tumor Necrosis Factor-\(\beta\)

*Kidney International* 1994;45:890
Cardiac Surgical Bleeding: Etiology

- **Complex operations**
  - Prolonged CPB time (> 2.5 hrs) results in shear stress induced platelet activation, soluble coagulation protein consumption and dilution
  - Deep hypothermic circulatory arrest (DHCA) results in hepatic sequestration of platelets

- **Low preoperative red cell mass**
  - Small body habitus with lower red cell mass more prone to hemodilution
  - Multifactorial preoperative anemia
  - Low red cell mass may be a marker of renal dysfunction

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\(^{\S}\) Both platelet number and function are significantly reduced during prolonged CPB runs

\(^{\dagger}\) 2011 Ann Thorac Surg;91: 944-82

\(^{\lambda}\) Semin Thorac Cardiovasc Surg 2000;12:326
W.A.R.

W: Warm
A: Assess
R: Restore/Recycle
Employ patient warming systems
- Forced air convective warming blankets
- Hydrogel energy conduction pads
- Intravascular catheter based systems
- Water blankets on the OR table
- Thoroughly rewarm prior to CPB separation

Employ fluid warming systems
Assess and maintain physiologic acid-base balance
- The coagulation system is run by enzyme systems that do not function optimally at non-physiologic pH
- Non-physiologic pH creates/exacerbates coagulopathy
- Make all efforts to maintain a pH of 7.4 during massive hemorrhage
- Allogeneic blood products may be preserved with citrate which can lower serum calcium thus Ca^{++}
- monitoring is essential
- Transfusion of RBCs can result in ↑K^{+}

Consider washing allogeneic RBC units in the cell saver to remove K^{+}, lactate & free Hb
Assess the integrity of the coagulation system

- “Active tests” such as the TEG or ROTEM likely provide the most effective assessments of the coagulation system
- Multiple prospective randomized controlled trials have established the clinical utility of employing algorithm based transfusion guidelines (INR, ACT & TEG)
- Note that the various published algorithms were tested for microvascular bleeding and not specifically for massive hemorrhage
- Frequent re-testing is necessary to gauge impact
W.A.R.
Assessment of Cardiac Surgical Bleeding
Assessment of Cardiac Surgical Bleeding

- Gross assessment of the surgical field is always the first step.

- Laboratory or Point of Care Device guided algorithms provide a quantitative and clinically effective assessment of cardiac surgical hemorrhage.
Assessment of Cardiac Surgical Bleeding

- Pre/Post-CPB thromboelastography (TEG)† with **Platelet mapping assay**, rotational thromboelastometry (ROTEM) or **Sonoclot†**
  - Afibrinogenemia → ↑K time or shallow α, or TEG FF
  - Soluble coagulation protein deficit → prolonged R time
  - Residual heparin effect → shortened heparinase R time
  - Fibrinolysis → % lysis at 30 minutes
  - Platelet dysfunction → decreased MA ★★
    (only platelet mapping will detect ADP or arachidonic acid related platelet dysfunction)
- Post-CPB ACT (can reflect intrinsic or common pathway dysfunction)
- Preoperative and post-CPB core lab coagulation tests
  - INR, aPTT, Platelets, fibrinogen concentration

† 2010 Acta Anaesthesiol Scand. 54:111-117
Assessment of Cardiac Surgical Bleeding

A little about the TEG…

**Figure 1**

Fibrinogen

INR + aPTT + Bleeding time

Platelets (75%)  
Fibrinogen (25%)
Assessment of Cardiac Surgical Bleeding

Employ a hemostasis monitoring protocol to improve the ability to detect coagulation dysfunction early when it is more amenable to treatment.
W.A.R. Restore

Treatment of Cardiac Surgical Bleeding
Concentrate efforts to restore the function of the coagulation system based on the results from frequent laboratory/POC device assessments.

Few data support the treatment of massive hemorrhage in the operating room environment.

The trauma literature is composed mostly of observational studies and recent literature†,‡ has established that the etiology of early trauma associated coagulopathy (hypotension/shock induced) is likely distinct from bypass related bleeding (Plt dysfunction/hemodilution).

†Hess JR et al. J Trauma 2008;65:748
Treatment of Cardiac Surgical Bleeding

Before we Restore some basics & pearls...

- Know the risk factors for bleeding and get blood products in the room or activate your [Massive Transfusion Protocol](#).
- Insure *thorough rewarmin*g to above 36°C prior to CPB separation and maintain body temperature during post-CPB period.
- Correct acid-base imbalances (coagulation is affected by extremes of unphysiologic pH).
- Ensure appropriate *protamine reversal*.
- Assess surgical field for obvious source of bleeding (if open chest).
- Monitor POC/core lab tests of coagulation and repeat frequently.
- Administer “*Rescue Antifibrinolytics*” if not dosed pre-CPB.
- Consider adding 5-10 cm H$_2$O of PEEP in treatment of closed chest patients to help stop venous bleeding.
Treatment of Cardiac Surgical Bleeding

- Protamine doses range from 0.7-1.3 mL (of 10 mg/mL) per 1000 IU of heparin administered.
- Avoid excessive protamine as it may lead to more bleeding & is associated with prolongation of the ACT, INR, aPTT & ↓Plt aggregation.† Unknown if there is clinical relevance to over administration of protamine (short half-life & has approximately 1/100th the anticoagulation effect of heparin).
- Heparinase TEG or Whole Blood Heparin concentration assays are the best way to determine if additional protamine is indicated.

†Anes Analg 1998;87:781
Treatment of Cardiac Surgical Bleeding

Appropriate heparin neutralization is best achieved with the whole blood heparin assay or a Heparinase TEG.
### Clinical Example of Incomplete Heparin Neutralization

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<th>Plain cup TEG</th>
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#### TEG Parameters

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#### Heparinase TEG

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The TEG results indicate incomplete heparin neutralization, requiring further treatment.
Optimal management of hemorrhage involves the use of transfusion algorithms. INR, aPTT, ACT, Fib, Plt and/or TEG based algorithms have all been proven to be effective in reducing shed mediastinal blood, transfusion requirements and reoperation rate. Studies repeatedly demonstrated clinical benefit when Physician Discretion was compared with Algorithm Guided Care (regardless of the basis of the algorithm), including algorithms using factor concentrates†.

References:
- Anes Analg 1999; 88: 312-9
- Anesth 2001; 94: 773-81
- Brit J Anaesth 2001; 86: 575-8
- Anesth 2011 Dec;115(6):1179-91

†Restore with a purpose: Allogeneic Hemostatic Banked Components
Sample Non-RBC Transfusion Algorithms

**TEG Guided Algorithm**

**Lab Guided Algorithm**

Brit J Anaesth 2004; 92: 178-86

Anes Analg 1999; 88: 312-9
Sample Non-RBC Transfusion Algorithms

Targeted OR Transfusion

Operating Room Transfusion Algorithm

- Microvascular bleeding by observation of surgical field
- Coagulation and Platelet Tests
- All normal
- ACT > Baseline
- Surgical Re-exploration of chest
- Protamine
- Fibrinogen <144 mg/dL

PLT <102 K/mm³ and/or TEG MA <48 mm
- Platelet transfusion

PT >16.6 (1.6) sec and/or aPPT >57 sec
- Fresh frozen plasma transfusion
- Cryoprecipitate transfusion

Targeted ICU Transfusion

ICU Transfusion Algorithm

Chest Tube Output
<150cc/hr (<2cc/kg/hr)

Do Nothing-Observe

Chest Tube Output
>150cc/hr (>2cc/kg/hr)

Add PEEP

Coagulation tests & TEG performed

All normal

Surgical Re-exploration of chest

ACT > Baseline

Protamine

PT >12.6 (1.2) sec

Fresh frozen plasma transfusion

aPPT >45 sec

Cryoprecipitate transfusion

PLT <140 K/mm³

and/or

TEG MA <55 mm

Platelet transfusion

Fibrinogen <200 mg/dL

Clinical Guidelines

Pre-Cardiopulmonary Bypass Transfusion Guideline for Cardiac Surgery

Department of Anesthesiology and Perioperative Medicine

Date: 11-03-2012

Cardiac Surgery related procedure?

No

Preoperative Central Lab & TEG Baseline Coagulation Studies

Normal

Abnormal

Avoid these Guidelines

45 < aPTT < 59
2° to hepatic dysfunction consider adding 2 units FFP to CPB circuit

aPTT ≥ 59
2° to hepatic dysfunction consider adding 2-4 units FFP to CPB circuit

1.3 < INR < 1.9
2° to hepatic dysfunction or coumadin consider adding 2 units FFP to CPB circuit

INR ≥ 1.9
2° to hepatic dysfunction or coumadin consider adding 2-4 units FFP to CPB circuit

E < 9 mm
Consider adding 2 units of FFP to CPB circuit

CPB

Have 2-4 units of FFP available Post-CPB

Have 2-4 units of FFP available Post-CPB

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Have 2-4 units of FFP available Post-CPB

Fib < 125 x 10^9 have 1-2 doses of Pts available Post-CPB

Have 2 units of FFP available Post-CPB

MA < 54 mm have 1-2 doses of Pts available Post-CPB

Angle < 50° or Fib < 150 mg/dl have 1-2 units cryo available Post-CPB
ROC AUC for use of Algorithms

AUC ~ 1.0

AUC 0.5

Nuttall G
What if no lab/POCT data is available to guide transfusion in massive hemorrhage?

- MTP based resuscitation is associated with lower mortality in trauma studies (Damage Control Resuscitation).
- Administering blood components in a 1:1:1 ratio (RBCs:Plasma:Platelets) approximates whole blood but is not equivalent to it.
- The question remains unanswered whether this will improve morbidity and mortality in cardiac surgical patients.

References:
Employ red cell salvage devices that use centrifugal washing to minimize transfusion of allogeneic RBCs

Newer generation devices permit processing of smaller collection volumes

Returning shed blood that has only been filtered should be strictly avoided

Washing allogeneic RBCs improves the quality of the transfusion
Treatment of Cardiac Surgical Bleeding

Restore with a purpose: Pharmacologic Adjuncts

- Antifibrinolytics (pre-CPB vs. Rescue)
- Recombinant activated factor VII (NovoSeven®)
- Desmopressin (DDAVP)
- Fibrinogen concentrate (Riastap®)
- Prothrombin complex concentrates (Konyne® or KCentra®)
Treatment of Cardiac Surgical Bleeding

Pharmacologic Adjuncts – Chemically Synthesized

- Antifibrinolytics (pre-CPB vs. Rescue)
- Class I Recommendation/Level Evidence A
  - ε-Aminocaproic acid
  - Tranexamic acid (↑seizure risk OR 7.4, P<0.001)

2011 JCTVA 25(1):20-5 (retrospective, n=604)
Treatment of Cardiac Surgical Bleeding

Pharmacologic Adjuncts – Chemically Synthesized

- **Desmopressin (DDAVP)**
  - Stimulates the release of factor VIII precursors, von Willebrand factor and tissue type plasminogen activator from vascular endothelium
  - **Dose at 0.3 μg/kg** (slow IV infusion to avoid ↓BP)
  - **Not recommended for routine use** – rather indicated when POC testing reveals platelet function defects $^\S$ (Class 3/Level A)
  - **Class IIb recommendation/Level of Evidence B**
  - Potentially useful in uremic patients and in some types of von Willebrand’s disease $^\dagger$

$^\S$ 2011 Ann Thorac Surg;91: 944-82
$^\dagger$ Klick JC. Avery EG. Anesthesiology 2nd ed. 2012; Chap 16; 196-217
Treatment of Cardiac Surgical Bleeding
Pharmacologic Adjuncts - Biologics

- Fibrinogen concentrate (RIASTAP) 
  - Indicated in treatment of afibrinogenemia; use for hypofibrinogenemia in cardiac surgery is OFF LABEL
  - Fibrinogen is the precursor to fibrin which serves as the proteinaceous scaffolding of a blood clot and promotes platelet aggregation
  - Goal fibrinogen level 200 mg/dL in cardiac surgical hemorrhage
  - Recent appreciation has been made of the potential contributions of fibrinogen in the treatment of severe hemorrhage
  - 1 Vial = 5 Units of Cryoprecipitate = 5 Units of FFP

2009 Expert Opin Biol Ther. 9:1325-1333.
§2012 Anes Analg;114: 261-274
†Klick JC. Avery EG. Anesthesiology 2nd ed. 2012; Chap 16; 196-217
Treatment of Cardiac Surgical Bleeding

Pharmacologic Adjuncts - Biologics

Prothrombin complex concentrates (PCCs) 3 v. 4 factor

- Originally intended as a treatment for Hemophilia B (Christmas disease)
- Balanced 4 factor PCC indicated for warfarin reversal
- Contains Factors II, VII‡, IX, X, C, S, ATIII, heparin
- Has been described as a rescue bleeding agent in cardiac surgery§ and is a standard rescue therapy in some centers 20-30 IU/kg – **OFF LABEL**
- Limited safety data available at present – not for routine use – thromboembolic events reported

‡Note that FEIBA (factor eight inhibitor bypass activity) contains activated Factor VII & inactivated II, IX, X

§2008 Crit Care 12;R105

‡Klick JC. Avery EG. Anesthesiology 2nd ed. 2012; Chap 16; 196-217
Treatment of Cardiac Surgical Bleeding

Pharmacologic Adjuncts - Biologics

- **Recombinant activated factor VII (Novo Seven®):** 35 – 90 µg/kg
  - OFF LABEL use for refractory life threatening bleeding
  - Not recommended for routine use due to increased incidence of stroke (OR 3.69, P = 0.03) – requires coagulation proteins to work
  - In practice most clinicians will give 1-2 rounds of blood products first using algorithm guidance and failure to improve triggers rVIIa use
  - Class IIb recommendation/Level of evidence B†
  - Rebound phenomenon (t½ = 4-6 hrs)

**RESCUE THERAPY**

§2011 J Cardiothorac Vasc Anes 25: 804-10
2009 Circulation 120;21-7
†2011 Ann Thorac Surg;91: 944-82
Treatment of Cardiac Surgical Bleeding

Pharmacologic Adjuncts

**Vitamin K**

- IV vitamin K will help to *slowly* increase the plasma concentration of vitamin K dependent coagulation proteins (II, VII, IX, X, C/S)
- It is indicated in the reversal of coumadin effect
- Commonly dosed at 0.5 to 1.0 mg via slow IV infusion (60 min) – in heavy hemorrhage doses of up to 10 mg are given
- Anaphylactic and anaphylactoid reactions have been described with its use
- It’s acute utility in massive hemorrhage is limited, even if associated with coumadin use; however administering IV vitamin K will help mitigate rebound coumadinization
Treatment of Cardiac Surgical Bleeding

Pharmacologic Adjuncts – Summary Biologics

- In general the use of the biologics (e.g., rVIIa, fibrinogen concentrate, PCCs) are not a first line therapy.
- Their use to treat cardiac surgical bleeding is OFF LABEL.
- These agents are used in much lower doses than the package insert recommends for their labeled use - ~33% of recommended doses.
- Consider their use after administering at least 2 rounds of banked hemostatic products.
- Thromboembolic events are a real concern.
Clinical Case
Clinical Case

64 YOM w/severe AI secondary to paravalvular leak of bioprosthetic AV, 2v CAD, ↓LVEF, mild pulmonary HTN, DM type II, HTN, ↑cholesterolemia, BL coag screen WNL (Fib 221 mg/dL – Plts 334)

Redo-sternotomy, CABG x2 and AVR (Edwards Perimount® bovine pericardial 23 mm) AXC 2:44 (Fib 157-Plts 268)

Noted tear in left pulmonary artery, re-AXC 1:03
Repair pulmonary artery

Off CPB 6:43
Left heart failure/cardiogenic shock $\rightarrow$ Inotropes + IABP

$\Delta$ 20 min $\rightarrow$ Right heart failure/cardiogenic shock

Back on CPB, RVAD (Abiomed AB5000)
(Fib 81 - Plts 189)

Off CPB 7:46 total
Clinical Case

The surgical team assesses the bleeding as **severe** following protamine administration of 0.7 mg per 100 IU Heparin. Next steps…?
Clinical Case

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Clinical Case – TEG #1

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Clinical Case – TEG #1

Heparinase

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**Clinical Case – TEG #1**

- s/p 70% Protamine
- 3 doses Plts
- 4 units FFP
- 1150mg RIASTAP
- 2 RBC

**Test Results:**

- T=36.8°
- pH 7.32
- CO₂ 41

**Parameters:**

- **SP** (min): 15.8
- **R** (min): 21.4
- **K** (min): 13.8
- **Angle** (deg): 59 – 74
- **MA** (mm): 55 – 74
- **G (d/sc)**: 3.5K – 3.2K
- **CI** (mL/100mL min): 47
- **EPL (%):** 0 – 15
- **LY30 (%):** 0 – 8

**Heparinase**
s/p 50 mg Protamine
2 doses Plts (total 5)
2 units FFP (total 6)
1150 mg RIASTAP (total 2300)
2 RBC (total 4)

T = 36.7°
pH 7.15;
CO₂ 66

OFF LABEL

Heparinase 11.8
4.7
38
56.7
Clinical Case – TEG #3

s/p 50 mg Protamine
rVIIa 35 μg/kg
3 units FFP (total 9)
1150mg RIASTAP (total 3450)

Heparinase

T=36.7°
pH 7.06;
CO₂ 41

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Heparinase 7.1 2.8 54.4 63.1
Clinical Case

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Clinical Case

Hemostasis achieved

Massive inflammatory tissue injury including lung injury with copious edema and blood from ETT for 3-4 hours

Oxygenation OK with recruitment maneuvers every 5-10 minutes but $\text{PaCO}_2 > 120 \text{ mmHg} & \downarrow \text{pH}$

Bleeding restarted (pH 6.96), loss of vascular tone, worsening left heart failure all unresponsive to medications and finally death
Thank You