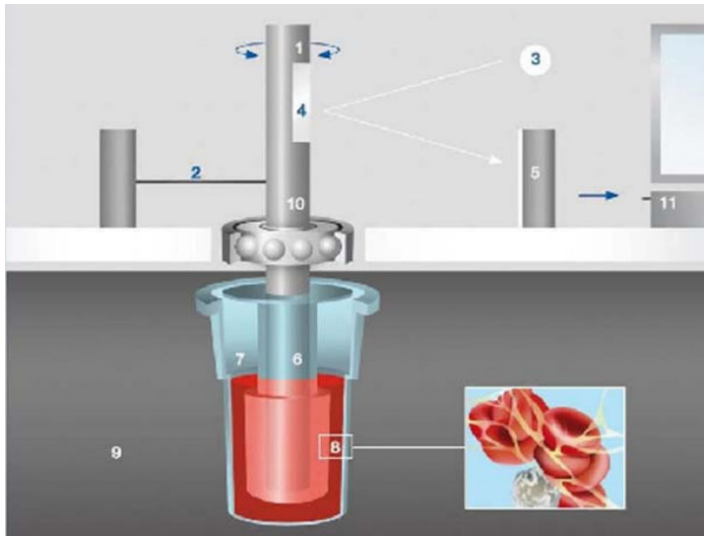
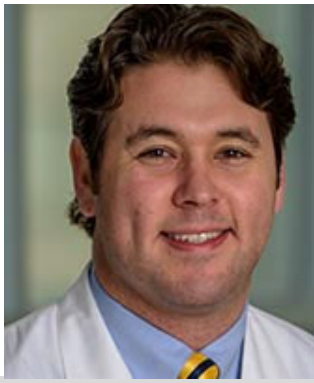
ROTEM Use in Obstetrics



David B. Nelson MD

Gillette Professorship of Obstetrics and Gynecology
Dedman Family Scholar in Clinical Care
Chief, Division of Maternal-Fetal Medicine
Associate Professor, Maternal-Fetal Medicine
Department of Obstetrics & Gynecology
University of Texas Southwestern Medical Center



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Disclosures

- *Author of Williams Obstetrics 26th edition and Senior Editor for Williams Obstetrics 27th edition.*
- *National Institute of Health (NIH). National Heart, Lung, and Blood Institute (NHLBI). RO1 HL142605-01*
- *PCORI. Improving Maternal Postpartum Access to Care through Telemedicine (IMPACT) Study.*
- *HemoSonics- UTSW OBGYN, CTA 202408-0061, Clinical Study Number: HEMCS-048*

Objectives for session

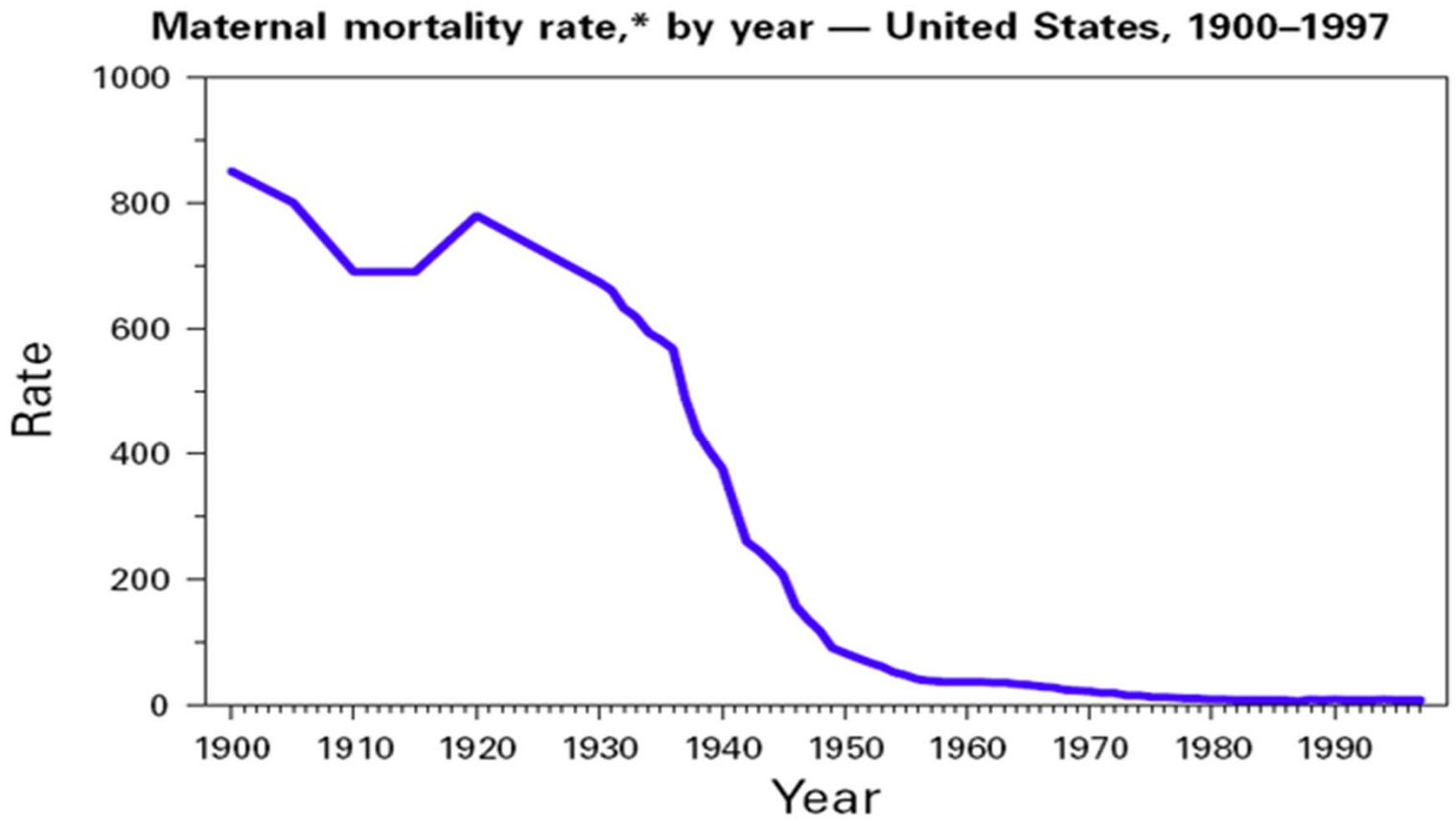
1. Review physiologic changes of pregnancy
2. Discuss management of obstetric hemorrhage
3. Describe utilization of resources in surveying coagulopathy
4. Characterize Rotational Thromboelastometry (ROTEM) indices.

Objectives for session

1. Review physiologic changes of pregnancy
2. Discuss management of obstetric hemorrhage
3. Describe utilization of resources in surveying coagulopathy

I-tem, U-tem, but do we use ROTEM in Obstetrics???

Emphasis on obstetric mortality



*Per 100,000 live births.

CDC. MMWR. October 01, 1999 / 48(38);849-858

Emphasis on obstetric mortality

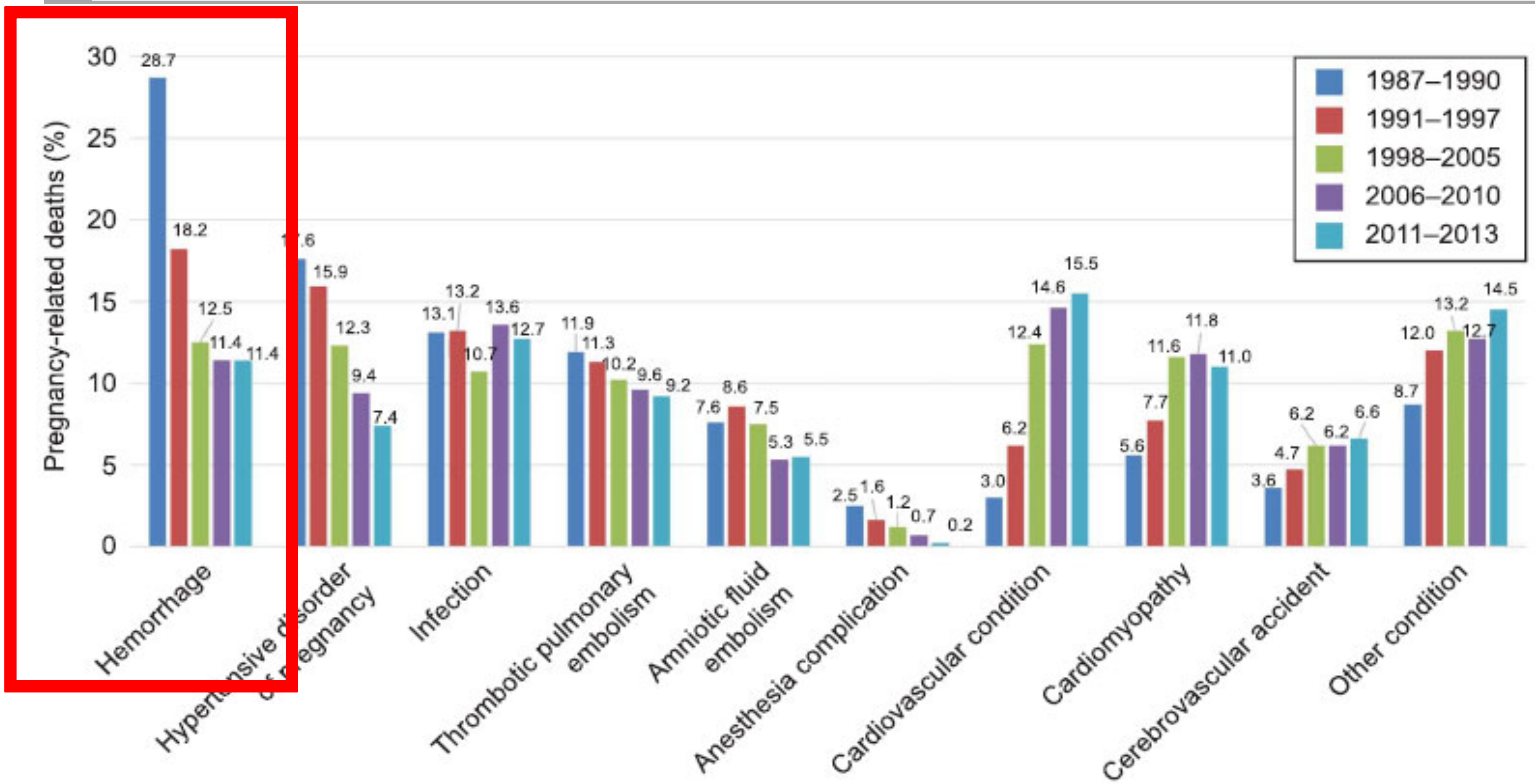
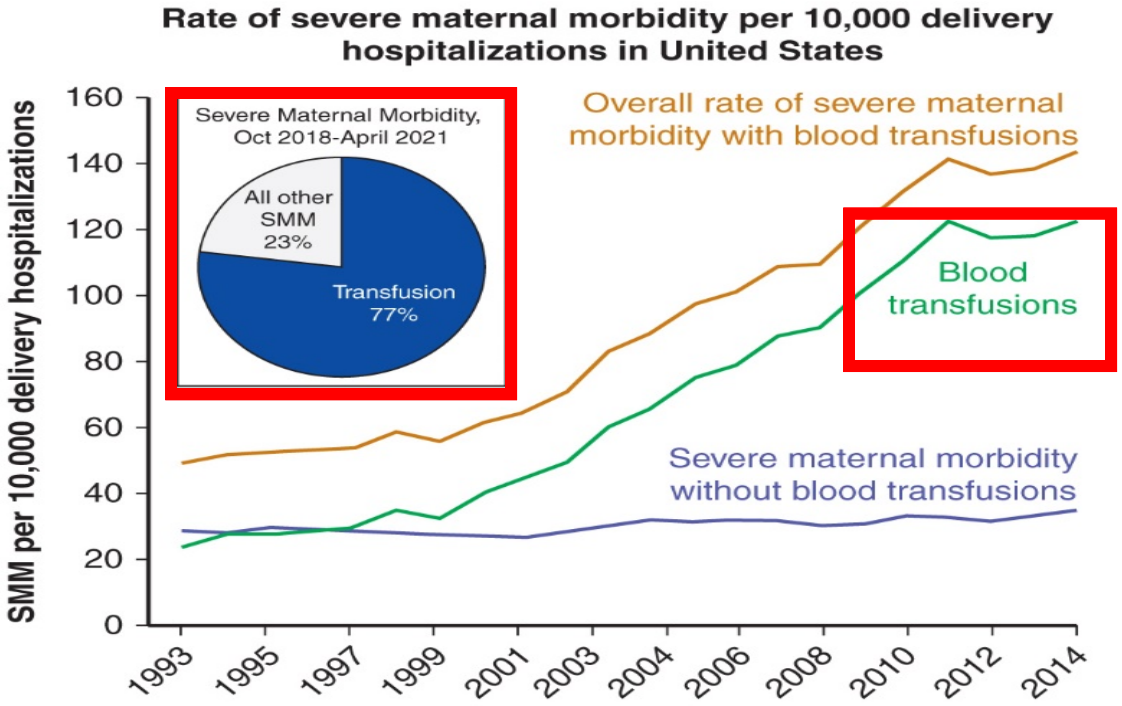


Figure 2. Population-level, cause-specific proportionate pregnancy-related mortality for 1987–1990, 1991–1997, 1998–2005, 2006–2010, and 2011–2013. Results are population-level and can be compared as absolute values.

Creanga. Pregnancy-Related Mortality in the United States. Obstet Gynecol 2017.

- Although hemorrhage is declining as the cause-specific for pregnancy-related mortality in the United States, it remains the #1 threat to women's health worldwide

Obstetric Hemorrhage remains an issue



- Although hemorrhage appears to be declining as the cause-specific for pregnancy-related mortality in the United States, it remains the **#1 threat** to women's health worldwide
- Blood transfusion represents more than three-fourths of the severe maternal morbidity in the United States **(#1 cause when included with SMM/SOC)**

CDC.gov

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Obstetric Hemorrhage remains an issue

Original Research

Postpartum Hemorrhage Trends and Outcomes in the United States, 2000–2019

Chiara M. Corbetta-Rastelli, MD, Alexander M. Friedman, MD, MPH, Nasim C. Sobhani, MD, Brittany Arditi, MD, MSCR, Dena Goffman, MD, and Timothy Wen, MD, MPH

OBJECTIVE: To analyze temporal trends in and risk factors for postpartum hemorrhage and to analyze the association of risk factors with postpartum hemorrhage–related interventions such as blood transfusion and peripartum hysterectomy.

METHODS: This repeated cross-sectional study analyzed delivery hospitalizations from 2000 to 2019 in the National (Nationwide) Inpatient Sample. Trends analyses were conducted using joinpoint regression to estimate the average annual percent change (AAPC) with 95% CIs. Unadjusted and adjusted survey-weighted logistic regression models were performed to evaluate the relationship between postpartum hemorrhage risk factors and likelihood of 1) postpartum hemorrhage, 2) postpartum hemorrhage that requires blood transfusion, and 3) peripartum hysterectomy in the setting of postpartum hemorrhage, with unadjusted odds ratios and adjusted odds ratios with 95% CIs as measures of association.

RESULTS: Of an estimated 76.7 million delivery hospitalizations, 2.3 million (3.0%) were complicated by postpartum hemorrhage. From 2000 to 2019, the rate of postpartum hemorrhage increased from 2.7% to 4.3% (AAPC 2.6%, 94% CI 1.7–3.5%). Over the study period, the proportion of deliveries to individuals with at least one postpartum hemorrhage risk factor increased from 18.6% to 26.9% (AAPC 1.9%, 95% CI 1.7–2.0%). Among deliveries complicated by postpartum hemorrhage, blood transfusions increased from 5.4% to 16.7% from 2000 to 2011 and then decreased from 16.7% to 12.6% from 2011 to 2019. Peripartum hysterectomy among hospitalized individuals with postpartum hemorrhage increased from 1.4% to 2.4% from 2000 to 2009, did not change significantly from 2009 to 2016, and then decreased significantly from 2.1% to 0.9% from 2016 to 2019 (AAPC −27.0%, 95% CI −35.2% to −17.6%). Risk factors associated with postpartum hemorrhage and transfusion and hysterectomy in the setting of postpartum hemorrhage included prior cesarean delivery with previa or placenta accreta, placenta previa without prior cesarean delivery, and antepartum hemorrhage or placental abruption.

CONCLUSION: Postpartum hemorrhage and related risk factors increased over a 20-year period. Despite the increased postpartum hemorrhage rates, blood transfusions, and hysterectomy rates decreased in recent years.

(Obstet Gynecol 2023;141:152–61)
DOI: 10.1097/AOG.0000000000004972

Postpartum hemorrhage is the leading cause of maternal mortality worldwide,[1] and is a significant cause of maternal morbidity and mortality in the United States.[2–4] Risk factors for postpartum hemorrhage include clinical factors that lead to uterine atony (prolonged use of oxytocin, high parity, chorioamnionitis, general anesthesia) and uterine overdistention (multiple gestations, polyhydramnios, macrosomia), cesarean delivery, uterine fibroids, and advanced maternal age.[5,6] Many of these risk factors appear to be increasing on a population basis.[7,8]

A prior study that evaluated postpartum hemorrhage trends from 2001 to 2012 by using the National

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Each author has confirmed compliance with the journal's requirements for authorship.

Corresponding author: Alexander Friedman, MD, MPH, Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Columbia University College of Physicians and Surgeons, New York, NY; email: amf2104@cumc.columbia.edu.

Financial Disclosure
Timothy Wen serves as a consultant on the medical advisory board for Delfina, Inc. Dena Goffman serves on the scientific advisory board for the Jada device through Organon and the Cooper Surgical Obstetrical Safety Council. She also received payment from Haymarket for postpartum hemorrhage education. The other authors did not report any potential conflicts of interest.

ISSN: 0029-7844/23

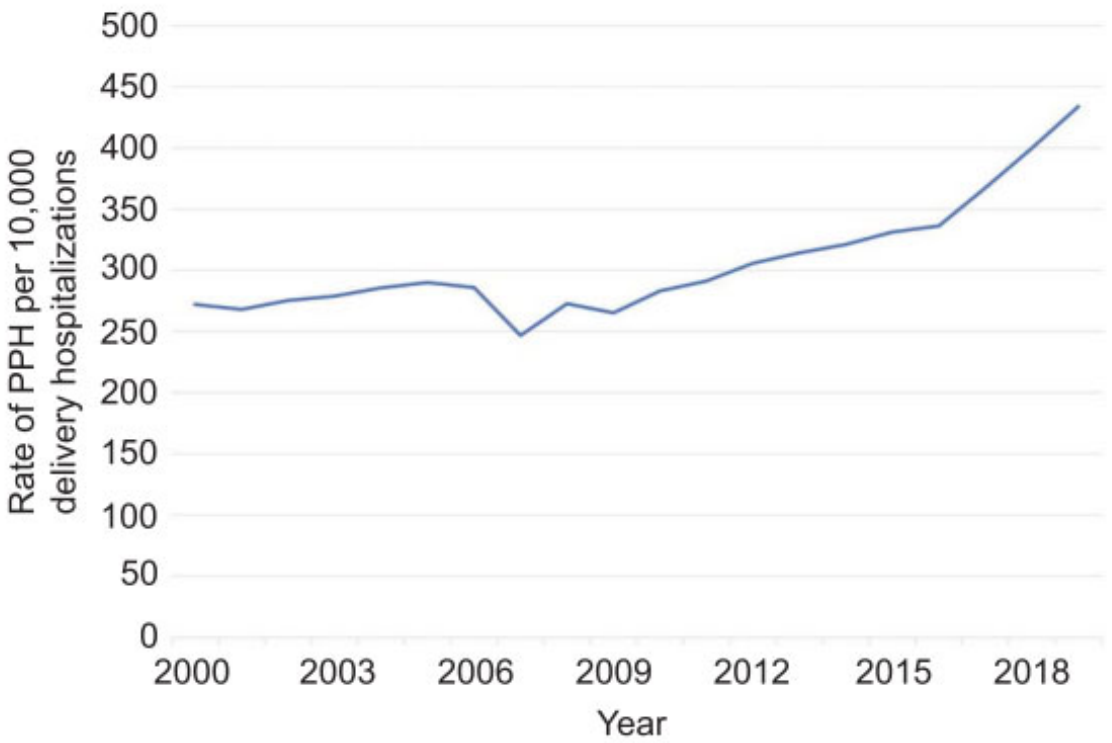

Fig. 2. Trends in postpartum hemorrhage (PPH) per 100,000 delivery hospitalizations by year over the 20-year study period.

Corbetta-Rastelli CM et al. Obstet Gynecol. Jan 2023

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Obstetric Hemorrhage remains an issue

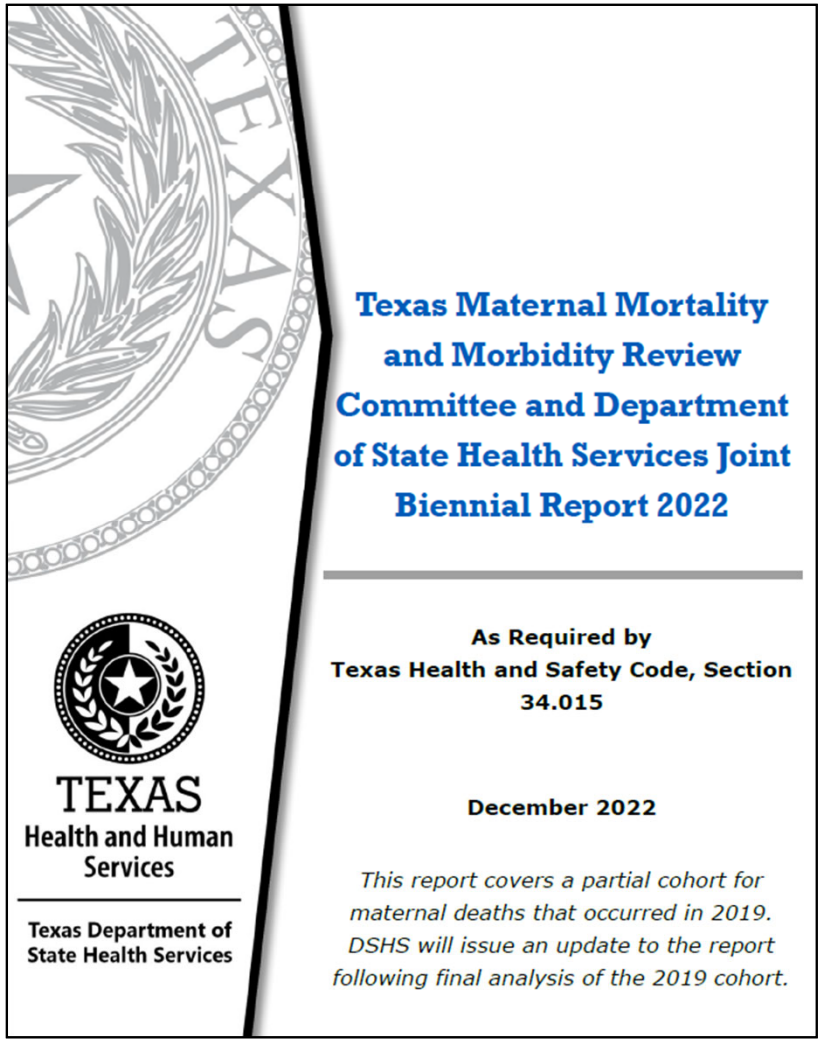
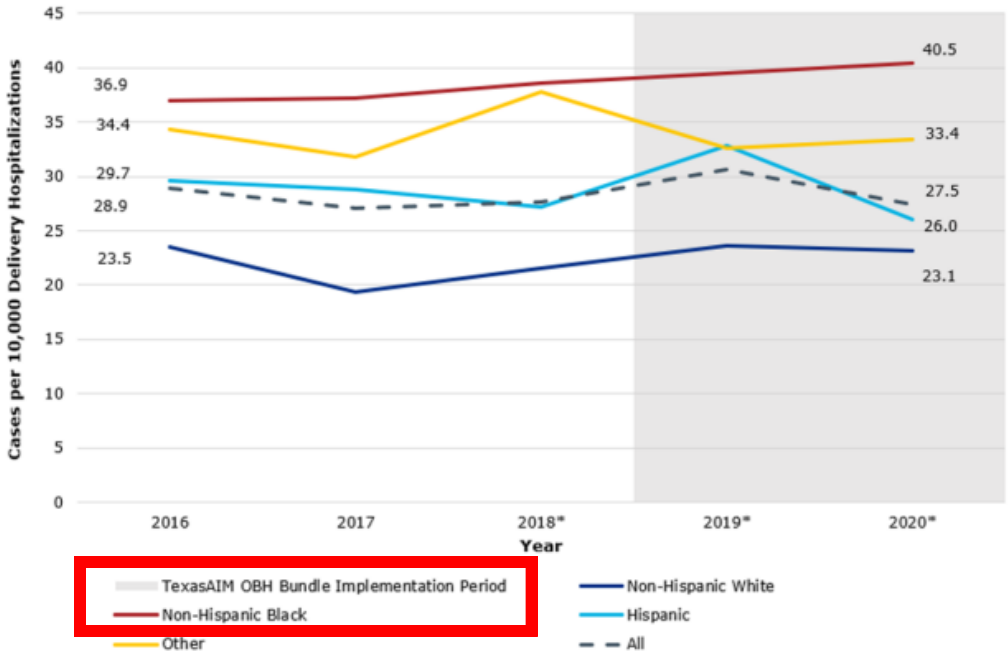


Figure G-6. Rate of Delivery Hospitalizations Involving SMM in Texas Associated with Hemorrhage, by Race and Ethnicity, per 10,000 Delivery Hospitalizations, 2016-2020



Texas Maternal Mortality and Morbidity Task Force Report, 2022

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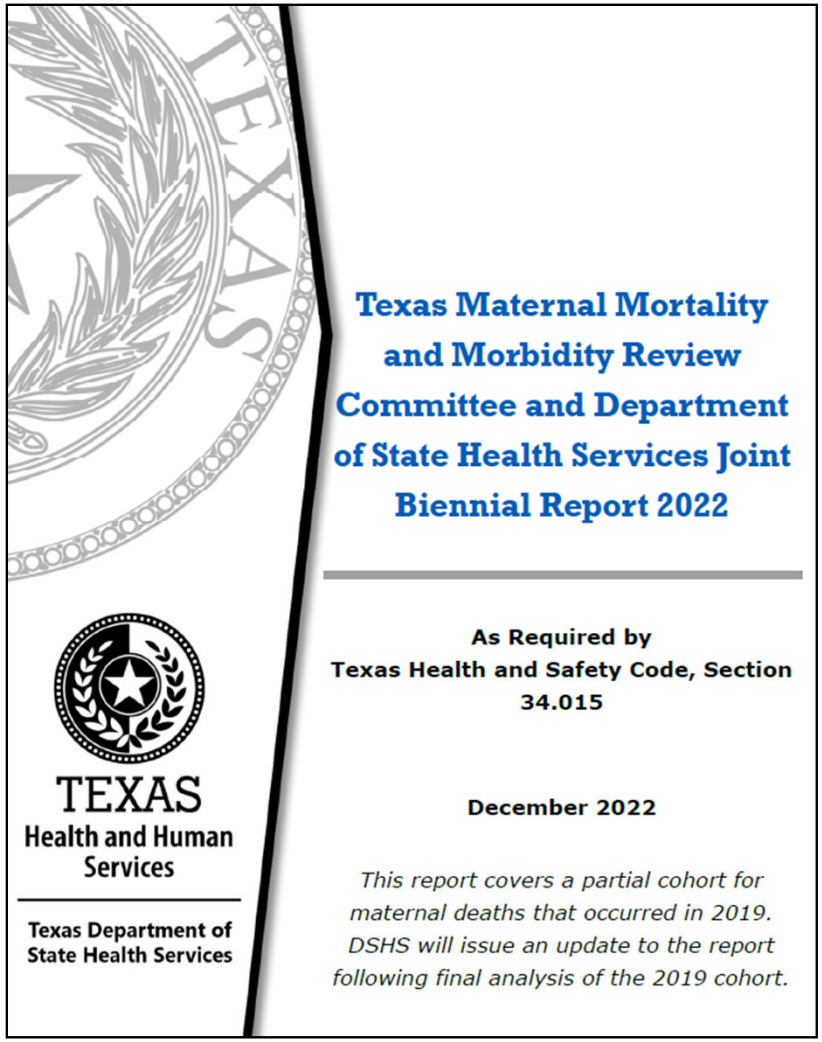
Obstetric Hemorrhage remains an issue



Underlying Cause of Death as determined by MMMRC*	Cases (Count)	Cases (Percent)	Contributing Factors (Count)	Contributing Factors (Average)
Hemorrhage (Excludes Aneurysms or Cerebrovascular Accident)	13	25%	103	7.9
Mental Health Conditions	9	17%	76	8.4
Embolism - Thrombotic (Non-Cerebral)	6	12%	70	11.7
Injury	5	10%	27	5.4
Cardiovascular Conditions	4	8%	36	9.0
Infection	4	8%	32	8.0
Cancer	3	6%	4	1.3
Cardiomyopathy	3	6%	26	8.7
Total	51		390***	7.6**

Texas Maternal Mortality and Morbidity Task Force Report, 2022

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Obstetric Hemorrhage remains an issue

88% of hemorrhage-related maternal deaths were preventable!

Texas Maternal Mortality and Morbidity Review Committee and Department of State Health Services Joint Biennial Report 2024

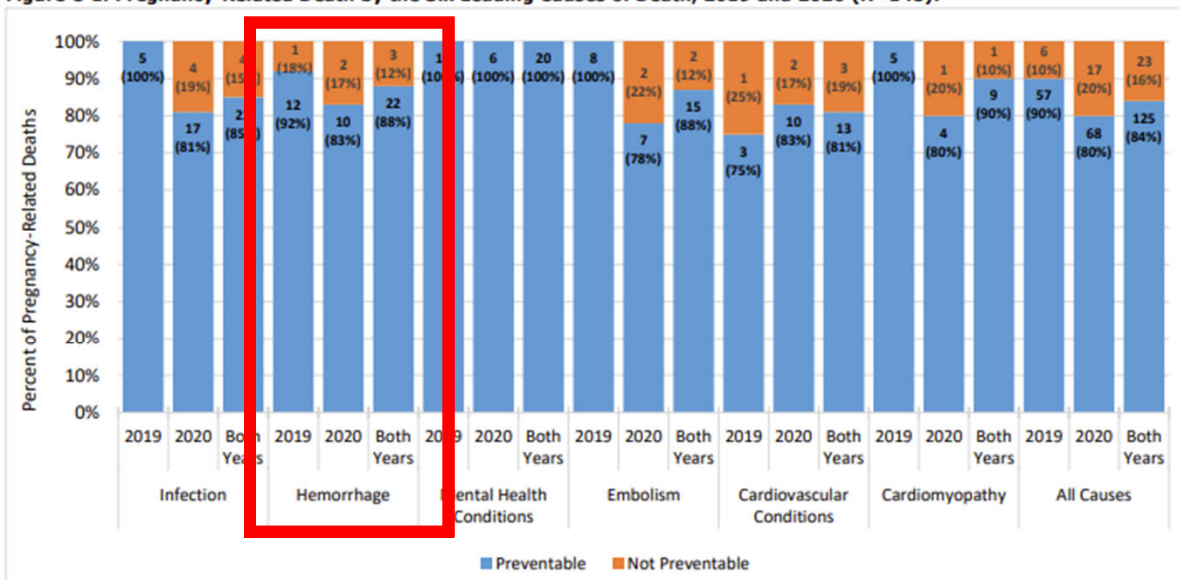
As Required by Texas Health and Safety Code, Section 34.015

September 1, 2024

TEXAS Health and Human Services

Texas Department of State Health Services

Figure C-1. Pregnancy-Related Death by the Six Leading Causes of Death, 2019 and 2020 (N=148).



PREPARED BY: Maternal and Child Health Epidemiologists (MCHE), Community Health Improvement (CHI) Division, DSHS.
DATA SOURCE: Texas Maternal Mortality and Morbidity Review Committee Data.
Pregnancy-related death is the death of a woman during pregnancy or within one year of the end pregnancy from a pregnancy complication, a chain of events initiative by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy.

Texas Maternal Mortality and Morbidity Task Force Report, 2024

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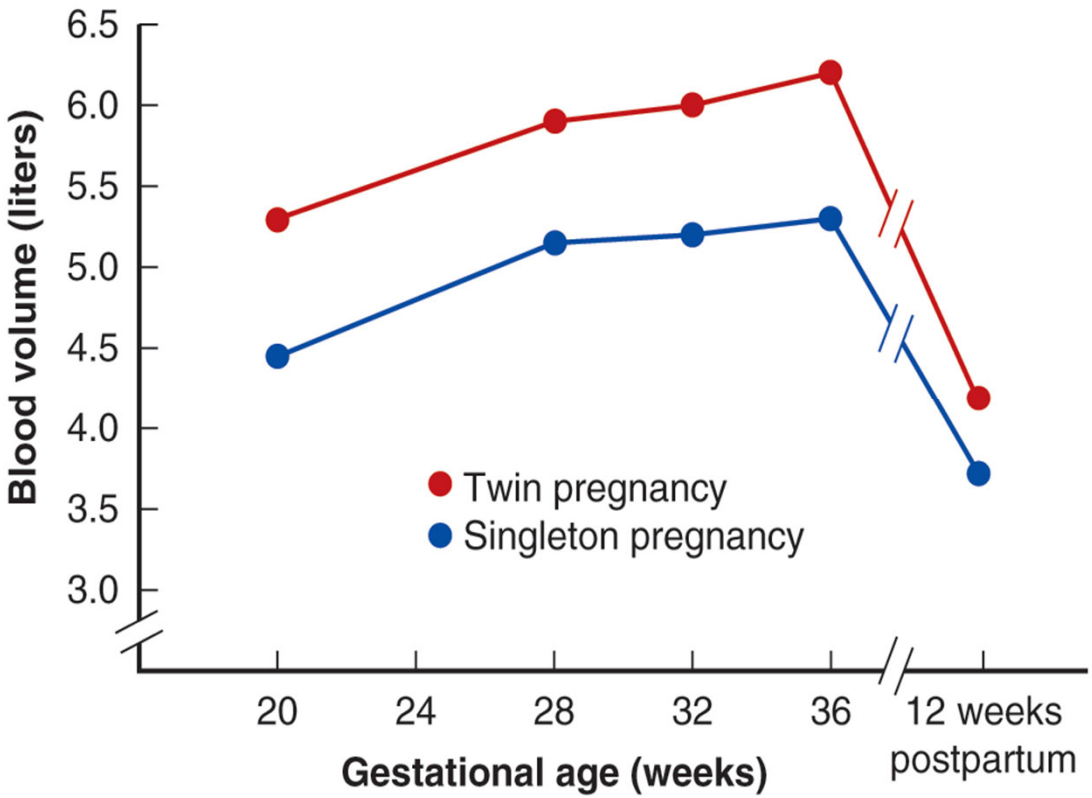
Physiologic changes of pregnancy

Physiologic changes of pregnancy

- Increased blood volume, Increased erythrocyte mass
- Nadir effect of blood pressure
- Increased Stroke Volume, Increased Heart Rate = Increased Cardiac Output
- Alterations in hematologic indices
- Increased glomerular filtration, results in diminished serum creatinine



Williams Obstetrics. 26th ed.

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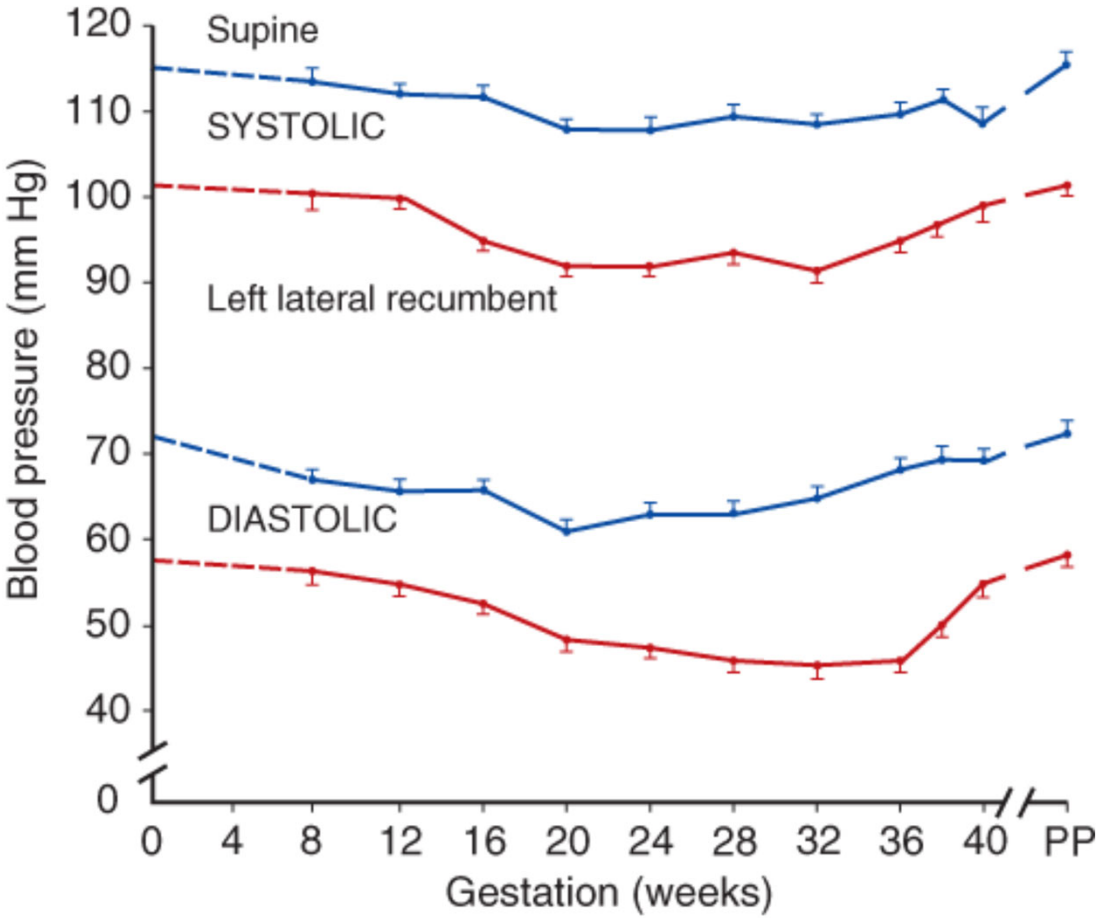
Cardiovascular adaptations



Source: F. Gary Cunningham, Kenneth J. Leveno, Steven L. Bloom, Catherine Y. Spong, Jodi S. Dashe, Barbara L. Hoffman, Brian M. Casey, Jeanne S. Sheffield: *Williams Obstetrics*, 25th Edition

Williams Obstetrics. 26th ed.

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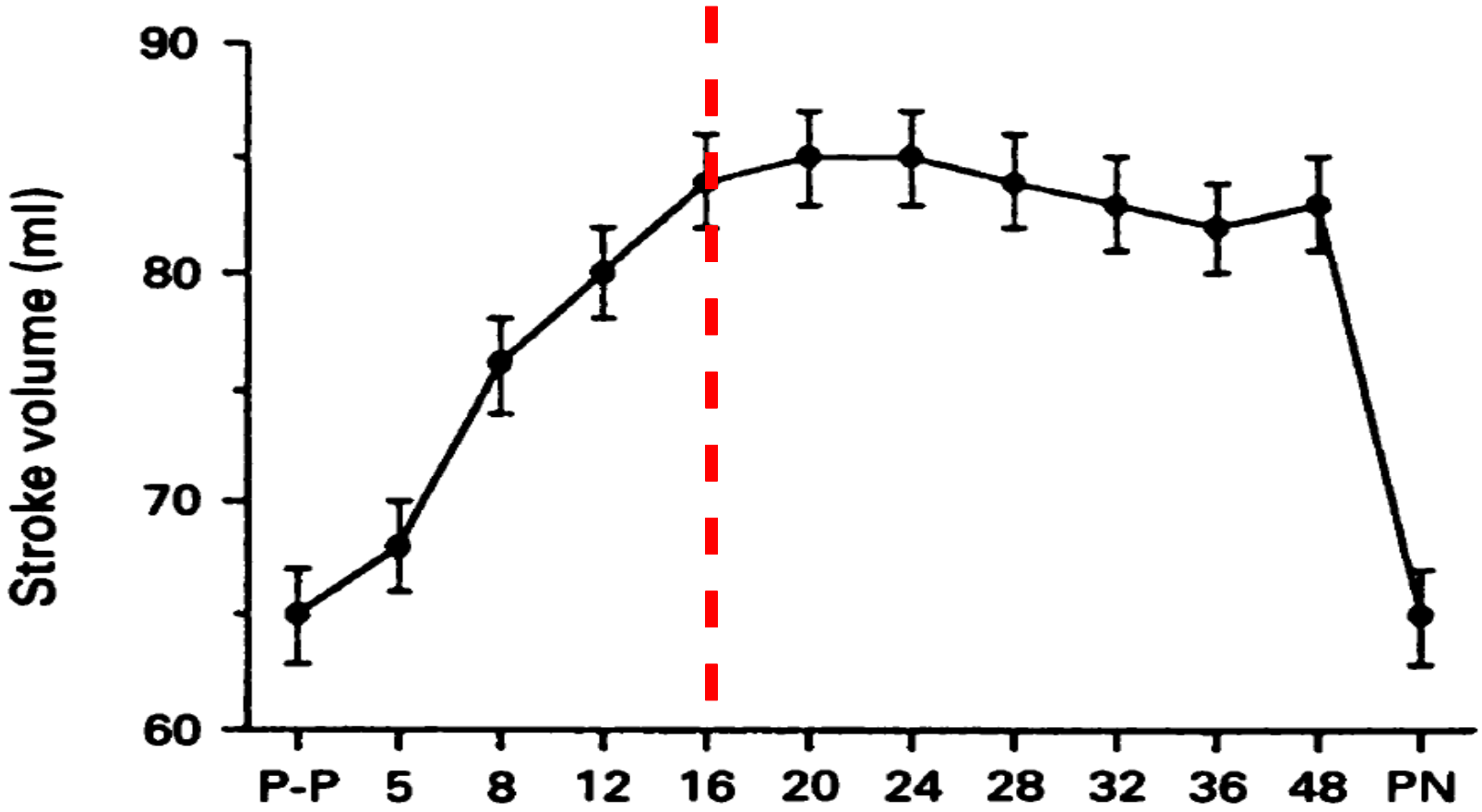
Cardiovascular adaptations



Hunter S, Robson SC. Br Heart J. 1992

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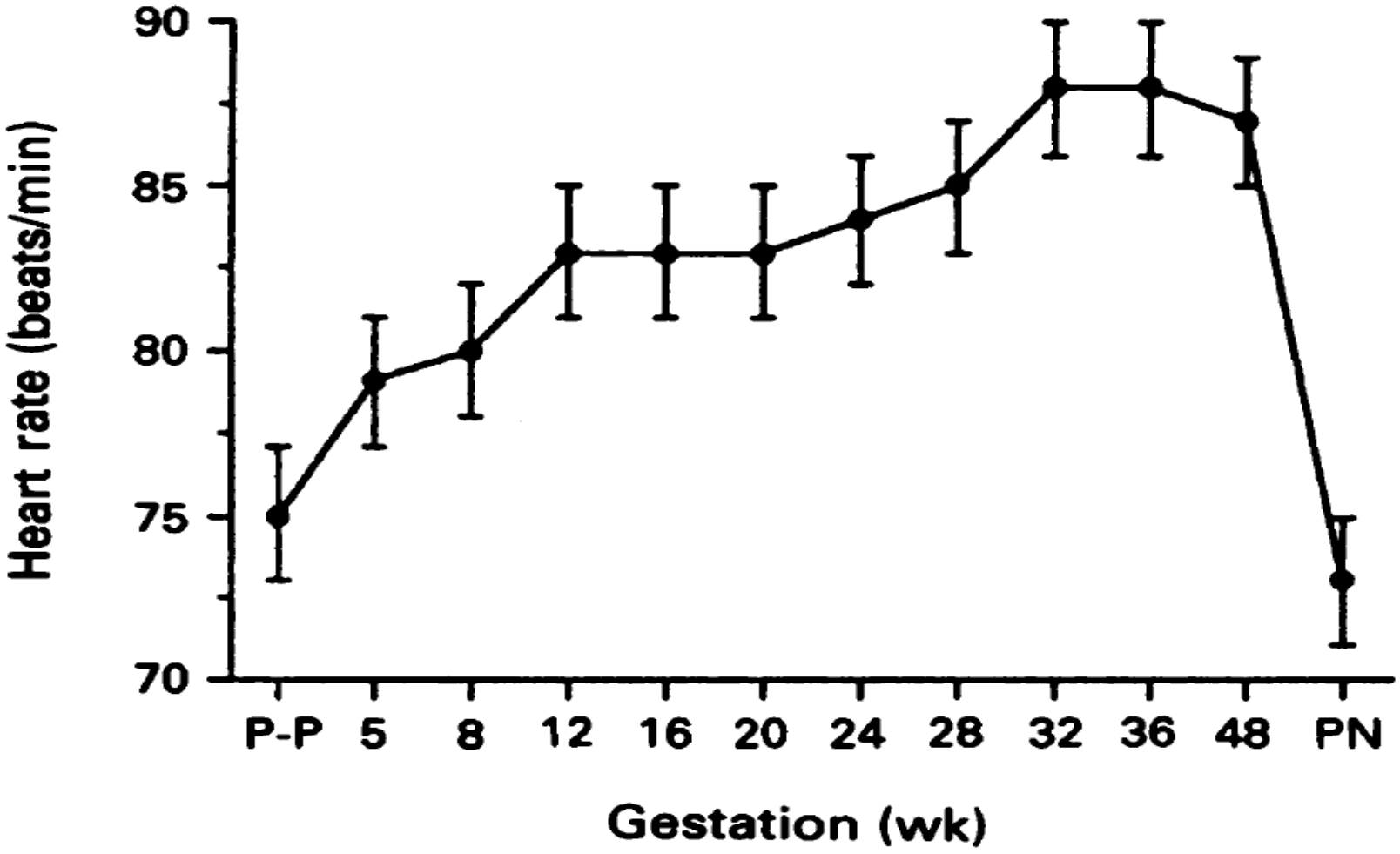
Cardiovascular adaptations



Hunter S, Robson SC. Br Heart J. 1992

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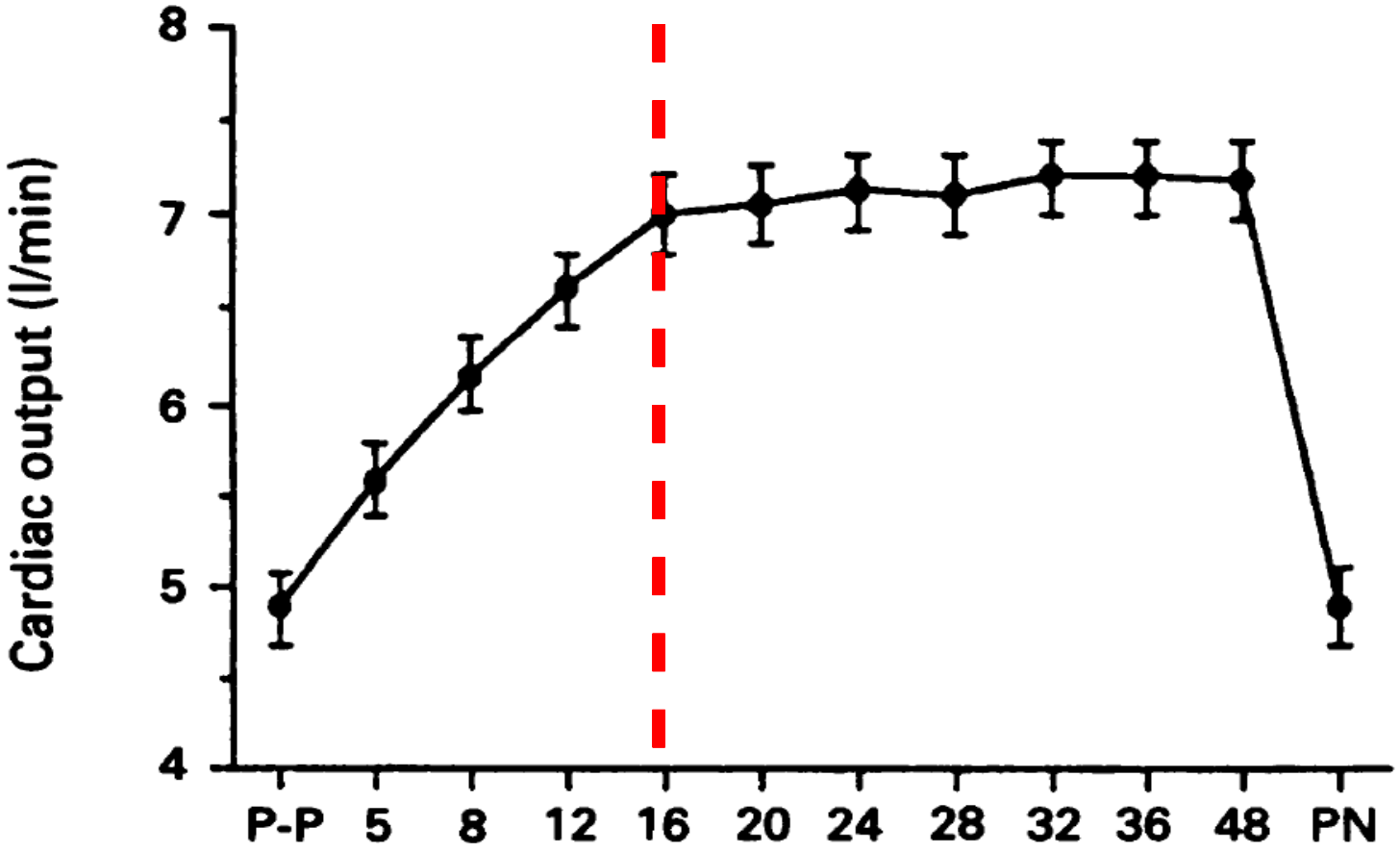
Cardiovascular adaptations



Hunter S, Robson SC. Br Heart J. 1992

Cardiovascular adaptations

Original Research ajog.org

OBSTETRICS

Cardiac magnetic resonance imaging to assess the impact of maternal habitus on cardiac remodeling during pregnancy

Robert D. Stewart, MD; David B. Nelson, MD; Susan A. Matulevicius, MD, MSCS; Jamie L. Morgan, MD; Donald D. McIntire, PhD; Mark H. Drazner, MD, MSc; F. Gary Cunningham, MD

BACKGROUND: It is well known that the maternal cardiovascular system undergoes profound alterations throughout pregnancy. Interest in understanding these changes has led investigators to use evolving and increasingly sophisticated techniques to study these changes, most recently with 2-dimensional echocardiography. Despite its clinical utility, echocardiography has limitations, and cardiac magnetic resonance imaging (CMRI) has become increasingly used for evaluation of cardiac structure and function.

OBJECTIVE: We used CMRI to evaluate cardiac remodeling according to maternal habitus throughout pregnancy and postpartum.

STUDY DESIGN: This was a prospective, observational study of nulliparous women aged 18-30 years, without preexisting medical conditions, conducted from October 2012 through December 2014. Women were classified according to prepregnancy body mass index (BMI) as either normal (BMI 18.5-24.9 kg/m^2) or overweight (BMI 25-35 kg/m^2). All women underwent CMRI during 5 epochs throughout gestation: 12-16 weeks, 26-30 weeks, 32-36 weeks, at delivery, and 3 months' postpartum. Using left ventricular mass (LVM) as a marker of cardiac remodeling, the 2 cohorts were compared.

RESULTS: There were 14 normal-weight (BMI 22.2 ± 1.3) and 9 overweight (BMI 29.1 ± 2.0) women who participated in the study. Beginning at 26-30 weeks and continuing to delivery, LVM of both normal-weight and overweight women was significantly increased compared with the respective first-trimester studies for each cohort ($P < .001$). LVM of both cohorts returned to their index values by 3 months' postpartum. The geometric ratio of LVM to left ventricular end-diastolic volume was calculated, and both normal-weight and overweight women demonstrated concentric remodeling throughout gestation, however this resolved by 12 weeks' postpartum.

CONCLUSION: There is substantial cardiac remodeling during pregnancy with significant increases in LVM that are proportional to maternal size. Left ventricular geometric remodeling was concentric in both normal-weight and overweight women. All changes in cardiac remodeling resolved by 3 months' postpartum.

Key words: cardiac magnetic resonance imaging, cardiac remodeling, concentric hypertrophy, left ventricular mass

Introduction

It is well known that the maternal cardiovascular system undergoes profound alterations throughout pregnancy, including increased cardiac output, heart rate, and plasma volume expansion.[1,2] Interest in understanding these changes has led investigators to use evolving and increasingly sophisticated techniques to study these changes, initially with dye-dilution techniques, then invasive right-heart catheterization, to now noninvasive techniques of cardiovascular assessment with 2-dimensional (2D) echocardiography.[3,4,6] With this latter technology it was shown that in response to these physiologic changes, cardiac remodeling accrues across pregnancy with increasing cardiac mass.[5-8]

Despite its clinical utility, echocardiography has limitations that include its wide interobserver and intraobserver variability, necessary geometric assumptions, and technical difficulty in evaluating obese subjects.[9-11] Over the past decade, cardiac magnetic resonance imaging (CMRI) has been shown to have superior high-resolution imaging capabilities free from the limitations of 2D echocardiography.[10,12-14] Due to the advantages of superior spatial resolution, CMRI has become the gold standard for assessment of regional and global systolic function, myocardial viability, and evaluation of complex congenital heart disease.[15-17]

To date there have been only a few reports that describe the CMRI in pregnant women. And although 2 recent studies described CMRI findings in healthy pregnant women compared with nonpregnant controls, neither addressed longitudinal changes across pregnancy.[15,16] Because of this, we designed the current study to evaluate changes in cardiac size according to maternal habitus throughout pregnancy and the postpartum period for both normal-weight and overweight women. A second aim of this study was to determine the pattern of geometric remodeling specific to pregnancy.

Materials and Methods

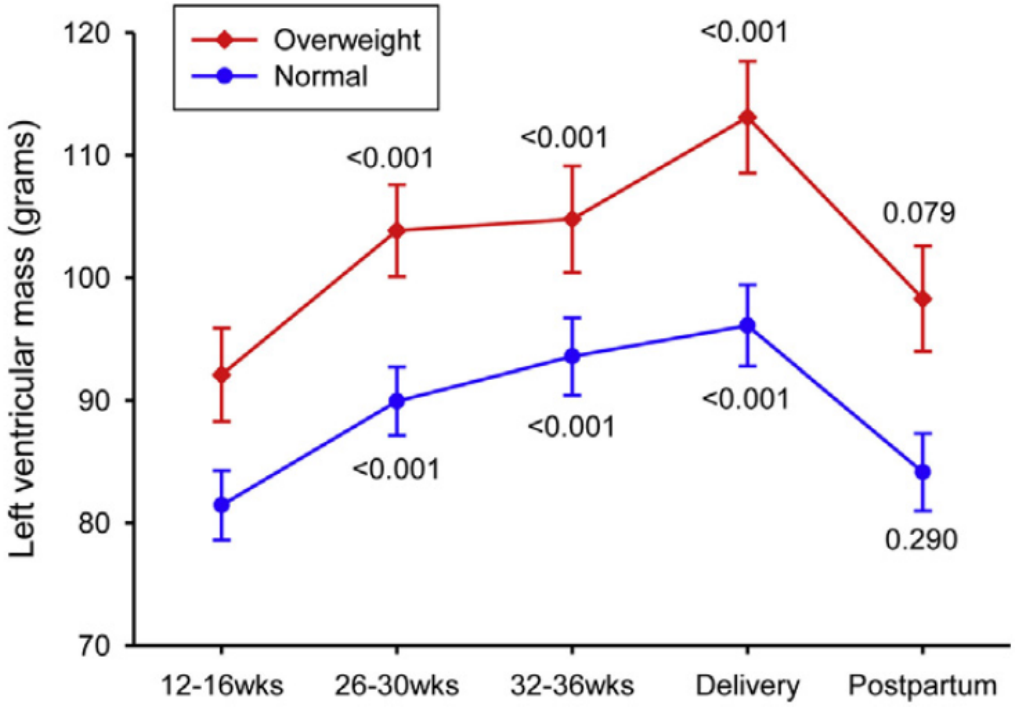
This was a prospective, longitudinal observational pilot study of nulliparous pregnant women from October 2012 through December 2014. Approval was obtained from the institutional review board of the University of Texas Southwestern Medical Center. The study included nulliparous women aged 18-30 years of age with singleton gestations, who had no current or chronic medical disorders—specifically, they had no hypertension, diabetes, or underlying cardiovascular disease. All women were nonsmokers, none used illicit drugs, and all abstained from alcohol during

Cite this article as: Stewart RD, Nelson DB, Matulevicius SA, et al. Cardiac magnetic resonance imaging to assess the impact of maternal habitus on cardiac remodeling during pregnancy. Am J Obstet Gynecol 2016;volume:xxx-x.ex.

0002-9378/$36.00

http://dx.doi.org/10.1016/j.ajog.2015.11.014

FIGURE 1
Left ventricular mass of normal and overweight women



Stewart RD et al. AJOG. 2016

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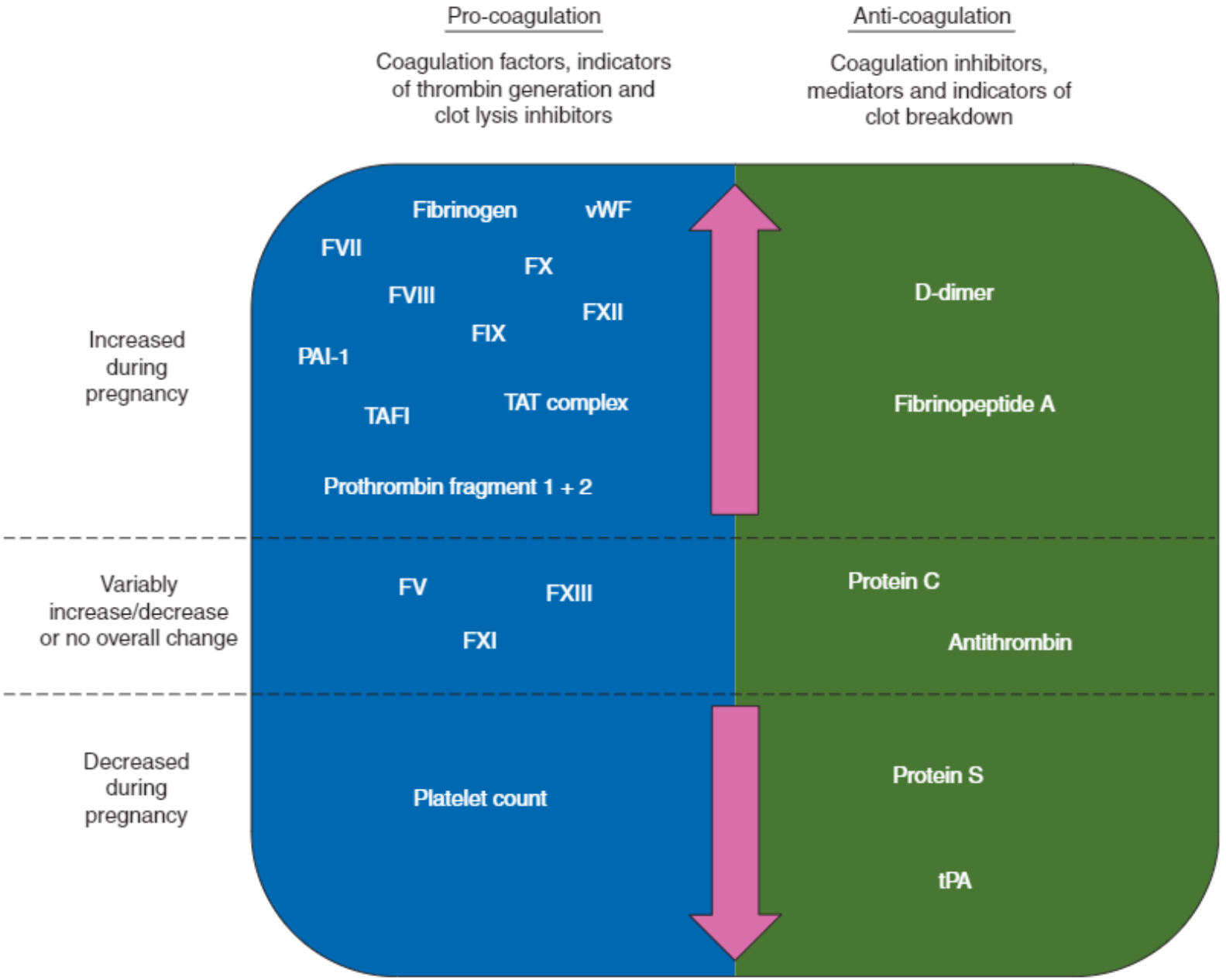

Solomon et al. Br J Anes. 2008

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Table 1. Normal Nonpregnant and Third-Trimester Reference Ranges for Procoagulants

	Nonpregnant Adult	Third Trimester
Antithrombin III, functional (%)	70–130	82–116
D-dimer (micrograms/mL)	0.22–0.74	0.13–1.7
Factor V (%)	50–150	60–88
Factor VII (%)	50–150	149–211
Factor VIII (%)	50–150	143–353
Factor IX (%)	50–150	164–235
Factor XI (%)	50–150	65–123
Factor XII (%)	50–150	129–194
Fibrinogen (mg/dL)	233–496	373–619
Homocysteine (micromoles/L)	4.4–10.8	3.2–21.4
International normalized ratio	0.9–1.04	0.80–0.94
Partial thromboplastin time, activated (sec)	26.3–39.4	24.7–35.0
Prothrombin time (sec)	12.7–15.4	9.6–12.9
Protein C, functional (%)	70–130	67–135
Protein S, total (%)	70–140	33–101
Protein S, free (%)	70–140	20–65
Protein S, functional activity (%)	65–140	16–42
Tissue plasminogen activator (ng/mL)	1.6–13	3.3–9.2
Tissue plasminogen activator inhibitor-1 (ng/mL)	4–43	67–92
von Willebrand factor (%)	75–125	121–260

Data compiled from References 14–16.

Nelson DB et al. Obstet Gynecol 2022

Table 1. Coagulation Parameters in the Nonpregnant and Pregnant States Stratified by First, Second, and Third Trimesters[10]

Coagulation Parameters	Nonpregnant Adult	1st Trimester	2nd Trimester	3rd Trimester
D-dimer (micrograms/mL)	0.22–0.74	0.05–0.95	0.32–1.29	0.13–1.7
Factor (%)				
V	50–150	75–95	72–96	60–88
VII	50–150	100–146	95–153	149–211
VIII	50–150	90–210	97–312	143–353
IX	50–150	103–172	154–217	164–235
XI	50–150	80–127	82–144	65–123
XII	50–150	78–124	90–151	129–194
Fibrinogen (mg/dL)	233–496	244–510	291–538	373–619
INR	0.9–1.04	0.89–1.05	0.85–0.97	0.88–0.94
PTT, activated (sec)	26.3–39.4	24.3–38.9	24.2–38.1	24.7–35.0
Protein C, functional (%)	70–130	78–121	83–133	67–135
Protein S, functional activity (%)	65–140	57–95	42–68	16–42
tPA (ng/mL)	1.6–13	1.8–6.0	2.4–6.6	3.3–9.2
tPA inhibitor-1 (ng/mL)	4–43	16–33	36–55	67–92

INR, international normalized ratio; PTT, partial thromboplastin time; tPA, tissue plasminogen activator.

Beware! Often electronic medical records do **NOT** register pregnant patients for referent ranges of laboratory values

Cunningham FG, Nelson DB. Obstet Gynecol. 2015

Case of obstetric hemorrhage

25-year-old G3P2 at term presents to triage…

Progress Notes Info

Author	Note Status	Last Update User	Last Update Date/Time
[redacted]			6:06 AM

Progress Notes

Expand All Collapse All

OB Triage Assessment Note

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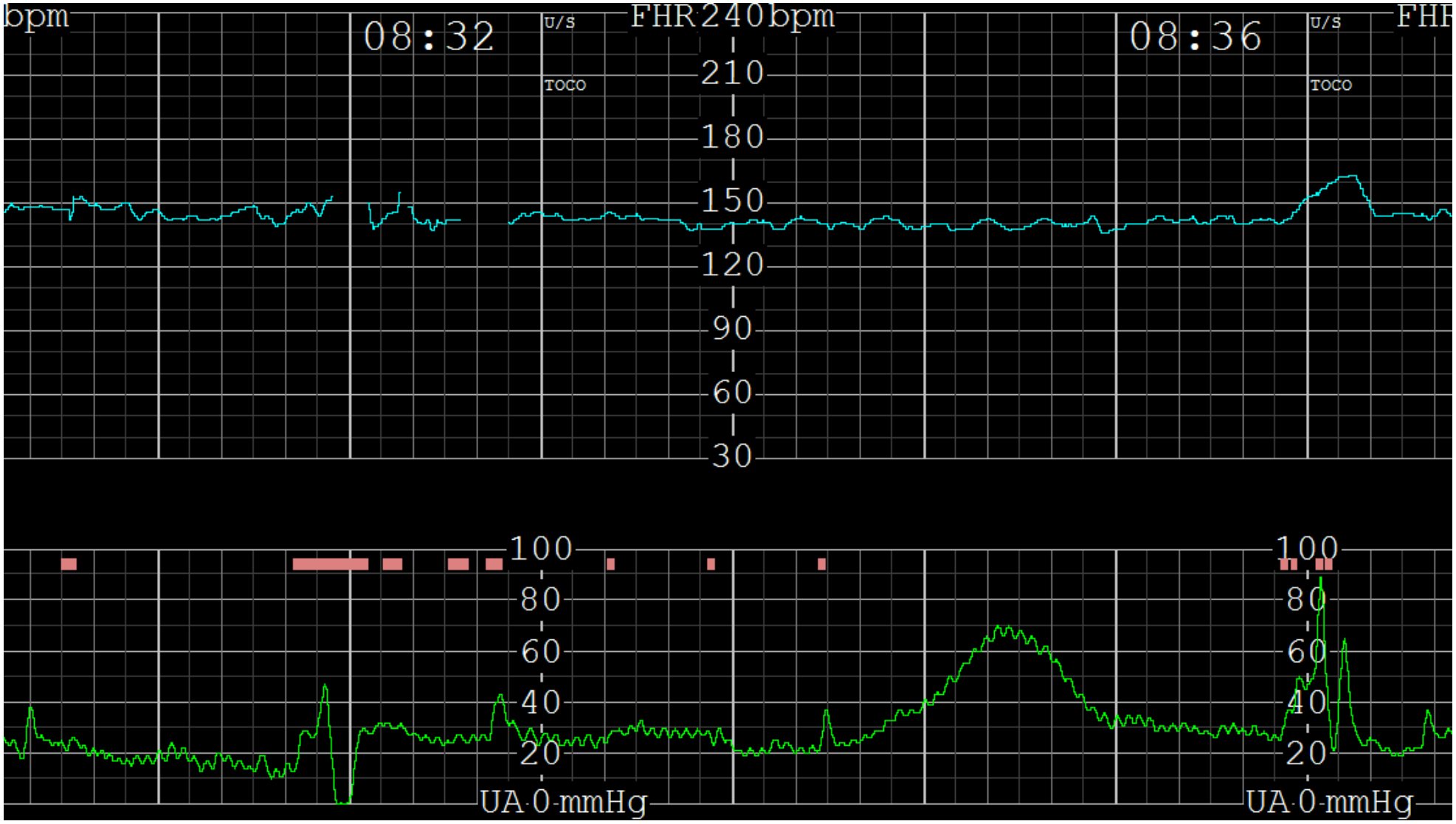
Subjective:

[redacted] is a 25 year old woman with complaints o vaginal bleeding since 3 am. Reports feeling like she urinated on herself and noted a small amount of blood in her underwear. She placed on a pad and went back to bed. Reports feeling her she urinated again about 15 minutes later and reports her pad full of blood. Patient reports sexual intercourse over 2 weeks ago. Vaginal exam yesterday afternoon here in triage. Reports good fetal movement. Denies contractions, leaking of fluid, headache, right upper quadrant pain, visual changes, fevers, chills, nausea and vomiting. Patient denies history of domestic violence or concerns with verbal, physical or emotional abuse.

Objective:

BP: 121/51 (07/10/17 0456), Pulse: 74 (07/10/17 0456), Temp: 36.7 °C (98.1 °F) (07/10/17 0456), Respiratory Rate: 20 (07/10/17 0456)
Patient's last menstrual period was 10/25/2016 (exact date).



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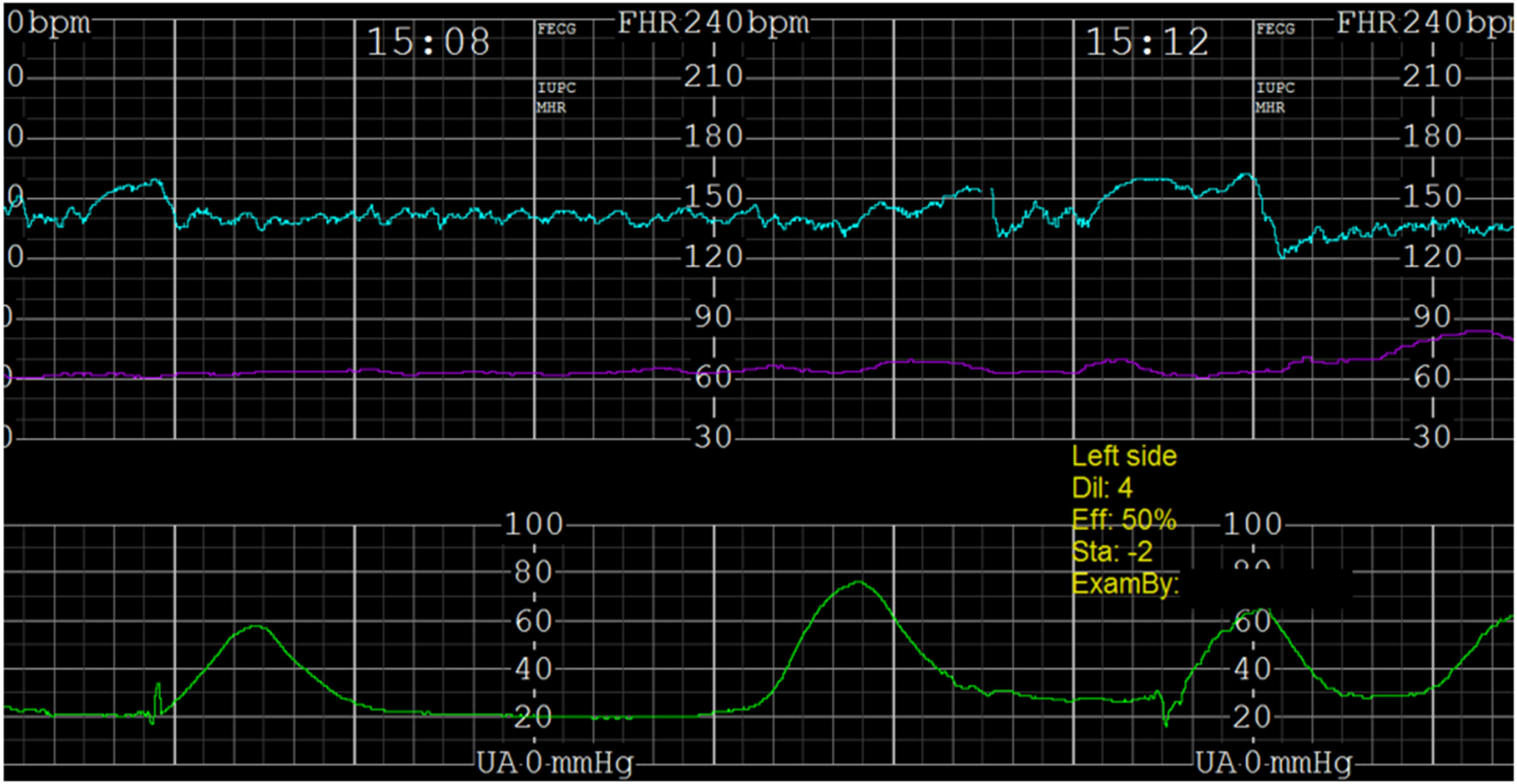
	7/10/2017 0639	7/10/2017 1251	7/10/2017 1500
OTHER CHEM			
Lactate			
POC Lactate			
COAG OTHER			
D-Dimer, Quantitative	2.305 * ▲	4.583 * ▲	4.657 * ▲
FIBRINOGEN	373 *	341 *	369 *
THROMBOELASTOMETRY			
EXTEM			
Extem CT			
Extem CFT			
Extem Angle			
Extem A20			
Extem MCF			
FIBTEM			
Fibtem A20			
Fibtem MCF			
APTEM			
Aptem CT			
Aptem CFT			
Aptem Angle			
Aptem A20			
Aptem MCF			
PROTIME W/ INR			
Protime	11.0	11.3	11.1
INR	1.0 *	1.0 *	1.0 *
PTT			
PTT	27.5 *	26.8 *	27.8 *
DIABETES			
Glucose POC			
POC Gluc			
CBC			
WBC	7.15	6.06	6.67
RBC	4.48	3.60 ▼	3.86 ▼
Hemoglobin	12.6	10.2 ▼	10.8 ▼
POC Hgb Measured			
Hematocrit	39.4	31.8 ▼	34.0 ▼
MCV	87.9	88.3	88.1
MCH	28.1	28.3	28.0



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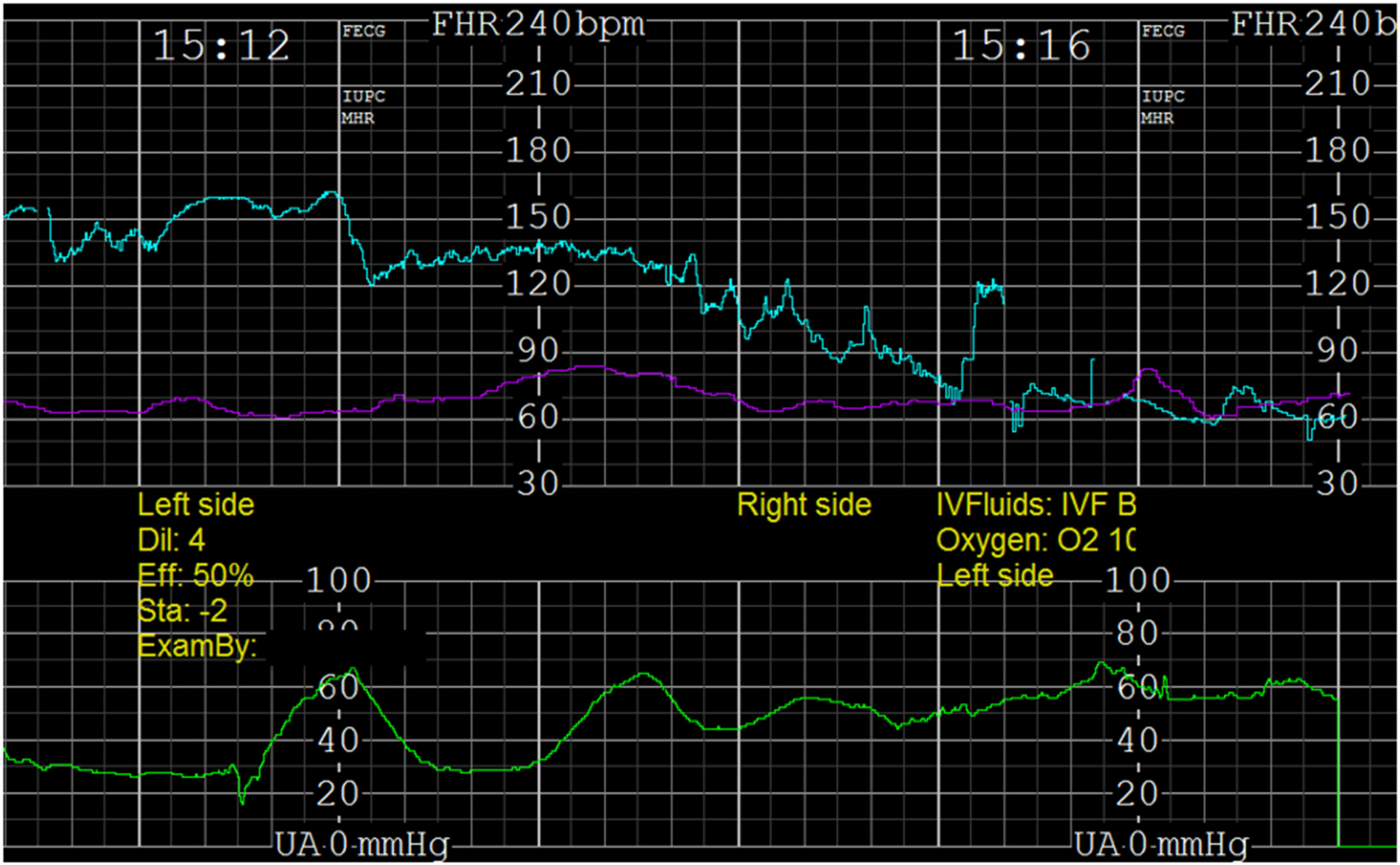

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OR PostOp Info

Author	Note Status	Last Update User	Last Update Date/Time
[redacted]			

OR PostOp

Staff C/S Operative Note

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Stat primary low transverse cesarean section under my supervision.

I was present from the start of surgery and I participated during the critical and key portions of this procedure which were the uterine incision, delivery of the infant and closure of the hysterotomy and any extensions and was immediately available during the remainder of the procedure. There appeared to be abe a < 10% abruption with clot most noticeable around the periphery of one side of the placenta.

	34 7/10/2017 1528
O2 CONTENT ART	
O2 SAT ART	
FO2 HB, ART	
HEMOGLOBIN, BG	
CORD BLOOD BG	
PH COA	7.05
PCO2 COA	98
PO2 COA	<29
HCO3 COA	26
O2 SAT COA	7
BASE EXC COA	-11.1
FIO2	

	34 7/10/2017 1528
O2 CONTENT ART	
O2 SAT ART	
FO2 HB, ART	
HEMOGLOBIN, BG	
CORD BLOOD BG	
PH COA	**7.05**
PCO2 COA	**98**
PO2 COA	**<29**
HCO3 COA	**26**
O2 SAT COA	**7**
BASE EXC COA	**-11.1**
FIO2	

B. Fetal Umbilical Artery Acidemia

1. Fetal umbilical artery pH less than 7.0, or base deficit greater than or equal to 12 mmol/L, or both, increases the probability that neonatal encephalopathy, if present, had an intrapartum hypoxic component; lesser degrees of acidemia decrease that likelihood.

ACOG and AAP Task Force. Neonatal Encephalopathy and Neurologic Outcome. Reaffirmed 2019.

Description of Operation:

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The patient was taken to the operating room where adequate anesthesia as described above was obtained. A vertical skin incision was made and carried down to the fascia. The fascia was incised and the rectus muscles separated in the midline. The peritoneum was entered and incised superiorly and inferiorly taking care to avoid the bowel and bladder. A bladder blade was inserted and a bladder flap was created. A uterine incision was made as described above and the infant was delivered in the cephalic position. Mouth and nares were bulb suctioned, the cord was clamped and cut, and the infant was handed to the pediatrician. The placenta was delivered and the uterine cavity examined. A 5cm inferior extension was noted and closed with #1 chromic. The uterine incision was closed in a running-lock fashion with #1-chromic. The peritoneum was then reapproximated with 2-0 chromic. The fascia was closed with 0-PDS suture and the subcutaneous tissue was reapproximated with 3-0 plain gut suture. The skin was closed with 4-0 vicryl suture and a sterile dressing was applied.

Timeline

- Admit 0800: 3 cm, vaginal bleeding report
- 1518: Fetal bradycardia, STAT Cesarean called
- 1528: Delivery
- 1533: Hemacue 10.4 g/dL, Uterine ATONY, 5 cm extension, abruption

Does simulation improve clinical performance in management of postpartum hemorrhage?

Shena J. Dillon, MD; Whitney Kleinmann, MD; Yevgenia Fomina, MD; Bethany Werner, MD; Steven Schultz, PharmD, MBA; Shannon Klucsarits, MD; Wilmer Moreno, MD; Alexandra Butsko, BSN, RN, RNC-OB; Donald D. McIntire, PhD; David B. Nelson, MD

BACKGROUND: Although simulation is now widely used to improve teamwork and communication, data demonstrating improvement in clinical outcomes are limited.

OBJECTIVE: This study aimed to examine the clinical performance and outcomes associated with postpartum hemorrhage because of uterine atony following the implementation of a multidisciplinary simulation program.

STUDY DESIGN: This was a prospective observational study of response to postpartum hemorrhage because of uterine atony in an academic medical center before (epoch 1: July 2017—June 2018) and after (epoch 2: July 2019—June 2020) implementing a multidisciplinary simulation program. A total of 22 postpartum hemorrhage simulations were performed from July 2018 to June 2019 involving more than 300 nursing, obstetrical, and anesthesia providers. The simulation program focused on managing postpartum hemorrhage events and improving teamwork and communication of the multidisciplinary teams. To evaluate the clinical effectiveness of the simulation program, the primary outcome was response to postpartum hemorrhage defined as the time from the administration of uterotonic medications to transfusion of the first unit of blood in the first 12 hours following delivery, comparing epoch 2 to epoch 1 following the implementation of a simulation program. Statistical analysis included the use of the Pearson chi-square test, Wilcoxon rank-sum test, Hodges-Lehmann statistic for differences, and bootstrap methods with a P value of $<.05$ considered significant.

RESULTS: Between July 1, 2017, and June 30, 2018, there were 12,305 patients who delivered, of which 495 patients (4%) required transfusion. Between July 1, 2019, and June 30, 2020, there were 12,414 patients who delivered, of which 480 patients (4%) required transfusion. When isolating cases of postpartum hemorrhage because of uterine atony in both transfused groups, there were 157 women in the presimulation group (epoch 1) and 165 women in the postsimulation group (epoch 2), respectively. There was no difference in age, race, parity, or perinatal outcomes between the 2 epochs. Women in epoch 2 began receiving blood products significantly earlier in the first 12 hours following delivery compared with women in epoch 1 (51 [range, 28—125] minutes vs 102 [range, 32—320] minutes; $P=.005$). In addition, there was a significantly decreased variation in the time from the administration of uterotonic medications to transfusion of blood in epoch 2 ($P=.035$). Furthermore, women in epoch 2 had significantly lower estimated blood loss than women in epoch 1 (1250 [range, 1000—1750] mL vs 1500 [range, 1000—2000] mL; $P=.032$).

CONCLUSION: The implementation of a multidisciplinary simulation program at a large academic center focusing on the management of postpartum hemorrhage was associated with an improved clinical response. Specifically, there were significantly faster times from the administration of uterotonic medications to transfusion of blood, decreased variance in the time from the administration of uterotonic medications to transfusion of blood, and lower estimated blood loss following the implementation of a simulation program. Because delay in treatment is a major cause of preventable maternal death in obstetrical hemorrhage, the results in our study provided clinical evidence that a simulation program may improve patient outcomes in such emergencies.

Key words: blood loss, clinical outcomes, estimated blood loss, multidisciplinary, postpartum hemorrhage, pregnancy, simulation, transfusion, uterotonic

Introduction

Hemorrhage continues to be one of the leading causes of severe maternal morbidity and mortality for women in the United States and worldwide.[1,2] Following national attention on maternal mortality, the Alliance for Innovation on Maternal Health (AIM) developed several safety bundles that hospitals could implement to address maternal mortality and morbidity, which included a hemorrhage bundle.[3] The development of safety bundles, along with the Preventing Maternal Deaths Act of 2018, prompted several states to form Maternal Mortality and Morbidity Review committees to assess which bundles were likely to make the most impact on their state's maternal morbidity and mortality rates.[4,5] When California reviewed their maternal mortality cases, they found that 95% of deaths due to hemorrhage had some chance of being prevented and 70% of deaths due to hemorrhage had a good to strong chance of being prevented.[6] When analyzing potential pitfalls, they found delay in diagnosis and delay in treatment as 2 of the most common problems that led to mismanagement of hemorrhage. Similarly, the state of Texas formed a Maternal Mortality and Morbidity Task Force and found that hemorrhage was 1 of the top 3 preventable causes of death in women in Texas from 2012 to 2015.[7] More than 50% of deaths due to hemorrhage among these women were classified as being somewhat likely or very likely to have been prevented, and they found similar causes of

Cite this article as: Dillon SJ, Kleinmann W, Fomina Y, et al. Does simulation improve clinical performance in management of postpartum hemorrhage? Am J Obstet Gynecol 2021;225:435.e1-8.

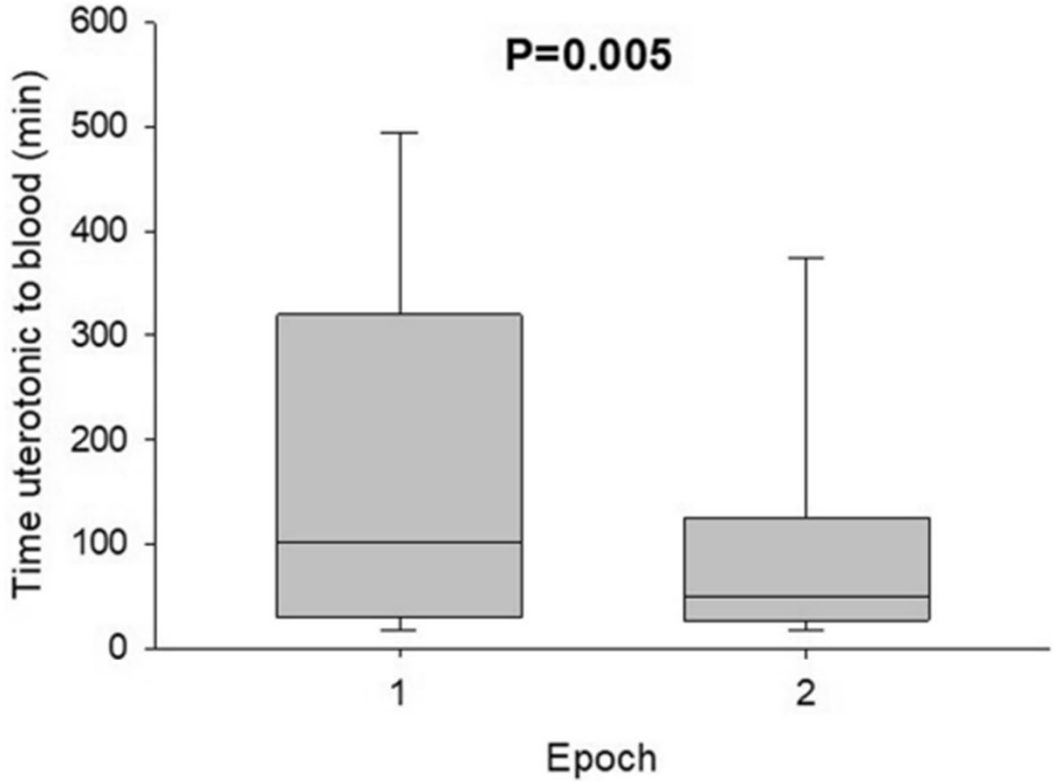
0002-9378/$36.00

https://doi.org/10.1016/j.ajog.2021.05.025

Click Video under article title in Contents at ajog.org

Multidisciplinary simulation program **improved** clinical response times to postpartum hemorrhage.

FIGURE 2
Time from administration of uterotonic to transfusion by epoch



Dillon et al. Postpartum hemorrhage simulation. Am J Obstet Gynecol 2021.

Dillon SJ et al, AJOG 2021

UT Southwestern Medical Center

Timeline

- Admit 0800: 3 cm, vaginal bleeding report
- 1518: Fetal bradycardia, STAT Cesarean called
- 1528: Delivery
- 1533: Hemacue 10.4 g/dL
- 1612: Hemacue 8.5 g/dL

Obstetric Hemorrhage Checklist

EXAMPLE

Complete all steps in prior stages plus current stage regardless of stage in which the patient presents.

Postpartum hemorrhage is defined as cumulative blood loss of greater than or equal to 1,000mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours. However, blood loss >500mL in a vaginal delivery is abnormal, and should be investigated and managed as outlined in Stage 1.

RECOGNITION:

- ☐ Call for assistance (Obstetric Hemorrhage Team)

Designate: ☐ Team leader _____ ☐ Checklist reader/recorder ☐ Primary RN

Announce: ☐ Cumulative blood loss ☐ Vital signs _____ ☐ Determine stage

STAGE 1: Blood loss >1000mL after delivery with normal vital signs and lab values. Vaginal delivery 500-999mL should be treated as in Stage 1.

INITIAL STEPS:

- ☐ Ensure 16G or 18G IV Access
- ☐ Increase IV fluid (crystalloid without oxytocin)
- ☐ Insert indwelling urinary catheter
- ☐ Fundal massage

MEDICATIONS:

- ☐ Ensure appropriate medications given patient history
- ☐ Increase oxytocin, additional uterotonics

BLOOD BANK:

- ☐ Confirm active type and screen and consider crossmatch of 2 units PRBCs

ACTION:

- ☐ Determine etiology and treat
- ☐ Prepare OR, if clinically indicated (optimize visualization/examination)

Oxytocin (Pitocin):
10-40 units per 500-1000mL solution

Methylergonovine (Methergine):
0.2 milligrams IM (may repeat);
Avoid with hypertension

15-methyl $PGF_2\alpha$ (Hemabate, Carboprost):
250 micrograms IM (may repeat in q15 minutes, maximum 8 doses); **Avoid with asthma; use with caution with hypertension**

Misoprostol (Cytotec):
800-1000 micrograms PR
600 micrograms PO or 800 micrograms SL

Tone (i.e., atony)
Trauma (i.e., laceration)
Tissue (i.e., retained products)
Thrombin (i.e., coagulation dysfunction)

STAGE 2: Continued Bleeding (EBL up to 1500mL OR ≥ 2 uterotonics) with normal vital signs and lab values *(*two or more uterotonics in addition to routine oxytocin administration; or ≥ 2 administrations of the same uterotonic)*

INITIAL STEPS:

- ☐ Mobilize additional help
- ☐ Place 2nd IV (16-18G)
- ☐ Draw STAT labs (CBC, Coags, Fibrinogen)
- ☐ Prepare OR

MEDICATIONS:

- ☐ Continue Stage 1 medications; consider TXA

BLOOD BANK:

- ☐ Obtain 2 units PRBCs (DO NOT wait for labs. Transfuse per clinical signs/symptoms)
- ☐ Thaw 2 units FFP

ACTION:

- ☐ For uterine atony --> consider uterine balloon or packing, possible surgical interventions
- ☐ Consider moving patient to OR
- ☐ Escalate therapy with goal of hemostasis

Tranexamic Acid (TXA)
1 gram IV over 10 min (add 1 gram vial to 100mL NS & give over 10 min; may be repeated once after 30 min)

Possible interventions:
- Bakri balloon
- Compression suture/B-Lynch suture
- Uterine artery ligation
- Hysterectomy

Huddle and move to Stage 3 if continued blood loss and/or abnormal VS

Safe Motherhood Initiative

ACOG

Revised September 2020

STAGE 3: Continued Bleeding (EBL > 1500mL OR > 2 RBCs given OR at risk for occult bleeding/ coagulopathy OR any patient with abnormal vital signs/labs/oliguria)

INITIAL STEPS:

- ☐ Mobilize additional help
- ☐ Move to OR
- ☐ Announce clinical status (vital signs, cumulative blood loss, etiology)
- ☐ Outline and communicate plan

MEDICATIONS:

- ☐ Continue Stage 1 medications; consider TXA

BLOOD BANK:

- ☐ Initiate Massive Transfusion Protocol (If clinical coagulopathy: add cryoprecipitate, consult for additional agents)

ACTION:

- ☐ Achieve hemostasis, intervention based on etiology
- ☐ Escalate interventions

Oxytocin (Pitocin):
10-40 units per 500-1000mL solution

Methylergonovine (Methergine):
0.2 milligrams IM (may repeat);
Avoid with hypertension

15-methyl $PGF_2\alpha$ (Hemabate, Carboprost):
250 micrograms IM
(may repeat in q15 minutes, maximum 8 doses)
Avoid with asthma;
use with caution with hypertension

Misoprostol (Cytotec):
800-1000 micrograms PR
600 micrograms PO or 800 micrograms SL

Tranexamic Acid (TXA)
1 gram IV over 10 min (add 1 gram vial to 100mL NS & give over 10 min; may be repeated once after 30 min)

Possible interventions:
- Bakri balloon
- Compression suture/B-Lynch suture
- Uterine artery ligation
- Hysterectomy

STAGE 4: Cardiovascular Collapse (massive hemorrhage, profound hypovolemic shock, or amniotic fluid embolism)

INITIAL STEP:

- ☐ Mobilize additional resources

MEDICATIONS:

- ☐ ACLS

BLOOD BANK:

- ☐ Simultaneous aggressive massive transfusion

ACTION:

- ☐ Immediate surgical intervention to ensure hemostasis (hysterectomy)

Post-Hemorrhage Management
- Determine disposition of patient
- Debrief with the whole obstetric care team
- Debrief with patient and family
- Document

Revised September 2020

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ACOG

Andrikopoulou M, D'Alton ME. Seminars in Perinatology, 2019

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STAGE 1: Activate Hemorrhage Protocol		
Clinical Trigger: CBL ≥ 500 mL vaginal / ≥ 1000 mL cesarean with *continued bleeding* or Signs of concealed hemorrhage: VS abnormal or trending (HR ≥ 110, BP ≤ 85/45, O2 sat < 95%, shock index 0.9) or Confusion		
MOBILIZE	**ACT**	**THINK**
Primary nurse, Physician or Midwife: ☐ Activate OB Hemorrhage Protocol and Checklist **Primary nurse:** ☐ Notify obstetrician or midwife (in-house and attending) ☐ Notify charge nurse ☐ Notify anesthesiologist **Secondary nurse:** ☐ Assist primary nurse as needed or assign staff member(s) to help	**Primary nurse or designee:** ☐ Establish IV access if not present, at least 18 gauge ☐ Increase IV oxytocin rate per hospital treatment guidelines ☐ Increase fluids ☐ Apply vigorous fundal/bi-manual massage **MOVE ON** to 2nd level uterotonic if no response (see Stage 2 meds below) ☐ Vital Signs, including O2 sat & level of consciousness (LOC) q5 minutes ☐ Record quantitative cumulative blood loss q5-15 minutes ☐ Administer oxygen to maintain O2 sat at > 95% ☐ Empty bladder: straight catheter or place Foley with urometer ☐ Convert to **high risk**: Type and Crossmatch for 2 units PRBCs STAT (where clinically appropriate if not already done) ☐ Keep patient warm **Physician or midwife:** ☐ Bimanual massage ☐ Careful inspection with good exposure: Rule out retained products of conception, laceration, hematoma **Surgeon (if intra-op)** ☐ Inspect for uncontrolled bleeding at all levels, esp. broad ligament, posterior uterus, and retained placenta	Consider potential etiology: • Uterine atony • Trauma/laceration • Retained placenta • Amniotic fluid embolism • Uterine inversion • Coagulopathy • Placenta accreta Convert to high risk and take appropriate precautions. Consider type and cross 2 units PRBCs where clinically appropriate if not already done. **Once stabilized:** Postpartum management with increased surveillance and response readiness assessment.
Triggers to Proceed to STAGE 2: ***Continued bleeding* w/ CBL < 1500 mL or VS remain abnormal**		

CMQCC OB Hemorrhage Toolkit V3.0 - Appendix B: Obstetric Hemorrhage Care Guidelines: Checklist Format, published 2022

Parkland

Post Partum Hemorrhage (PPH)Checklist

Initial Actions

- ❑ Call for assistance
- ❑ Response team to the bedside
  - Delivering attending MD/CNM
  - Primary RN
  - Anesthesiologist
- ❑ Brief: appoint leader, recorder, nursing roles
- ❑ Identify hemorrhage stage and document EBL & interventions

STAGE 1 PPH

Normal vital signs and lab values:

Blood loss > 500 mL vaginal - OR - blood loss > 1000 mL cesarean

- ❑ Record VS/O_2 saturation every 5 minutes
- ❑ Monitor cumulative blood loss
- ❑ Insert foley catheter
- ❑ Ensure IV access: 16 gauge if possible
- ❑ Increase IV uid (crystalloid: estimated blood loss in 2:1 ratio without oxytocin)
- ❑ Fundal massage
- ❑ Determine and treat etiology (4 T's - Tone, Trauma, Tissue, Thrombin)
- ❑ **Contact blood bank: type and crossmatch 2 units PRBCs**

Medications for Uterine Atony

Oxytocin **(Pitocin)**	10-40 international units/liter intravenously, or 10 units IM if no IV access
Methylergonovine **(Methergine)**	0.2 milligrams intramuscularly (may be repeated every 2-4 hours)
15-methyl $PGF_{2\alpha}$ **(Hemabate, Carboprost)**	250 micrograms intramuscularly (may repeat every 15 minutes, maximum 8 doses)
Misoprostol **(Cytotec)**	800-1000 micrograms rectally

STAGE 2 PPH

Normal vital signs and lab values:

Continued bleeding EBL up to 1500 mL OR any patient requiring ≥ 2 uterotonics

- ❑ Obtain 2nd IV access (16 gauge if possible)
- ❑ STAT labs, with coags & brinogen
- ❑ Medications: continue medications from Stage 1
- ❑ Transfuse per clinical signs/symptoms
  - Notify blood bank of OB hemorrhage, bring 2 units PRBCs to bedside, thaw 2 units FFP. **DO NOT wait for labs!**
- ❑ For uterine atony → Consider uterine balloon or packing, possible surgical interventions
- ❑ Consider moving patient to OR (better exposure, potential D&C)
- ❑ Mobilize additional team members as necessary
- ❑ Warming blanket

STAGE 3 PPH

Abnormal vital signs/labs/oliguria:

Continued bleeding EBL > 1500 mL OR > 2 units PRBCs given OR patient at risk for occult bleeding (post-cesarean) & DIC

- ❑ Outline management plan → Serial re-evaluation → Communicate plans with hemorrhage team
- ❑ Transfusion → RBC-FFP-Platelets in a 6:4:1 ratio (active Massive Transfusion Protocol - MTP) → If coagulopathic, add cryoprecipitate. Consider consultation for alternative agents
- ❑ Identify etiology for bleeding (if still unclear)
- ❑ Rule out lacerations (exam), coagulopathy (labs), occult bleeding (imaging)
- ❑ Achieve hemostasis immediately, interventions based on etiology
- ❑ Adopt additional measure (if poor response)

STAGE 4 PPH

Cardiovascular Collapse:

For patients with cardiovascular collapse in setting of massive hemorrhage consider the following etiologies:

- ❑ Profound hypovolemic shock (blood loss not replaced)
- ❑ AFE (sudden CV collapse followed by heavy uterine bleeding from uterine relaxation and associated coagulopathy)

- Immediate surgical interventions to ensure hemostasis (hysterectomy) may be necessary.
- Simultaneous aggressive blood and factor replacement & medical interventions initiated regardless of the patient's coagulation status.
- Expeditious hemostasis is the only step that will maximize survival rates for these critical patients.

Post-Hemorrhage Management

- ❑ Debrief with entire care team
- ❑ Document after team debrief
- ❑ Discuss interventions with patient/family members

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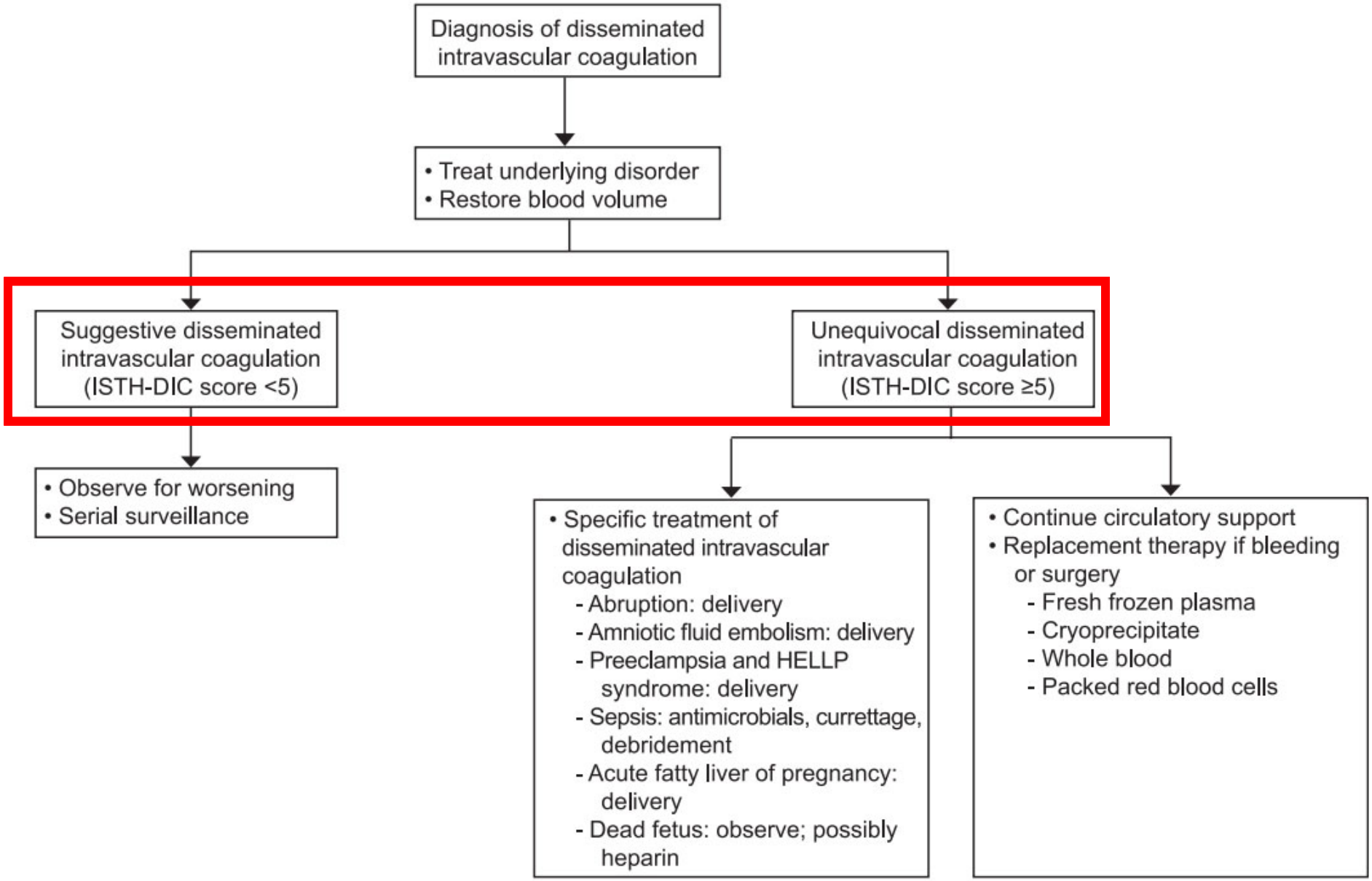
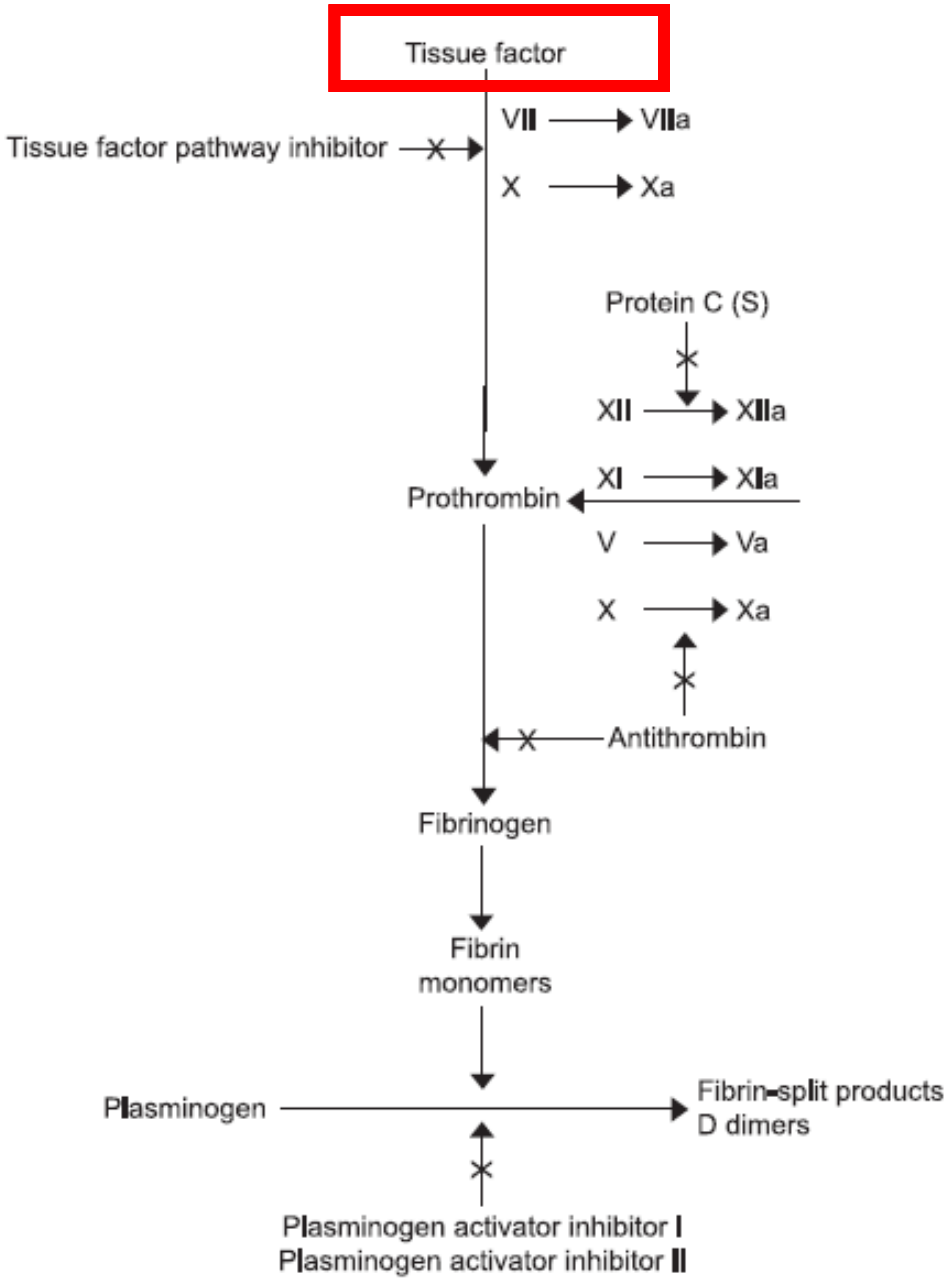


Cunningham FG, Nelson DB. Obstet Gynecol. 2015



Cunningham FG, Nelson DB. Obstet Gynecol. 2015

Timeline

- Admit 0800: 3 cm, vaginal bleeding report
- 1518: Fetal bradycardia, STAT Cesarean called
- 1528: Delivery
- 1533: Hemacue 10.4 g/dL
- 1612: Hemacue 8.5 g/dL
- 1612: Transfusion initiated, 2 units Packed Red Blood Cells

Timeline

- Admit 0800: 3 cm, vaginal bleeding report
- 1518: Fetal bradycardia, STAT Cesarean called
- 1528: Delivery
- 1533: Hemacue 10.4 g/dL
- 1612: Hemacue 8.5 g/dL
- 1612: Transfusion initiated, 2 units Packed Red Blood Cells
- 1643: Cesarean delivery finished

Progress Notes

Maternal-Fetal Medicine Faculty
Labor and Delivery High-risk Unit

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I was called to OR suite at approximately 1645 following emergent cesarean delivery by L+D East team for fetal bradycardia and concern for placental abruption. Indices of lab studies noted by Dr [redacted] with elevated PTT of 46 at 1528. Delivery events reviewed with the team. Delivery at approximately 1530, closure of abdomen, and prior to transfer our of operative suite, bleeding noted per vagina. I arrived at approximately 1645 to OR suite. At that time, lower uterine segment atony. She had received 2 doses of Carboprost and been given 2 units of packed red blood cells. Fundus with lower uterine segment atony with continued active bleeding. HR 90s-100s, BP 100s/70s, scant concentrated urine in Foley catheter tubing.
MFM L+D West team assuming care of this case.
Hold transfer out of OR. Resuscitation to be conducted in OR suite as resources are most available. OB

Timeline

- Admit 0800: 3 cm, vaginal bleeding report
- 1518: Fetal bradycardia, STAT Cesarean called
- 1528: Delivery
- 1533: Hemacue 10.4 g/dL
- 1612: Hemacue 8.5 g/dL
- 1612: Transfusion initiated, 2 units Packed Red Blood Cells
- 1643: Cesarean delivery finished
- 1645: MFM team in room

How personality affects teamwork: a study in multidisciplinary obstetrical simulation

Shena J. Dillon, MD; Whitney Kleinmann, MD; Angela Seasely, MD; Rebecca Ames, CNM; Phyllis Dyess-Nugent, PhD, RN, WHNP-BC; Donald D. McIntire, PhD; Ellen Suen, DPA; David B. Nelson, MD

BACKGROUND: Multidisciplinary simulation has been shown to improve teamwork in the obstetrical literature by providing a safe, but realistic, environment for participants to learn. However, the impact of team members' personality traits on how the team performs during an obstetrical emergency has not been studied in medicine.

OBJECTIVE: Our objective was to evaluate teamwork and communication of simulation participants in association with personality traits within a multidisciplinary obstetrical simulation program.

STUDY DESIGN: This was a prospective observational study of postpartum hemorrhage simulations involving participants from Obstetrics, Nursing, Midwifery, and Anesthesia. Before simulation, individual personality testing was performed on participants using the Big Five Inventory. Each team was scored using the Clinical Teamwork Scale after simulation. Communication and teamwork scores were evaluated for association, and personality traits were analyzed for association with teamwork and communication. For each personality trait, an interaction model was tested for 3 of the team scores: teamwork, communication, and situational awareness. Analysis of variance with 2 level interactions was used in this effort.

RESULTS: From July 2018 to June 2019, 22 obstetrical simulations were performed with a total of 270 staff. Overall, teamwork was significantly associated with communication for each team. When examining individual personality scores, neuroticism was negatively associated with teamwork when coupled with communication. That is, increased neuroticism was significantly associated with increased communication that was detrimental to the overall teamwork. Other personality traits were not significantly associated with teamwork and communication (P=.03).

CONCLUSION: In a multidisciplinary simulation, communication was positively associated with teamwork, and specific personality traits negatively affected team performance.

Key words: communication, personality testing, simulation, teamwork

Introduction

In 2012, a joint statement was released from several professional organizations in women's healthcare defining quality care on labor and delivery (L&D).[1] This statement was endorsed by both the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine in addition to many other organizations that advocate for women's health. Chief among these recommendations was to improve maternal and fetal outcomes in L&D by fostering teamwork and communication. This was in response to the 2000 report from the Institute of Medicine (now the National Academy of Medicine) named To Err is Human, which listed communication failure as a major cause of medical errors.[2] In particular, a recommendation of the joint statement of 2012 was to incorporate regularly scheduled simulations into hospital systems. The purpose of these simulations was to educate and prepare unit staff for unexpected emergencies. Because these emergent clinical events can be rare, simulation has served as a reliable and repeatable platform for education. The rationale for this recommendation was that communication failures are especially prone to occur during emergencies and contribute to most sentinel events.[3]

Simulation is becoming more prevalent in medical education.[4–7] Initially, this took the form of basic task trainers to teach specific competencies on an individual level.[8] More recently, there has been expansion of simulation to include team dynamics.[9–11] Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS), an evidenced-based set of teamwork tools disseminated by the Department of Defense, provides a framework for effective communication.[12,13] The implementation of TeamSTEPPS communication techniques has been shown to reduce the incidence of obstetrical adverse events and improve neonatal resuscitation.[14,15] TeamSTEPPS implementation has also been used in L&D units to improve multidisciplinary teamwork during high-stress situations.[16]

There have been previous studies in obstetrics that show simulation and team-based training improve multidisciplinary teamwork and communication.[17–22] However, there is a paucity of data on how individual personalities affect teamwork in medical settings. Looking outside of medicine, the data are conflicted. Virgă et al[23] found that conscientiousness was associated with improved teamwork among psychology students but that individual neuroticism scores improved teamwork, which is not what they had expected. In a similar study looking at manufacturing workers, teams with members who scored lower in neuroticism had higher team performance.[24] However, a meta-analysis of Big Five personality data and team performance that included both professional and student teams failed to show a direct, simple relationship between personality trait (neuroticism) and team performance.[25]

Because of the interest in quality care and the incorporation of simulation with teamwork and communication, our hypothesis was that individual personality traits would affect teamwork and

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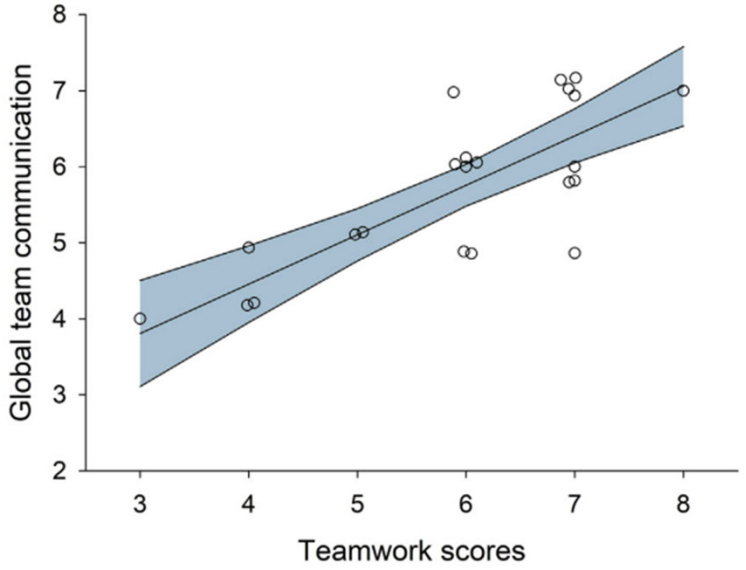
https://doi.org/10.1016/j.ajogmf.2020.100303

Communication was **positively** associated with teamwork when examining team response to postpartum hemorrhage.

FIGURE 3
Relationship between teamwork and overall communication (Pearson correlation, 0.81; P<.001)



Dillon et al. Personality and teamwork. AJOG MFM 2021.

Dillon SJ et al, AJOG MFM. 2021

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MFM L+D West team assuming care of this case.
Hold transfer out of OR. Resuscitation to be conducted in OR suite as resources are most available. OB Anesthesia faculty , [redacted] to OR.
I ordered additional 2 units PRBC, 2 unit FFP, emergent labs: CBC, fibrinogen. Additional dose of Carboprost (total 3) and 1000 mcg rectal misoprostol.
At this time, I am concerned for coagulopathy associated with abruption with marked hypovolemia as evidenced by declining hemoglobin and oliguria. Noted moderate thrombocytopenia, and I expect a declining fibrinogen. ISTH-DIC scoring reviewed with team.
Plan for aggressive volume resuscitation with additional transfusion of blood products. Component therapy necessary.
Resuscitation and recovery of hematologic indices is critical. We are actively providing uterine massage as resuscitation is underway. Re-entry of abdomen in the setting of coagulopathy could be fatal and as such we are attempting to resuscitate aggressively.
[redacted]

	7/10/2017 1647
COAG OTHER	
D-Dimer, Quantitative	
FIBRINOGEN	<60 * !!
Protime	20.2 ▲
INR	1.7 * ▲
PTT	
PTT	74.7 * ▲
DIABETES	
Glucose POC	
POC Gluc	
CBC	
WBC	11.69 ▲
RBC	3.53 ▼
Hemoglobin	10.1 ▼
PLATELETS	43 * ▼
MPV	12.9 ▲
HEMOLYSIS	

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Maternal-Fetal Medicine Faculty
Labor and Delivery High-risk Unit
I was called to OR suite at approximately 1645 following emergent cesarean delivery by L+D East team for fetal bradycardia and concern for placental abruption. Indices of lab studies noted by Dr. [redacted] with elevated PTT of 46 at 1528. Delivery events reviewed with the team. Delivery at approximately 1530, closure of abdomen, and prior to transfer our of operative suite, bleeding noted per vagina. I arrived at approximately 1645 to OR suite. At that time, lower uterine segment atony. She had received 2 doses of Carboprost and been given 2 units of packed red blood cells. Fundus with lower uterine segment atony with continued active bleeding. HR 90s-100s, BP 100s/70s, scant concentrated urine in Foley catheter tubing.
MFM L+D West team assuming care of this case.
Hold transfer out of OR. Resuscitation to be conducted in OR suite as resources are most available. OB Anesthesia faculty , Dr. [redacted] OR.
I ordered additional 2 units PRBC, 2 unit FFP, emergent labs: CBC, fibrinogen. Additional dose of Carboprost (total 3) and 1000 mcg rectal misoprostol.
At this time, I am concerned for coagulopathy associated with abruption with marked hypovolemia as evidenced by declining hemoglobin and oliguria. Noted moderate thrombocytopenia, and I expect a declining fibrinogen. ISTH-DIC scoring reviewed with team.
Plan for aggressive volume resuscitation with additional transfusion of blood products. Component therapy necessary.
Resuscitation and recovery of hematologic indices is critical. We are actively providing uterine massage as resuscitation is underway. Re-entry of abdomen in the setting of coagulopathy could be fatal and as such we are attempting to resuscitate aggressively.
Dr. [redacted] arrived at 1700.
As of 1723. Resuscitation insufficient with piecemeal blood component therapy. Massive transfusion protocol activated at 1723.
See additional documentation to follow.

Timeline

- Admit 0800: 3 cm, vaginal bleeding report
- 1518: Fetal bradycardia, STAT Cesarean called
- 1528: Delivery
- 1533: Hemacue 10.4 g/dL
- 1612: Hemacue 8.5 g/dL
- 1612: Transfusion initiated, 2 units Packed Red Blood Cells
- 1643: Cesarean delivery finished
- 1645: MFM team in room
- 1723: Massive Transfusion Protocol

Parkland Hospital Massive Transfusion Protocol Products

Shipment #	Red Cells 5 units	Plasma 5 units	Platelets 1 dose	Cryoprecipate 1 dose
1	X	X		
2	X	X	X	
3	X	X		X
4	X	X	X	
5	X	X		
6	X	X	X	X
7	X	X		
8	X	X	X	
9	X	X		X
10	X	X	X	

Timeline

- Admit 0800: 3 cm, vaginal bleeding report
- 1518: Fetal bradycardia, STAT Cesarean called
- 1528: Delivery
- 1533: Hemacue 10.4 g/dL
- 1612: Hemacue 8.5 g/dL
- 1612: Transfusion initiated, 2 units Packed Red Blood Cells
- 1643: Cesarean delivery finished
- 1645: MFM team in room
- 1723: Massive Transfusion Protocol
- 1800: Still active bleeding from atony

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OR Surgeon

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Faculty note
Patient with continued uterine atony and active vaginal bleeding despite aggressive resuscitation and medical therapies.
Disseminated intravascular coagulopathy.
Decision to proceed with laparotomy, exploration, and surgical management of postpartum hemorrhage.
I was present with team and scrubbed case for re-entry. Re-entry of abdomen at 1800.
Hemoperitoneum identified. Evacuation of blood and clot. No overt area of active significant bleeding. Denuded area along lower uterine segment at anterior right, however, uterine atony persisted following inspection of pelvis. Decision to proceed with hysterectomy for life-saving measures.
Supracervical hysterectomy performed by Drs. [redacted] under my direct supervision.
Massive transfusion protocol remained active during hysterectomy.
Bilateral ovaries preserved.
Cuff closed.
Vagina inspected following cuff closure with dark blood evacuated but no further blood loss.
Cuff inspected and without active bleeding.
OB Anesthesia discontinued massive transfusion protocol.
Serial labs noted.
I spoke with Dr. [redacted] from SICU who presented to OR for anticipated transfer of care for postoperative recovery.
Brief events reviewed.
EBL from cesarean delivery 1.75L
EBL thereafter estimated to be 3.25L.
Total EBL 5L for case, and I suspect that this is an underestimate.
Abdomen closed after inspection.
Transfer to SICU.
Serial surveillance of coagulation and hematologic indices. Specifically, fibrinogen, platelets, and hematocrit.
Electrolyte derangements associated with large volume resuscitation to be reviewed.
Magnesium prophylaxis given abruption, thrombocytopenia initiated within the OR and to be continued for 24 hours following delivery. Given renal clearance, plan close observation with titration to therapeutic levels. OB team to follow within ICU.
After the procedure, Dr. [redacted], Unit manager [redacted], Parkland Spanish interpreter, and the chaplain debriefed the family of the events, findings, and management.
OB ECU resident, [redacted] L+D resident, [redacted] should emergent needs arise.
See additional documentation to follow.
Greatly appreciate the multidisciplinary care in this case.
OB MFM to follow within SICU.
David Bryan Nelson, MD

Transferred to Surgical Intensive Care…

	7/10/2017 1656	7/10/2017 1705	7/10/2017 1800	7/10/2017 1804	7/10/2017 1825	7/10/2017 1842	7/10/2017 1933
OTHER CHEM							
Lactate							
POC Lactate						5.2 !!	4.3
COAG OTHER							
D-Dimer, Quantitative							
FIBRINOGEN !!			199 *				
THROMBOELASTOMETRY							
EXTEM		!			!		
Extem CT		336 ▲			83 ▲		
Extem CFT		1397 ▲			194 ▲		
Extem Angle		16 ▼			55 ▼		
Extem A20		19 ▼			48 ▼		
Extem MCF		23 ▼			54		
FIBTEM					!		
Fibtem A20		See comment *			6 ▼		
Fibtem MCF		See comment *			6 ▼		
APTEM		!			!		
Aptem CT		383 ▲			83 ▲		
Aptem CFT		1395 ▲			194 ▲		
Aptem Angle		17 ▼			56 ▼		
Aptem A20		19 ▼			49 ▼		
Aptem MCF		27 ▼			55		

This was 2017…where ROTEM was being utilized predominantly in the postoperative setting

	7/10/2017 1656	7/10/2017 1705	7/10/2017 1800	7/10/2017 1804	7/10/2017 1825	7/10/2017 1842	7/10/2017 1933
OTHER CHEM							
Lactate							
POC Lactate						5.2 !!	4.3
COAG OTHER							
D-Dimer, Quantitative							
FIBRINOGEN !!			108 * ▼				
THROMBOELASTOMETRY							
EXTEM		!			!		
Extem CT		336 ▲			83 ▲		
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Extem Angle		16 ▼			55 ▼		
Extem A20		19 ▼			48 ▼		
Extem MCF		23 ▼			54		
FIBTEM					!		
Fibtem A20		See comment *			6 ▼		
Fibtem MCF		See comment *			6 ▼		
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Aptem A20		19 ▼			49 ▼		
Aptem MCF		27 ▼			55		

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Resources to manage coagulopathy

Viscoelastic Tests in the Management of Obstetric Hemorrhage

Clinical Expert Series CME

Point-of-Care Viscoelastic Tests in the Management of Obstetric Hemorrhage

David B. Nelson, MD, Olutoyosi Ogunkua, MD, and F. Gary Cunningham, MD

Obstetric hemorrhage remains the leading cause of maternal morbidity and mortality worldwide. Thromboelastography and rotational thromboelastometry are laboratory methods of assessing the kinetics of blood clot formation through real-time measurement of viscoelastic clot strength and may aid in management of severe hemorrhage. Although first described more than 70 years ago, viscoelastic testing devices are now available that allow for rapid point-of-care use of this technology to aid in real-time management of blood product replacement in cases of severe hemorrhage. These devices can be used to visually estimate multiple facets of hemostasis—coagulation, platelet function, and fibrinolysis—within 10–20 minutes. They have been used successfully in cardiac surgery, trauma, and liver transplantation and have potential for use in management of obstetric hemorrhage. Goals with their use include targeted transfusion of blood and its components for specific coagulation deficiencies. To date, however, published experiences with the use of these viscoelastic tests for obstetric hemorrhage have been limited. Because of the increasing use of the point-of-care tests by anesthesiologists, surgeons, and intensivists, the purpose of this report is to familiarize obstetricians with the technology involved and its use in severe hemorrhage complicating pregnancy.

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Postpartum hemorrhage continues to be the leading preventable cause of maternal morbidity and death worldwide.[1] In the United States, 10.7% of all pregnancy-related deaths during 2014–2017 were associated with postpartum hemorrhage.[2] Owing to the significant contribution of postpartum hemorrhage to maternal morbidity and mortality, national organizations, including the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, now recommend a multidisciplinary approach to hemorrhage prevention and management.[3–5] This approach includes safety bundles, stage-based protocols, and standardized checklists for treatment of maternal hemorrhage at the earliest stage possible.[3–5] Existing efforts emphasize the need for early recognition and timely resuscitation, escalation of care, and, if necessary, deployment of a massive transfusion protocol to prevent hypoperfusion that can lead to multi-organ dysfunction and coagulopathy.

Laboratory assessment is an essential component of the management of obstetric patients with postpartum hemorrhage.[1,6] This is especially true in the setting of large-volume blood loss requiring massive transfusion. The standard approach to laboratory testing has been the use of serial hematologic indices ordered emergently during the hemorrhage and transfusion therapy.[5] Given the time-sensitive nature of responding to such life-threatening events, deployment of blood products often occurs before these studies are available owing to the time it takes to get the blood sample to the laboratory and for such testing to be performed.

Given the need for more timely information and a better understanding of the consequences of

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Each author has confirmed compliance with the journal's requirements for authorship.

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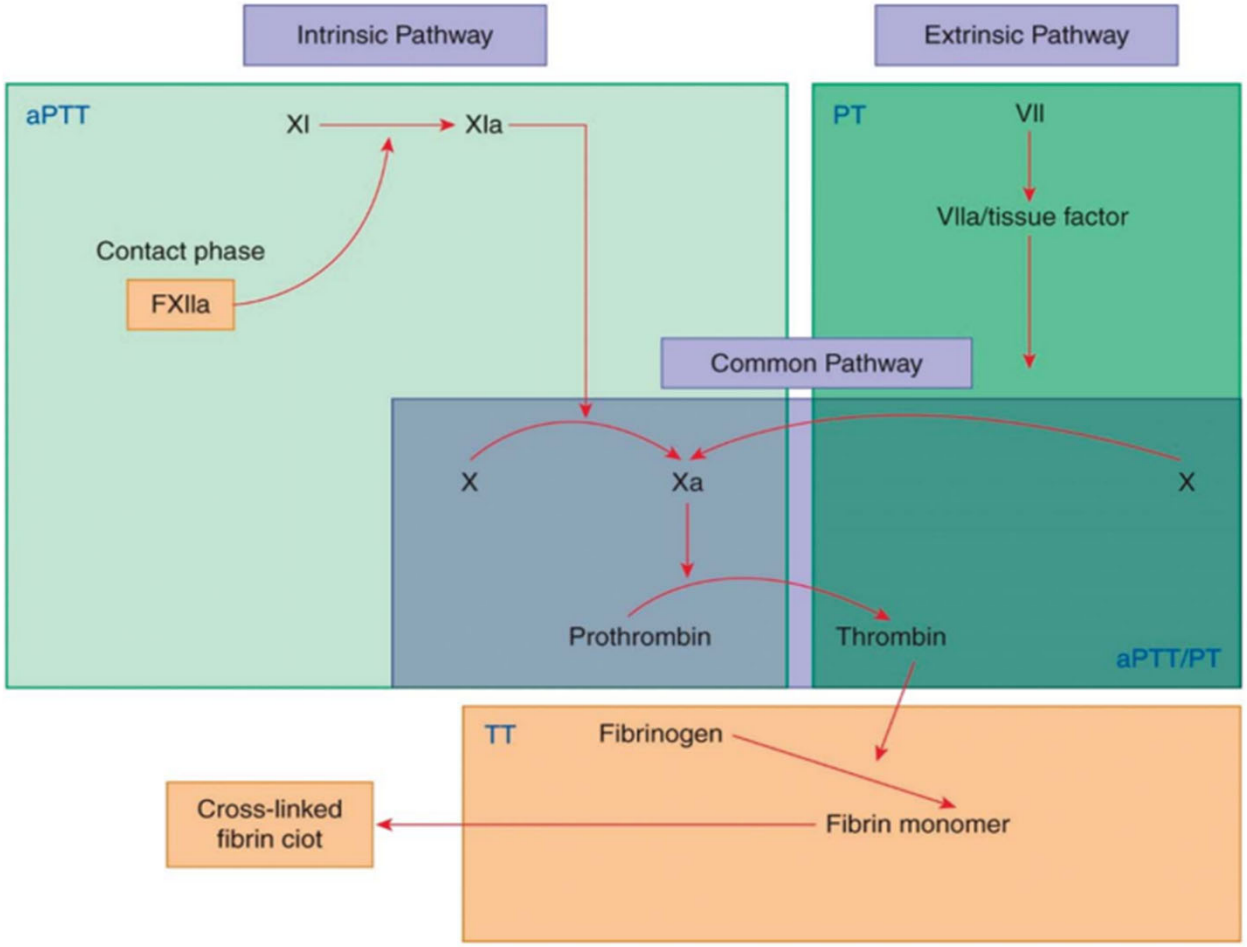
Simplified schemata of coagulation pathways



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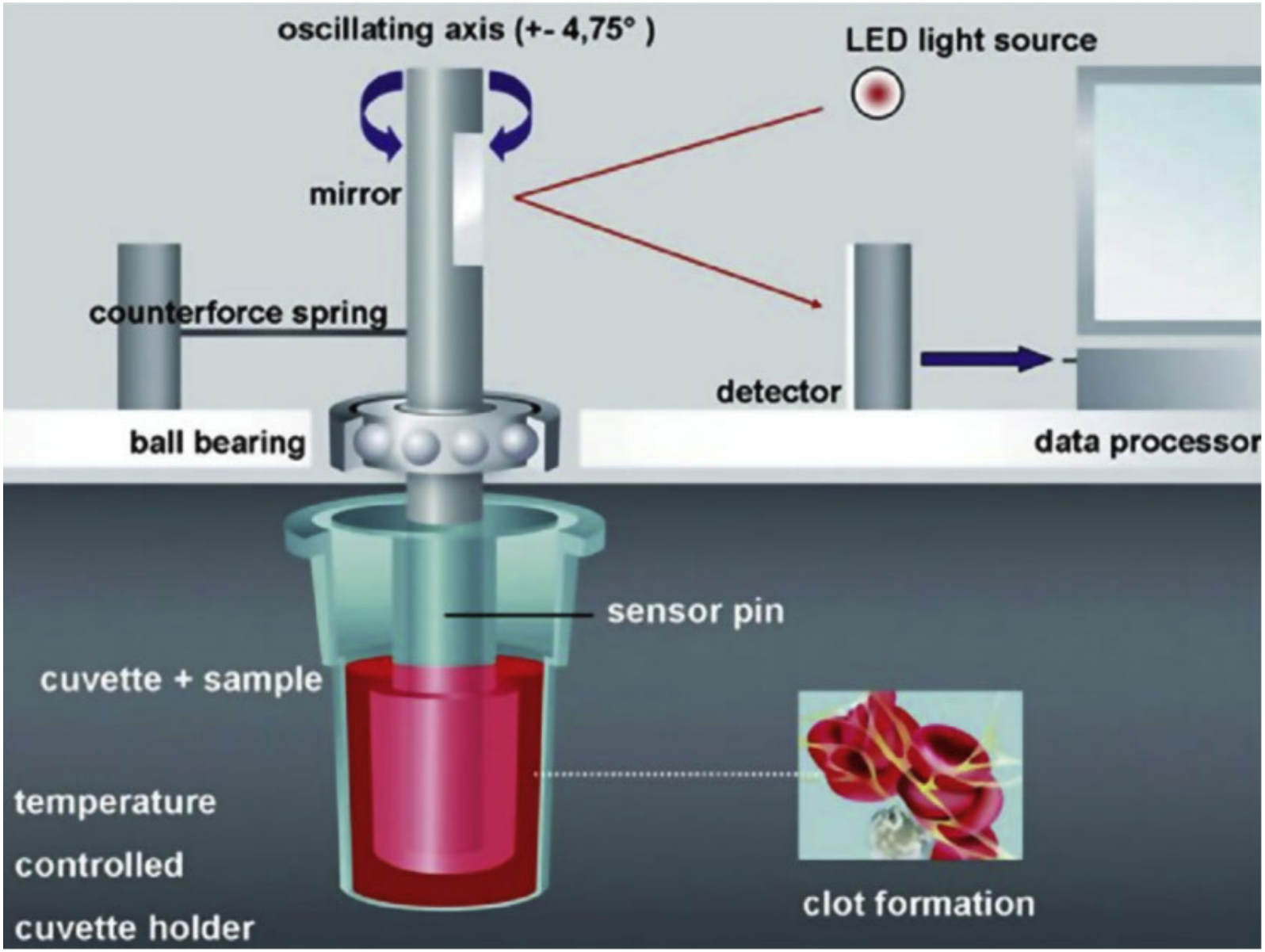

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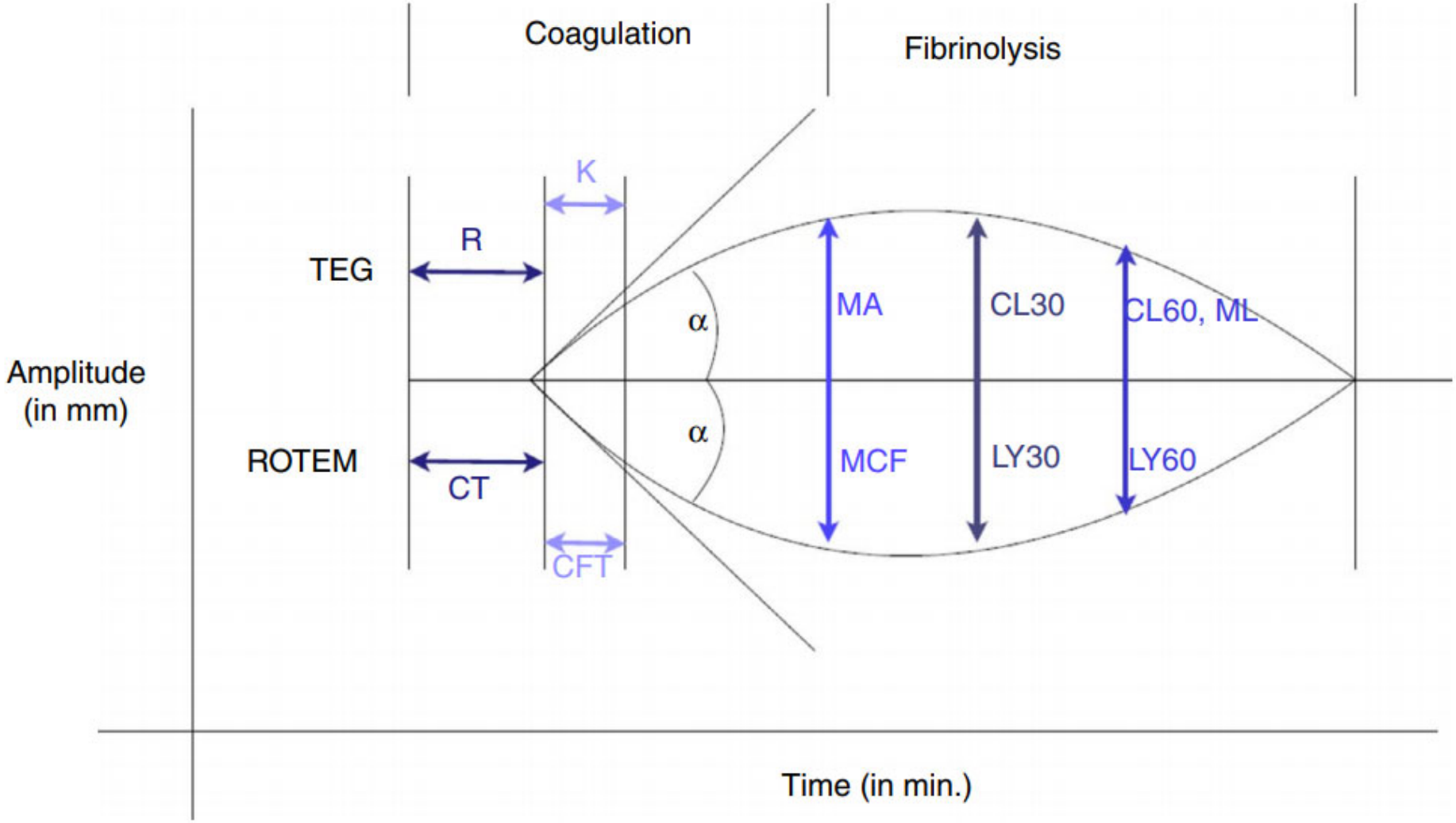

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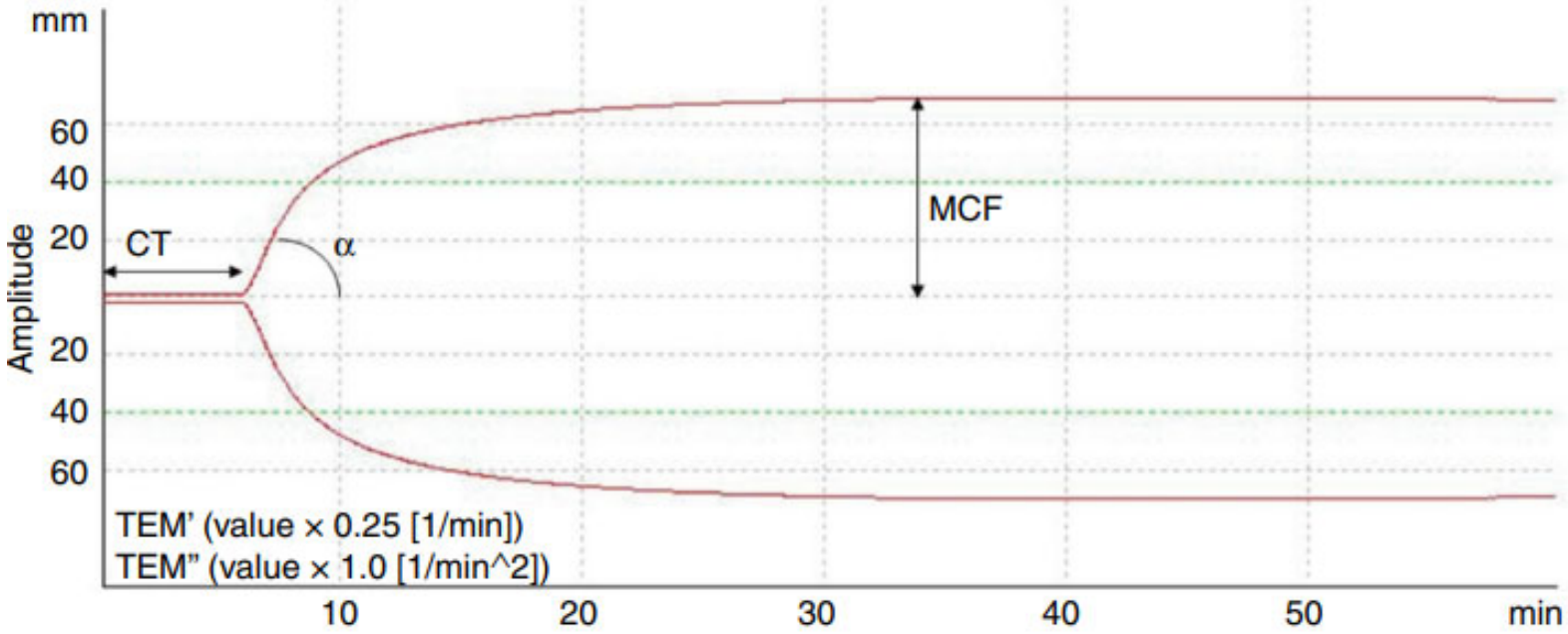

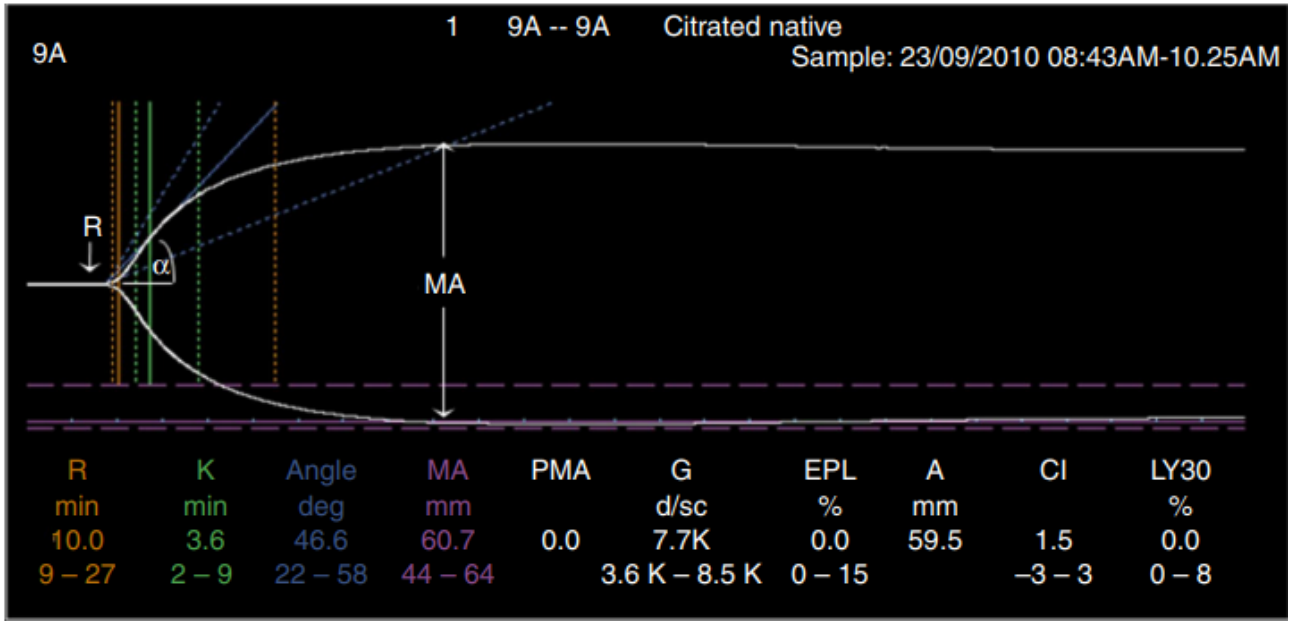

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Table 2. Terminology Used in Thromboelastography and Rotational Thromboelastometry

Function	Definition	TEG	ROTEM	Description
Clotting time	Time to clot initiation	R (reaction time)	CT (clotting time)	Prolongation may indicate deficiency of procoagulants or presence of anticoagulants
Clot kinetics	Time from clot initiation to form clot at 20-mm amplitude	K (kinetics)	CFT (clot formation time)	Possible early indicator of clot deficiency or hypercoagulability
Alpha angle	Angle formed by a line tangent to curve through clot initiation point (rapidity of clot formation)	α (alpha)	α (alpha)	Estimates rapidity of clot formation; prolongation suggests platelet dysfunction or deficiency, fibrinogen deficiency, or both; shortening may indicated hypercoagulability
Clot strength	Amplitude (mm) at maximum curve width (clot firmness)	MA (maximum amplitude)	MCF (maximum clot firmness)	Clot strength (firmness) at time X in minutes, eg, A5, A10, A30
Fibrinolysis	Percentage of clot lysis at 30 and 60 min after maximum clot strength achieved	CL30, CL60	LY30, LY60	Indicates clot lysis at time X in minutes, eg, LY30, LY60, and possible need for antifibrinolytic agents

TEG, thromboelastography; ROTEM, rotational thromboelastometry.

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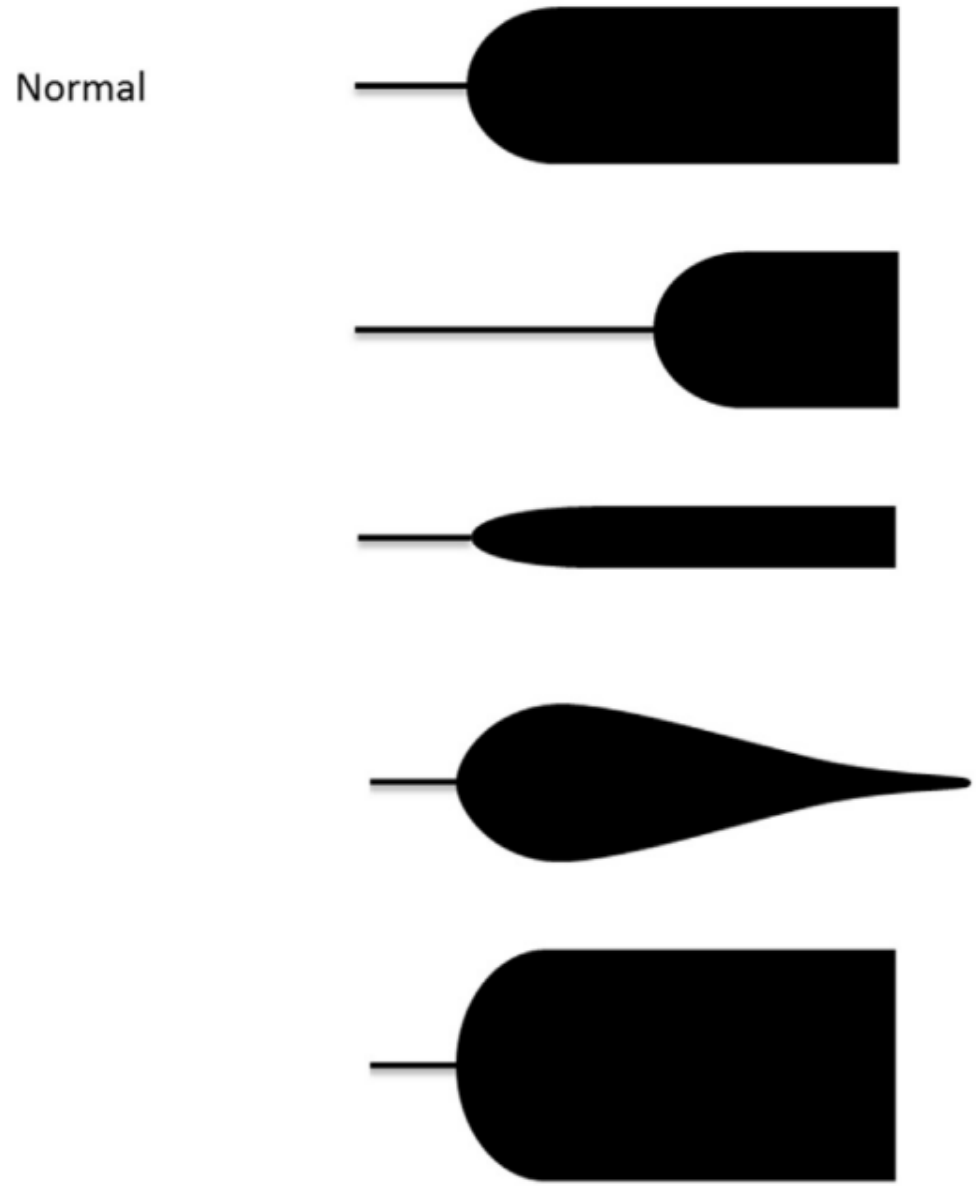

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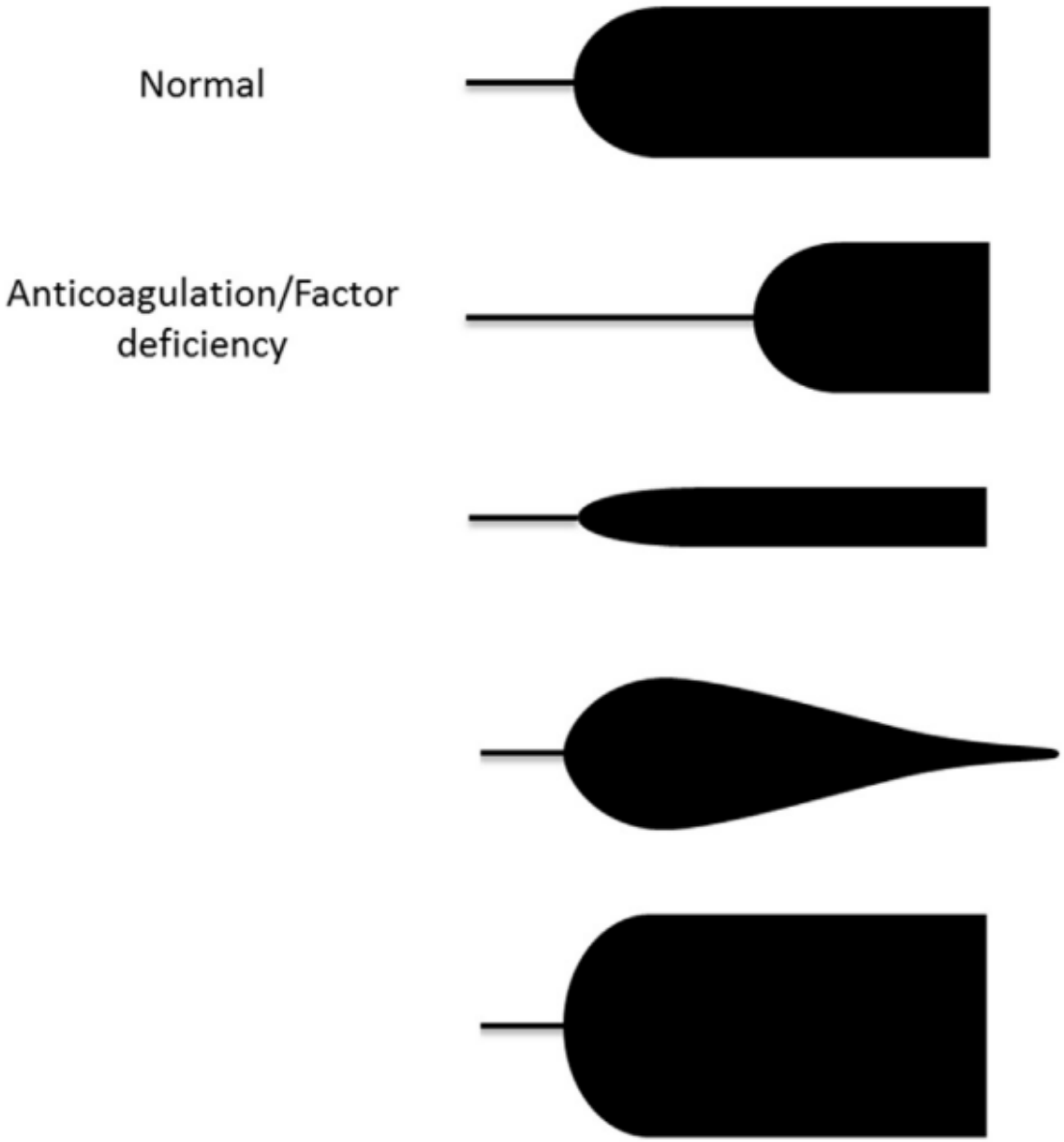

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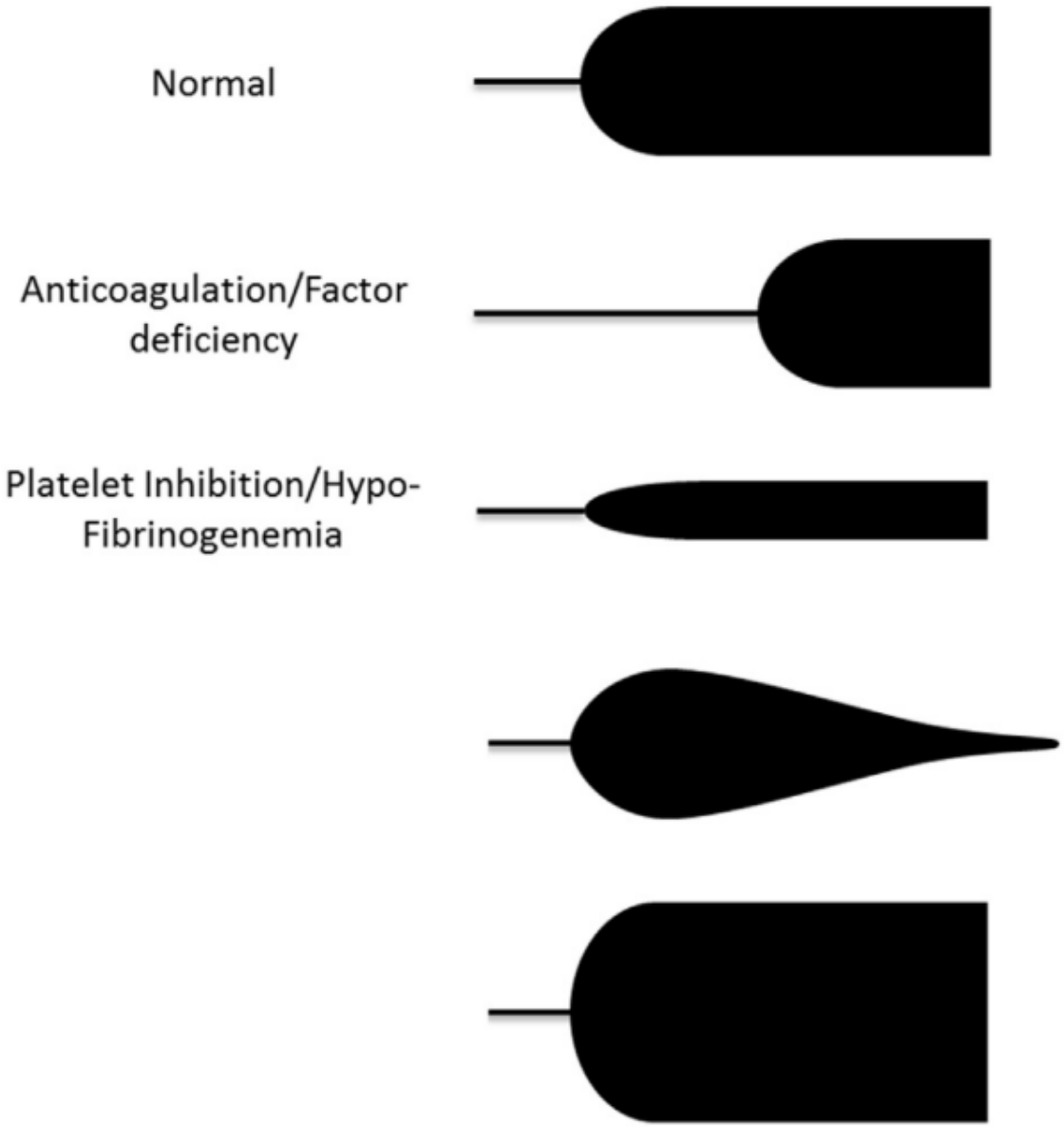

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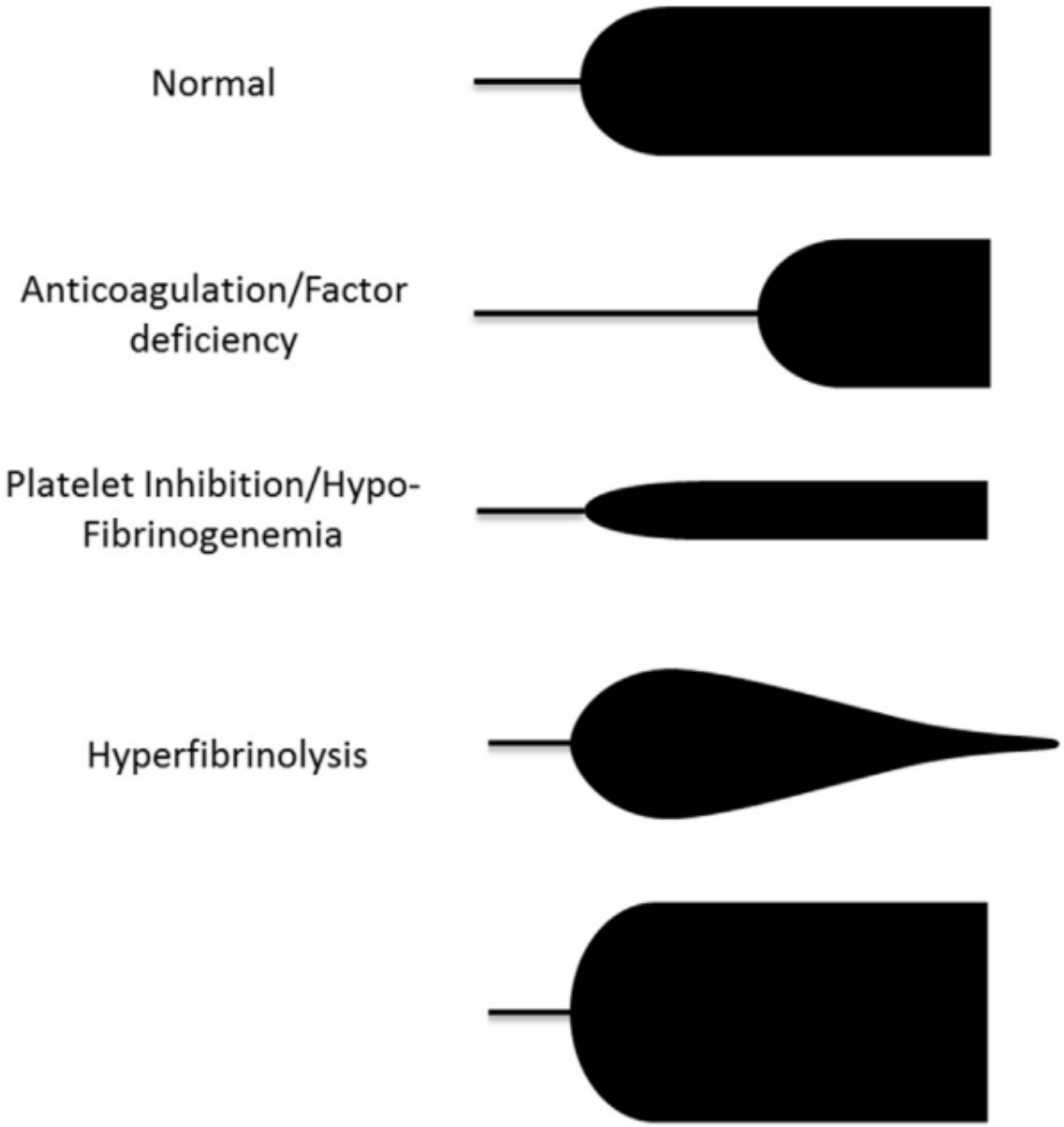

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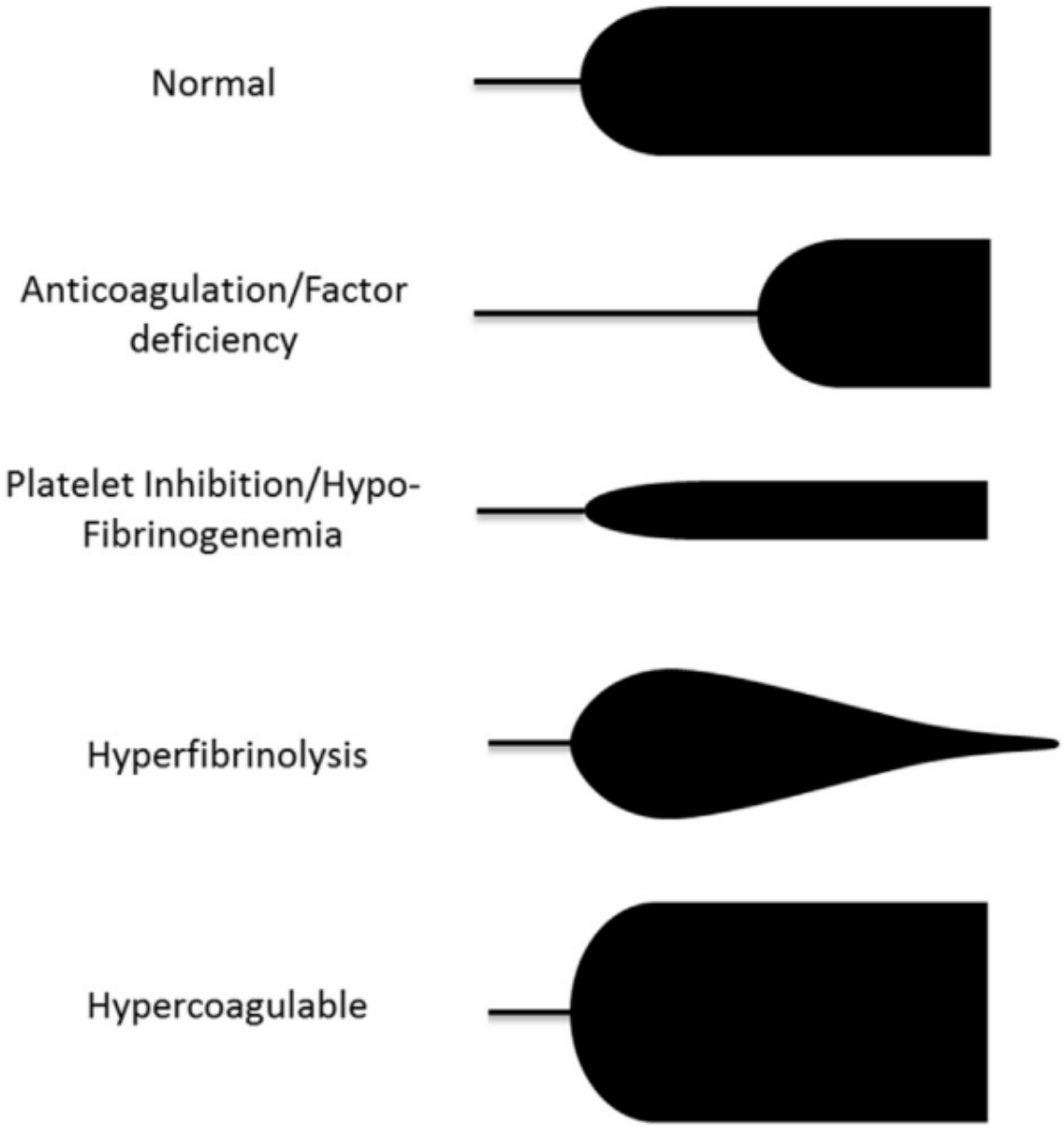

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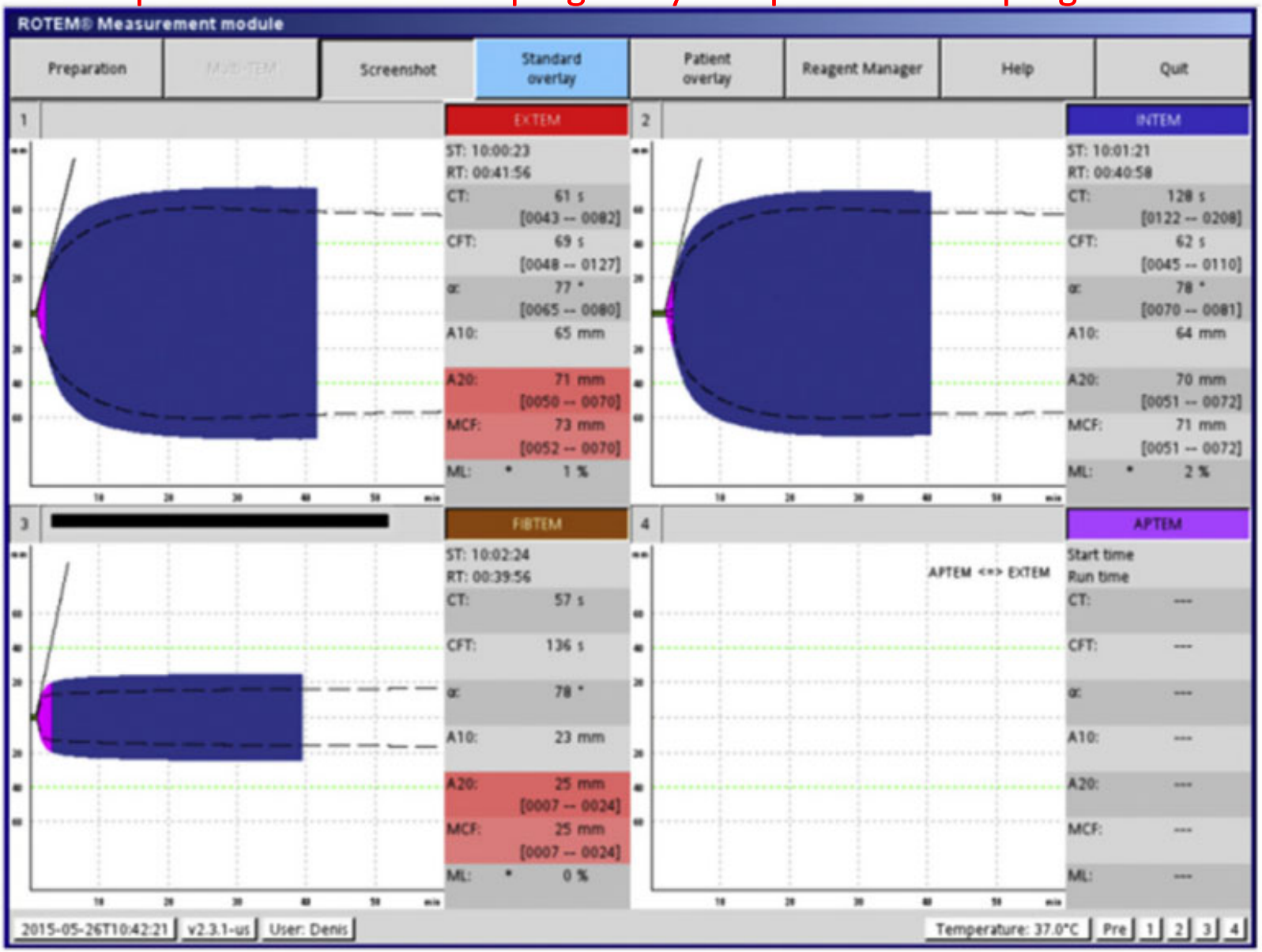
ROTEM parameters in normal pregnancy compared to non-pregnant state



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Rotational thromboelastometry assays

- **INTEM**—intrinsic clotting: clot activation is stimulated by reagents with phospholipid and ellagic acid. This assay provides information similar to that of the activated partial thromboplastin time. It is most often prolonged with heparin therapy, and treatment is with fresh-frozen plasma.

- **EXTEM**—extrinsic clotting: activated by recombinant tissue factor. This assay provides information similar to that of the prothrombin time. Prolongation suggests a deficiency of coagulation factors in the extrinsic pathway, for example, with vitamin K antagonists.

- **FIBTEM**—fibrinogen assay: cytochalasin D is added to inhibit polymerization of actin to block platelet contribution to clot formation. This assay is used to identify hypofibrinogenemia, and it is used most often in obstetric hemorrhage.

- **APTEM**—aprotinin fibrinolysis: aprotinin inhibits fibrinolysis, and it is used in conjunction with tissue factor and compared with EXTEM analysis to assess fibrinolysis.

- **HEPTEM**—heparin neutralization: heparinase is added to neutralize unfractionated heparin and used with INTEM reagent and compared with INTEM analysis to assess heparin effects on clotting. Without heparinase, unfractionated heparin-treated samples will result in a flat line. This assay is used principally in patients given unfractionated heparin while undergoing cardiopulmonary bypass.

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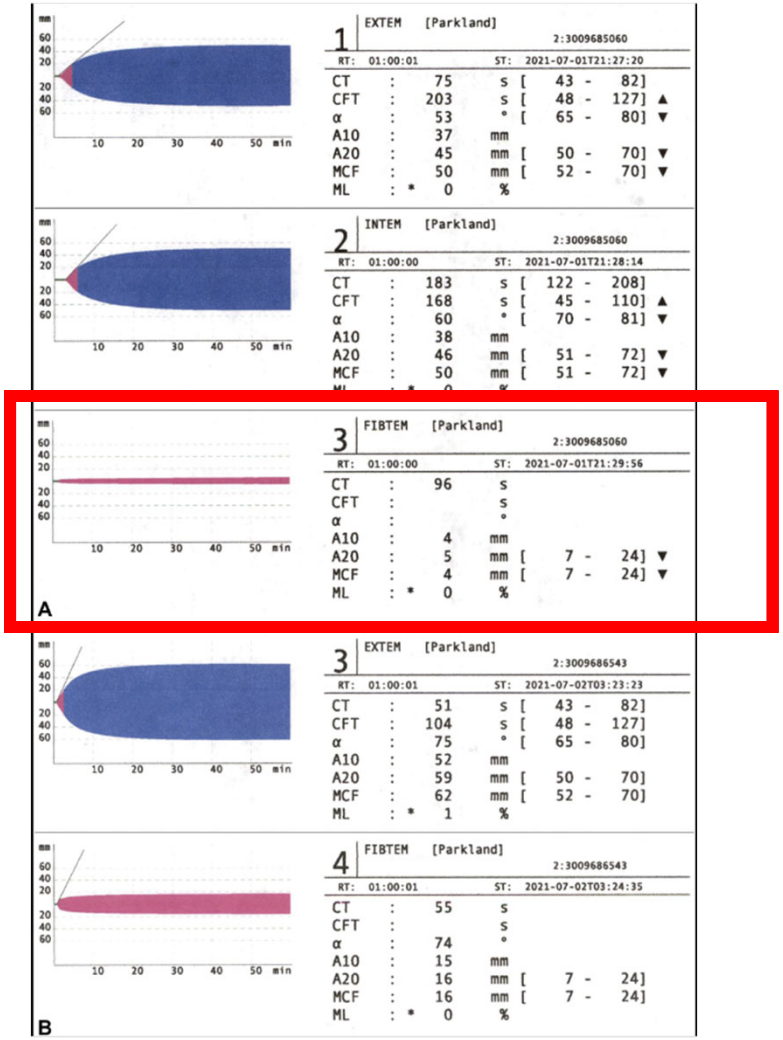
Rotational thromboelastometry assays

- **INTEM**—similar to that of the activated partial thromboplastin time.
- **EXTEM**—similar to that of the prothrombin time.
- **FIBTEM**—fibrinogen assay, used to identify hypofibrinogenemia, and it is used most often in obstetric hemorrhage.
- **APTEM**—compared with EXTEM analysis to assess fibrinolysis.
- **HEPTEM**—heparin neutralization.



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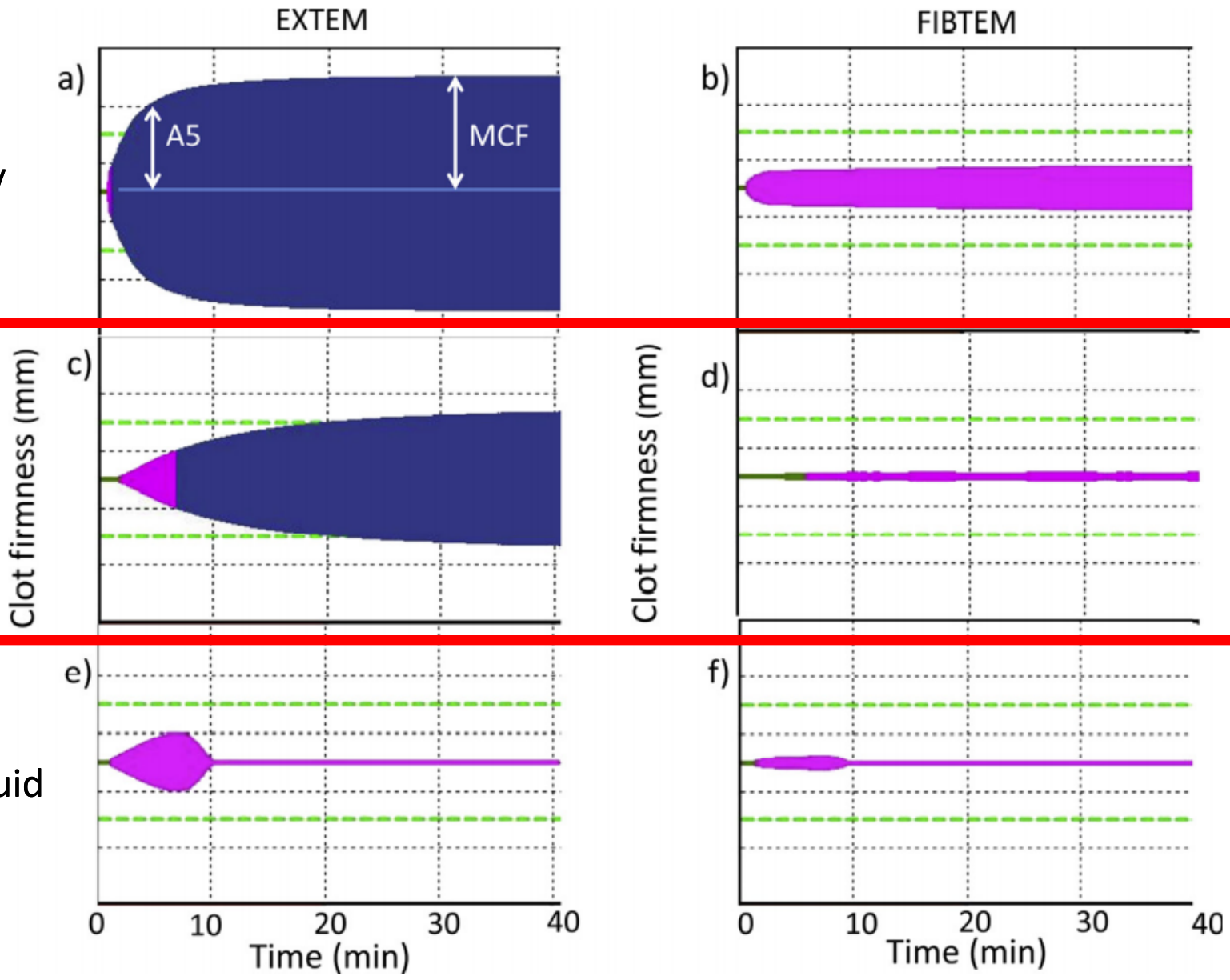
Normal pregnancy

Postpartum hemorrhage

Amniotic fluid embolism



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No difference in ROTEM values at <20 weeks with bleeding

European Journal of Obstetrics and Gynecology 304 (2025) 36–40

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Full length article

Case-control study of clotting differences using ROTEM testing in pregnant patients with early vaginal bleeding

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ARTICLE INFO

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ABSTRACT

Background: Vaginal bleeding in early pregnancy is a common presentation in the Emergency Department (ED), often resulting in pregnancy loss. Hypercoagulability exceeding normal physiological changes may be associated with miscarriage, but conventional clotting tests do not reliably detect this effect. Rotational thromboelastometry (ROTEM), which performs a more comprehensive clotting evaluation, may demonstrate coagulopathic abnormalities contributing to vaginal bleeding and miscarriage in early pregnancy that are not present in normal gestation.

Objective: This study aimed to evaluate the relationship between coagulation results from ROTEM testing in patients undergoing active evaluation for possible miscarriage compared to samples taken from asymptomatic patients with healthy pregnancies.

Study Design: This was a prospective case control study from a single center. Patients with chief complaint of vaginal bleeding in early pregnancy (less than 20 weeks) were recruited from the ED for ROTEM testing. These results were compared to healthy pregnant women presenting for routine prenatal care at our hospital's obstetrical clinic. Crude results were analyzed using *t*-test for ROTEM measures, and differences were then compared using multiple linear regression, controlling for patient age, race, ethnicity, number of prior pregnancies, and estimated gestational age (EGA) in weeks. ROTEM measurements of interest were the clot formation kinetics using EXTEM, INTEM, and NATEM tracings.

Results: Over the study, 46 patients were recruited from the ED and 51 from the obstetric clinic. Both groups had similar mean ages, and racial and ethnic distribution. ED patients had earlier EGA than OB clinic patients, 7.6 weeks vs. 10.7 weeks, but higher patient age and higher number of prior pregnancies. ROTEM results were not significantly different between groups on univariate analysis except for INTEM CFT and INTEM MCF. After controlling for the patient age and estimated gestational age, no ROTEM result differed between groups.

Conclusion: In pregnant patients presenting to the ED with vaginal bleeding before 20 weeks, ROTEM differences were not different in comparison to healthy pregnant patients at the same gestation stage. This suggests that ROTEM clotting profiles may not be useful in the evaluation of vaginal bleeding within this population.

Introduction

Vaginal bleeding in early pregnancy affects almost one fourth of pregnancies and is a common presentation in the Emergency Department (ED) [1,2]. Patients experiencing first trimester vaginal bleeding have high rates of adverse pregnancy outcomes, including a reported 58 % rate of miscarriage [3–5]. Physiological changes in pregnancy cause recognizable hypercoagulable changes, and prior research has proposed that exaggerated hypercoagulability may result in miscarriage due to disruption of flow in the utero-placental vasculature [6–9]. Supporting

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Available online 19 November 2024

Table 2
ROTEM Data.

	Group					
	VB		Control		Univariate p-value	Adjusted p-value
Channel (Ref. Range)	Mean	Std	Mean	Std		
EXTEM CT (42–82)	78.45	14.93	74.36	10.3	0.16	0.13
EXTEM CFT (48–127)	77.82	21.27	73.55	19.32	0.36	0.69
EXTEM MCF (52–70)	67.29	4.32	68.52	4.48	0.22	0.42
EXTEM AUC	6689.5	413.66	6823.5	435.4	0.17	0.34
EXTEM LI45	95.32	3.02	96.1	2.49	0.34	0.37
INTEM CT (122–208)	198.33	38.85	193.7	28.96	0.55	0.41
INTEM CFT (48–127)	71.43	19.4	62.68	12.5	0.02	0.08
INTEM MCF (52–70)	65.88	3.94	67.82	3.98	0.03	0.20
INTEM AUC	6569.1	403.71	6726.2	391.89	0.09	0.38
INTEM LI45	93.62	3.9	94.71	3.18	0.28	0.27
NATEM CT	512.4	110.65	500. 2	113. 5	0.65	0.76
NATEM CFT	127.31	37	116.8	30.93	0.21	0.30
NATEM MCF	62.29	4.84	63.93	4.29	0.14	0.24
NATEM AUC	6271	463.09	6424.5	400.1	0.13	0.22
NATEM LI45	95.61	3.68	95.85	3.11	0.85	0.64

In this study, differences in ROTEM coagulation profiles in patient samples taken at the time of evaluation for threatened miscarriage did not differ from coagulation testing performed under routine conditions during prenatal clinic visits. Subjects in our study groups differed in patient age and obstetric history, but both groups had similar racial and ethnic breakdown, including a high rate of minority presence in our study. Neither group had significant past medical history which might have been likely to affect our results. On evaluation of coagulation profiles with multiple ROTEM channels, findings showed normal mean ROTEM measures in both groups with no difference in any outcome of interest that would have indicated exaggerated hypercoagulability in our sample population.

Maher P et al. Eur J Ob Gyn. 2024

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Obstetrics

OBSTETRICS

Viscoelastometric-guided early fibrinogen concentrate replacement during postpartum haemorrhage: OBS2, a double-blind randomized controlled trial

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[†]The OBS2 study team is listed in the Acknowledgements section.

Abstract

Background: Postpartum haemorrhage (PPH) can be exacerbated by haemostatic failure. We hypothesized that early fibrinogen replacement, guided by viscoelastometric testing, reduces blood product usage and bleed size.
Methods: Women with PPH 1000–1500 ml were enrolled. If Fibtem A5 was ≤15 mm and bleeding continued, subjects were randomized to fibrinogen concentrate or placebo. The primary outcome compared the number of units of red blood cells, plasma, cryoprecipitate and platelets transfused.
Results: Of 663 women enrolled 55 were randomized. The adjusted incidence rate ratio (IRR) (95% CI) for the number of allogeneic units transfused in the fibrinogen group compared with placebo was 0.72 (0.3–1.7), P=0.45. In pre-specified subgroup analyses, subjects who had a Fibtem A5 ≤12 mm at the time of randomization and who received fibrinogen concentrate received a median (25th–75th centile) of 1 (0–4.5) unit of allogeneic blood products and had an additional 300 (100–350) ml blood loss whereas those who received placebo also received 3 (0–6) units of allogeneic blood products and had 700 (200–1550) ml additional blood loss; these differences were not statistically significantly different. There was one thrombotic event in each group.
Conclusions: Infusion of fibrinogen concentrate triggered by Fibtem A5 ≤15 mm did not improve outcomes in PPH. Pre-specified subgroup analyses suggest that fibrinogen replacement is not required if the Fibtem A5 is >12 mm or Clauss fibrinogen >2 g litre^{-1}, but an effect below these levels cannot be excluded. The raised fibrinogen at term appears to be a physiological buffer rather than required for haemostasis.

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Conclusions:

Infusion of fibrinogen concentrate triggered by **A5 < 15 mm did not improve outcomes** in postpartum hemorrhage, however, pre-specified subgroup analyses suggest that fibrinogen replacement is not required if the **Fibtem A5 is > 12** mm…

Collins PW et al. Br J Anes. 2017

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Viscoelastic testing data at present

Original Article

Thromboelastography versus Standard Coagulation Assays in Patients with Postpartum Hemorrhage

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Am J Perinatol

Abstract

Objective Thromboelastography (TEG), a point-of-care test that measures blood's dynamic viscoelastic properties, is routinely used to guide resuscitation in surgical specialties with high hemorrhage risk. Patients with ongoing postpartum hemorrhage (PPH) often develop coagulopathy and hypofibrinogenemia. Timely assessment of fibrinogen is crucial because cryoprecipitate for repletion requires thawing time prior to administration. TEG may provide rapid assessment of coagulopathy in ongoing hemorrhage but this has not been thoroughly studied. Our objective was to determine if TEG accurately reflects coagulopathy in ongoing PPH when compared with standard assays.

Study Design This was a retrospective cohort study of people with ongoing PPH (quantified blood loss >1,000 mL), from January 1, 2016, to December 31, 2019. TEG variables and standard coagulation parameters were compared in patients who had both assays drawn simultaneously. As a secondary analysis, patients who had TEG were compared with those who did not. The Mann–Whitney, Fisher's exact, Kruskal–Wallis, Spearman's rho, and logistic regression tests were used for analysis. Significance was set at $p < 0.05$.

Results A total of 680 patients were included, 69 of whom had TEG and coagulation parameters drawn simultaneously and were included in the primary analysis. The remainder were included in the secondary analysis. TEG variables and coagulation assays correlated significantly—prolonged R with increased PTT (rho 0.25, $p = 0.04$), prolonged K and decreased α angle with decreased fibrinogen (rho −0.61, $p < 0.001$; rho 0.24, $p < 0.001$), and decreased maximum amplitude with decreased platelets (rho 0.62, $p < 0.001$). Those who had thromboelastographic assays had higher blood loss and need for interventions to manage hemorrhage than those who did not.

Conclusion TEG correlated significantly with standard laboratory assays in ongoing PPH, including for patients with hypofibrinogenemia. Given the point-of-care nature and rapid turnaround time, TEG should be considered for timely hemorrhage evaluation and directed resuscitation of coagulopathy.

Keywords
- postpartum hemorrhage
- thromboelastography
- coagulopathy
- fibrinogen
- massive transfusion

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Table 2 Hemorrhage characteristics of TEG versus no TEG group

	TEG ($n = 69$)	No TEG ($n = 611$)
QBL (mL)	1,638 ± 22	3,799 ± 391
1,000–1,999	482 (78.9%)	9 (13%)
2,000–2,999	116 (19%)	30 (43.5%)
>3,000	13 (2.1%)	30 (43.5%)
Blood products	66 (96%)	342 (56%)
Massive transfusion	41 (59%)	23 (4%)
Bakri balloon	27 (39%)	48 (8%)
Interventional radiology (IR)	1 (1%)	0 (0%)
Surgical intervention	37 (54%)	53 (9%)
Dilation and curettage	7	29
Exploratory laparotomy	1	0
Hysterectomy	14	0
Other	15	24
Composite endpoint	66 (96%)	383 (63%)

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ROTEM data at present

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Original Article

Rotational thromboelastometry for the transfusion management of postpartum hemorrhage after cesarean or vaginal delivery: A single-center randomized controlled trial

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Introduction

Postpartum hemorrhage (PPH) continues to be the leading cause of preventable maternal morbidity and mortality worldwide. Despite ample availability of resources in the United States, a database analysis demonstrated an increase in PPH from 2010 to 2014, from 2.9 to 3.2% [1]. Early detection of coagulopathy and tailored transfusion management may mitigate PPH and associated morbidity, as low fibrinogen (<200 mg/dL) at PPH onset predicts the progression to severe PPH and need for interventional procedures [2,3]. Rotational thromboelastometry (ROTEM®) point-of-care (POC) testing enables rapid assessment of global coagulation with specific detection of low-fibrinogen states and hyperfibrinolysis [4]. In addition to normal ROTEM® reference ranges for pregnant women that have been established for clinical use [5–11], prophylactic administration of fibrinogen concentrate is not indicated [12] and impactful ROTEM® thresholds for fibrinogen replacement are being defined [13,14].

Use of ROTEM® during PPH has demonstrated that coagulopathy is relatively rare and cannot be predicted solely by volume of blood lost [15]. Replacing a fixed-ratio massive transfusion protocol ("shock pack") with a ROTEM®-based algorithm for fibrinogen replacement lowered the use of allogeneic blood products and improved transfusion-related patient outcomes after PPH [16]. However, contemporary practice precludes the empiric use of fixed ratio massive transfusion for PPH, and the effectiveness of ROTEM® for PPH has not been compared to empiric management in a randomized controlled setting. In this single center randomized controlled trial (RCT), we report the impact of ROTEM® on the transfusion management of PPH after cesarean delivery (CD) or vaginal delivery (VD). The primary aim was to compare the total number of blood products transfused in the intervention group compared to standard of care. Secondary aims were to compare transfusion-associated morbidity between groups. We hypothesized that ROTEM® use during PPH would lower total blood product transfusion number (including packed red blood cells [PRBC], fresh frozen plasma [FFP], platelets, cryoprecipitate, fibrinogen concentrate, or cell salvage units). Secondary outcomes included number of each product type transfused, transfusion-associated morbidity (i.e., hysterectomy rate, need for intensive care unit [ICU] admission, transfusion-associated circulatory overload [TACO], transfusion-related acute lung injury [TRALI]), and length of stay.

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Table 1
Participant characteristics.

Characteristic	ROTEM® (*N* = 23)	Control (*N* = 26)	Standardized difference[a]
Age (years), mean ± SD [min, max]	36 ± 5 [26, 46]	36 ± 5 [26, 46]	−0.051
BMI (kg/m^2), mean ± SD [min, max]	31 ± 6 [21, 46]	34 ± 9 [21, 63]	−0.317
Gestational age (weeks), mean ± SD [min, max]	36 ± 2 [30, 39.]	37 ± 2 [32, 40]	−0.280
Gravidity, median (Q1, Q3) [min, max]	4 (2, 5) [2, 9]	3 (2, 4) [1, 8]	0.409
Parity, median (Q1, Q3) [min, max]	1 (1, 2) [0, 3]	1 (1, 2) [0, 4]	−0.144
Race, n (%)			0.429
White	13 (56.5)	17 (70.8)	
Black	5 (21.7)	5 (20.8)	
Asian	4 (17.4)	2 (8.3)	
Hispanic or Latino	1 (4.3)	0 (0)	
Unavailable (not included in percentage calculation)	0	2	
Ethnicity, n (%)			−0.125
Hispanic	3 (13.6)	4 (18.2)	
Non-Hispanic	19 (86.4)	18 (81.8)	
Unavailable (not included in percentage calculation)	1	4	
Number of babies delivered n (%)			−0.046
1	20 (87)	23 (88.5)	
2	3 (13.0)	3 (11.5)	
Anesthesia type, n (%)			0.439
CSE	15 (65.2)	14 (53.8)	
Epidural	3 (13.0)	4 (15.4)	
General	0 (0)	2 (7.7)	
Spinal	5 (21.7)	6 (23.1)	
Delivery type, n (%)			0.165
Scheduled Cesarean	19 (82.6)	20 (76.9)	
Unscheduled Cesarean	3 (13.0)	5 (19.2)	
Vaginal	1 (4.3)	1 (3.8)	

ROTEM® = Rotational thromboelastometry; SD = Standard deviation; BMI = Body mass index; kg = Kilos; *m* = Meter; Q1, Q3 = Interquartile range; CSE = Combined spinal epidural.
[a] An absolute standardized difference greater than 1.96 $\sqrt{2/n}$ = 0.38 was considered to indicate greater difference than would be expected by chance.

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Table 2
Results from the intention-to-treat analysis.

Outcome	ROTEM®(N = 23)	Control(N = 26)	Effect size(95% CI)	P-value
Primary outcome				
Total blood products transfused, median (Q1, Q3) [min, max]	1.6 (0, 7) [0, 38.1]	2 (1, 5.1) [0, 23]	0.89 (0.45 to 1.73)[a]	0.738
Components of primary outcome				
Total PRBCs transfused (units), median (Q1, Q3) [min, max]	1 (0, 4) [0, 16]	2 (1, 3) [0, 9]	0.84 (0.42 to 1.60)[a]	0.594
Total FFP transfused (units), median (Q1, Q3) [min, max]	0 (0, 3) [0, 9]	0 (0, 2) [0, 9]	1.01 (0.57 to 1.81)[a]	0.972
Total platelets transfused (units), median (Q1, Q3) [min, max]	0 (0, 0) [0, 4]	0 (0, 0) [0, 2]	1.22 (0.84 to 1.80)[a]	0.307
Total cryoprecipitate transfused (units), median (Q1, Q3) [min, max]	0 (0, 0) [0, 3]	0 (0, 0) [0, 2]	1.04 (0.72 to 1.52)[a]	0.846
Total fibrinogen concentrate transfused (g), median (Q1, Q3) [min, max]	0 (0, 0) [0, 3]	0 (0, 0) [0, 2]	1.04 (0.72 to 1.53)[a]	0.833
Cell salvage transfused (units), median (Q1, Q3) [min, max]	0 (0, 0.7) [0, 4.7]	0 (0, 0) [0, 1.1]	1.81 (1.08 to 3.30)[a]	0.023
Secondary outcomes				
Coagulopathy, n (%)	1 (4.3)	5 (19.2)	0.23 (0.03 to 1.80)[b]	0.194
Albumin (mL), median (Q1, Q3) [min, max]	0 (0, 250) [0, 3000]	0 (0, 0) [0, 500]	1.49 (0.93 to 2.48)[a]	0.099
Crystalloids (mL), median (Q1, Q3) [min, max]	3000 (2500, 3400) [1000, 4300]	3000 (2000, 3500) [1250, 4569]	1.00 (0.51 to 1.97)[a]	0.999
Blood loss, EBL or QBL (mL), median (Q1, Q3) [min, max]	2100 (1800, 2844) [1200, 10,000]	2000 (1500, 2600) [1000, 4743]	1.51 (0.78 to 3.24)[a]	0.228
TRALI or TACO, n (%)	0 (0)	0 (0)	–	–
ICU admission, n (%)	2 (8.7)	1 (3.\8)	2.26 (0.22 to 23.33)[b]	0.594
Hysterectomy performed, n (%)	13 (56.5)	14 (53.8)	1.05 (0.63 to 1.74)[b]	0.851
Length of stay (days), median (Q1, Q3) [min, max]	4 (4, 9) [3, 38]	4 (4, 5) [2, 20]	1.45 (0.77 to 2.96)[a]	0.258

ROTEM® = Rotational thromboelastometry; PRBCs = Packed red blood cells; FFP = Fresh frozen plasma; mL = Milliliter; EBL = Estimated blood loss; QBL = Quantitation of blood loss; TRALI = Transfusion-related acute lung injury; TACO = Transfusion-associated circulatory overload (TACO); ICU = Intensive care unit.

[a] Wilcoxon-Mann-Whitney odds.

[b] Risk ratio.

Lumbreras-Maquez MI et al. J Gynecol Obstet Human Reprod 2022

ROTEM data at present

The Choice between Plasma-Based Common Coagulation Tests and Cell-Based Viscoelastic Tests in Monitoring Hemostatic Competence: Not an either–or Proposition

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Semin Thromb Hemost 2022;48:769–784.

Abstract

There has been a significant interest in the last decade in the use of viscoelastic tests (VETs) to determine the hemostatic competence of bleeding patients. Previously, common coagulation tests (CCTs) such as the prothrombin time (PT) and partial thromboplastin time (PTT) were used to assist in the guidance of blood component and hemostatic adjunctive therapy for these patients. However, the experience of decades of VET use in liver failure with transplantation, cardiac surgery, and trauma has now spread to obstetrical hemorrhage and congenital and acquired coagulopathies. Since CCTs measure only 5 to 10% of the lifespan of a clot, these assays have been found to be of limited use for acute surgical and medical conditions, whereby rapid results are required. However, there are medical indications for the PT/PTT that cannot be supplanted by VETs. Therefore, the choice of whether to use a CCT or a VET to guide blood component therapy or hemostatic adjunctive therapy may often require consideration of both methodologies. In this review, we provide examples of the relative indications for CCTs and VETs in monitoring hemostatic competence of bleeding patients.

Keywords
- thromboelastography
- hemorrhage
- thrombosis
- anticoagulants

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Issue Theme Emerging Use of Viscoelastography in Thrombosis and Hemostasis: A Challenge to Conventional Coagulation Tests?; Guest Editors: Hau C. Kwaan, MD, FRCP, Mark Walsh, MD, FACEP, Paul F. Lindholm, MD, and Maha Othman, MD, MSc, PhD

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Table 1 Comparison of common coagulation tests and viscoelastic tests

Common coagulation tests	Viscoelastic tests
• Longer turnaround time	• Shorter turnaround time
• Lower costs of reagents	• Higher costs of reagents
• Ideal for batch analysis	• Requires extensive quality control
• Requires centrifugation	• Centrifugation not required
• Does not analyze whole blood; unreflective of in vivo hemostasis	• Analyzes whole blood; more reflective of in vivo hemostasis without endothelial contribution
• Ideal for monitoring warfarin and heparin dosage	• Ideal for monitoring warfarin/ heparin patients with acute trauma
• Insensitive detection of fibrinolysis	• Detects fibrinolysis
• Requires collection of information regarding factor concentration, platelet function, and fibrinogen from a variety of instruments	• Information regarding the coagulation of whole blood is produced by one device
• Only analyzes the initiation of blood clot formation	• Analyzes the integrity of the entire blood clot formation
• Associated with inadequate blood product ratio usage	• Associated with reduced blood product waste and decreased costs

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ROTEM data at present

The Choice between Plasma-Based Common Coagulation Tests and Cell-Based Viscoelastic Tests in Monitoring Hemostatic Competence: Not an either–or Proposition

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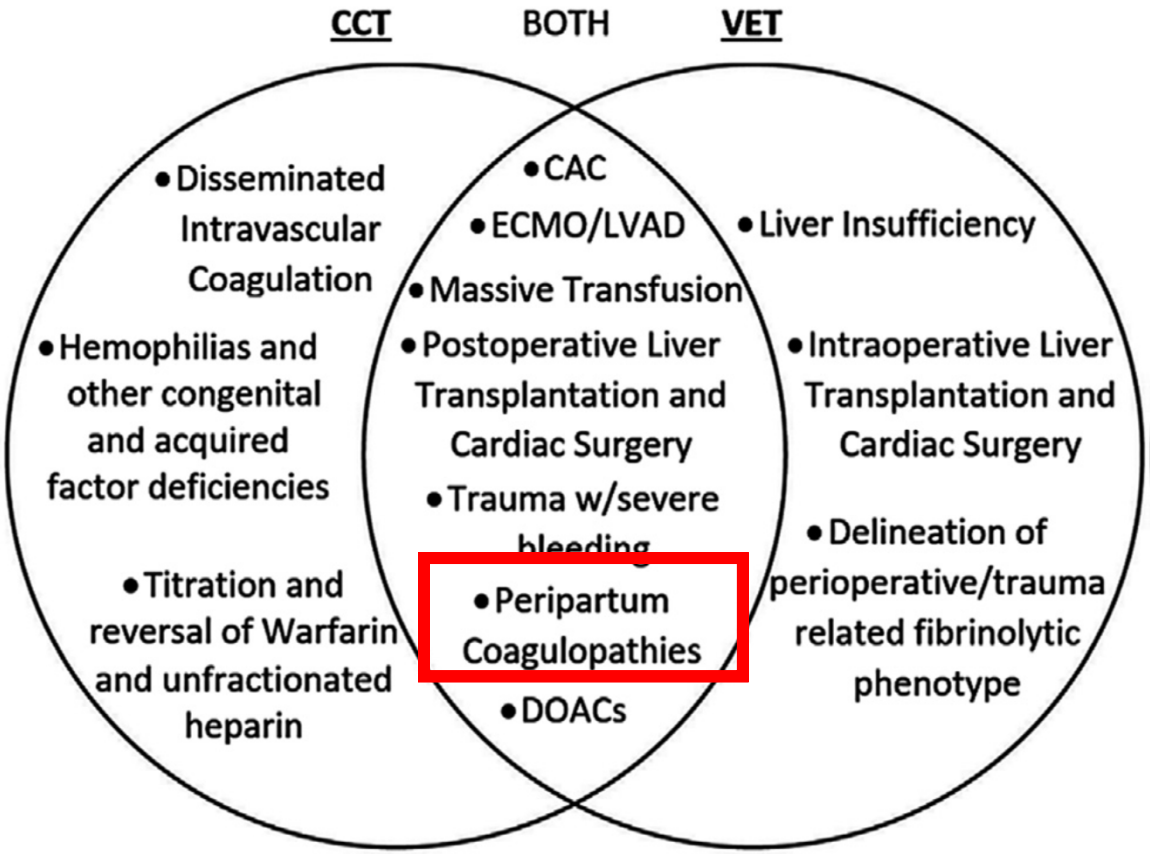

Bunch CM et al. Semin Thromb Haemost. 2022

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ROTEM data at present

Expert Review

Emerging technology for early detection and management of postpartum hemorrhage to prevent morbidity

Megan G. Lord, MD; Joaquin A. Calderon, MD; Homa K. Ahmadzia, MD, MPH; Luis D. Pacheco, MD, MPH

Despite advances in hemorrhage detection and management, postpartum hemorrhage remains the single leading cause of maternal death worldwide. Within the United States, hemorrhage is the leading cause of maternal death on the day of delivery and within the first week after delivery. Blood transfusion after hemorrhage represents a large proportion of severe maternal morbidity during and after delivery. Blood loss during delivery has historically been assessed visually by inspecting soiled pads, linens, and laparotomy sponges. These methods underestimate the volume of blood loss by as much as 40%, becoming increasingly inaccurate as blood loss increases. Young, healthy obstetrical patients compensate for blood loss via peripheral vasoconstriction, maintaining heart rate and blood pressure in a normal range until over 1 L of blood has been lost. A significant decrease in blood pressure along with marked tachycardia (>120 bpm) may not be seen until 30% to 40% of blood volume has been lost, or 2.0 to 2.6 L in a healthy term pregnant patient, after which the patient may rapidly decompensate. In resource-poor settings especially, the narrow window between the emergence of significant vital sign abnormalities and clinical decompensation may prove catastrophic. Once hemorrhage is detected, decisions regarding blood product transfusion are routinely made on the basis of inaccurate estimates of blood loss, placing patients at risk of underresuscitation (increasing the risk of hemorrhagic shock and end-organ damage) or overresuscitation (increasing the risk of transfusion reaction, fluid overload, and alloimmunization). We will review novel technologies that have emerged to assist both in the early and accurate detection of postpartum hemorrhage and in decisions regarding blood product transfusion.

Key words: compensatory reserve, postpartum hemorrhage, postpartum hemorrhage detection, rotational thromboelastometry, thromboelastography, thromboelastometry, viscoelastic hemostasis assays

The scope of the problem

Postpartum hemorrhage (PPH) remains the single leading cause of maternal death worldwide.[1] In the United States, obstetrical hemorrhage is the primary cause of approximately 11% of maternal deaths overall and is the leading cause of maternal death on the day of delivery and in the first week after delivery.[2,3] Severe hemorrhage of ≥1500 mL occurs in 0.4% of deliveries[4] and is life-threatening in approximately 0.1% of deliveries.[5] Blood product transfusion is a major contributor to maternal morbidity.[6] Young, healthy patients compensate for hemorrhage via peripheral vasoconstriction; when volume loss is profound, the resulting hypoperfusion can lead to multiorgan failure, hemorrhagic shock, and pituitary necrosis.[7]

Early detection of postpartum hemorrhage

The importance of early detection

Although hemorrhage remains a leading cause of maternal death, 70% of maternal deaths from hemorrhage seem to be preventable.[8] Early hemorrhage detection, accurate quantification of blood loss, and early intervention are crucial to improving maternal outcomes[9]—coagulopathy is most likely when the diagnosis of PPH is delayed or the volume of blood loss is underestimated.[10] Protocols have been developed to improve early recognition of PPH

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M.G.L. has no financial conflict of interest. M.G.L. is involved in research on the AccuFlow sensor but has no financial relationship with the makers of that device. The AccuFlow sensor is discussed in this manuscript alongside its major competitors.

J.A.C. has no conflict of interest.

H.K.A.'s research makes use of a rotational thromboelastometry (ROTEM) delta analyzer, which is on loan from the device manufacturer, Instrumentation Laboratory Company, Bedford, Massachusetts. She does not receive any direct funding from the Instrumentation Laboratory Company, and the Instrumentation Laboratory Company is not involved in any way in the design or conduct of her research. The ROTEM delta analyzer is discussed in this manuscript alongside its major commercial competitor (thromboelastography), with equal time spent in the discussion of both products. Furthermore, H.K.A. participated in consulting work for HemoSonics on 1 occasion in the past. No device produced or designed by HemoSonics is discussed in this manuscript.

L.D.P. is part of the medical consultant board of Coagulant Therapeutics. No product produced or designed by Coagulant Therapeutics is discussed in this manuscript.

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TABLE 3
Final recommendations

Topic of interest	Recommendations
Novel sensors for early detection of PPH	Although many sensors are under investigation, no commercially available technology provides sufficiently accurate estimates of blood loss to justify routine clinical use.
	Further studies should be performed, and the algorithms behind these technologies may be refined to improve test performance in an obstetrical population.
	As obstetrical hemorrhage outcomes depend not only on the actual volume of blood loss or the hemoglobin nadir but also on the patient's response to hemorrhage, alternative endpoints should be considered in such studies.
Application of viscoelastic tests to guide management of PPH	Pregnancy-specific reference ranges should be established for the existing viscoelastic assays.
	Prospective, randomized trials are needed to confirm the clinical use and cost savings associated with this technology.
	If viscoelastic hemostatic assays are used, fibrinogen assessment seems to be more reliable in obstetrical hemorrhage than other viscoelastic parameters.
	In case of heavy bleeding, hypotension, or tachycardia, massive transfusion protocols should be initiated and blood products transfused while awaiting results of further testing. Once available, the results of viscoelastic hemostatic assays may be used to guide transfusion of additional blood products.

PPH, postpartum hemorrhage.

Lord. New technology for postpartum hemorrhage. Am J Obstet Gynecol MFM 2022.

Lord MG et al. AJOG MFM. 2022

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Expert Review

Emerging technology for early detection and management of postpartum hemorrhage to prevent morbidity

Megan G. Lord, MD; Joaquin A. Calderon, MD; Homa K. Ahmadzia, MD, MPH; Luis D. Pacheco, MD, MPH

The scope of the problem

Postpartum hemorrhage (PPH) remains the single leading cause of maternal death worldwide.[1] In the United States, obstetrical hemorrhage is the primary cause of approximately 11% of maternal deaths overall and is the leading cause of maternal death on the day of delivery and in the first week after delivery.[2,3] Severe hemorrhage of ≥1500 mL occurs in 0.4% of deliveries[4] and is life-threatening in approximately 0.1% of deliveries.[5] Blood product transfusion is a major contributor to maternal morbidity.[6] Young, healthy patients compensate for hemorrhage via peripheral vasoconstriction; when volume loss is profound, the resulting hypoperfusion can lead to multiorgan failure, hemorrhagic shock, and pituitary necrosis.[7]

Despite advances in hemorrhage detection and management, postpartum hemorrhage remains the single leading cause of maternal death worldwide. Within the United States, hemorrhage is the leading cause of maternal death on the day of delivery and within the first week after delivery. Blood transfusion after hemorrhage represents a large proportion of severe maternal morbidity during and after delivery. Blood loss during delivery has historically been assessed visually by inspecting soiled pads, linens, and laparotomy sponges. These methods underestimate the volume of blood loss by as much as 40%, becoming increasingly inaccurate as blood loss increases. Young, healthy obstetrical patients compensate for blood loss via peripheral vasoconstriction, maintaining heart rate and blood pressure in a normal range until over 1 L of blood has been lost. A significant decrease in blood pressure along with marked tachycardia (>120 bpm) may not be seen until 30% to 40% of blood volume has been lost, or 2.0 to 2.6 L in a healthy term pregnant patient, after which the patient may rapidly decompensate. In resource-poor settings especially, the narrow window between the emergence of significant vital sign abnormalities and clinical decompensation may prove catastrophic. Once hemorrhage is detected, decisions regarding blood product transfusion are routinely made on the basis of inaccurate estimates of blood loss, placing patients at risk of underresuscitation (increasing the risk of hemorrhagic shock and end-organ damage) or overresuscitation (increasing the risk of transfusion reaction, fluid overload, and alloimmunization). We will review novel technologies that have emerged to assist both in the early and accurate detection of postpartum hemorrhage and in decisions regarding blood product transfusion.

Key words: compensatory reserve, postpartum hemorrhage, postpartum hemorrhage detection, rotational thromboelastometry, thromboelastography, thromboelastometry, viscoelastic hemostasis assays

Early detection of postpartum hemorrhage

The importance of early detection

Although hemorrhage remains a leading cause of maternal death, 70% of maternal deaths from hemorrhage seem to be preventable.[8] Early hemorrhage detection, accurate quantification of blood loss, and early intervention are crucial to improving maternal outcomes[9]—coagulopathy is most likely when the diagnosis of PPH is delayed or the volume of blood loss is underestimated.[10] Protocols have been developed to improve early recognition of PPH

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M.G.L. has no financial conflict of interest. M.G.L. is involved in research on the AccuFlow sensor but has no financial relationship with the makers of that device. The AccuFlow sensor is discussed in this manuscript alongside its major competitors.

J.A.C. has no conflict of interest.

H.K.A.'s research makes use of a rotational thromboelastometry (ROTEM) delta analyzer, which is on loan from the device manufacturer, Instrumentation Laboratory Company, Bedford, Massachusetts. She does not receive any direct funding from the Instrumentation Laboratory Company, and the Instrumentation Laboratory Company is not involved in any way in the design or conduct of her research. The ROTEM delta analyzer is discussed in this manuscript alongside its major commercial competitor (thromboelastography), with equal time spent in the discussion of both products. Furthermore, H.K.A. participated in consulting work for HemoSonics on 1 occasion in the past. No device produced or designed by HemoSonics is discussed in this manuscript.

L.D.P. is part of the medical consultant board of Coagulant Therapeutics. No product produced or designed by Coagulant Therapeutics is discussed in this manuscript.

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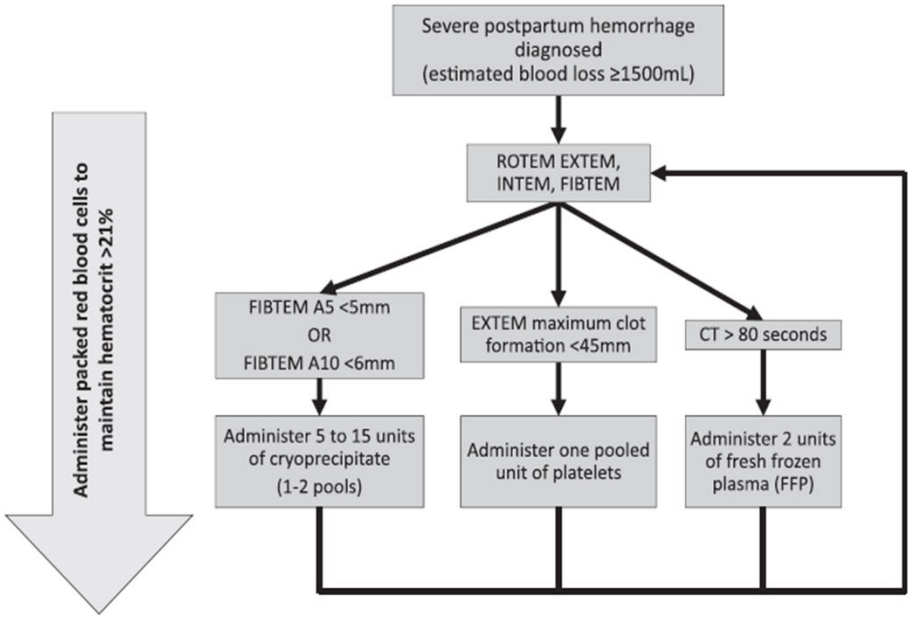
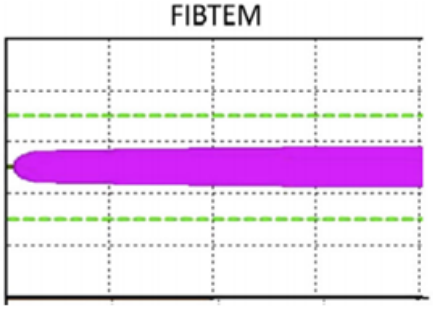
FIGURE 3
Sample protocol for ROTEM-based management of postpartum hemorrhage[4]





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ROTEM data at present

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Review Article

Viscoelastic haemostatic point-of-care assays in the management of postpartum haemorrhage: a narrative review

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Summary

Viscoelastic haemostatic assays provide rapid testing at the bed-side that identify all phases of haemostasis, from initial fibrin formation to clot lysis. In obstetric patients, altered haemostasis is common as pregnancy is associated with coagulation changes that may contribute to bleeding events such as postpartum haemorrhage, as well as thrombosis events. In this narrative review, we examine the potential clinical utility of viscoelastic haemostatic assays in postpartum haemorrhage and consider the current recommendations for their use in obstetric patients. We discuss the clinical benefits associated with the use of viscoelastic haemostatic assays due to the provision of (near) real-time readouts with a short turnaround, coupled with the identification of coagulation defects such as hypofibrinogenaemia. The use of viscoelastic haemostatic assay-guided algorithms may be beneficial to diagnose coagulopathy, predict postpartum haemorrhage, reduce transfusion requirements and monitor fibrinolysis in women with obstetric haemorrhage. Further studies are required to assess whether viscoelastic haemostatic assay-guided treatment improves clinical outcomes, and to confirm the utility of prepartum viscoelastic haemostatic assay measurements for identifying patients at risk of postpartum haemorrhage.

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Introduction

Altered haemostasis is common in obstetric patients as pregnancy is associated with increases in coagulation factors and changes in pro- and anti-fibrinolytic factors [1–3]. Haemostatic assessment is vital for identifying and correcting major haemostatic abnormalities that can contribute to events such as postpartum haemorrhage (PPH) [4]. The timely identification of coagulopathy is paramount as obstetric haemorrhage is the leading cause of maternal mortality, accounting for 27% of the 295,000 maternal deaths reported worldwide [5].

Laboratory processing times for 'standard' coagulation tests can be long, which may hinder the detection of coagulopathy in actively bleeding patients [6–8], and are often too slow to be clinically relevant in acute/rapidly evolving bleeding events [8–10]. Such traditional coagulation tests are based on indirect measurements, capturing the 'past' rather than the 'current' haemostatic picture [11] and since coagulation disturbance may occur rapidly after severe PPH, laboratory test results may not provide timely maternal haemostatic data [12–15]. Alternatively, whole blood viscoelastic haemostatic assays

Table 2 Guidelines for the use of viscoelastic haemostatic assays (VHA) in obstetrics.

Recommendations for the use of VHAs in obstetrics	
Network for the Advancement of Patient Blood Management, Haemostasis and Thrombosis in collaboration with the International Federation of Gynaecology and Obstetrics, the European Board and College of Obstetrics and Gynaecology, and the European Society of Anaesthesiology [75]	• Assess haemostatic competence and risk of coagulopathy in severe ongoing PPH through laboratory tests or viscoelastic haemostatic tests to guide appropriate, goal-directed use of haemostatic blood components and pro-haemostatic agents (Grade 1B) • Fibrinogen levels should be monitored early in severe ongoing PPH to consider cryoprecipitate or fibrinogen concentrate substitution at a plasma level < 2 $g.l^{-1}$ or FIBTEM A5 < 12 mm (Grade 1C) • Transfuse a standard dose of plasma (15–20 $ml.kg^{-1}$) in severe ongoing PPH guided by abnormalities in coagulation tests (prothrombin time, INR and/or APTT > 1.5 times normal or R prolongation in TEG or CT prolongation in ROTEM) (Grade 2C) • Transfusing a standard dose of platelets (5–10 $ml.kg^{-1}$) in severe ongoing PPH guided by abnormalities in laboratory tests (e.g. platelet count < 75 × $10^9.l^{-1}$, reduced clot strength related to impaired platelet function as measured by TEG or ROTEM, or reduced platelet function as measured by a platelet function test) (Grade 1C)
Position of the French Working Group on Peri-operative Haemostasis on viscoelastic testing [76]	• Fibrinogen concentration should be rapidly evaluated in the event of PPH, and VHAs may be useful in this regard • Given the limitations of VHAs in evaluating fibrinolytic activity, it is proposed not to guide the administration of tranexamic acid on VHAs but to administer it as soon as possible in the event of PPH
Society for the Advancement of Blood Management administrative and clinical standards for patient blood management programs [77]	• Robust diagnostic coagulation testing must be available within a clinically useful time frame and include a means to assess both quantitative and qualitative platelet or plasma coagulation factor abnormalities • In some cases, near-patient or point-of-care coagulation testing may provide the best combination of clinical utility and timeliness • Viscoelastic whole blood coagulation testing such as thromboelastography or rotation thromboelastometry should be considered in the setting of traumatic haemorrhage, organ transplantation, obstetrical haemorrhage and cardiovascular surgery
Use of viscoelastic haemostatic assays in the management of major bleeding; British Society for Haematology [16]	• Viscoelastic haemostatic assays are not usually helpful for predicting postpartum haemorrhage when taken during labour in a non-bleeding pregnant woman (Grade 2C) • Viscoelastic haemostatic assays may be used as part of an agreed algorithm to manage postpartum haemorrhage when the local institution's major obstetric haemorrhage protocol is activated (Grade 2C) • During ongoing major postpartum haemorrhage, if the FIBTEM A5 is > 12 mm, fibrinogen replacement is unlikely to improve clinical haemostasis (Grade 2B) • During major postpartum haemorrhage, if FIBTEM A5 is < 7 mm, or < 12 mm with ongoing bleeding, fibrinogen replacement may improve clinical haemostasis (Grade 2C) • In a bleeding pregnant or postpartum patient, tranexamic acid should not be withheld based on TEG or ROTEM parameters (Grade 1B)
Prevention and management of postpartum haemorrhage; Royal College of Obstetricians and Gynaecologists [13]	• Laboratory or near-patient testing leads to the appropriate use of blood components (Evidence level 3) • Coagulopathies may evolve rapidly, and repeated testing (such as every 30 min) during continued bleeding and observation of trends are more useful than single measurements (Evidence level 3) • Viscoelastic haemostatic assays combined with an agreed treatment algorithm have been associated with decreased blood loss and blood product use (Evidence level 4)
American Society of Anesthesiologists; guidelines for peri-operative blood management (including obstetric	• If coagulopathy is suspected, obtain viscoelastic assays (e.g. TEG and ROTEM), when available, as well as platelet count. They both strongly agree that if viscoelastic assays are not available, obtain standard coagulation tests (e.g. INR, APTT, fibrinogen concentration), as well as platelet count for monitoring
Guidelines for obstetric anaesthetic services; Association of Anaesthetists/ Obstetric Anaesthetists' Association [78]	• Strongly recommended that there should be equipment to enable bed-side estimation of coagulation such as TEG or ROTEM

A5, amplitude at 5 min; APTT, activated partial prothrombin time; CT, clotting time; FIBTEM, fibrin-based thromboelastometry; INR, international normalised ratio; PPH, postpartum haemorrhage; ROTEM, rotational thromboelastometry; TEG, thromboelastography.

Dias JD et al. Anesthesia. 2022

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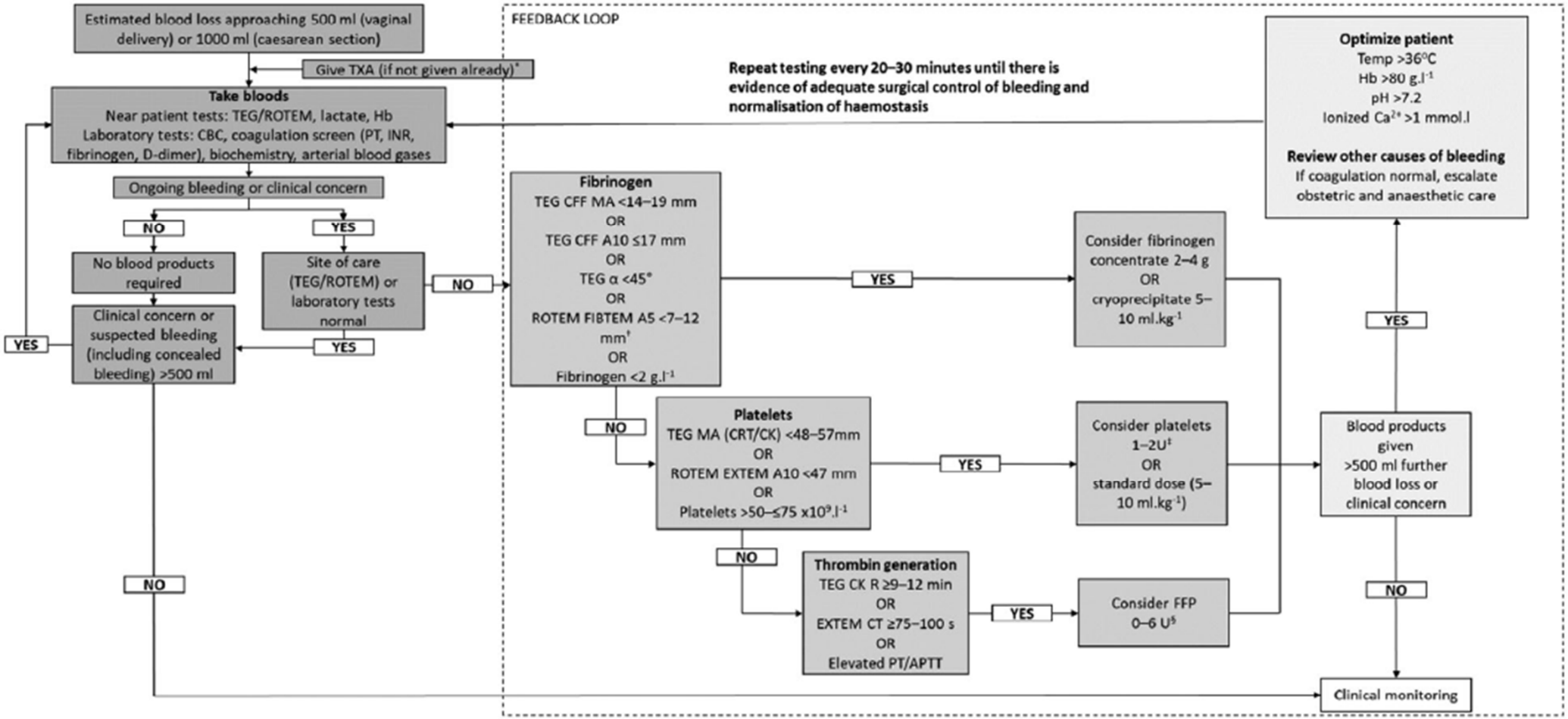
ROTEM data at present…but the algorithms differ depending on institution (and require accurate interpretation)



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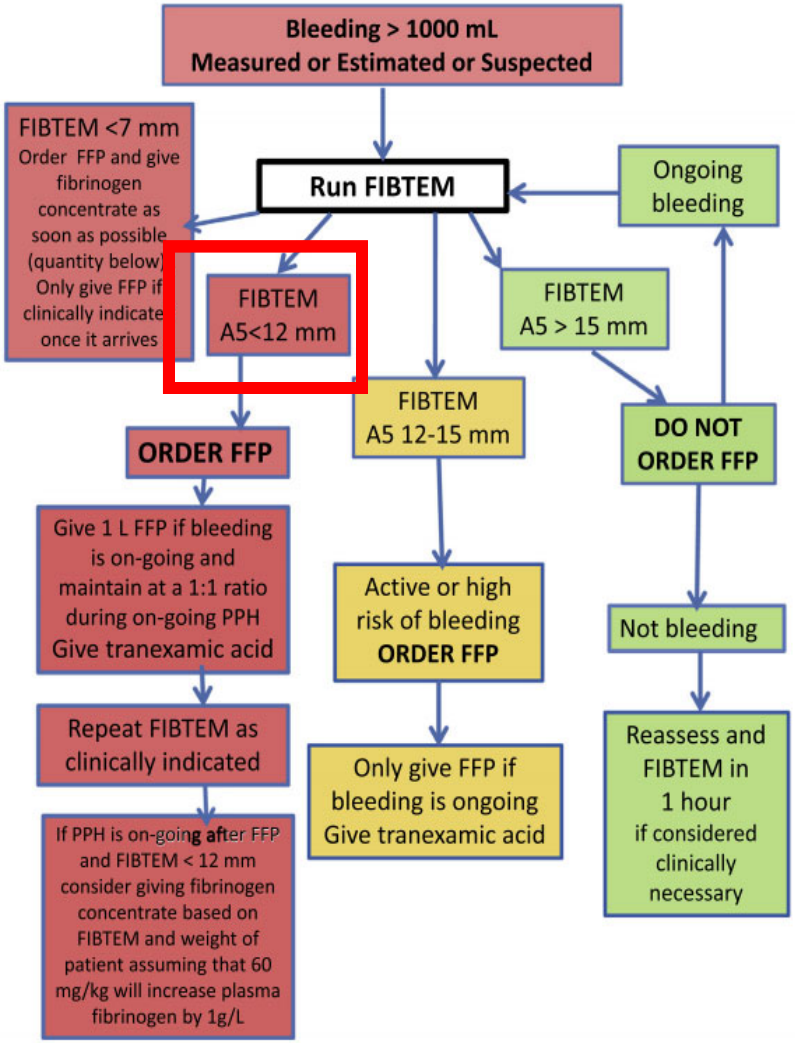
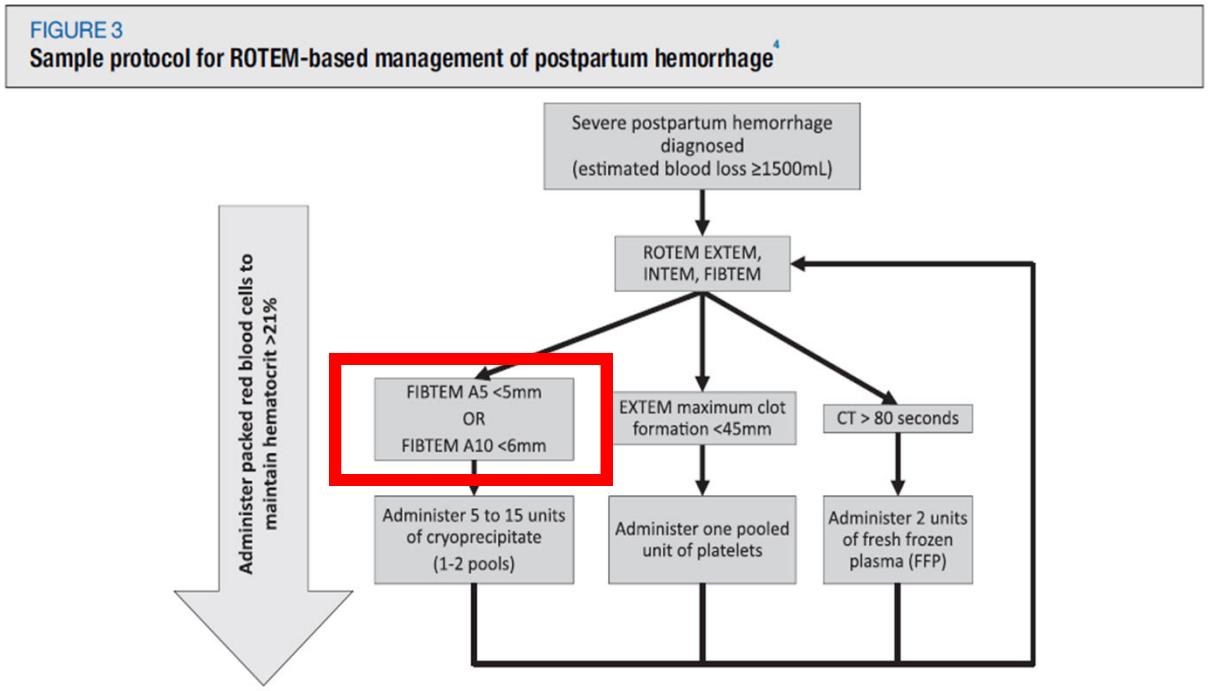


Collins PW et al. Int J Ob Anes. 2019



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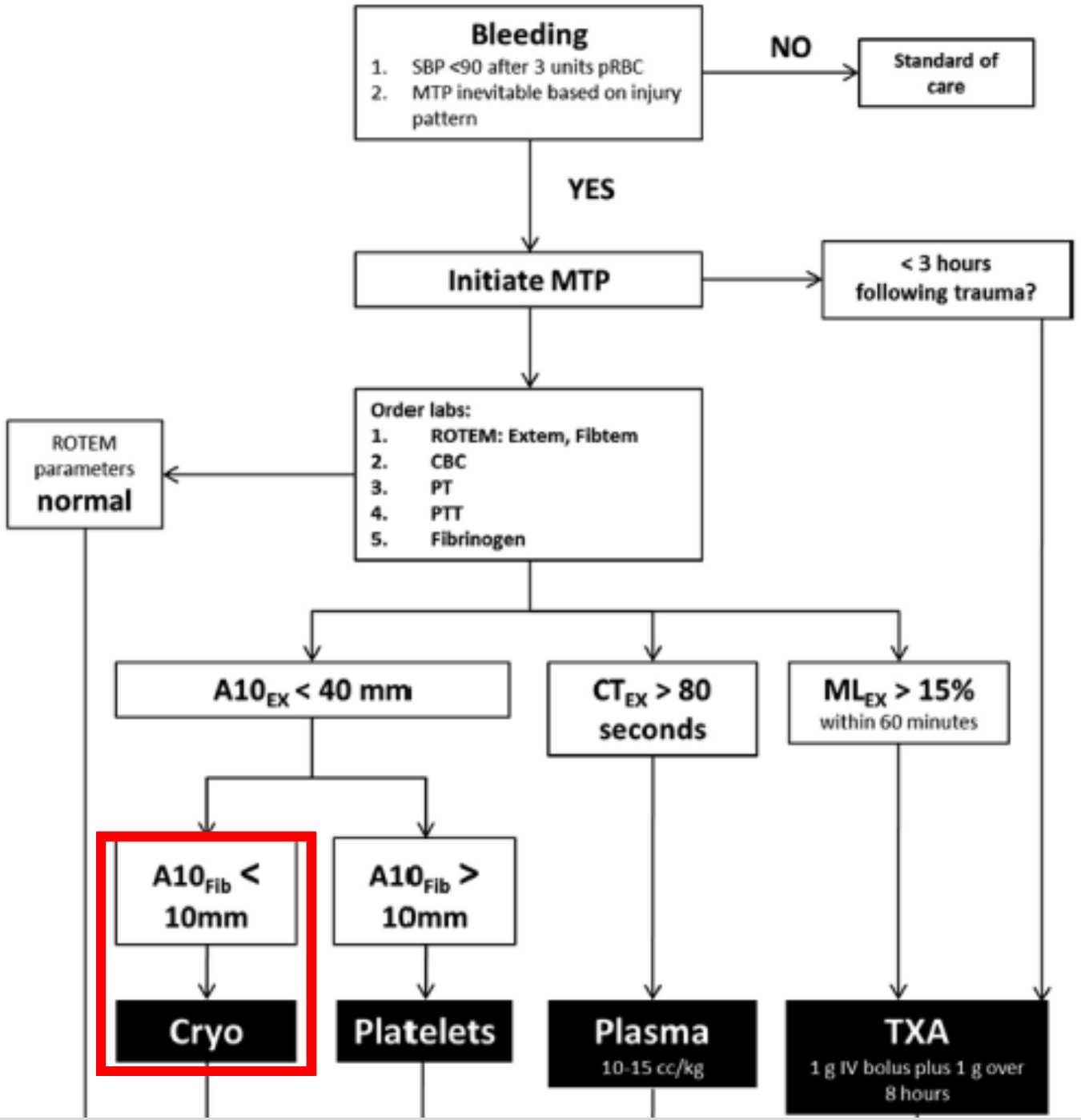
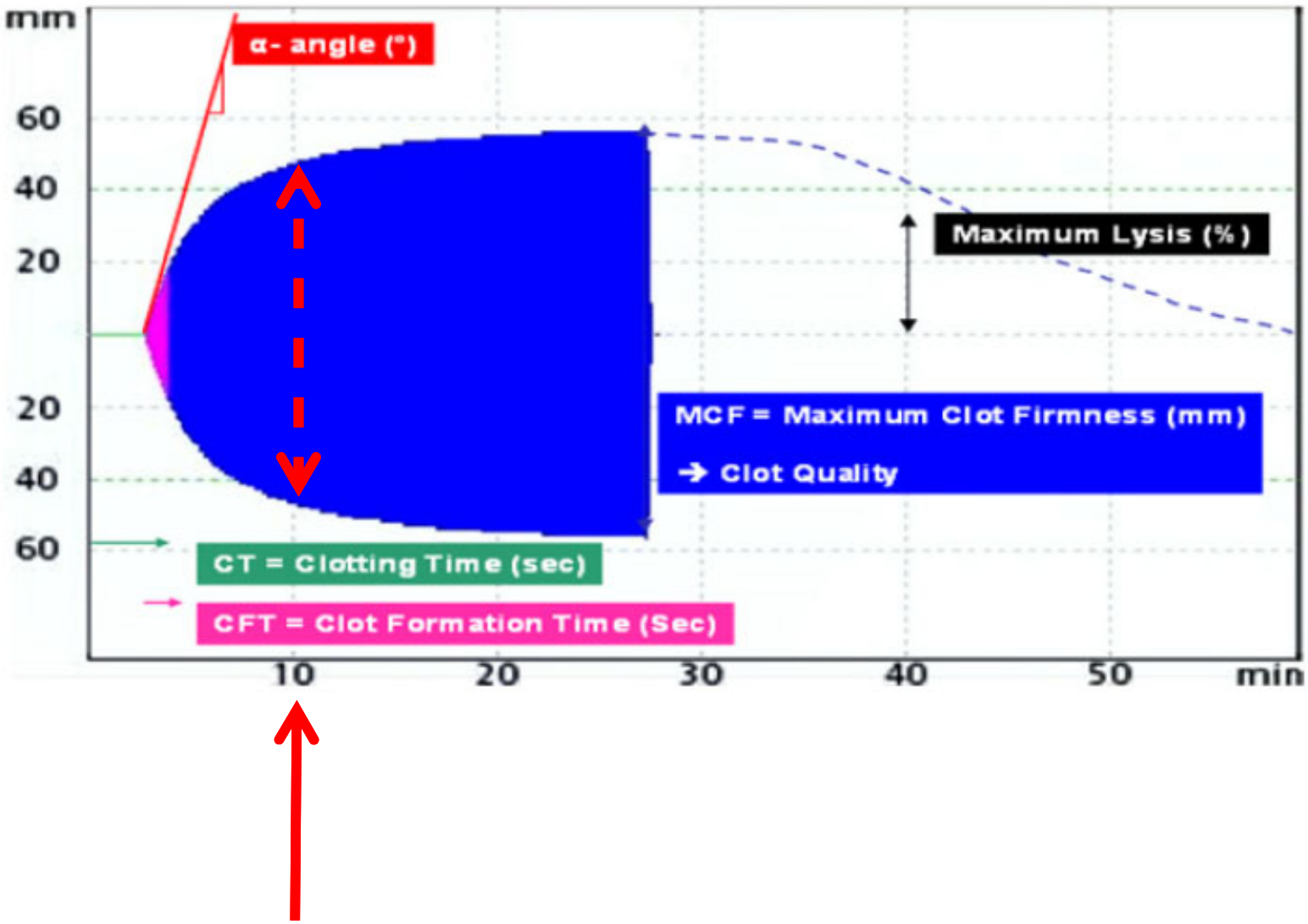
Parkland Trauma Algorithm



Rotem Curve and Parameters



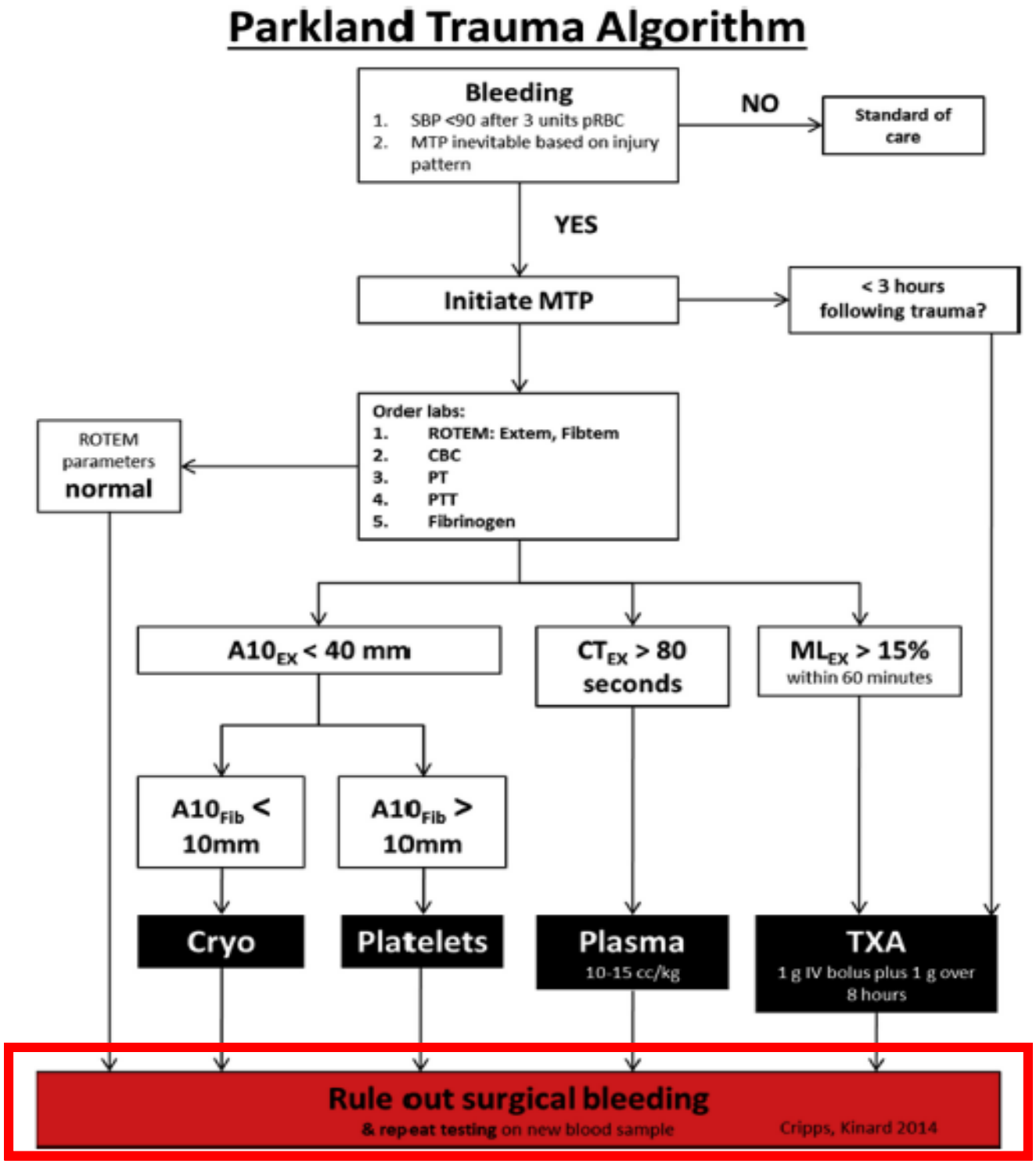


Fig. 3. Parkland Memorial Hospital Algorithm for ROTEM guided transfusions in trauma.

Do we ROTEM???

- Viscoelastic hematologic testing may show promise…

- Risk of misinterpretation when used by inadequately trained personnel

- Limited data in obstetric population and in the management of hemorrhage but literature is accumulating, especially in European and Anesthesia literature (FIBTEM may be used as early marker)
  - –Obesity
  - –Gestational hypertension and preeclampsia

ROTEM measured across BMI, HELLP, and Preeclampsia

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Baseline rotational thromboelastometry (ROTEM) values in a healthy, diverse obstetric population and parameter changes by pregnancy-induced comorbidities

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ABSTRACT

Background: Point-of-care testing provides a representation of the patient's coagulability status during effective postpartum hemorrhage management. Baseline values of rotational thromboelastometry (ROTEM) have not yet been reported in a heterogeneous obstetric population. This study aimed to establish a baseline for a diverse population representative of the United States. The secondary aim was to evaluate the association of these hematologic parameters with comorbidities, race, and socioeconomic factors.

Methods: The study was a retrospective review of collected ROTEM values of women undergoing vaginal or cesarean delivery with a history of or at risk for postpartum hemorrhage. Patients were divided into healthy and comorbid groups. Exclusion criteria for both groups included active or recent bleeding, receipt of blood products or clot-enhancing factors, and liver disease. Mean values of ROTEM by race and comorbidities were included. Median values were reported for intrinsic pathway thromboelastometry (INTEM), extrinsic pathway thromboelastometry (EXTEM), and fibrin polymerization thromboelastometry (FIBTEM) amplitude at 10 minutes (A10) and 20 minutes (A20), coagulation time, clot formation time, and maximum clot firmness.

Results: A total of 681 records were reviewed; 485 met inclusion criteria, and 267 met healthy criteria. The mean (standard deviation) demographics for maternal age (years), body mass index (kg/m^2), and gestational age (weeks) were 32.2 (5.7), 34 (7.3), and 35.4 (5), respectively. The median INTEM, EXTEM, and FIBTEM A10 were 63, 65, and 23 mm. The mean for INTEM, EXTEM, and FIBTEM A10 was increased for those who were Black or obese, whereas a decreased FIBTEM and EXTEM A10 was noted in those who were Asian or those who had the hemolysis, elevated liver enzymes, low platelet syndrome.

Conclusions: Our heterogeneous population presents ROTEM values within the interquartile range of those previously reported in European studies. Black race, obesity, and preeclampsia were associated with hypercoagulable profiles.

KEYWORDS HELLP syndrome; hypercoagulability; point-of-care viscoelastic testing; rotational thromboelastometry

Postpartum hemorrhage remains a worldwide leading cause of maternal morbidity and mortality.[1] Decades of research have identified fibrinogen as an early biomarker to predict postpartum hemorrhage (PPH). A plasma fibrinogen level ≤2 g has been shown to have a 100% predictive value for progression to severe PPH.[2–5] Hence, early recognition and replacement of this factor is critical for PPH management.[3–7] Over the last decade, obstetric anesthesiologists have relied on fibrinogen values to indicate an increased risk, and thus preparation, for bleeding.[2,3,5,8] For each 1 g/L decrease in fibrinogen, the odds ratio for PPH was 2.63 (1.66–4.16; $P < 0.0001$).[2] With the emphasis on early recognition, some experts have scrutinized the efficiency of the laboratory Clauss fibrinogen, which can have a turnaround of 45 to 60 minutes.[9] Clinically, the inability of early recognition may result in

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Parameters	BMI (n) ≤35 (308)	BMI (n) >35 (178)	*P* value	HELLP (n) Yes (24)	HELLP (n) No (461)	*P* value	Preeclampsia (n) Yes (87)	Preeclampsia (n) No (398)	*P* value
FIBTEM									
CT	57.1 (16.0)	59.1 (15.4)	0.20	54.7 (10.1)	58.0 (16.0)	0.13	61.8 (28.3)	57.0 (11.3)	0.12
Alpha angle	74.8 (4.8)	76.6 (4.4)	<0.001	74.6 (4.8)	75.5 (4.7)	0.35	75.9 (5.7)	75.4 (4.5)	0.46
MCF	24.8 (6.3)	27.7 (6.6)	<0.001	24.9 (8.4)	25.9 (6.4)	0.54	27.5 (7.3)	25.5 (6.3)	0.022
A10	22.6 (5.6)	25.5 (5.7)	<0.001	21.8 (6.2)	23.7 (5.8)	0.12	24.9 (6.3)	23.4 (5.6)	0.035
A20	24.2 (5.8)	27.4 (6.3)	<0.001	23.6 (7.1)	25.4 (6.1)	0.24	26.9 (7.0)	25.0 (5.9)	0.025
EXTEM									
CT	61.6 (21.8)	63.8 (37.0)	0.46	59.0 (9.3)	62.6 (29.0)	0.13	66.5 (40.5)	61.5 (24.9)	0.28
CFT	74.3 (26.1)	68.0 (33.4)	0.032	104.7 (55.1)	70.2 (26.1)	0.002	73.5 (31.1)	71.6 (28.7)	0.61
Alpha angle	76.0 (3.6)	77.2 (5.0)	0.004	74.4 (5.3)	76.5 (4.1)	0.046	76.3 (4.9)	76.4 (4.0)	0.86
MCF	69.9 (5.7)	70.9 (7.6)	0.11	63.4 (8.4)	70.6 (6.2)	<0.001	70.0 (6.5)	70.3 (6.5)	0.62
A10	62.6 (7.0)	64.7 (7.8)	0.003	55.0 (10.1)	63.8 (6.9)	<0.001	63.1 (8.4)	63.4 (7.1)	0.77
A20	68.5 (6.2)	70.5 (5.9)	<0.001	62.3 (9.8)	69.6 (5.7)	<0.001	68.6 (7.2)	69.4 (5.9)	0.36
INTEM									
CT	165.0 (39.0)	161.8 (38.4)	0.39	159.2 (31.8)	164.1 (39.1)	0.46	168.3 (45.2)	162.8 (37.2)	0.30
CFT	70.5 (30.5)	67.6 (34.7)	0.36	98.4 (44.7)	67.9 (30.6)	<0.001	70.0 (29.8)	69.3 (32.6)	0.86
Alpha angle	76.2 (4.6)	77.0 (4.9)	0.051	73.5 (5.1)	76.6 (4.7)	0.003	76.7 (4.2)	76.4 (4.8)	0.69
MCF	67.8 (6.2)	68.9 (8.4)	0.11	61.8 (8.0)	68.5 (6.9)	<0.001	68.5 (6.9)	68.1 (7.2)	0.71
A10	60.8 (7.3)	62.6 (8.3)	0.014	53.4 (9.2)	61.9 (7.4)	<0.001	61.3 (8.2)	61.5 (7.7)	0.86
A20	66.9 (6.6)	68.3 (7.3)	0.035	60.5 (8.7)	67.8 (6.6)	<0.001	67.1 (7.4)	67.5 (6.8)	0.73

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Do we ROTEM???

- Point-of-care test may show promise…
- Risk of misinterpretation when used by inadequately trained personnel
- Limited data in obstetric population and in the management of hemorrhage

Most importantly:

YOU MUST RULE OUT SURGICAL BLEEEDING!!!

That is, ROTEM should not be used in the setting of audible blood loss!!!

More data coming for "point of care"
ROTEM sigma and TEG 6s

Original Research

Comparative retrospective study on the validity of point-of-care testing device for massive obstetrical hemorrhage: dry hematology vs thromboelastography

Eishin Nakamura, MD; Shigetaka Matsunaga, PhD; Akihiko Kikuchi, PhD; Yasushi Takai, PhD

BACKGROUND: Early recognition of hypofibrinogenemia and prompt initiation of transfusion therapy in patients with massive obstetrical hemorrhage can improve prognosis. There are reports on the usefulness of point-of-care testing, which provides quicker test results compared with fibrinogen measurements using the conventional Clauss method.
OBJECTIVE: This study aimed to compare and investigate the diagnostic accuracy of dry hematology and thromboelastography in point-of-care testing for the diagnosis of hypofibrinogenemia.
STUDY DESIGN: A single-center, retrospective study of 126 massive obstetrical hemorrhage cases with point-of-care testing before treatment was initiated. The correlation of fibrinogen values with the Clauss method and the diagnostic accuracy for hypofibrinogenemia were compared between dry hematology and thromboelastography.
RESULTS: Fibrinogen value in dry hematology showed a strong positive correlation with values measured by the Clauss method, and the diagnostic accuracy for hypofibrinogenemia was high, but there were many residuals above 100 mg/dL, and the distribution of these residuals was not uniform. Although thromboelastography cannot be used to directly measure fibrinogen values, maximum amplitude citrated functional fibrinogen, amplitude-10 citrated rapid thromboelastography, and amplitude-10 citrated functional fibrinogen showed a strong positive correlation with fibrinogen values using the Clauss method, and no significant difference in correlation or diagnostic accuracy was observed relative to dry hematology.
CONCLUSION: Dry hematology and thromboelastography were equally accurate in diagnosing hypofibrinogenemia, with results correlating well with fibrinogen values measured by the Clauss method.

Key words: hypofibrinogenemia, point-of-care testing, postpartum hemorrhage, uterine hemorrhage

Introduction

Massive obstetrical hemorrhage (MOH) is a life-threatening condition and one of the leading causes of maternal death.[1] MOH often presents with coagulopathy, especially when fibrinogen initially falls below the hemostatic threshold and requires high-dose coagulation factor replacement. Because blood fibrinogen levels correlate with the severity of MOH,[2] it is important to diagnose hypofibrinogenemia early and initiate appropriate coagulation factor replacement. In recent years, point-of-care testing (POCT), a rapid and simple measurement of blood coagulation function, has attracted attention, and there have been many reports on its clinical effectiveness in the field of obstetrics.[3,4] The CG02N whole blood coagulation analyzer (A&T Corporation, Kanagawa, Japan) can rapidly and quantitatively measure fibrinogen levels, whereas TEG 6s (Haemonetics Corporation, Braintree, MA) does not directly measure fibrinogen levels but performs a comprehensive evaluation of coagulation and hemostatic function, including the influence of platelets, using whole blood. TEG 6s can measure the viscoelasticity of blood clots using various reagents simultaneously, resonating the clots and expressing their amplitudes graphically. ROTEM (Pentapharm GmbH, Munich, Germany), which is based on the principle of thromboelastometry, is also widely used in daily clinical practice and its use has been reported in many cases.[3] The measurement principles of thromboelastography and thromboelastometry are generally the same, with the only difference being the pins and cups of the testing equipment. Our medical institution uses the CP3000 (Sekisui Medical Co, Ltd, Tokyo, Japan), which measures fibrinogen using the Clauss method for the definitive diagnosis of hypofibrinogenemia, but it has drawbacks such as a long examination time, large size, and high cost of the device for installation in a primary medical institution. The aforementioned POCT equipment enables testing in a short time and at low cost, and test results are reported to correlate well with fibrinogen levels in conventional blood testing.[5] Because POCT devices can quickly and easily assess blood coagulation activity, there have been many reports of their use in the field of emergency medicine, such as trauma[6] and cardiac surgery,[7] and some reports of use for MOH.[8] However, studies comparing the usefulness of each POCT instrument in treating MOH are scarce, and no studies have compared the usefulness of dry hematology and thromboelastography. Therefore, we retrospectively examined the diagnostic accuracy of POCT (dry-hematology, thromboelastography, or both) in MOH cases seen at our institution in correlation with fibrinogen levels measured by the Clauss method to detect hypofibrinogenemia (≤150 mg/dL, ≤200 mg/dL), which is particularly important in MOH. In addition, Bland–Altman plots were used to measure the residuals

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TABLE 3
Area under the curve values using receiver operating characteristic curves for hypofibrinogenemia of ≤150 mg/dL and ≤200 mg/dL

Group		AUC value for fibrinogen ≤150 mg/dL	95% CI	AUC value for fibrinogen ≤200 mg/dL	95% CI	Correlation coefficient for fibrinogen values by Clauss method
Analysis 1 (measured by CG02N)	Fibrinogen measured by CG02N	0.969	(0.925–1.000)	0.881	(0.798–0.963)	0.794
Analysis 2 (measured by TEG 6S)	MA-CFF (mm)	0.936	(0.837–1.000)	0.940	(0.851–1.000)	0.74
	A-10 CRT (mm)	0.987	(0.952–1.000)	0.920	(0.822–1.000)	0.57
	A-10 CFF (mm)	0.962	(0.891–1.000)	0.946	(0.838–1.000)	0.67

Analysis 1 and Analysis 2 show correlation coefficients between fibrinogen values determined by the Clauss method and each item in TEG 6s.

A-10 CFF, amplitude-10 citrated functional fibrinogen; *A-10 CRT*, amplitude-10 citrated rapid thromboelastography; *AUC*, area under the curve; *CI*, confidence interval; *MA-CFF*, maximum amplitude citrated functional fibrinogen.

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TABLE 4
Area under the curve values using receiver operating characteristic curve for hypofibrinogenemia at ≤150 mg/dL and ≤200 mg/dL

Group		AUC value for fibrinogen ≤150 mg/dL	95% CI	*P* value[a]	AUC value for fibrinogen ≤200 mg/dL	95% CI	*P* value[a]	Correlation coefficient for fibrinogen values by Clauss method
Fibrinogen measured by: CG02N (mg/dL)		0.961	(0.882–1.000)	—	0.949	(0.878–1.000)	—	0.91
TEG 6s	MA-CFF (mm)	0.952	(0.885– 1.000)	.758	0.933	(0.835–1.000)	.777	0.87
	A-10 CRT (mm)	0.942	(0.854–1.000)	.325	0.961	(0.903–1.000)	.726	0.87
	A-10 CFF (mm)	0.961	(0.882–1.000)	1	0.957	(0.897–1.000)	.795	0.91

Analysis 3 and comparison with AUC values of CG02N for hypofibrinogenemia were done using Clauss method correlation coefficients between fibrinogen values and each item.

A-10 CFF, amplitude-10 citrated functional fibrinogen; *A-10 CRT*, amplitude-10 citrated rapid thromboelastography; *AUC*, area under the curve; *CI*, confidence interval; *MA-CFF*, maximum amplitude citrated functional fibrinogen.

[a] *P* value of *t*-test comparing CG02N against AUC values for hypofibrinogenemia.

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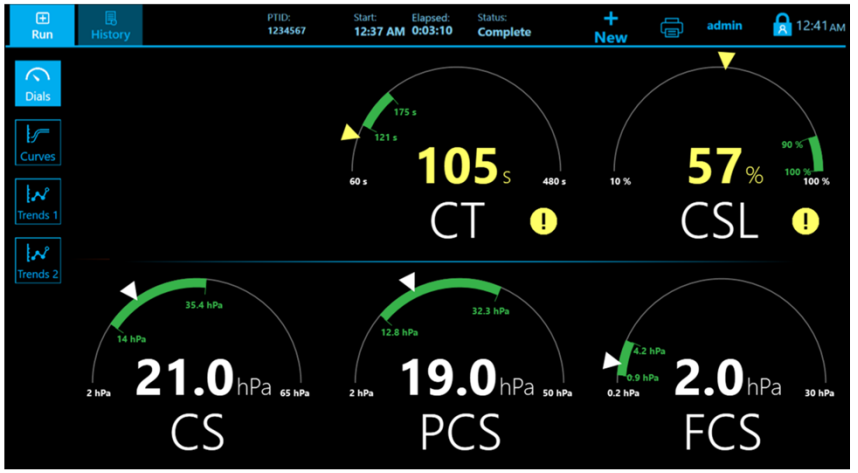

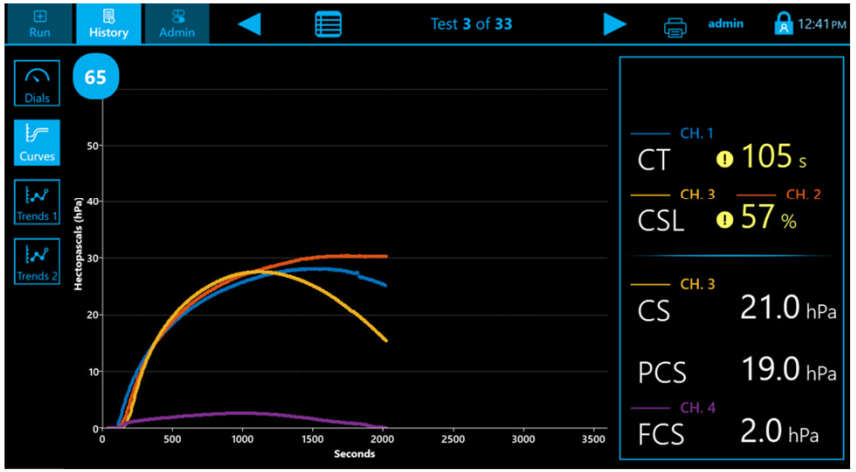

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Conclusions

- Transfusion remains the leading component of SMM
- Standardized response to obstetric hemorrhage should be encouraged—use of checklists and simulation offer great promise to mitigate adverse outcomes
- Recall physiologic changes of pregnancy and the impact on hematologic parameters
- ROTEM offers a unique perspective in the response to bleeding but does not currently substitute for volume resuscitation

Clinical “pearls”

- “Normal” referent ranges for most laboratory analytes registered within electronic medical records are often for non-pregnant values

- Multidisciplinary care is paramount

Thank you!

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