New gadgets at Labor floor: A preliminary comparison of ROTEM Sigma, ROTEM Delta And Clauss Fibrinogen for the Obstetric Patients

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"Background"

- Postpartum hemorrhage (PPH): is the leading cause of maternal morbidity and mortality throughout the world.[1]
- During PPH, Fibrinogen is the first coagulation factor to diminish, consequently, there is a current theory that fibrinogen levels should be used to guide PPH management.[2] Repletion of fibrinogen to baseline is likely needed to enable a recovery to hemostatic competence in severe PPH.
- Point-of-care viscoelastic assays, such as rotational thromboelastometry (ROTEM), provide faster coagulation assessment than **standard laboratory tests (SLTs)** (approximately 10 minutes vs. 45 minutes).
- It has been recommended that **fibrinogen levels >200** mg/dL and,
  - **FIBTEM A5 >7 mm (**measured by **Rotem Sigma)**
  - **FIBTEM A10 >8 mm (**measured by **Rotem Sigma)**
  - **FIBTEM A5 >10 mm (**measured by **Rotem Delta)** is required to reverse coagulopathy and maintain hemostatic competence in a patient presenting with PPH.
- Most common sources of replacement of fibrinogen are **Cryoprecipitate** and **fibrinogen concentrate**

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"Study Design/Methods"

- This study compared coagulation results obtained from the automated **ROTEM® Sigma** and the **ROTEM® Delta** with **SLTs** during PPH.
- We hypothesized that ROTEM® Sigma would deliver rapid, reliable results with less variability than ROTEM® Delta.
  - The primary aim was to compare the performance of FIBTEM parameters between ROTEM® Delta and ROTEM® Sigma in obstetric patients.
  - The secondary aim was to evaluate their ability to predict critical fibrinogen thresholds that guide treatment initiation, supporting the development of a PPH management algorithm using ROTEM® Sigma.
- After IRB approval, blood samples for standard laboratory tests (SLTs) and ROTEM samples were obtained from pregnant women presenting for labor at Yale New Haven Hospital from 2022– 2024. Data are presented as mean ± standard deviation.
- Correlations between fibrinogen concentrations and FIBTEM amplitudes at 5 minutes (A5), 10 minutes (A10), and 20 minutes (A20) were calculated.

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"Results"

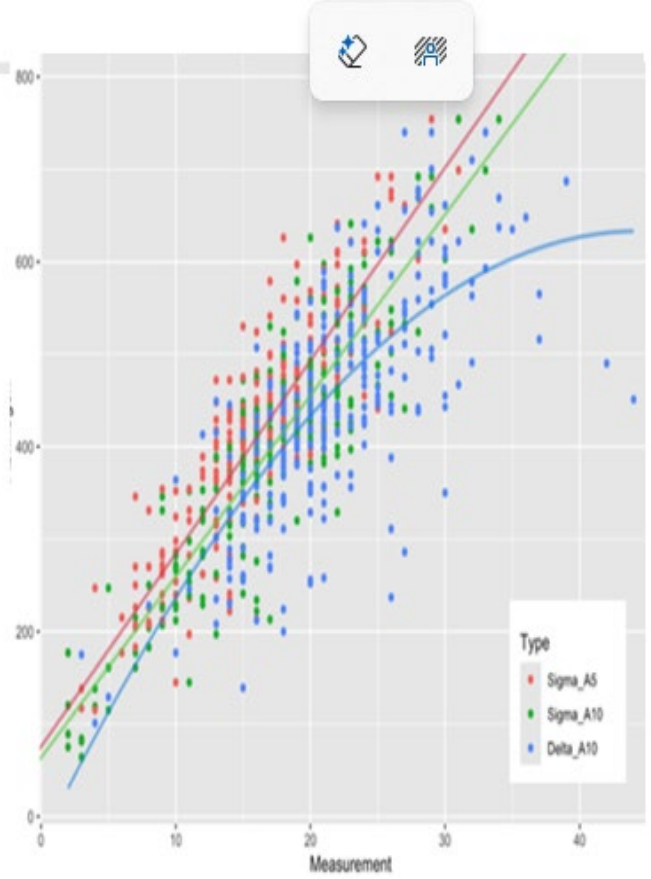
- Results: A total of 627 fibrinogen samples were analyzed, including 282 ROTEM® Sigma and 278 ROTEM® Delta measurements.
  - Simultaneous Sigma and Delta samples were available from 67 patients. Descriptive statistics of Fibrinogen and FIBTEM values of pregnant women are shown in (figure 1-A);

A

	Descriptive Statistics					
	Rotem Sigma				Rotem Delta	
	A5	A10	A20	Fibrinogen	A10	Fibrinogen
Mean (SD)	16.2 (5.73)	17.9 (6.13)	19.5 (6.28)	413 (315)	21.9 (6.18)	450 (123)
Median (IQR)	16.5 (13-20)	18.0 (15-22)	20 (16-24)	427 (333-485)	21.0 (18-25)	443 (376-521)

  - **FIBTEM Sigma** amplitudes demonstrated strong linear correlations with fibrinogen levels (A5 r=0.89, A10 r=0.89, A20 r=0.88).
  - In contrast, the association between **Delta FIBTEM A10** and fibrinogen was non-linear, with a Spearman correlation of 0.74 (figure 1-B).

B



"Results"

- Among paired samples, concordance correlation between Sigma and Delta A10 values was 0.80.
- The mean difference between Delta and Sigma A10 was 1.59 ± 2.46, with **Delta** values **higher**, likely due to **platelet contamination** resulting from fewer platelet inhibitors used in **Delta** (**one** vs. **two in Sigma**).
- Predictive performance for fibrinogen thresholds using FIBTEM parameters is summarized in (figure 1-C).

- **Conclusions:**
  - Cartridge-based **ROTEM® Sigma** provides rapid and more reliable fibrinogen assessment with reduced variability compared to **ROTEM® Delta**.
  - Sigma FIBTEM parameters, particularly **A5**, correlated more strongly with conventional coagulation tests.
  - **Predicting fibrinogen levels using ROTEM® Sigma may facilitate earlier initiation of goal-directed transfusion protocols in bleeding obstetric patients, minimizing delays associated with SLTs**
- **References:**

  - 1. Say L, et al. Lancet Glob Health 2014; 2: e323–33
  - 2. Collins PW, et al. Int J Obstet Anesth. 2019;37:106–117

Sigma_A5	Pred_Fibrinogen	Lower_CI	Upper_CI
3	138	120	156
4	159	142	176
5	180	164	196
6	201	186	216
7	222	208	235
8	243	230	255
9	263	252	275
10	284	274	295
11	305	295	315
12	326	317	335

Sigma_A10	Pred_Fibrinogen	Lower_CI	Upper_CI
4	142	124	160
5	162	145	178
6	181	166	197
7	201	186	215
8	220	207	234
9	240	227	252
10	259	248	271
11	279	268	290
12	299	289	308
13	318	309	327

Delta_A10	Pred_Fibrinogen	Lower_CI	Upper_CI
6	139	91	187
7	164	121	207
8	189	151	227
9	213	179	247
10	236	207	266
10.6	250	223	277
11	259	233	285
12	281	259	304
13	303	283	322
14	323	306	341

INCLUSION CRITERIA

1. (EBL >1200 ml) that requires a second uterotonic or (tranexamic acid "TXA")
2. hemodynamic unstable
3. EBL>1500 cc & ongoing bleeding
4. requirement for at **least 2 units of PRBCs**
5. suspected placenta accreta

If fulfilling these criteria →

- On average Cryo (5 units/bag "1 dose") has at least 1.25-1.5 gm of fibrinogen
- **Draw blood samples (sample 0)**
  - POC: (FIBTEM, TEG 6S)
  - hemostatic (CBC, fibrinogen, coags)
- **Assess clinical status** (EBL, BP, HR, RR, SpO_2)
- **Check HCT (i-Stat), transfuse 2 units of PRBCs, TXA**

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THROUGH OUT
continue routine obstetric practice according to standardized protocol for PPH (uterotonics, Bakery, Jada, B-Lynch,)

FIBTEM-A5 / (fibrinogen (I) level)

Fibryga 4g	**≤ 4 mm (I level ≈ 1.5 g/L)**	***Cryo 4 doses***
Fibryga 3g	**≤ 8 mm (I level ≈ 2.0 g/L)**	***Cryo 3 doses***
	8-10 mm (I level 2.0-3.0 g /L)	
Fibryga 2g	**Active bleeding**	***Cryo 2 doses***
	≥ 11 mm (I level ≈ 3 g/L)	**NO Bleeding**

Administer blood products according to POC and ongoing bleeding.

Bleeding AND EXTEM A5<35 mm AND FIBTEM A5 >10 mm---1-2 Platelets
Bleeding AND CT > 80 sec AND FIBTEM A5 >10 mm-----2 units of FFP

No fibrinogen replacement currently required
OBSERVATION
Repeat POC after 20-30 min

New clinical concerns
1. Further 500 mL bleeding
2. hemodynamic unstable
3. New microvascular oozing