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XXVIII CONGRESSO NAZIONALE

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MZ EVENTS

PALERMO 5-7 Ottobre
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Shock emorragico

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BJOG An International Journal of Obstetrics and Gynaecology
Royal College of Obstetricians & Gynaecologists

Review Article

The prevention and treatment of postpartum haemorrhage: what do we know, and where do we go to next?

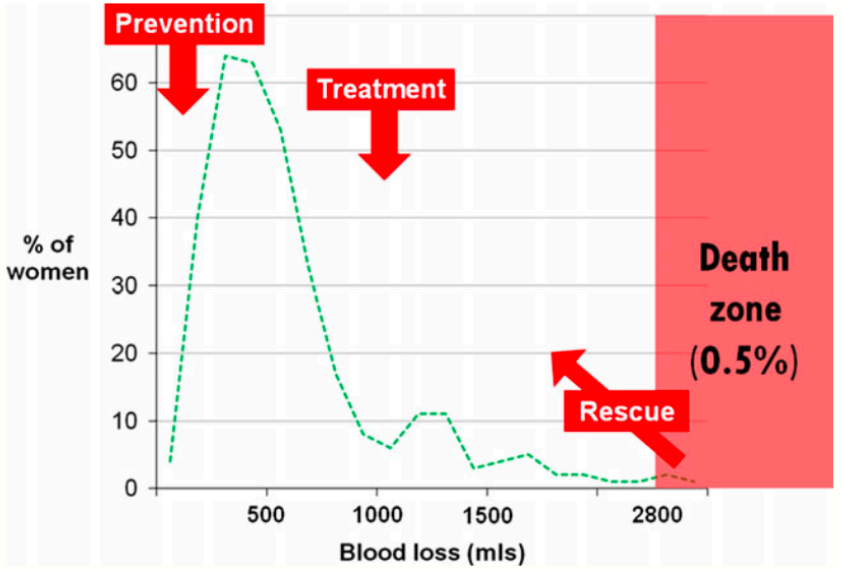
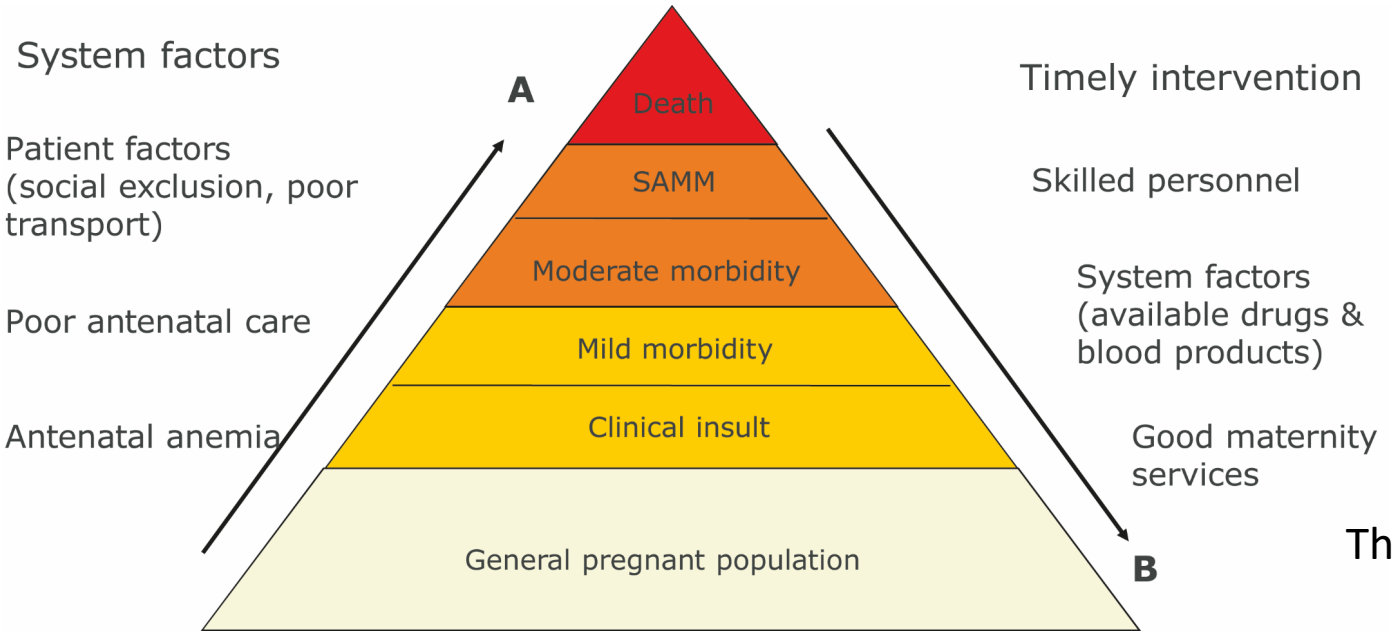


Figure 1. Histogram of blood loss at delivery showing the death zone at a loss of over 40% blood volume, and the three strategies for intervention. The data were adapted from Hoj,[58] with corrections to the published data. The Diagram is from Weeks.[59]

Postpartum Haemorrhage (PPH) remains the most common cause of maternal mortality worldwide.

It is responsible for around 30% of maternal deaths, equivalent to 86000 deaths per year annually or ten deaths every hour

SEVERE ACUTE MATERNAL MORBIDITY (SAMM)



The WHO defines *near miss* as the case of a woman allegedly died but survived complications arising during pregnancy, childbirth or within 42 days of termination of pregnancy

Geller SE Am J Obstet Gynecol 2004;191:939-44

SEVERE ACUTE MATERNAL MORBIDITY (SAMM)

- PPH>1500 ml
- Decreased in peripartum hemoglobin concentration ≥ 4 g/dl
- Acute transfusion ≥ 4 units of blood
- DIC o shock
- Need for additional non-obstetric procedures (interventional radiology/hysterectomy/laparotomy)
- Blood loss leading to the compromisson of vital organs
- Admission to intensive care

SHOCK EMORRAGICO

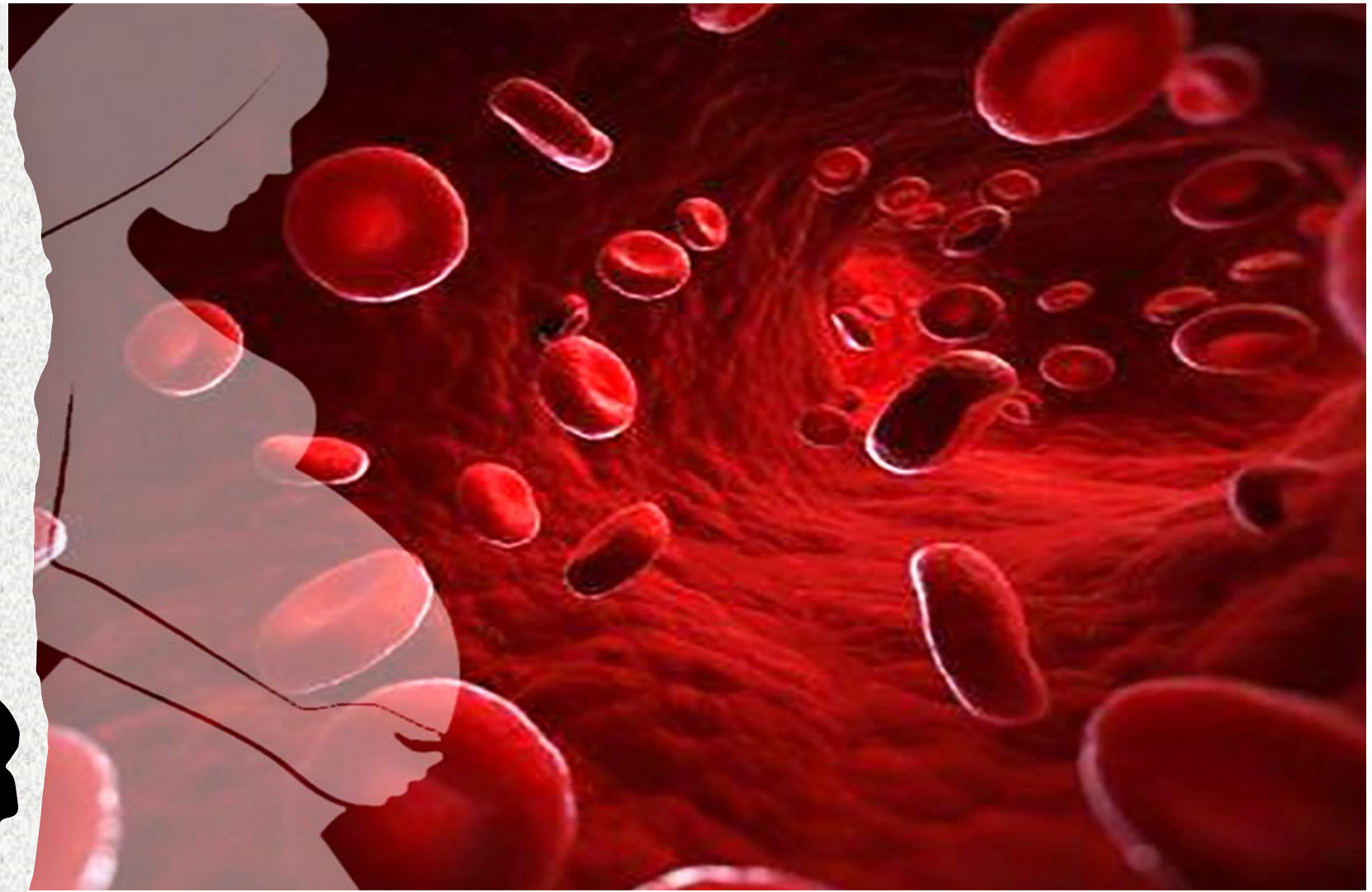
Tissue hypoperfusion resulting from an acute and prolonged decrease in circulating blood volume

DETERMINANTS OF GRAVITY

- The rate at which the bleeding develops
- The consistency of the volume of blood lost
- The efficency of compensatory mechanisms
- The possibility of controlling the haemostasis

Do too little too late

Cantwel,2011



«Golden hour»

CONTINUOUS REVALUATION

1. Recognize etiological causes
2. Maintain uterine contractility with physical/pharmacological means
3. Obtain and maintain blood volume (Oxygen transport capacity)
4. Prevent/treat coagulopathy and transfer to the operating room

HOW LONG DO WE HAVE?

It is estimated that in the absence of treatment the exitus occurs within:

2 hours in postpartum hemmorrhage

ISS SNLG, RCOG, AOGOI

Failure to identify and Prepare the patient with risk factors

Delay in treatment due to underestimation of blood loss

Inattention regarding the modification of vital signs

Symptomatic treatment of haemmorrhage failure of etiologic identification

Delay in the identification of the limit between physiology and criticality

Delay in the availability of blood products

Delay in laboratory diagnostics

Lack of a treatment algorithm

Insufficient Competence and training

Ineffective Interdisciplinary communication

Inadequate organization

The most common errors in the management of PPH

PBM

Pregnancy	Delivery	Postpartum
Screening for iron deficiency and anemia Treatment according to trimester and severity	Transfusion and coagulation algorithm Point-of-care diagnostics	Screening and treatment of iron deficiency and anemia, where clinically indicated
Screening and treatment of coagulation disorders Measurement of fibrinogen in late pregnancy	Cell saver	Close monitoring of blood loss
	Rational, restrictive use of allogenic blood products	

Transfusion Medicine and Hemotherapy 2023, Patient blood management in pregnancy, Kaserer A et al
Arch Gynecol Obstet. 2019 Nov 14. Patient blood management (PBM) in pregnancy and childbirth: literature review and expert opinion Surbek D et al

Low Risk	Medium Risk	High Risk
No previous uterine incision	Prior cesarean birth(s) or uterine surgery	**Placenta previa**
Singleton pregnancy	Multiple gestation	**Suspected placenta accreta or percreta**
≤4 previous vaginal births	>4 previous vaginal births	**Ht <30 and other risk factors**
No know bleeding disorder	Chorioamnionitis	**Plt <100.000**
No history of PPH	History of PPH	**Active bleeding (greater than show) on admit**
	Large uterine fibroids	**Know coagulopathy**
	Estimated fetal >4Kg	**Hb <10gr/dl**
	Morbid obesity (BMI> 35)	

Ossigeno

RISK IDENTIFICATION

The PPH can occur in any pregnancy and most women with PPH (61%) have no risk factors other than maternal age and c-section

Bateman BT, Berman MF, Riley LE, Leffert LR (2010) The epidemiology of postpartum hemorrhage in a large, nation wide sample of deliveries. Anesth Analg

Dilla A.J. et al. ***Clinical validation of risk statification criteria for peripartum hemorrhage****. Obstet Gynecol 2013;122:120-6*

…but also

Presence of additional risk factors during labor:

Prolonged second stade (>4 hours)
Prolonged labor (with or without oxytocin)
Use of oxytocin
Labor /birt hasty
Therapy with MgSO4

….if one of these conditions is present:

The risk level moves to the next one: low…..medium….high

Dilla A.J. et al. Clinical validation of risk statification criteria for peripartum hemorrhage Obstet Gynecol 2013; 122: 120-6

4T'

TONUS 70%

- Uterine anomalies
- Previous history of PPH
- Uterine Atony
- Uterine Infections
- Use of oxytocin for induction
- Stop/descent PP
- Fast/prolonged labor

TRAUMA 20%

- Instrumental birth
- Laceration of the cervix, Vagina and perineum
- Uterine rupture or inversion

TISSUE 10%

- Retention of placenta
- Abnormalities of the placentation

TROMBIN 1%

- Anticoagulant Therapy
- Congenital and acquired coagulation abnormalities
- DIC
- MEF
- ELA

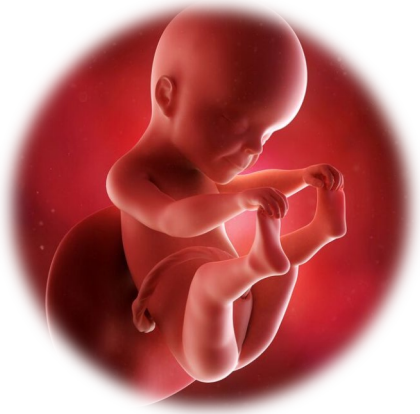
OTHER CAUSES

Non evident hemorrhage:hemoperitoneum, Spleen/liver rupture)

PLETHORA GRAVIDARUM: protective hypervolemia

- The cardiac output increases from 30% to 50% starting with the 6°week
- The total blood volume increases in proportion to the cardiac output, but the increase in plasma volume is greater with respect to the mass of red blood cells

- ☐ The plasma volume increases by 48% equal to 1250 ml
- ☐ The eritrocitaria mass increases by 18% equal to 250 ml
- ☐ The hematocrit is reduced from 40% to 33%
- ☐ Hemoglobin is reduced by diluition (from 13.3 to approximately 12.1 g/dl)



Reduction of blood viscocity which improves placental perfusion by promoting maternal fetal exchanges of gas and nutrients

The pregnant woman is physiologically different

"Seeing is not believing - it is only seeing."

George MacDonald,
The Princess and the Goblin

- Not all bleeding is visible
- The visual estimate underestimates by about 30-50%
- Quantifying blood loss (QBL) is signifucantly more accurate than EBL (Estimated Blood Loss)
- QBL reduces the risk of underestimation and delay in treatment
- Simulation can improve EBL's visual ability but that ability deteriorates within 9 months

QUANTIFYING IS BETTER THAN ESTIMATING

HOW TO MEASURE THE QBL

Measuring the loss of fluids and blood using graduated bags and/or weigh
The gauze soaked in blood and clots

Measure the loss before and after the birth

1 gram = 1 milliliter of blood

	CLASS 1 Compensated	CLASS 2 Mild	CLASS 3 Moderate	CLASS 4 Severe
BLOOD LOSS (%)	**(10-15%)**	**(15-25%)**	**(25-35%)**	**(35-45%)**
SYSTOLIC PRESSURE	Normal	Slight reduction (80-100 mmHg)	Strong reduction (70-80 mmHg)	Notable reduction (50-70mmHg)
HEART RATE	> 100 bpm	< 100 bpm	> 120 bpm	> 140 bpm
RESPIRATORY RATE	14-20	20 – 30	30 - 40	> 45
SIGNS AND SYMPTOMS	Palpitations, tremor, tachycardia	Weakness, sweating, tachycardia	Shaking,pallor, oliguria	Collapse,hunger for air, anuria
SHOCK INDEX	> 0.6	≥ 0.6 to < 1.0	≥ 1.0 to < 1.4	≥ 1.

- Observation and Integration
- Integration and uterotonics
- Urgent active Management
- Critical active Management (mortality of 50% if not treated promptly)

In healthy pregnant and postpartum women, cardiologic physiologic compensatory mechanisms prevent changes in vital signs until a large volume of blood has been lost (usually >1000ml). Hence, changes in clinical and vital signs that result from hemorrhage appear late in the process and may not lead early identification of PPH

FIGO recommendations on the management of postpartum hemorrhage 2022

transform routine clinical parameters into a more accurate indicator of hypovolemia, such as the shock index (SI). SI is defined as the ratio of heart rate to systolic blood pressure.[3,4] The SI may improve the predictive capability of individual clinical signs, which aids early identification of women at risk of hypovolemia as the result of obstetric causes.[5] Moreover, the SI has been proposed as a reliable indicator of adverse maternal outcomes,[6] and its values have been set to indicate clinical management.[7] However, the association between shock parameters and advanced treatment

ity and an SI>1 increases the likelihood of blood transfusion.[11,12] To date, standard obstetric SI has been defined as 0.7–0.9 compared with 0.5–0.7 for the nonpregnant population, taking into account that the hemodynamic changes of pregnancy may delay the recogni-

has been introduced as a simple and clinically effective vital sign.

The SI has been shown to have an inverse linear relationship with left ventricular stroke work in acute circulatory failure. Therefore, a concurrent reduction of left ventricular stroke work (induced by hemorrhage, trauma, or sepsis) was associated with an elevation of the SI and a deterioration in left ventricular mechanical performance. Poor left ventricular function or persistent abnormal

The SI, together with the rule of 30, are important tools that may aid clinicians in an emergency to determine the amount of blood loss and the degree of hemodynamic instability. Before the fall in systolic

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A Systematic Review of the Relationship between Blood Loss and Clinical Signs

Rodolfo Carvalho Pacagnella[1]*, João Paulo Souza[2], Jill Durocher[3], Pablo Perel[4], Jennifer Blum[3], Beverly Winikoff[3], Ahmet Metin Gülmezoglu[2]

- **Introduction:** This systematic review examines the relationship between blood loss and clinical signs and explores its use to trigger clinical interventions in the management of obstetric haemorrhage.
- **Conclusion:** This systematic review found a substantial variability in the relationship between blood loss and clinical signs, making it very difficult to establish specific cut-off points for clinical signs that could be used as triggers of clinical interventions. However, the shock index was found to be an accurate indicator of compensatory changes in the cardiovascular system due to blood loss.

Shock Index
HR/sBP
0,5 – 0,7
0,7 – 0,9

Shock Index Obstetric
if > 1 indicator of clinical severity and need for transfusion

Cochrane Database Syst Rev 2014 Feb; 2014 Treatment for primary postpartum haemorrhage
PLoS One. 2013;8(3):e57594 A systematic review of the relationship between blood loss and clinical signs.
Pacagnella RC1, Souza JP, Durocher J, Perel P, Blum J, Winikoff B, Gülmezoglu AM.

THE RULE OF 30

If…..

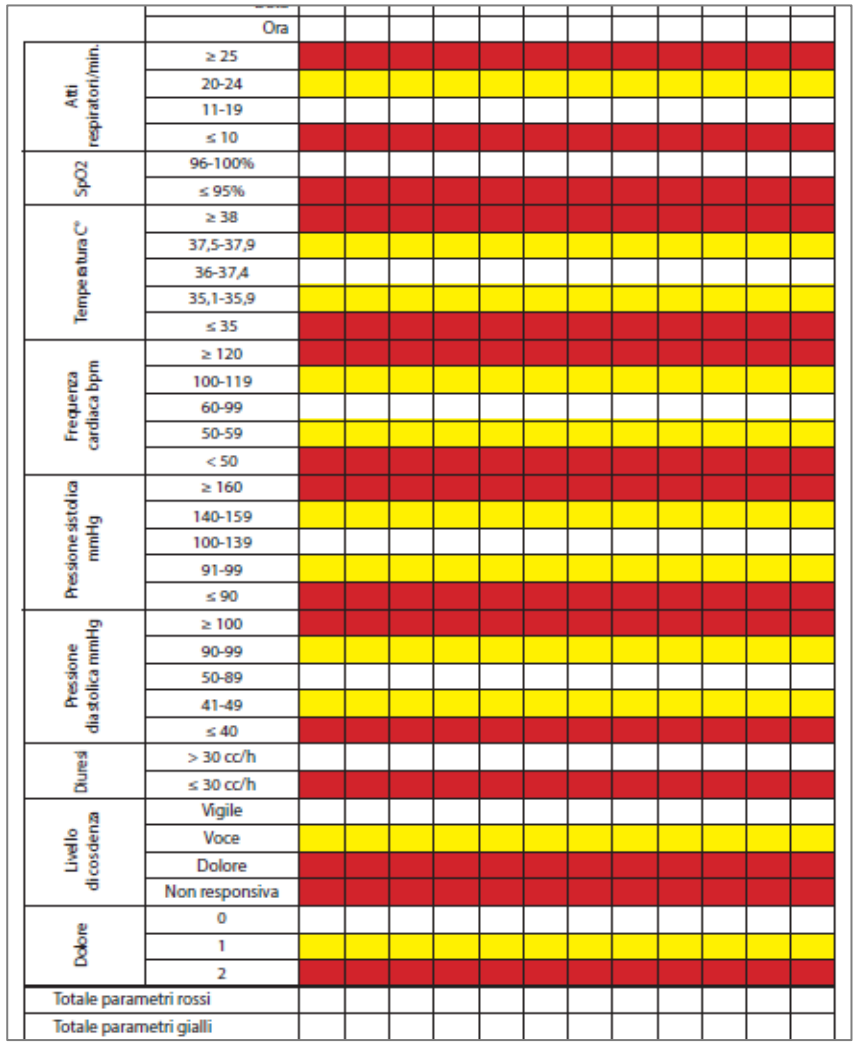
PAS fall of30 mmHg
Increased heart rate by 30/min
Increased Respiratory rate by 30/minuto
Diuresis Output <30ml/hour
Hb (Hct) decreased by 30%

….it is probable that the woamn has lost 30% of the volume of the circulating blood, resulting in a panel of

MODERATE to SEVERE SHOCK

SCHEDA MEOWS

Modified Early Obstetrics Warning System



	Ora												
Atti respiratori/min.	≥ 25												
	20-24												
	11-19												
	≤ 10												
SpO2	96-100%												
	≤ 95%												
Temperatura C°	≥ 38												
	37,5-37,9												
	36-37,4												
	35,1-35,9												
	≤ 35												
Frequenza cardiaca bpm	≥ 120												
	100-119												
	60-99												
	50-59												
	< 50												
Pressione sistolica mmHg	≥ 160												
	140-159												
	100-139												
	91-99												
	≤ 90												
Pressione diastolica mmHg	≥ 100												
	90-99												
	50-89												
	41-49												
	≤ 40												
Diuresi	> 30 cc/h												
	≤ 30 cc/h												
Livello di cosdenza	Vigile												
	Voce												
	Dolore												
	Non responsiva												
Dolore	0												
	1												
	2												
Totale parametri rossi													
Totale parametri gialli													

	Red trigger	Yellow trigger
Temperature; °C	< 35 or > 38	35–36
Systolic BP; mmHg	< 90 or > 160	150–160 or 90–100
Diastolic BP; mmHg	> 100	90–100
Heart rate; beats.min^{-1}	< 40 or > 120	100–120 or 40–50
Respiratory rate; breaths.min^{-1}	< 10 or > 30	21–30
Oxygen saturation; %	< 95	–
Pain score	–	2–3
Neurological response	Unresponsive, pain	Voice

1		**Repeat parameter check between 30- and 60 minutes.**
2	Or	**Call a doctor for evaluation. Repeat parameters every 30 minutes.**
1		
>2	Or	**Call doctor for immediate evaluation. Repeat parameters every 15 minutes.**
>1		

Singh S, McGlennan A, et al. A validation study of the CEMACH recommended modified early obstetric warning system (MEOWS). Anaesthesia 2012

✓ Transmission of information that requires immediate attention and decisions

✓ Improves communication between professionals

✓ Standardization of information

(Randma et al,2014- De Meestreet et al, 2013)

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RACCOMANDAZIONI

In presenza di EPP si raccomanda come trattamento farmacologico di prima linea:

- **ossitocina 5 UI in bolo endovenoso lento (non meno di 1-2 minuti; non meno di 5 minuti in donne con rischio cardiovascolare)**

oppure

- **ergometrina (2 fiale 0,2 mg per via intramuscolare)**

oppure

- **combinazione di ossitocina 5 UI per via endovenosa (non meno di 1-2 minuti; non meno di 5 minuti in donne con rischio cardiovascolare) ed ergometrina (2 fiale 0,2 mg intramuscolare) da associare a una terapia di mantenimento con ossitocina per infusione (10 UI in soluzione isotonica per 2 ore).**

raccomandazione forte, prove di qualità molto bassa

In presenza di EPP, si raccomanda di associare al trattamento farmacologico il massaggio del fondo dell'utero fino alla sua contrazione o alla riduzione del sanguinamento avvertendo la donna che la manovra può essere dolorosa.

raccomandazione forte, prove di qualità bassa

Si raccomanda di valutare come trattamento farmacologico di seconda linea, in presenza di EPP non responsiva al trattamento di prima linea:

- **ergometrina (2 fiale 0,2 mg intramuscolare)**

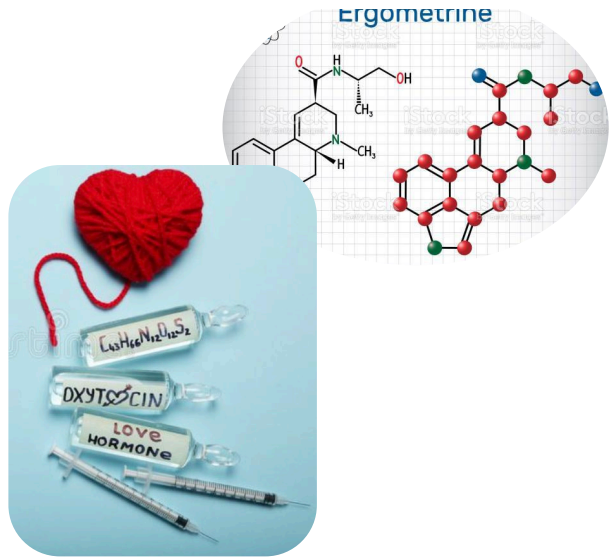
e/o

- **sulprostone (1 fiala 0,50 mg per via endovenosa in 250 cc; da 0,1 a 0,4 mg/h fino a un max di 1,5 mg nelle 24 ore).**

raccomandazione debole, prove di qualità molto bassa

In assenza di prove che permettano di raccomandare un intervento farmacologico di seconda linea come più efficace rispetto agli altri si raccomanda di scegliere il trattamento in base alle condizioni cliniche della paziente, all'expertise del professionista, alla disponibilità dei farmaci e alle loro controindicazioni.

raccomandazione di buona pratica clinica basata sull'esperienza del *panel*



Uterotonic Theraphy

LINEA GUIDA

Sistema nazionale per le linee guida

Emorragia post partum:
come prevenirla,
come curarla

Blood Gas Analysis: pH, Hb, Lac, BE

Complete blood count, coagulation profile

ROTEM/TEG

Transfusion center: request 4 U leucodepleted red blood cells

DO NOT WAIT FOR THE LABORATORY RESULTS TO START THE TREATMENT

…..check the following parameters every 30-60 minutes

FATAL TRIAD: *ACIDOSIS HYPOTERMIA COAGULOPATHY*

Causes of Obstetric DIC :

Systemic activation of coagulation, with formation of intravascular thrombin deposits and fibrin which cause thrombosis of small and medium caliber vessels e resulting in organ dysfunction and bleeding

Placental abruption
Severe Preeclampsia pr HELLP syndrome
Acute fatty liver in pregnancy
Embolism of amniotic fluid
Intrauterine fetal death
Sepsis
Diluition coagulopathy secondary to massive transfusion

DIFFERENTIAL DIAGNOSIS

CONSUMPTION COAGULOPATHY

CONSEQUENT TO THE LOST OF COAGULATION FACTORS DUE TO A MASSIVE BLOOD LOSS, WITHOUT THE ACTIVATION OF COAGULATION CASCADE

It doesn't determine uterine atony

DIC

THE CONSUMPTION OF COAGULATION FACTORS IS DETERMINED BY A PRIMARY INTRAVASCULAR ACTIVATION OF COAGULATION CASCADE. TRIGGERED BY A PRIMARY PATHOLOGY (PREECLAMPSIA, SEPSIS, PLACENTAL ABRUPTION, AMNIOTIC EMBOLISM, PROLONGED RETENTION OF DEAD FETUS)

Circulants fibrin degradation products (fdp) can cause uterine atony

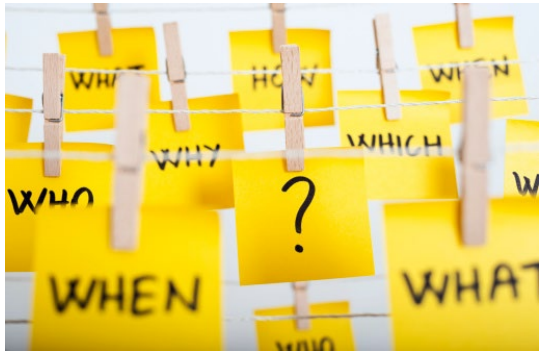
Objectives:

- Hb >8gr/dL
- PLT >50x10^9 /L
- PT ratio <1.5 in respect to normal
- aPTT <1.5 in respect to normal
- Concentration of Fibrinogen >2gr/L

Maintain :

Ht > 21 - 24% *T >34 °C* *pH > 7,20.* *Ca++>1*

STRATEGIES FOR REANIMATION



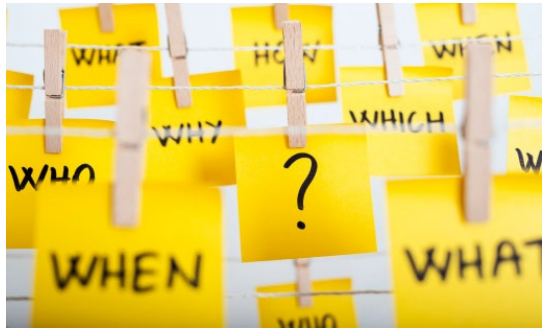
Restore circulating volume with cristalloid solutions while waiting for blood components….

…to sustain volemia and warrant adequate tissue perfusion

- **Boluses of 500ml**
- **Balanced crystalloid solutions to reduce risk of Hyperchloremic acidosis**
- **After the administration of each bolus, physicians must assess the clinical status of patients**

FIGO, 2022

STRATEGIES FOR REANIMATION



TARGET

MAP 50-60 mmHg

PAS 80-90 mmHg

Until major bleeding has been controlled

(RECCOMENDATION 1C)

The concept of hypotensive resuscitation is because administering small crystalloid volumes reduces the risk of diluitional coagulopathy

FIGO, 2022

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FIGO recommendations on the management of postpartum hemorrhage 2022

HYPOTENSIVE RESUSCITATION

11.2.1 | Hypotensive resuscitation

The concept of hypotensive resuscitation is because administering small crystalloid volumes reduces the risk of dilutional coagulopathy

11.2.4 | Aggressive approach and adverse outcomes

During hemorrhagic shock the endothelial glycocalyx becomes thinner and administration of large amounts of crystalloids exacerbates this state, leading to fluid extravasation that may cause cerebral, cardiac, and pulmonary edema.[7,10,11] Third spacing may also lead to cardiac dysfunction, worsen hemodynamics, and decrease kidney perfusion. Decreased kidney perfusion occurs because of an increase in intra-abdominal pressure, which can additionally result in abdominal compartment syndrome.[7,11]

Aggressive Approach

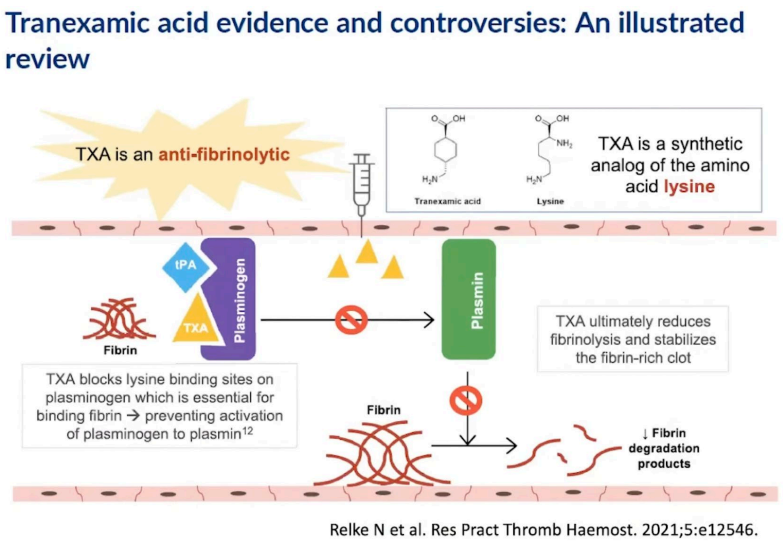
11.2.2 | Intravenous fluids

Among the initial strategies for reanimation, the administration of crystalloids in small boluses of 500 ml is recommended.[10] Scientific evidence recommends the use of balanced crystalloid solutions such as Ringer's lactate owing to the risk of hyperchloremic acidosis and the worsening of kidney function with chlorine-rich fluids (saline solution).[7] This is particularly important for LMICs, where saline-based solutions are in abundance. After the administration of each bolus, physicians must assess the clinical status of patients, looking for an improvement in signs and symptoms of shock resulting from blood loss.[10]

11.2.3 | Targeted blood pressure

The difference between aggressive and hypotensive resuscitation lies within targeted blood pressure management.[4] Mean arterial pressure (MAP) represents the perfusion of the majority of organs, therefore providing the target for clinicians to guide fluid administration.[11] Hemorrhagic shock animal models have demonstrated a positive benefit in survival with MAP between 55–60 mm Hg during active bleeding.[10] The European guideline on management of major bleeding and coagulopathy following trauma recommends permissive hypotension with a systolic blood pressure target of 80–90 mm Hg (MAP 50–60 mm Hg) until major bleeding has been controlled (Recommendation Grade 1C).[12]

TRANEXAMIC ACID



WHO and ISS recommendation suggest early **antifibrinolytic** administration,within 3 hours of delivery of **1gr in 10minutes** in women with PPH after vaginal or c section birth, in addition to standard treatment with uterotonics, repeatable after 30 minutes or within 24 hours of the first dose, in case of recurrence of hemorrhage

WOMAN Trial Collaborators. Lancet 2017; 389: 2105–16.
WHO recommendation on tranexamic acid for the treatment of postpartum haemorrhage. Geneva: World Health Organization; 2017

The decision to initiate red cell transfusion is CLINICAL

Red cell transfusion: homogrup/ Zero Rh neg

1U increases Hb of 1gr/dL and Hct of 2-3%

Trigger transfusion platelet is $75x10^9$ ·

Woman RhD neg receives Platelet RhD pos

prophylaxis anti-D is necessary

Fresh frozen plasma, when bleeding persists even after administration of red cells. Dosage: 15-20ml/kg.

Risk TACO/TRALI

TEG / ROTEM

…each morphology has its own meaning

Normal
R;K;MA;Angle = Normal

Anticoagulants/hemophilia
Factor Deficiency
R;K = Prolonged;
MA;Angle = Decreased

Platelet Blockers
Thrombocytopenia/
Thrombocytopathy
R ~ Normal; K = Prolonged;
MA = Decreased

Fibrinolysis (UK, SK, or t-PA)
Presence of t-PA
R ~ Normal;
MA = Continuous decrease
LY30 > 7.5%; WBCLI30 < 97.5%;
Ly60 > 15.0%; WBCLI60 < 85%

Hypercoagulation
R;K = Decreased;
MA;Angle = Increased

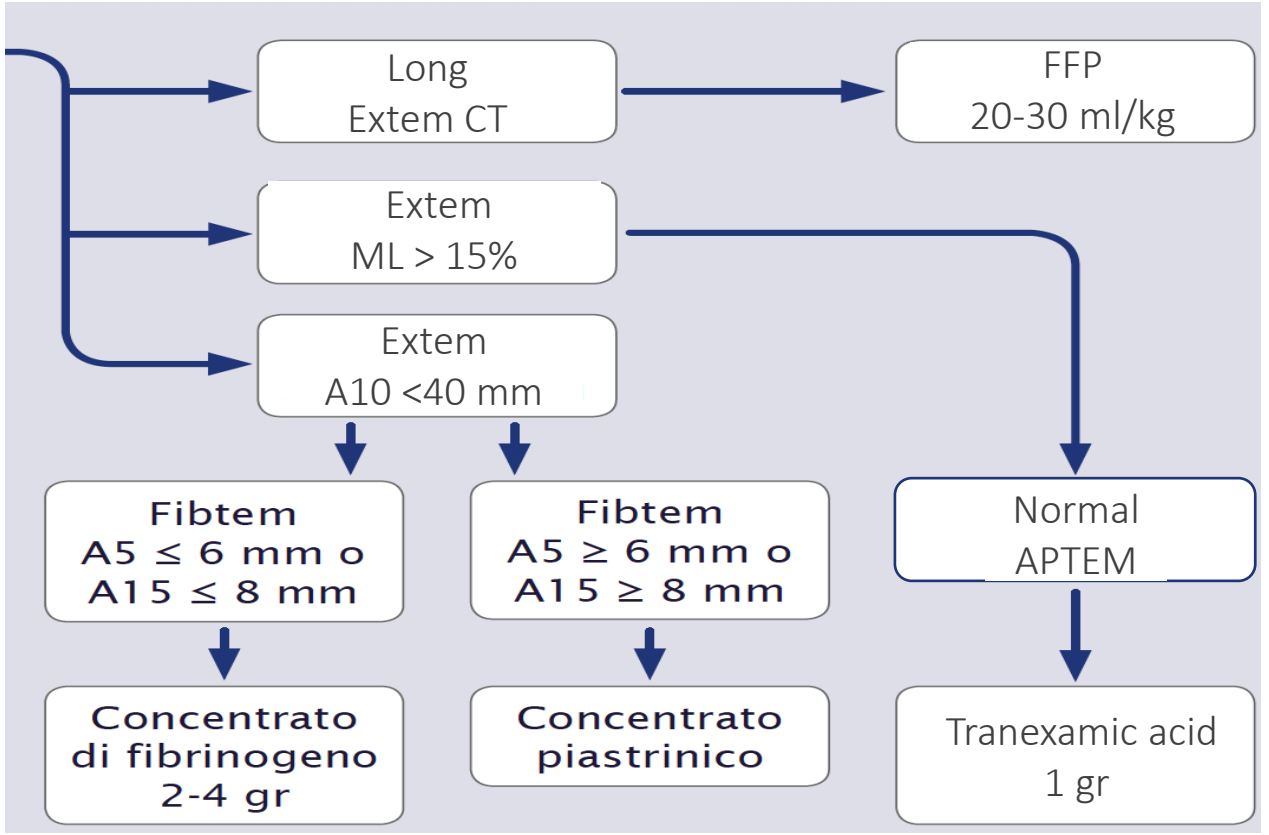
D.I.C
Stage 1
Hypercoagulable state with
secondary fibrinolysis

Stage 2
Hypocoagulable state

The daily-practiced post-partum hemorrhage management: an Italian multidisciplinary attended protocol

G. Affronti[1], V. Agostini[2], A. Brizzi[3], L. Bucci[4], E. De Blasio[5], M.G. Frigo[6], C. Giorgini[7], M. Messina[8], A. Ragusa[9], F. Sirimarco[10], A. Svelato[9]

Clin Ter 2017; 168 (5):e307-316



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TRANSFUSION PRACTICE

TRANSFUSION MEDICINE WILEY

Practical approach to transfusion management of post-partum haemorrhage

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Abstract

Objectives: To describe transfusion management during post-partum haemorrhage (PPH) and the usefulness of standard or point-of-care (POC) laboratory tests for guiding haemostatic management.

Background: PPH is the leading cause of maternal mortality and severe maternal morbidity worldwide. Despite the efforts made in recent years, PPH is often burdened by preventable death. Recent data from the active Italian Obstetric Surveillance System (ItOSS) highlighted the following main critical issues: inadequate communication between healthcare professionals, inability to correctly and promptly assess the severity of haemorrhage, delays in diagnosis and treatment, failure to request blood promptly and inappropriate monitoring post-partum.

Materials and Methods: Data in the literature have been compared with the rotational thromboelastometry (ROTEM)- and the thromboelastography (TEG)-guided algorithms applied in the authors' departments.

Results: PPH transfusion therapy may have an empirical approach based on the standard use of blood products or a targeted approach based on coagulation monitoring by laboratory or POC tests. Here, the authors describe how they manage PPH in their departments, according to the Italian guidelines, along with the addition of a ROTEM- and a TEG-guided algorithms developed by themselves.

Conclusion: Although the proposed algorithms have not been validated by trials or observational studies conducted in our departments, we believe that these indications could be useful for supporting clinical practice. Furthermore, we deem it appropriate to emphasise the importance of a multidisciplinary approach and the need for standardised and shared protocols to support the decisions of healthcare professionals.

KEYWORDS
blind transfusion therapy, coagulation, postpartum haemorrhage, pregnancy, rotational thromboelastometry-guided algorithm, thromboelastography-guided algorithm

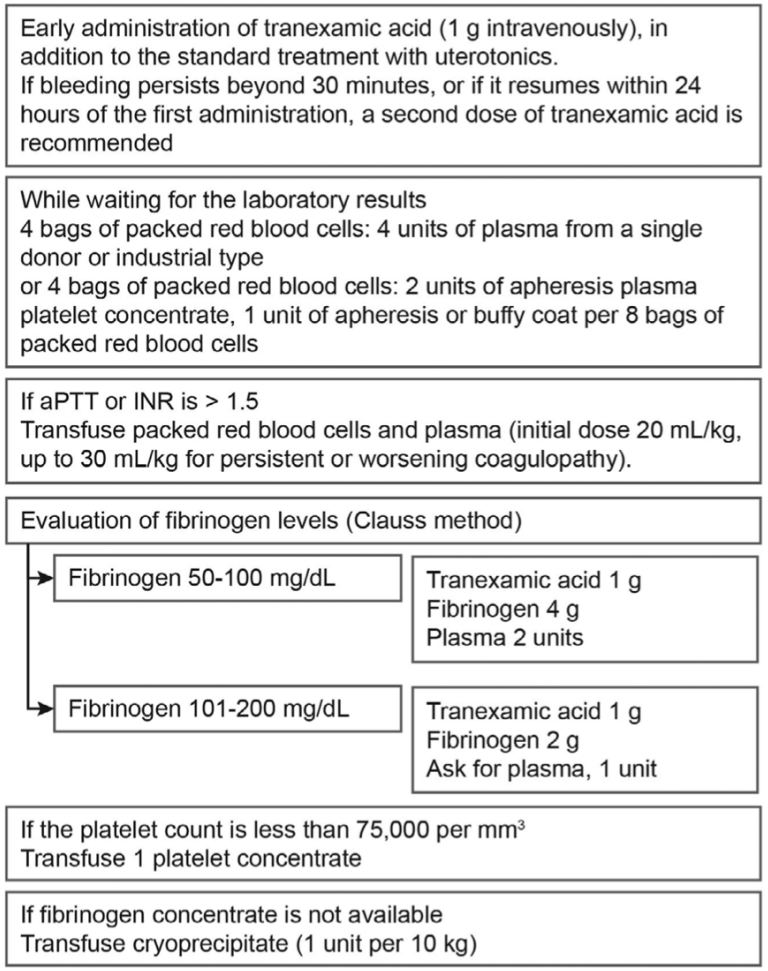


FIGURE 1 Blind transfusion therapy.[9] aPTT, activated partial thromboplastin time; INR, international normalised ratio

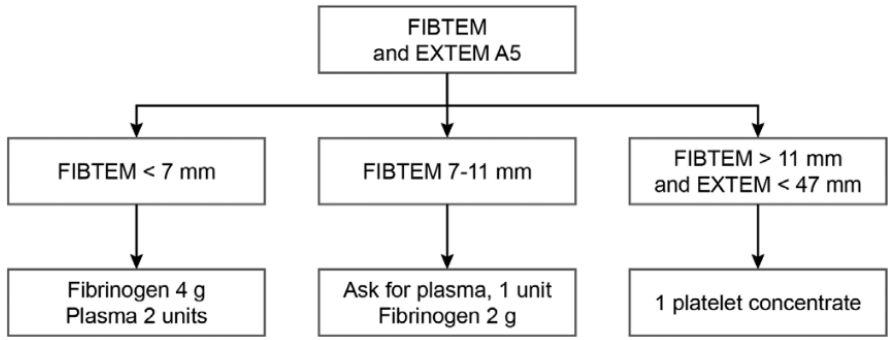


FIGURE 2 ROTEM-guided transfusion therapy

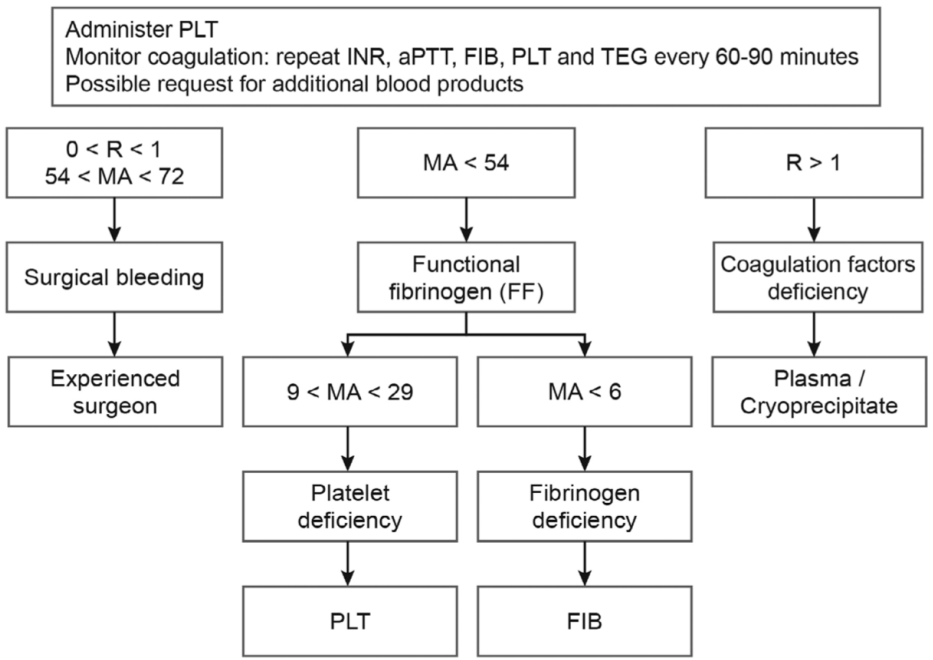


FIGURE 3 TEG-guided transfusion therapy.[9] aPTT, activated partial thromboplastin time; FIB, fibrinogen; INR, international normalised ratio; PLT, platelets

Increases during pregnancy: 4-6gr/L nel III trim.

Level <2g/L : TARGET replacement

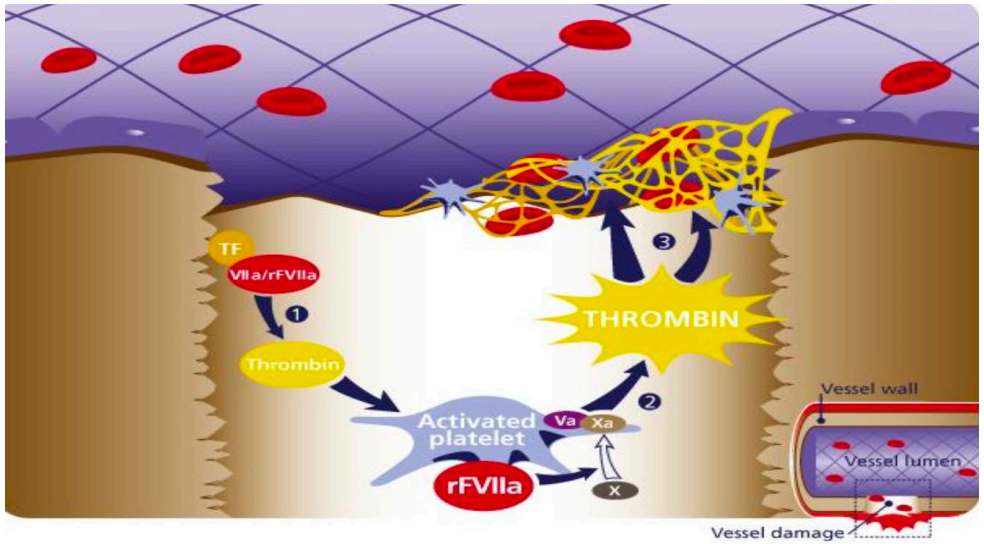
Accurate Biomarker of moderate to severe PPH progression

1° factor that is reduced during PPH

	FIBRINOGENO CONCENTRATO	CRIOPRECIPITATO
Efficacia	Buona	Buona
Tempo di preparazione	Breve	Lungo (scongelamento)
Costo	Elevato	Basso
Rischio infettivo	Basso (pastorizzazione)	Moderato (NO pastorizzaz)
Rischio Reazioni Trasfusion	Basso (anafilassi)	Elevato (reaz allergiche)
Fattori coagulazione	I (1gr)	I (200-300mg) VIII (80-120U) XIII (40-60U) vWF (80U)
Gruppo sanguigno ABO	Non necessario	ABO noto
Conservazione	Temperatura ambiente	Congelato (max 1 anno)

FIBRINOGEN

rFVIIa

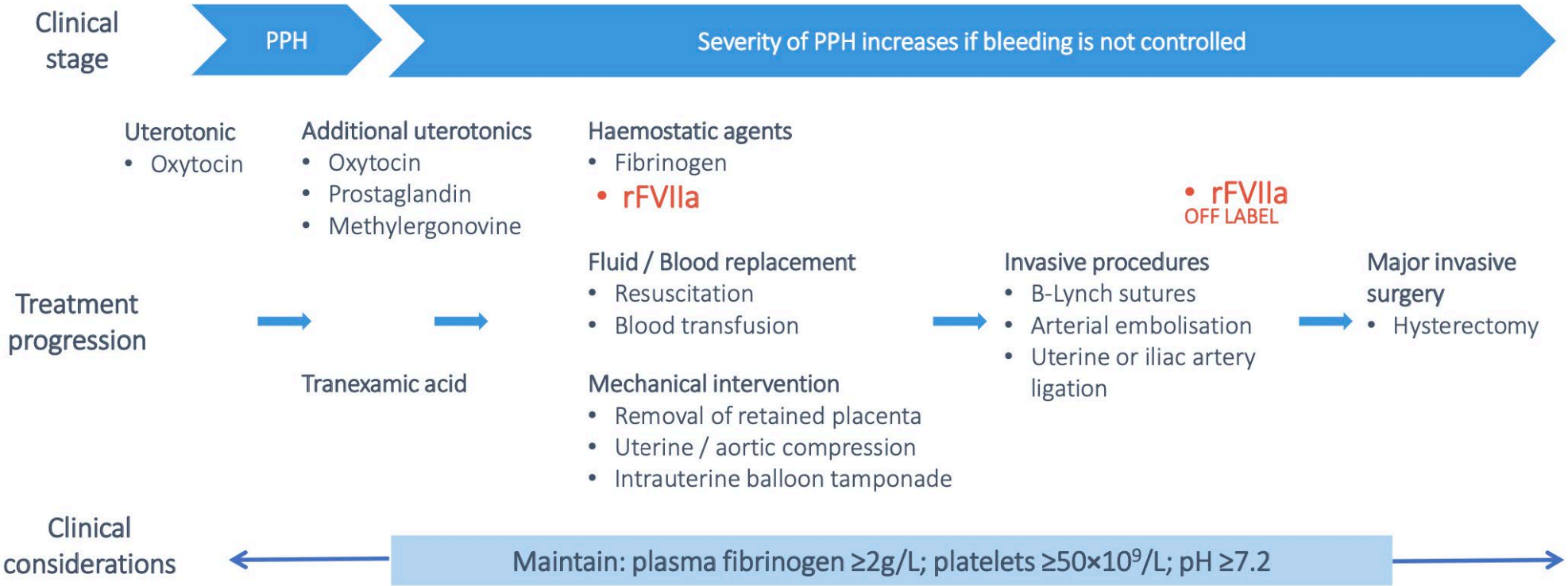


…update, May 2022

il rFVIIa is indicated for treatment sPPH,
when uterotonics are not sufficient
to achieve hemostasis

Dosage: 60-90 µg/Kg bolus ev.
Peak 10 minutes
If the response is insufficient,
repeat a second dose after 30 minutes

Recombinant human FVIIa for reducing the need for invasive second-line therapies in severe refractory postpartum hemorrhage: a multicenter, randomized, open controlled trial G. LAVIGNE 2015 International Society on Thrombosis and Haemostasis



rFVIIa in the management of sPPH after the new indication

Journal of Thrombosis and Haemostasis, **13**: 520–529 DOI: 10.1111/jth.12844

ORIGINAL ARTICLE

Recombinant human FVIIa for reducing the need for invasive second-line therapies in severe refractory postpartum hemorrhage: a multicenter, randomized, open controlled trial

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RCT France-Swisse
April 2007 - November 2010

- The study aimend to evaluate the efficacy and safety of a single dose of FVIIa in women with ongoing sPPH after failure with sulprostone
- Randomizzate 84 women with sPPH: 42 used rFVIIa after failure with Sulprostone

42 woman managed with the «standard of care» of the home centre

(P = 0.93). The patients' baseline characteristics are presented in Table 2.

Primary outcomes

The primary efficacy outcomes are detailed in Table 3. Interventional hemostatic procedures (i.e. the composite primary efficacy outcome) were required for 93% (n = 39/42) of patients in the standard care arm and for 52% (n = 22/42) of patients in the intervention arm (P < 0.0001; RR = 0.56; 95% CI, 0.42–0.76). The mean number of patients who needed to be treated with rhu-FVIIa (number needed to treat, NNT) to avoid one composite outcome was 2.6. Only the number of arterial embolization procedures was significantly lower in the intervention arm than in the standard care arm. The percentage of peripartum hysterectomies was 7% (n = 3) in the intervention arm and 19% (n = 8) in the standard care arm (RR = 0.375 (0.107–1.32); P = 0.11).

No effect of treatment by center interaction on the primary efficacy outcome was detected. Indeed, the RR value adjusted for the eight centers was 0.7 with 95% CI 0.55–0.9 (Breslow-Day test, P = 0.06). The result did not change even when only the five centers that enrolled at least five patients were included in the analysis (RR = 0.71; 95% CI, 0.55–0.91; Breslow-Day test, P = 0.3).

The time to initiation of a second-line treatment was not different between groups: the median delay was 30 min (95% CI, 15–80 min) standard care arm and also 60 min; P = 0.93) for the 22 arm who did not respond to r

In deviation from the t failed to be measured. The bag to quantify postpartum the devices were provided teams, but were only margi the systematic measurement impossible.

To determine the proportion who required blood products assessed before and after randomization, the absolute numbers of transfused PRBCs and

	rFVIIa	Reference	Odds ratio (OR)	Relative reduction in risk of invasive procedure (%)	P-value
End-point: Almeno una procedura invasive (compressione suture uterine, embolizzazione vascolare, ligatura vascolare, isterectomia) dopo randomizzazione, n/N (%)	21/42 (50.0)	38/42 (90.5)	0.11	44.7%	<0.0001

Table 3 Efficacy outcomes

Outcomes	Standard arm (N = 42) n (%)	Intervention arm (N = 42) n (%)	Absolute difference [95% CI]	Relative risk [95% CI]	Mean NNT	P
Primary efficacy outcome	39 (93)	22 (52)	41% [18; 63]	0.56 [0.42; 0.76]	2.6	< 0.0001
Arterial embolization	24 (57)	12 (29)	28% [−4; 61]	0.5 [0.29; 0.86]	3.5	0.0082
Arterial ligation	12 (29)	9 (21)	8% [−30; 44]	0.75 [0.35; 1.59]	14	0.45
Peripartum hysterectomy	8 (19)	3 (7)	12% [−28; 52]	0.38 [0.11; 1.32]	8.4	0.11
Others*	6 (14)	4 (10)	4% [−36; 44]	0.67 [0.20; 2.19]	25	0.50
B-lynch sutures, Bakri Balloon and variants with hemostatic intention						

Events VTE/ATE

	Randomised controlled trial (FAS)*		Observational studies									
			Bern University Study		PPH Consortium						UniSeven (FAS)‡	ANZHR (FAS)‡‡
					Denmark (FAS)**		Netherlands (FAS)††		UK (FAS)			
	rFVIIa N=51	Ref N=33	rFVIIa N=52	No rFVIIa N=113	rFVIIa N=40	No rFVIIa N=190†	rFVIIa N=23	No rFVIIa N=144	rFVIIa N=13	No rFVIIa N=149	rFVIIa N=87	rFVIIa N=166
Arterial TEs, n(%)	0	0	0	0	0	1 (0.5)	0	1 (0.7)	0	0	0	1 (0.6)§
Venous TEs, n(%)	2 (3.9)	0	0	1 (0.9)	1 (2.5)	2 (1.1)	1 (4.3)	2 (1.4)	0	4 (2.9)	0	2 (1.2)
All TEs, n(%)	2 (3.9)	0	0	1 (0.9)	1 (2.5)	3 (1.6)	1 (4.3)	3 (2.1)	0	4 (2.9)	0	3 (1.8)

rFVIIa treated:

VTEs: in 1.2% of patients
ATEs: in 0.2% of patients

NOT rFVIIa treated:

VTEs: in 1.4% of patients
ATEs: in 0.2% of patients

Deaths

	Randomised controlled trial (FAS)*		Observational studies										
			Bern University (FAS)		PPH Consortium						UniSeven**		ANZHR (FAS)
					Denmark (FAS)		Netherlands (FAS)		UK (FAS)		All exposed	FAS	
	rFVIIa N=51	Ref N=33	rFVIIa N=52	No rFVIIa N=113	rFVIIa N=40	No rFVIIa N=199	rFVIIa N=37	No rFVIIa N=1223	rFVIIa N=13	No rFVIIa N=149	rFVIIa N=111	rFVIIa N=87	rFVIIa N=166
Maternal deaths	0	0	0	0	0	2 (1.0)	2 (5.4)	5 (0.4)	0	2 (1.3)	1 (0.9)	0	13 (7.8)

NOTE: All deaths in ANZHR were assessed as unlikely related to rFVIIa by a physician from Monash University (Study site). Most patients died due to uncontrolled bleeding (despite large transfusion volumes) and possibly remoteness from speciality care.

❖ rFVIIa:resource among the options available in PPHs management

No increase tromboembolic risk

«The use of rFVIIa in addition to current standard care may improve outcomes without further increasing the risks associated with sPPH»

PALERMO 5-7 Ottobre
XXVIII CONGRESSO NAZIONALE

European Society of Regional Anaesthesia & Pain Therapy
ESRA ITALIA

EJA

Eur J Anaesthesiol 2023; **40:**226–304

GUIDELINES

CELL SALVAGE

Management of severe peri-operative bleeding: Guidelines from the European Society of Anaesthesiology and Intensive Care

Second update 2022

- Cell salvage is well tolerated in obstetric setting, provided that precautions are taken against rhesus isoimmunisation

GRADO C

- We suggest that using peri-operative cell salvage during caesarean section with high risk of haemorrhage may decrease homologous transfusion

GRADO 2B

CELL SALVAGE

Use:

- **Abnormalities of the placentation**
- **Risk factors for PPH**
- **Coagulation disorders with the need for transfusions**

Precautionary measures:

- **The use of a separate suction source for amniotic fluid**
- **Starting blood collection after delivery of the placenta**
- **Using a leukocyte depletion filter can further reduce the transfusion of amniotic fluid markers and bacteria**

Studies show that when collected blood is filtered through a leokocyte depletion filter, fetal squamous cells are present in levels comparable to those in maternal blood after the placenta is separated and that amniotic-fluid derived TF, which can cause disseminated intravascular coagulation, can be successfully removed.

Transfusion Medicine and Hemotherapy 2023, Patient blood management in pregnancy, Kaserer A et al

SIMULATION AS A PREVENTION STRATEGY IN OBSTETRIC EMERGENCIES	3T's
Improve the integrated multidisciplinary approach.	**Team**
Develop standardized protocols.	**Time**
Face the most common emergency situations encountered in a complex and articulated scenario such as the place of birth with major competence, appropriateness and safety.	**Target**

Thanks