POCT in Practice

PBM: The Future of Transfusion

December 6th 2012

East of England RTC

Sue Mallett
Royal Free London NHS Foundation Trust

Patient Blood Management
The 3 Pillars

- Pre-operative optimization of anaemia
- Minimizing intra-operative blood loss
  - Surgical technique
  - Hypothermia
  - Fluid management & cell salvage
  - Timely diagnosis of and management of coagulopathy
- Physiological tolerance of anaemia
  - Restrictive transfusion thresholds

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Variability in Transfusion Practice

TRANSFUSION PRACTICE

The ongoing variability in blood transfusion practices in cardiac surgery

*Stephanie A. Snyder-Ramos,† Patrick Möhnle,† Yi-Shin Weng, Bernd W. Böttiger, Alexander Kulier, Jack Levin, and Dennis T. Mangano for the Investigators of the Multicenter Study of Perioperative Ischemia, MCSPI Research Group**

Despite widespread availability of clinical practice guidelines the variability in transfusion practice both within and between institutions is profound and has changed little over the last 20 years.

JAMA The Journal of the American Medical Association

Variation in Use of Blood Transfusion in Coronary Artery Bypass Graft Surgery

Elliott Bennett-Guerrero, MD
Yue Zhao, PhD
Sean M. O'Brien, PhD
T. B. Ferguson Jr, MD
Eric D. Peterson, MD, MPH
James S. Gammie, MD
Howard K. Song, MD, PhD

Context Perioperative blood transfusions are costly and have safety concerns. As a result, there have been multiple initiatives to reduce transfusion use. However, the degree to which perioperative transfusion rates vary among hospitals is unknown.

Objective To assess hospital-level variation in use of allogeneic red blood cell (RBC), fresh-frozen plasma, and platelet transfusions in patients undergoing coronary artery bypass graft (CABG) surgery.

Design, Setting, and Patients An observational cohort of 102 470 patients undergoing primary isolated CABG surgery with cardiopulmonary bypass during calendar year 2008 at 798 sites in the United States, contributing data to the Society of Thoracic Surgeons Adult Cardiac Surgery Database.

Main Outcome Measures Perioperative (intraoperative and postoperative) transfusion of RBCs, fresh-frozen plasma, and platelets.

Results At hospitals performing at least 100 on-pump CABG operations (82 446 cases at 408 sites), the rates of blood transfusion ranged from 7.8% to 92.8% for RBCs, 0% to 97.5% for fresh-frozen plasma, and 0.4% to 90.4% for platelets. Multivariable analysis including data from all 798 sites (102 470 cases) revealed that after adjustment for patient-level risk factors, hospital transfusion rates varied by geographic location ($P=.007$), academic status ($P=.03$), and hospital volume ($P<.001$). However, these 3 hospital characteristics combined only explained 11.1% of the variation in hospital risk-adjusted RBC usage. Case mix explained 20.1% of the variation between hospitals in RBC usage.

Conclusion Wide variability occurred in the rates of transfusion of RBCs and other blood products, independent of case mix, among patients undergoing CABG surgery with cardiopulmonary bypass in US hospitals in an adult cardiac surgical database.

JAMA. 2010;304(14):1568-1575 www.jama.com

PATIENTS WHO UNDERGO CARdiac surgery receive a significant proportion of the 14 million units of allogeneic red blood cells (RBCs) transfused annually in the United States.[1] Numerous observational studies in patients who underwent cardiac surgery have shown an association between RBC transfusion and adverse outcome, including morbidity, mortality, resource utilization, and quality of life.[2-9] To date, no large randomized trials of transfusion thresholds have been conducted in cardiac surgery to our knowledge to address this issue.

Almost 20 years ago, the study by Goodnough et al[10] demonstrated that there was significant practice variability in transfusion practices at 18 US centers. However, this study and subsequent studies[11-14] were limited in size and did not adjust for hospital or patient factors. Since these earlier studies, the Society of Thoracic Surgeons (STS) and Society of Cardiovascular Anesthesiologists published transfusion recommendations in 2007.[15] However, the degree to which guidelines have resulted in consensus in community transfusion practice is unknown. Therefore, the primary goal of our study was to assess use of RBC, fresh-frozen plasma, and platelet transfusions in coronary artery bypass graft (CABG) surgery in contemporary practice. Our analyses specifically addressed the degree to which transfusion practices varied among US hospitals, after adjusting for patient characteristics.

See also pp 1559 and 1610.

METHODS

Data Source

The STS Adult Cardiac Surgery Database (ACSD) was established in 1989 to report outcomes following cardiothoracic surgical procedures.[16-20] The database captures clinical information from the majority of US cardiac surgical procedures. A recent analysis demonstrated that more than 80% of patients undergoing CABG operations in the United States in 2007 were represented in the STS database.[21] Sites enter patient data using uniform definitions (available at http://www.sts.org) and cer-

Author Affiliations: Divisions of Perioperative Clinical Research (Dr Bennett-Guerrero), Biostatistics (Drs Zhao and O'Brien), and Cardiology (Dr Peterson), Duke Clinical Research Institute, Duke University Medical Center, Durham, North Carolina; Department of Cardiovascular Sciences, East Carolina Heart Institute, Greenville, North Carolina (Dr Ferguson); Division of Cardiac Surgery, University of Maryland Medical Center, Baltimore (Dr Gammie); and Division of Cardiothoracic Surgery, Oregon Health and Science University, Portland (Dr Song).
Corresponding Author: Elliott Bennett-Guerrero, MD, Division of Perioperative Clinical Research, Duke Clinical Research Institute, Duke University Medical Center, PO Box 3094, Durham, NC 27710 (elliott.bennettguerrero@duke.edu).

80,000 Primary CABG
408 US Hospitals

VARIABILITY in
TRANSFUSION PRACTICE

RBC: 7.8% - 98.8%
FFP: 0 – 97.5 %
Platelets: 0.4 % - 90.4%

30% variation could be accounted for by case mix, case volume & academic status

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FFP: 0 – 97.5 %
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30% variation could be accounted for by case mix, case volume & academic status

70% variability is unaccountable

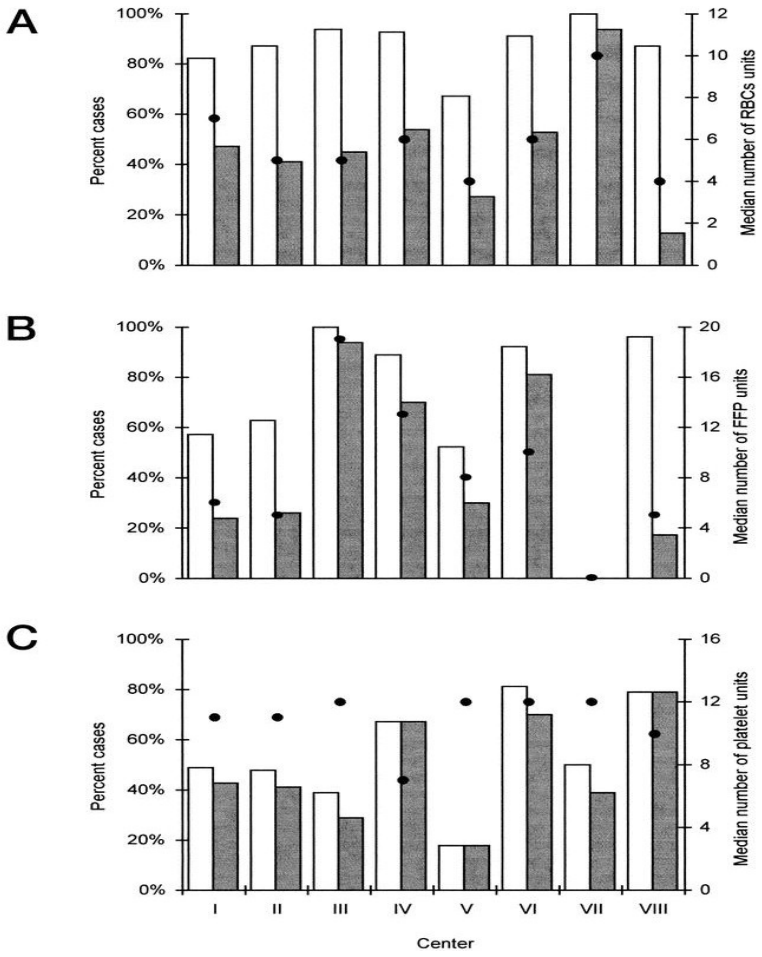
Variability in Transfusion Practice

Ozier: Anesth Analg 2003;97:671-9

RBC

FFP

Platelets



Transfusion RBC
Percentage: 60 -100%
Median : 2 – 11 units

Transfusion FFP
Percentage 0 – 100%
Median: 0 - 20 units

Transfusion Platelets
Percentage: 15 – 80%

LIVER TRANSPLANTATION 17:149-158, 2011

ORIGINAL ARTICLE

Differential Effects of Plasma and Red Blood Cell Transfusions on Acute Lung Injury and Infection Risk Following Liver Transplantation

Alexander B. Benson,[1] James R. Burton, Jr,[2] Gregory L. Austin,[2] Scott W. Biggins,[2] Michael A. Zimmerman,[3] Igal Kam,[3] Susan Mandell,[4] Christopher C. Silliman,[5] Hugo Rosen,[2] and Marc Moss[1]

Rev Bras Anestesiol
2011; 61: 3: 286-292

SCIENTIFIC ARTICLE

Association between the Use of Blood Components and the Five-Year Mortality after Liver Transplant

Bruno Salomé de Morais, TSA [1], Marcelo Dias Sanches [2], Daniel Dias Ribeiro [3], Agnaldo Soares Lima [2], Teresa Cristina de Abreu Ferrari [4], Malvina Maria de Freitas Duarte [5], Guilherme Henrique Gomes Moreira Cançado [6]

The Impact of Intraoperative Transfusion of Platelets and Red Blood Cells on Survival After Liver Transplantation

Survival rate changes with transfusion of blood products during liver transplantation

[Le taux de survie change avec la transfusion de produits sanguins pendant la transplantation hépatique]

Luc Massicotte MD,* Marie-Pascale Sassine PhD,* Serge Lenis MD FRCPC,* Robert F. Seal MD FRCPC,‡ André Roy MD FRCSC†

Transfusion of RBC

Dose related increase in Mortality & Morbidity

- Mortality OR 1.77
- Renal Failure OR 2.00
- Prolonged ventilatory support OR 1.79
- Serious infection OR 1.76
- Cardiac complications OR 1.55
- Neurological events OR 1.37

Karcontik et al Transfusion 2004;44: 1453-62
Koch et al. Crit Care Med 2006;34: 1608-16
Murphy et al. Circulation 2007;116: 2544-52

Stokes *et al. BMC Health Services Research* 2011, **11**:135
http://www.biomedcentral.com/1472-6963/11/135

BMC
Health Services Research

RESEARCH ARTICLE Open Access

Impact of bleeding-related complications and/or blood product transfusions on hospital costs in inpatient surgical patients

Michael E Stokes[1*], Xin Ye[2], Manan Shah[3], Katie Mercaldi[4], Matthew W Reynolds[4], Marcia FT Rupnow[2] and Jeffrey Hammond[2]

Overall the rate of bleeding related complications was 29.9% (7.5% to 47.4%)

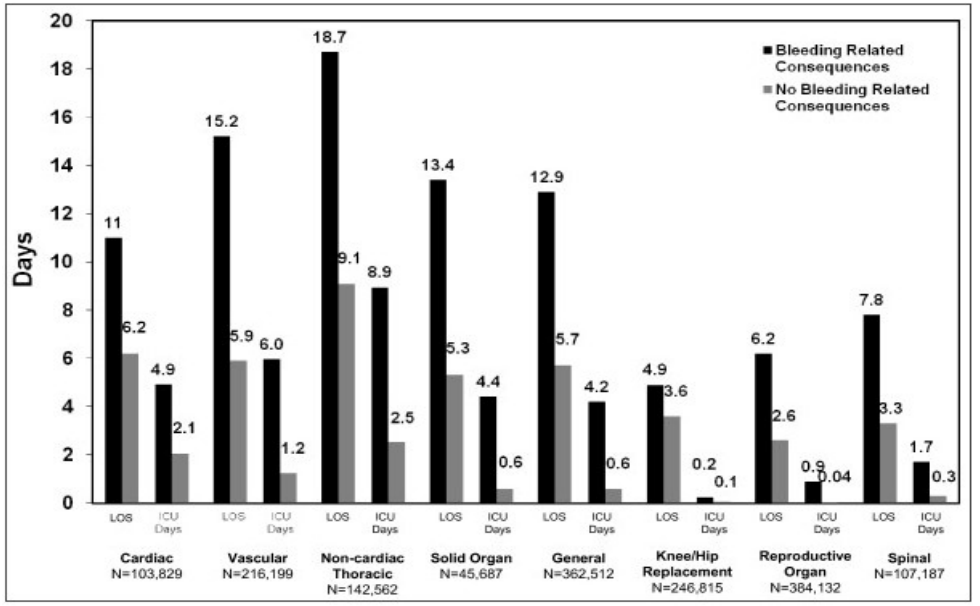


Figure 1

Mean Hospital LOS and ICU Days by Surgical Cohort and Complication Status.

Impact of bleeding-related complications and/or blood product transfusions on hospital costs in inpatient surgical patients
BMC Health Serv Res. ;11:135-135.

Stokes *et al. BMC Health Services Research* 2011, **11**:135
http://www.biomedcentral.com/1472-6963/11/135

BMC
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RESEARCH ARTICLE Open Access

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Incremental LOS associated with bleeding related complications or transfusion was 6.0 days (1.3 to 9.6)

Incremental cost associated with bleeding related complications or transfusion (adjusted for covariates)

$ 17,279 for spinal surgery
$ 15,123 for vascular
$ 13,210 for solid organ
$ 13,473 for non-cardiac thoracic
$ 10,279 for cardiac
$ 4,354 for general

Variability in Transfusion Practice

Wide variability in transfusion practice is an indicator of excessive and inappropriate transfusion

Variability in Transfusion Practice

How do we spot what is making the difference?

Do transfusion guidelines influence clinical practice?

bjh Guideline

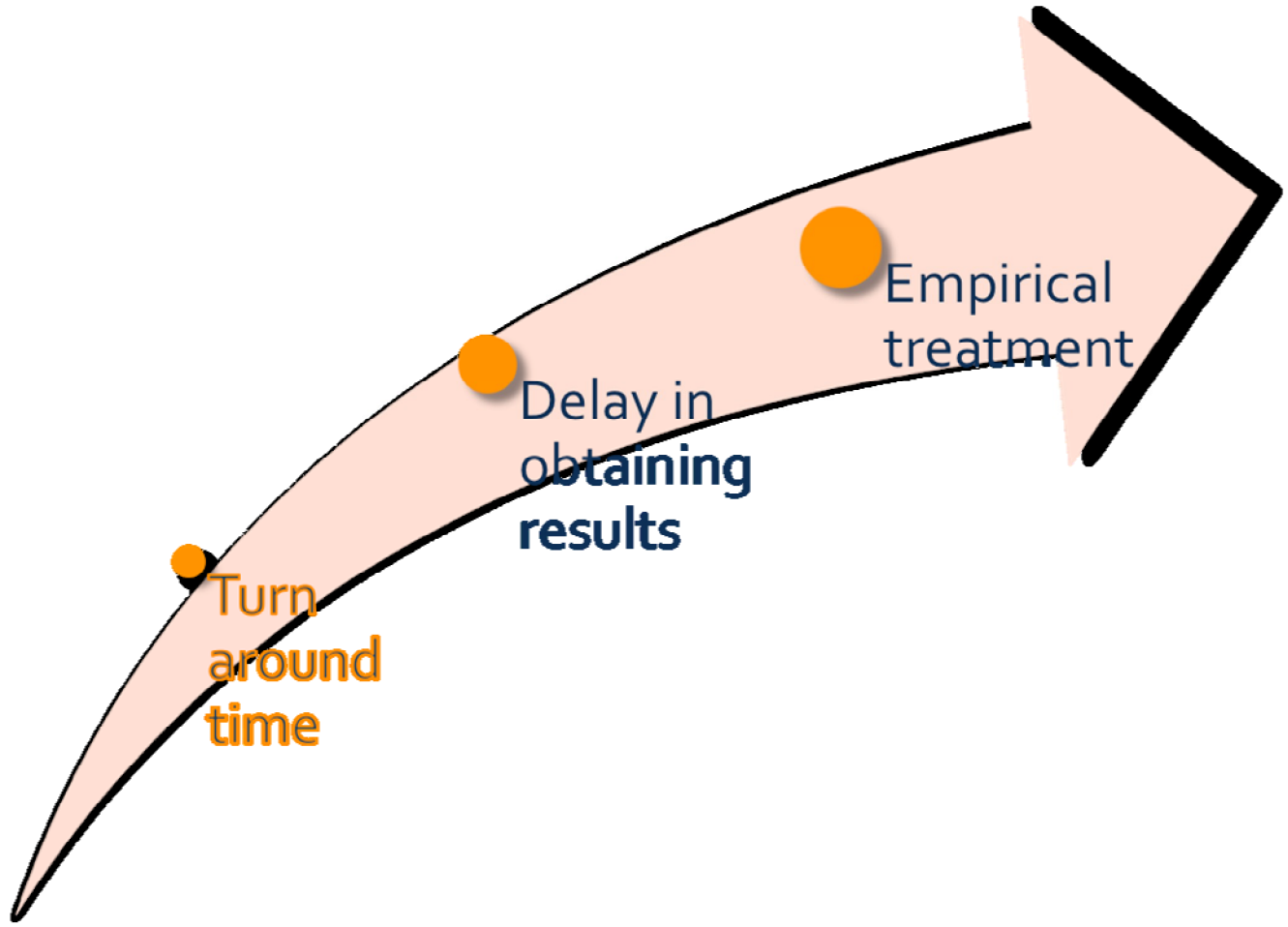
Guidelines on the management of massive blood loss

British Committee for Standards in Haematology: Writing Group: D. Stainsby,[1] S. MacLennan,[1] D. Thomas, [2] J. Isaac[3] and P. J. Hamilton[4]

[1]National Blood Service [2]Morriston Hospital, Swansea [3]University Hospitals, Birmingham [4]Royal Victoria Infirmary, Newcastle upon Tyne, UK

Request laboratory investigations	FBC, PT, APTT, Thrombin time, Fibrinogen (Clauss method); blood bank sample, biochemical profile, blood gases and pulse oximetry Ensure correct sample identification Repeat tests after blood component infusion	Results may be affected by colloid infusion Ensure correct patient identification May need to give components before results available

Laboratory coagulation tests



Is Clinical Discretion Okay?

102 elective CABG

POC group

Hepcon
PFA 100
TEG

Lab Group

INR
APPT
Platelet Count

Clinical discretion

102 retrospective controls

Avidan M,S et al 2004 BJA 92 (2); 178-176

Clinical Discretion

Table 3 Blood components received. The table shows the number of patients (%) in each group that received transfusions. LAG=laboratory-guided algorithm; POC=point of care; CD=clinician discretion

Blood component	LAG group (n=51)	POC group (n=51)	CD group (n=108)	P (χ^2 test)
Packed red blood cells	35 (69)	34 (68)	92 (85)	0.01
Fresh frozen plasma	0	2 (4)	16 (15)	0.003
Platelets	1 (2)	2 (4)	14 (13)	0.02

Avidan M,S et al 2004 BJA 92 (2); 178-176

Modern Coagulation Management

"Transfusion of coagulation products should be guided by POC tests that assess haemostatic function in a timely and accurate fashion"

Society of Thoracic Surgeons & Cardiovascular Anesthesiologists. Ann Thorac Surg 2007,83:S27-86

Clinical Practice Guidelines for Perioperative Blood Transfusion & Blood Conservation in Cardiac surgery

ANESTHESIA & ANALGESIA®
The Gold Standard in Anesthesiology

IARS
International Anesthesia Research Society
Celebrating 90 Years of Excellence

SPECIAL ARTICLE

Effect of the Perioperative Blood Transfusion and Blood Conservation in Cardiac Surgery Clinical Practice Guidelines of the Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists upon Clinical Practices

Donald S. Likosky, PhD,* Daniel C. FitzGerald, CCP,† Robert C. Groom, CCP,‡ Dwayne K. Jones, CCP, CPC,§ Robert A. Baker, PhD, CCP (Aus),‖ Kenneth G. Shann, CCP,¶ C. David Mazer, MD, FRCPC,# Bruce D. Spiess, MD,** and Simon C. Body, MBChB, MPH††

1400 surveys (32% response rate) returned: mainly USA & Canada, also UK, Europe and Australia
78% of anesthesiologists had read all or part of the guidelines
20% reported institutional discussion
Majority reported no change in practice in response to guidelines

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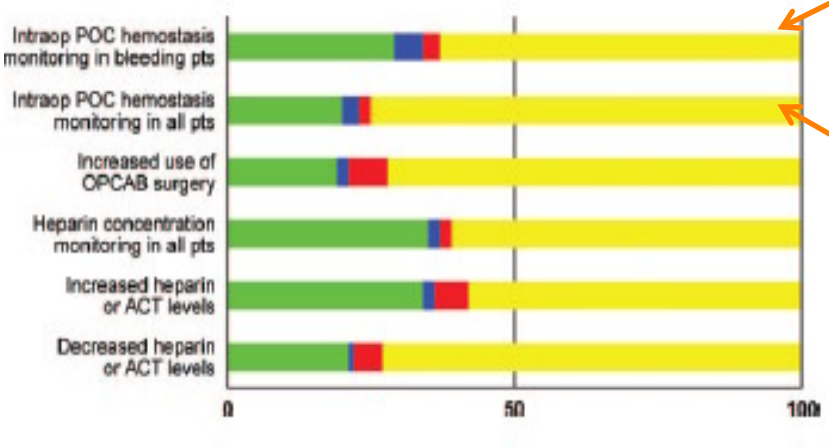
Change in clinical practice following published guidelines



Intraop POC haemostasis monitoring in bleeding patients

Intraop POC haemostasis monitoring in all patients

Colour key:

Green: Already doing this
Blue: New change in practice
Red: Unrelated change in practice
Yellow: NO CHANGE

Why guidelines are not enough to influence clinical practice

Insufficient high quality evidence supporting guidelines

Institutional support for implementation

Requirement for senior leadership to endorse guidelines
& to be involved in their implementation

Educational programmes, audit & feedback

POC: Cost of equipment & reagents
Processes to ensure validity & quality of results
Demonstrate that there is a change in practice

Why guidelines are not enough to influence clinical practice

Leadership is essential to change practice
A local "champion" that cares

RFH: Our Experience of POCT

Liver Transplant Centre since 1989
All OLT cases Protocol TEG monitoring

RFH: Our Experience of POCT

Liver Transplant Centre since 1989
Protocol TEG monitoring for all cases

Everyone else: No POC monitoring routinely available pre -1998

Introduced POC Hb in 1998: No transfusion without prior Hb recorded

In 2006 introduced simple POC coagulation testing (FBC& INR)

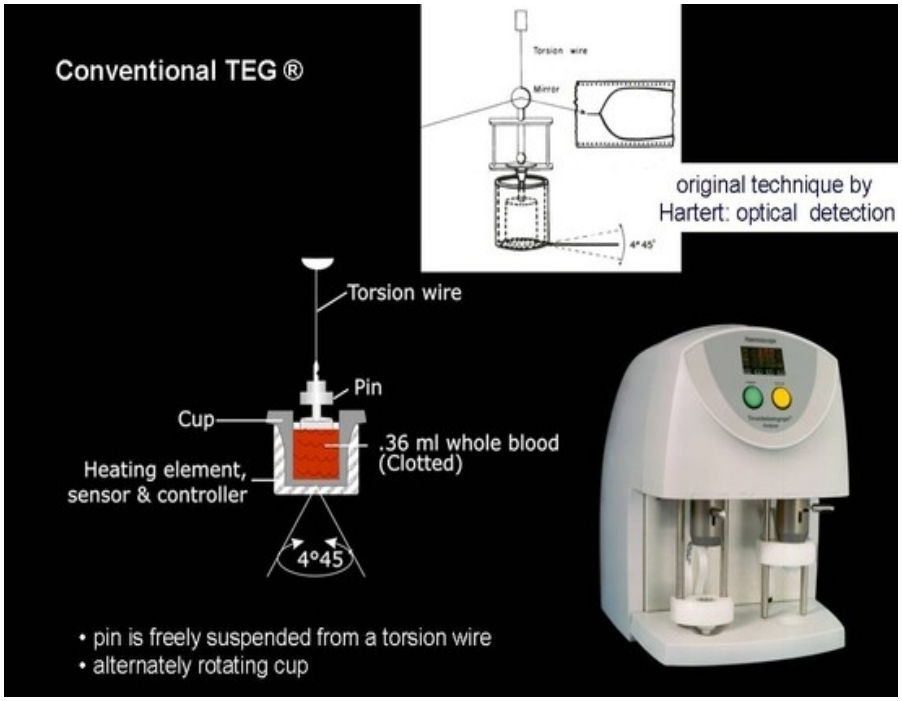
- Audit
- Pilot study & validation of equipment
- BMS to oversee POC lab: QC & QA, training & competency assessments
- TEG available and increasingly used for a wide variety of surgical cases
- Introduction of TEG platelet mapping (Service innovation development)

RFH POCT Laboratory

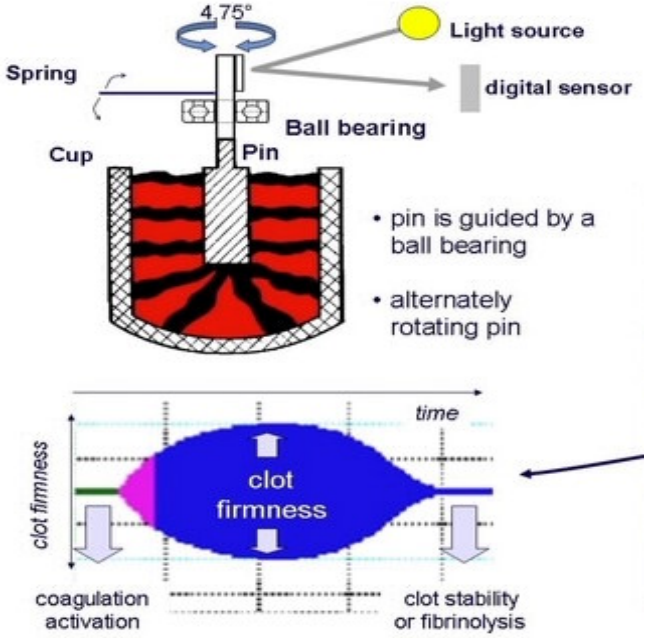
- Located in main theatre complex
- CPA accredited satellite laboratory: “Outreach of central pathology Lab”
- Training for all users
- EQA participation
- Appropriate maintenance and QC
- BMS supervision and troubleshooting
- INR, FBC, TEG, Platelet mapping, ABG

VHA: Viscoelastic Haemostatic Assays : Principles of Measurement

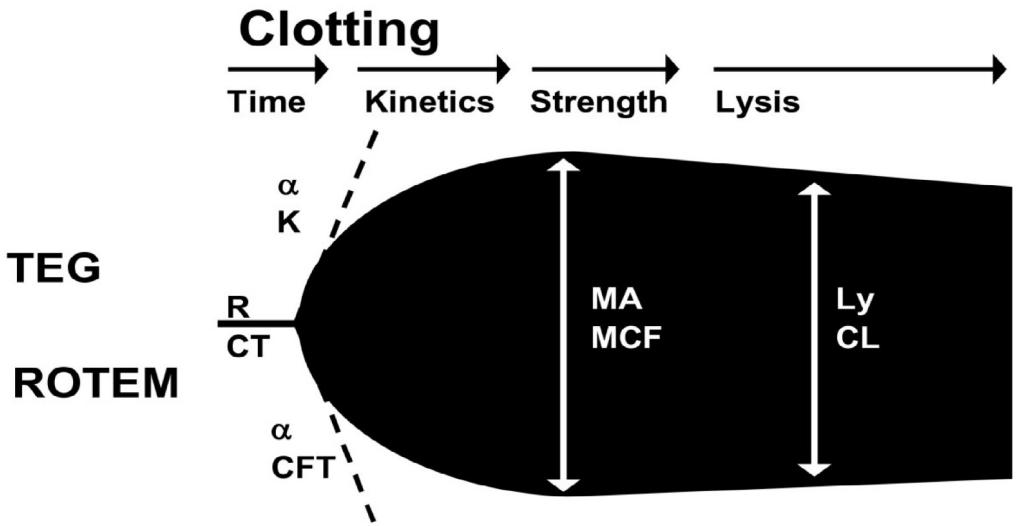
TEG ®



ROTEM ®



Schematic of TEG/ ROTEM parameters



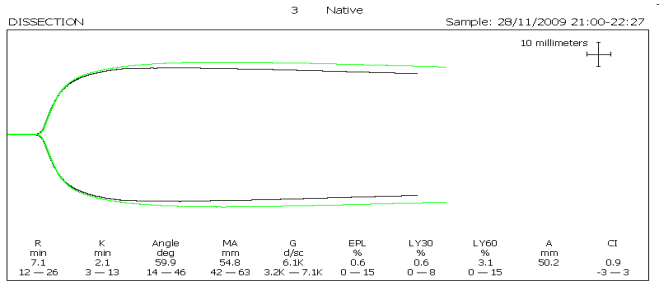
What do we need to know?

1: Is clot forming & how rapidly? Clotting factor levels & anticoagulants

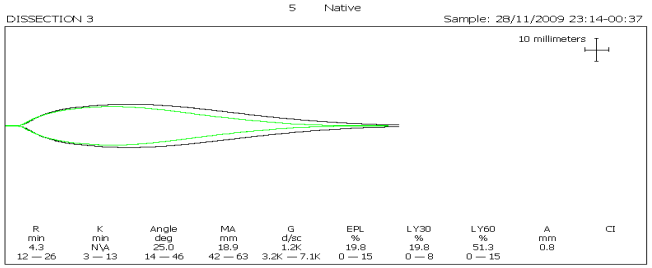
2: How strong is the clot? Platelets & Fibrinogen

3: Is it stable? Fibrinolysis

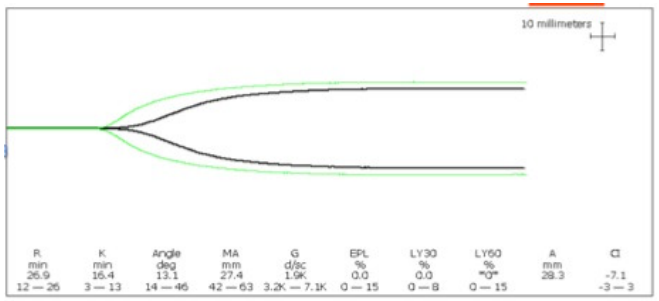
Examples of Different Haemostatic Profiles on TEG®



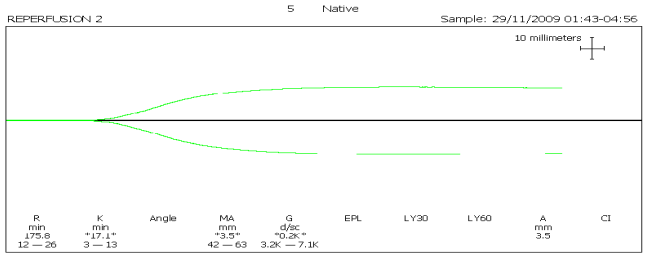
Normal trace



Fibrinolysis



Thrombocytopenia or low fibrinogen

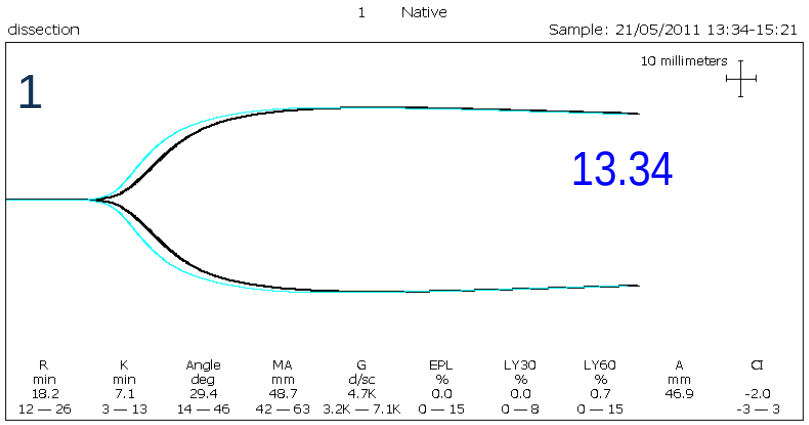


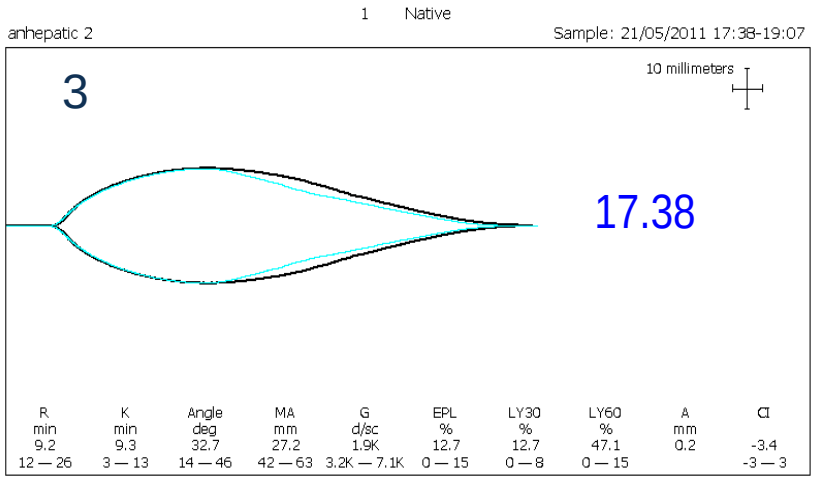
Heparin effect reversed by Heparinase (green trace)

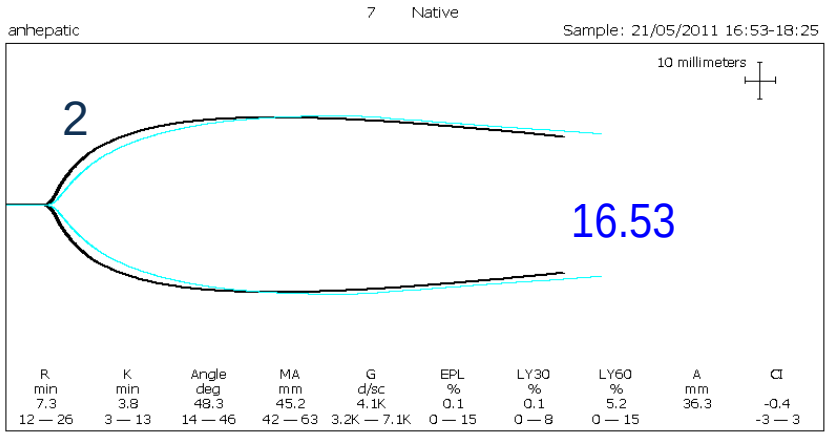
Massive Blood Loss in OLT

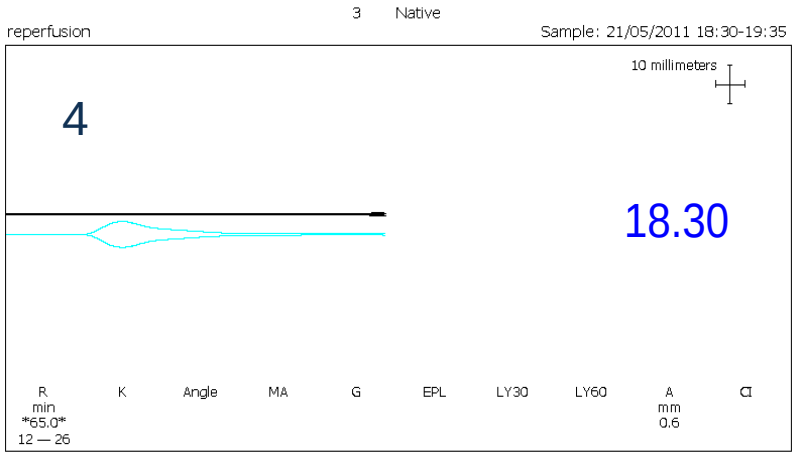
49 male ALD, previous TIPSS

Hb 11.5, INR 1.4, Platelets 99,000, Fibrinogen 2.4 g

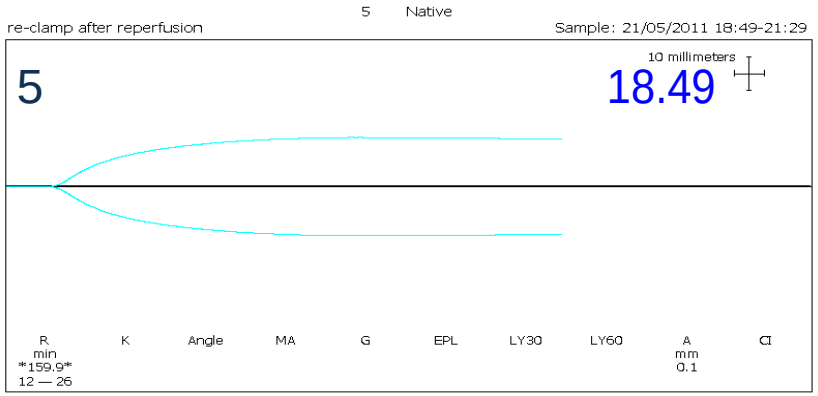


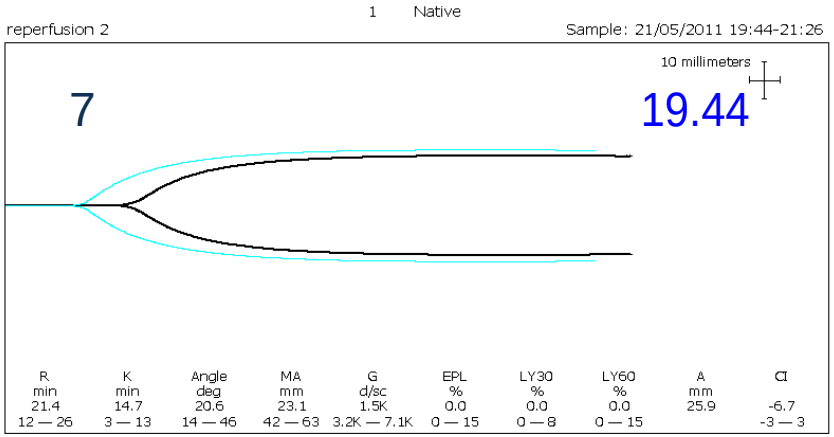




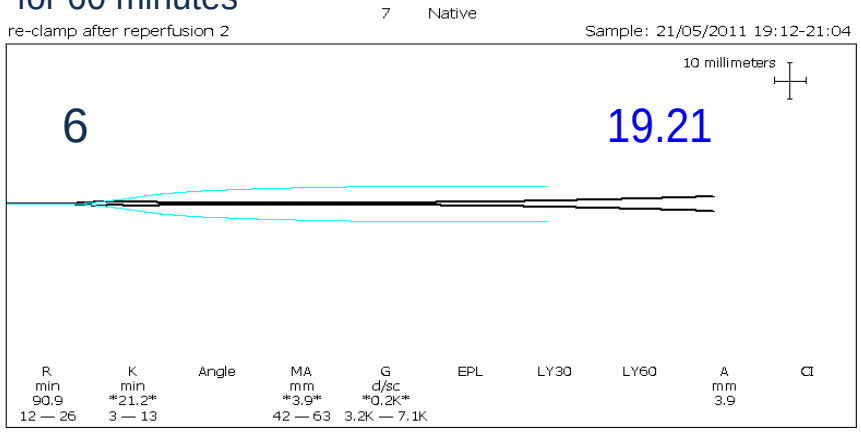


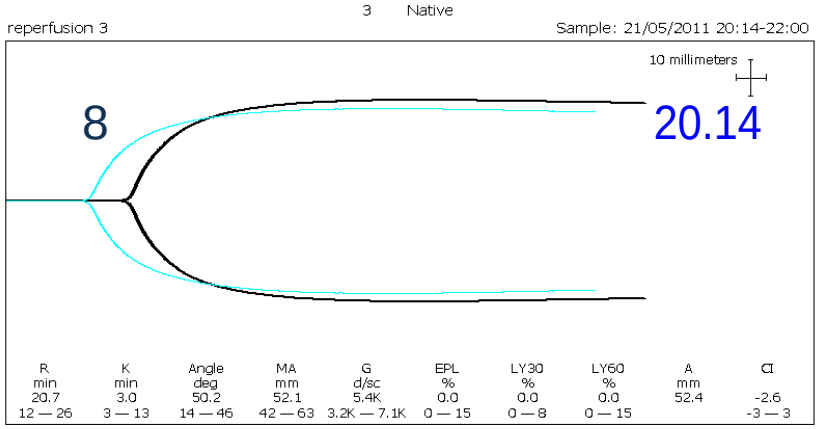
Uncontrolled bleeding from upper caval anastomosis following reperfusion: TIPSS had migrated towards right atrium, resulting in tearing of upper cava on removal of stent





Transfusion rate 300 – 400 mls/min through RIS, for 60 minutes



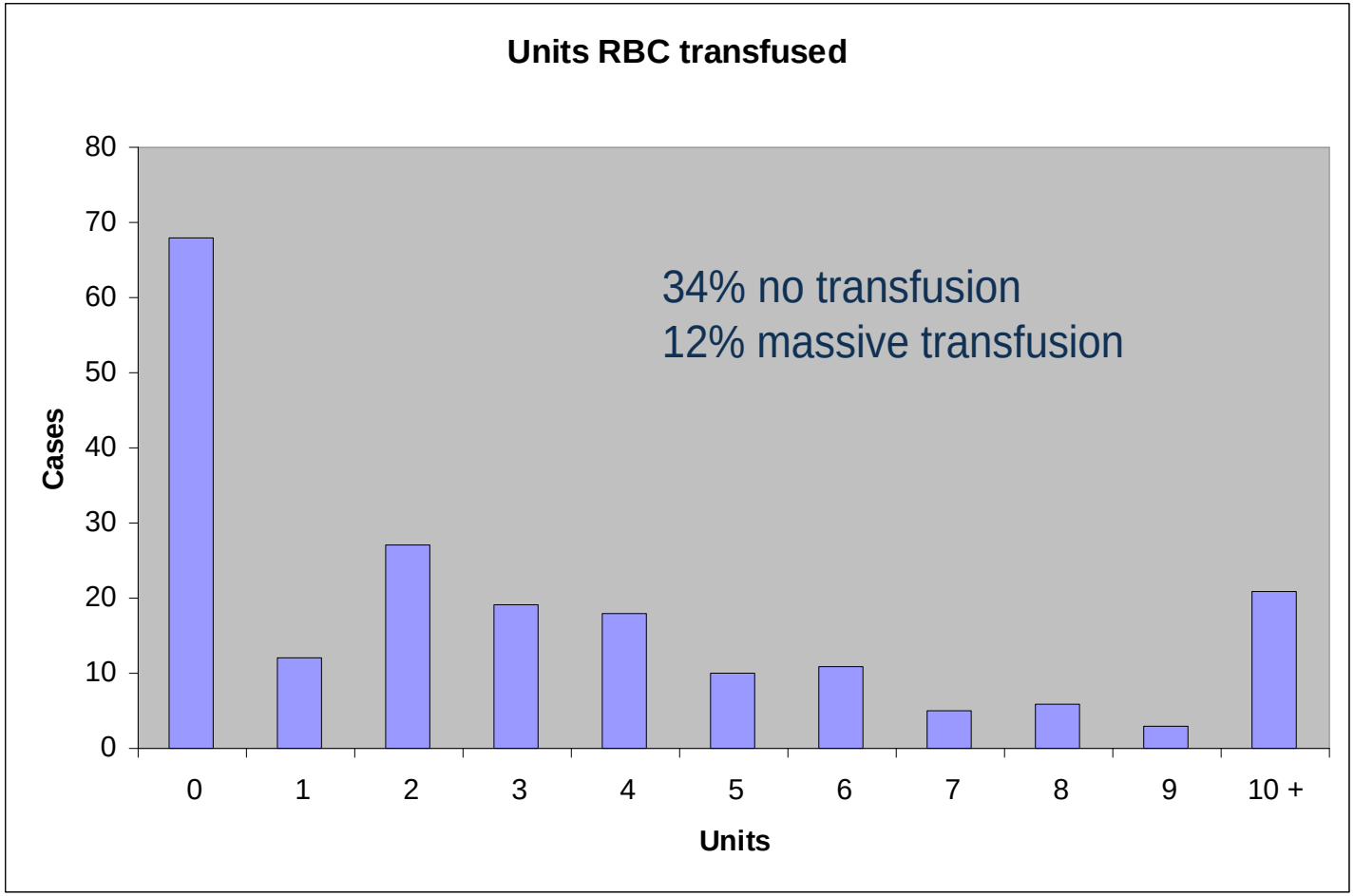


Normal coagulation at end of case: 37,000 mls transfused through RIS.

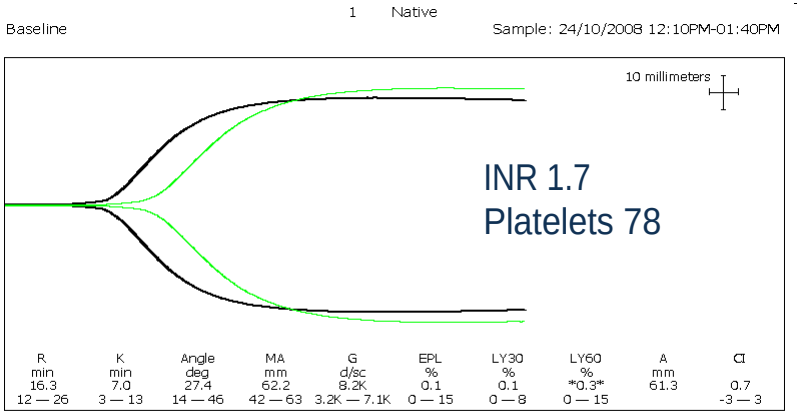
40 units RBC, 40 units of FFP, 9000 mls cell saver blood, 6 pools platelets, 6g fibrinogen concentrate, 3000 units PCC

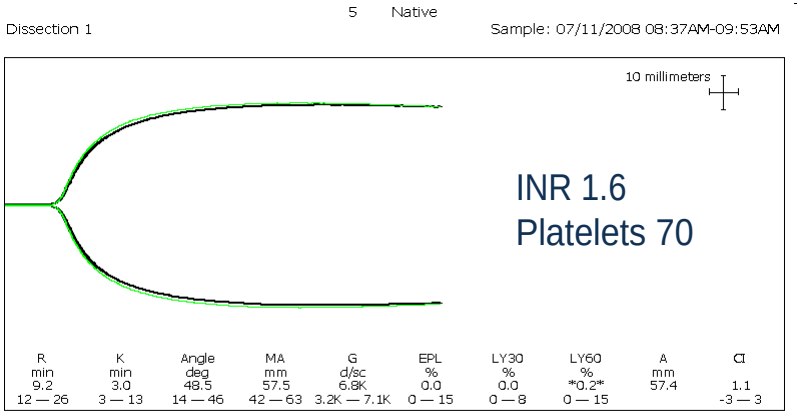
3500 iu PCC and 3 grams of TA

200 consecutive OLT



TEG and OLT





60% of patients with ESLD have NORMAL baseline TEGs

25% are hypocoagulable

15% are hypercoagulable

2011

Thrombelastography (TEG) or thromboelastometry (ROTEM) to monitor haemotherapy versus usual care in patients with massive transfusion (Review)

Afshari A, Wikkelsø A, Brok J, Møller AM, Wetterslev J

THE COCHRANE COLLABORATION®

9 RCTs in over 700 patients
TEG/ROTEM monitoring reduced transfusions and overall blood loss

VET proven value in directing haemostatic interventions & minimizing transfusion in liver transplantation, cardiac surgery & trauma
BUT
POC moderate complexity: Fully trained & competent users
Experience & familiarity in analyzing traces requires that tests are done on regular basis
Require proper maintenance, QC etc.

Algorithms based on simple POCT improve transfusion decision making

- ACT, INR, Platelet count
- Patients receive fewer transfusions of FFP & platelets
- Use of algorithms result in greater use of specific types of blood components
- More directed therapy may correct haemostatic defect more effectively

Nuttall G et al. Anesthesiology 2002,94:773-82

Avidan M,S et al BJA 2004 92 (2); 178-176

Samama & Ozier. Vox Sang 2003;84, 251-255

Despotis GJ et al. Anesthesiology 1994;84:338-351

Reducing red blood cell transfusion in elective surgical patients: The role of audit and practice guidelines

Mallett S. Anaesthesia 2000;55:1013-1019

Elective surgical patients over two 3 month periods: similar case mix

Initial survey of transfusion attitudes & practice
Transfusion trigger 8-9 g/dl

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1996
Preoperative Hb: 12 (2.27)
32% (n=96) of cross matched patients transfused: 66% of all transfusions were 2 unit transfusions
EBL associated with 2 unit transfusion: median 610 mls (374)
Postoperative Hb: 12.4 (1.8)

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Introduced Haemocue for POC Hb monitoring
Ran concurrent Laboratory Hb for first three months

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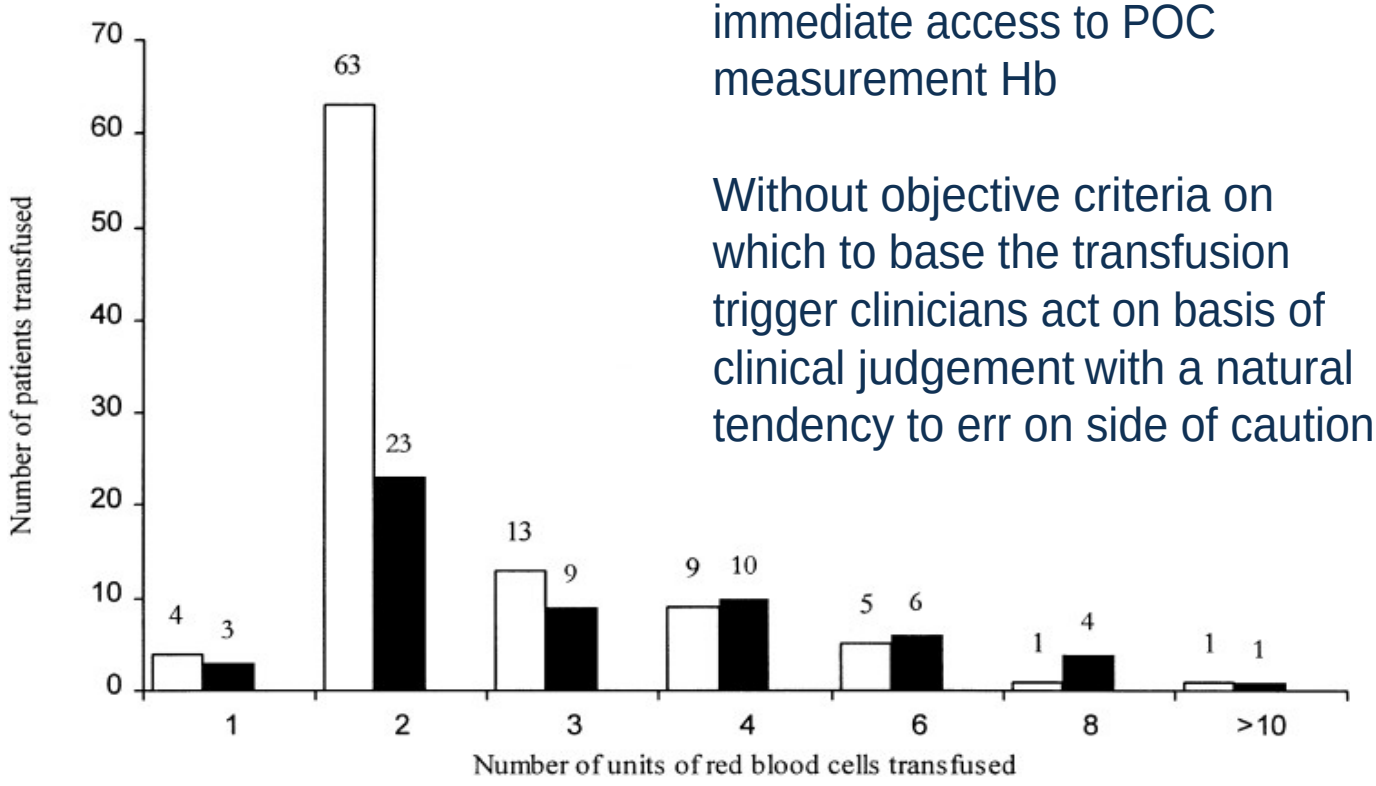
EBL associated with 2 unit transfusion: median 610 mls (374)
Postoperative Hb: 12.4 (1.8)

1998
Preoperative Hb: 11.6 (1.9)
18% of cross matched patients transfused: 41% of transfusions were 2 unit transfusions
EBL associated with 2 unit transfusion: median 1317 mls* (644)
Post operative Hb : 9.9 (2.4)*

Reducing red blood cell transfusion in elective surgical patients:
The role of audit and practice guidelines

Mallett S. Anaesthesia 2000;55:1013-1019



Reduction in transfusion due to immediate access to POC measurement Hb

Without objective criteria on which to base the transfusion trigger clinicians act on basis of clinical judgement with a natural tendency to err on side of caution

Simple POCCT: FBC

- Designed for POC testing
- Compact
- User friendly
- Automated QC & QA
- FBC in 3minutes.

Simple POCCT: INR

- INR/PT in 2 minutes
- Whole blood
- Cuvette system
- Portable
- Internal QC

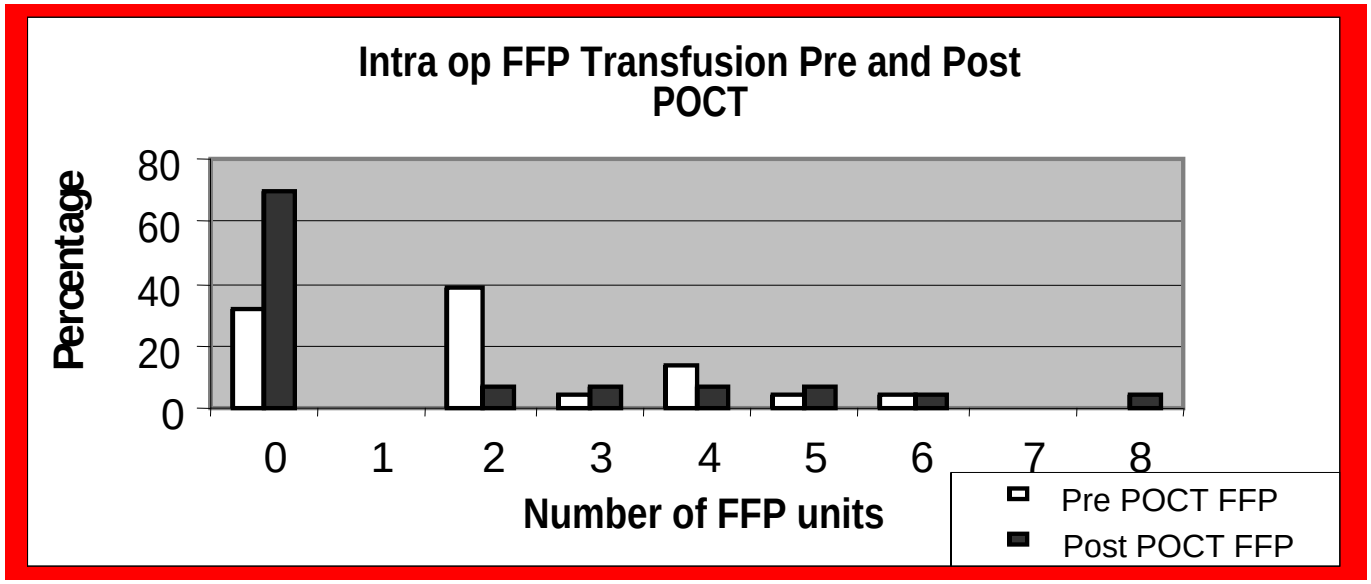
Operating Theatres: Rapid coagulation screen

Rapid INR : patients on or who have discontinued warfarin

Guide transfusion of FFP

POC vs Central Lab Coagulation testing during haemorrhagic surgery: Toulon P et al. Thromb Haemost. 2009;101:394-401

FFP and Liver Resection



Prior to POC INR testing:

70% liver resection patients received intra operative FFP

Post POC INR testing

70% had no intra operative FFP: INR < 1.5

Tight control of coagulopathy in the immediate postoperative period is associated with improved long-term outcomes after intra-operative massive transfusion.

Konstantinos G. Miltsios, Dominik A. Krzanicki, Fabiana Lucci, Karen M. Thompson, Katherine M.H. James, Susan V. Mallett.
Department of Anaesthesia, Royal Free Hospital, London, U.K.

	Group A INR≥1.5 (n=58)	Group B INR<1.5 (n=39)
Initial PC (units)	8	8
Initial FFP (units)	4.5	6

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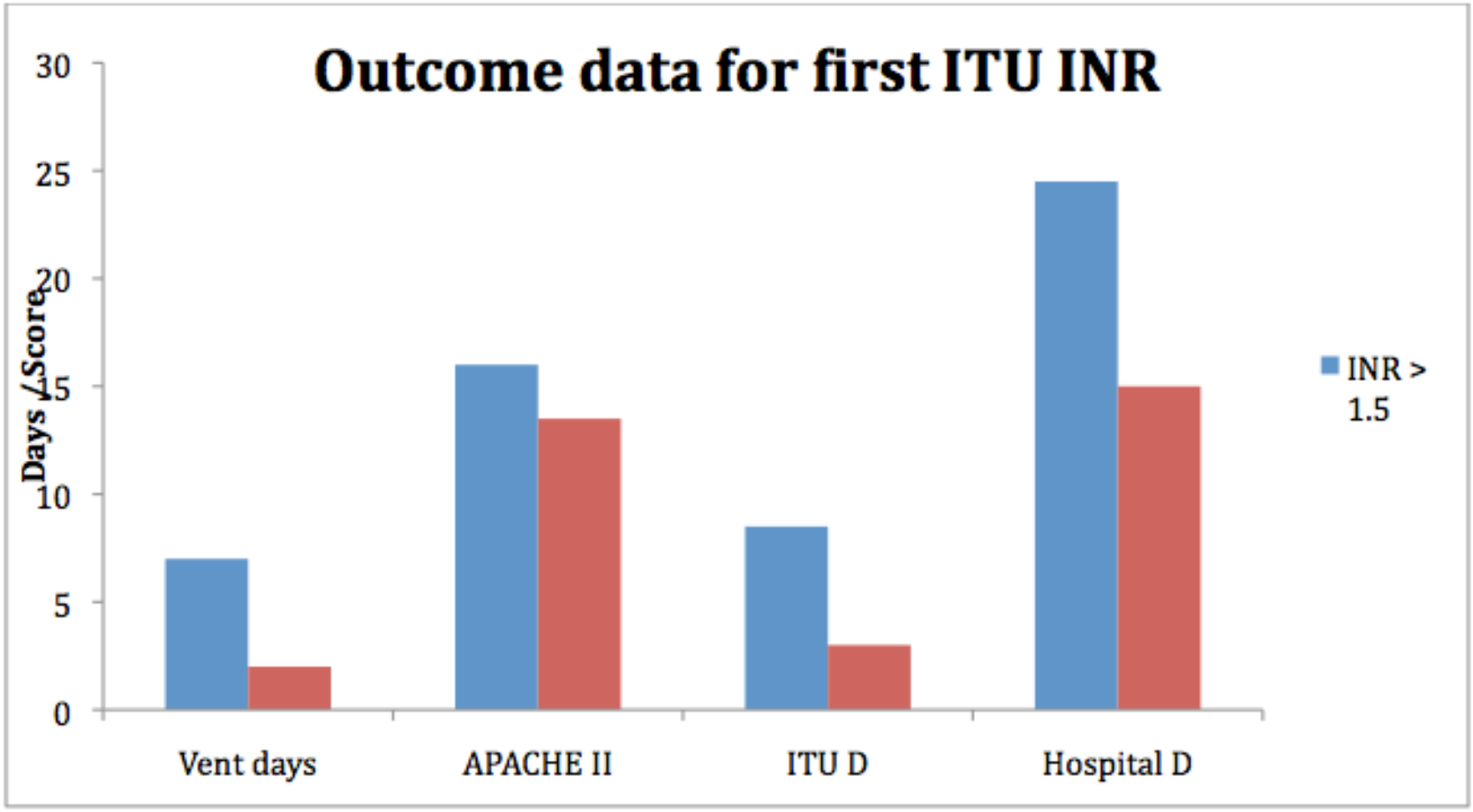
	Group A INR≥1.5 (n=58)	Group B INR<1.5 (n=39)
Initial PC (units)	8	8
Initial FFP (units)	4.5	6
ITU stay (days)	5	3
Hospital stay (days)	24	19
Post-op PC (units)	2	0
Post-op FFP (units)	2	0
Return to theatre	23.6%	5.6%
RRT post-op	32.1%	6.3%
30 day survival	50%	76.9%
1 year survival	38%	56%

Arrival on ITU post theatre
Initial Coagulation Screen

Value	Triggering	Not triggering
Hb < 8	32	138
INR> 1.5	78	79
Platelets < 75,000	42	127

High INR may be reflection of low fibrinogen as well as low clotting factor activity


Outcome data for first ITU INR
30
25
20
15
10
5
0
Days /Score
Vent days
APACHE II
ITU D
Hospital D
INR > 1.5

POCT in Practice

Allows rapid result reporting to provide timely information on which to base informed decisions

Facilitates goal directed management of coagulopathy & assessment of the efficacy of haemostatic interventions

Reduces unnecessary & empirical transfusion of blood and blood products

POCT should be an essential component of PBM programmes

Patient Blood Management

Improve clinical outcome by avoiding unnecessary exposure to blood & blood components

3 Pillars:

1: Pre-operative optimization of anaemia

2: Minimize blood loss

- Cell salvage
- POC Monitoring
- Haemostatic drugs: TA

3: Optimization of tolerance of anaemia