Evaluating Blood Hemostasis in Pregnant Women using the Thromboelastograph 6s System – A Prospective Observational Study.

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Background and Study Objectives

- TEG® 6s Hemostasis Analyzer (Haemonetics Corporation) is a viscoelastic point-of-care test to assess coagulation function.
- Advantages over its predecessor, the TEG 5000, particularly in its portability, reduced sample volume requirements, and capacity to perform multiple assays, including the assessment of platelet function. [Neal].
- In addition to R time, K time, TEG 6s system measures maximum amplitude citrated functional fibrinogen MA CFF, MACRT and FLEV
- Primary objective of this study is to evaluate the validity of the TEG 6s system in assessing coagulation in pregnant patients.
- Secondary objective of this study is to validate the TEG 6s system as a point-of-care coagulation assessment tool for hypertensive parturients

TEG® 6s Reference Guide

The TEG® 6s analyzer runs tests simultaneously, providing specific and timely information.

Test	Parameter	Interpretation Consideration
CK	↑R	↓Clotting factor activity
CFF	↓MA	↓Fibrinogen
CRT	↓MA	↓Platelet activity*
CK	↑LY30	Hyperfibrinolysis

* If CFF-MA normal

CK Citrated Kaolin - An intrinsic pathway activated assay identifies underlying hemostatic characteristics and risk of bleeding, thrombosis or hyperfibrinolysis.

CFF Citrated Functional Fibrinogen - Used in conjunction with RapidTEG to assess relative contribution of platelets and fibrin to overall clot strength.

CRT Citrated RapidTEG™ - An intrinsic and extrinsic pathway activated assay speeds the coagulation process to more rapidly assess clot strength.

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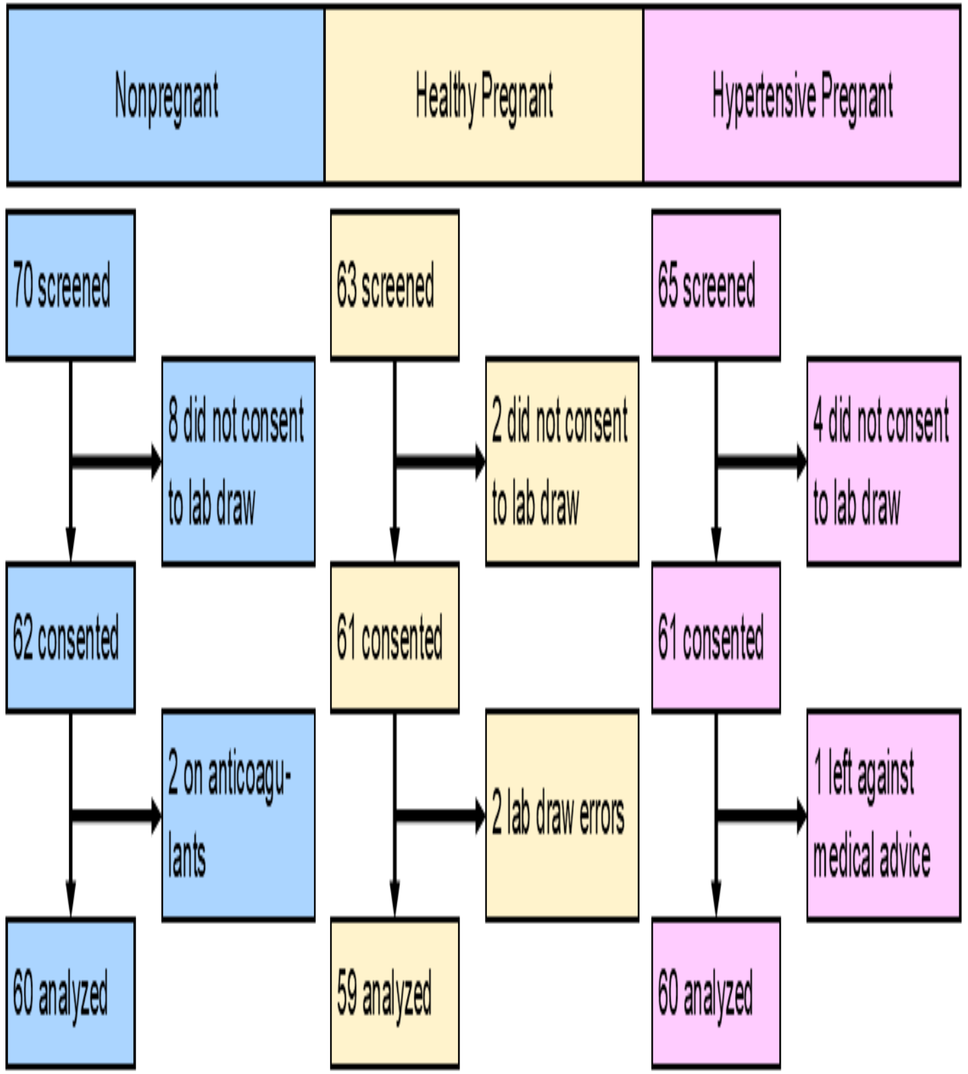
Study Design and Methods

- Prospective observational study , approval of the Emory University Institutional Review Board and the Grady Research Oversight Committee .
- **Inclusion criteria** - Gestational ages between 24 and 41 weeks. And a group of healthy non pregnant females.
- **Exclusion criteria –** unable to provide consent and non-pregnant patients using hormonal contraceptives, with known coagulation disorders, and on antiplatelet or anticoagulant medications.
- Informed written consent, blood samples were drawn at the time of admission to the labor and delivery unit from the parturient and during an elective surgery from the non-pregnant group. Blood was analysed for analyzed: R time, K time, MA CFF, MA CRT and FLEV.
- Additionally, for hypertensive pregnant patients blood samples were analyzed at the Grady Laboratory to assess coagulation parameters
- **Power Analysis :** In reviewing similar studies using thromboelastography in obstetrics, the sample size ranged 49-93 to achieve an 80% power and alph 0.05. We conclude that a sample size of 60 patients per group.



Results

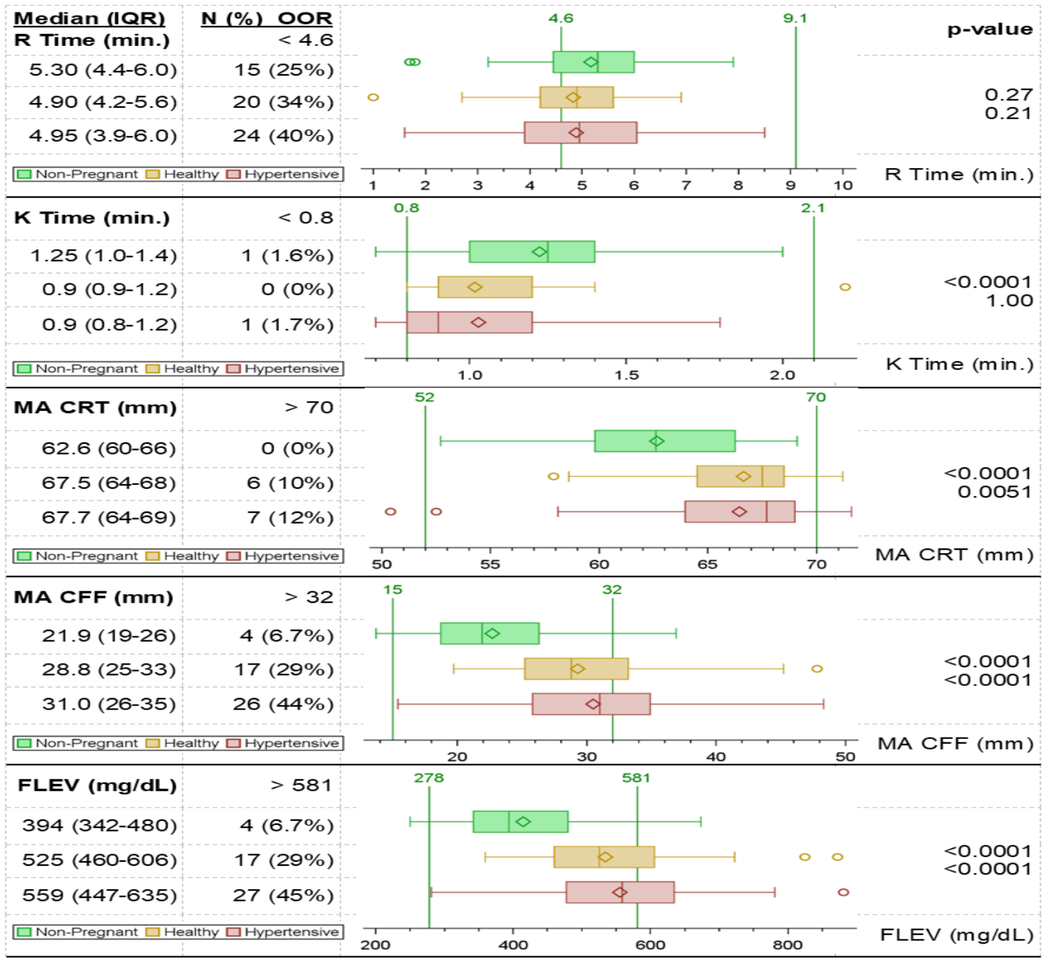


Figure 2: Coagulation Measures by Pregnancy Status. Rectangles form the Q1, median and Q3 of the data, the diamond the mean, with circles beyond the whiskers the outliers. The first p-value is from the Kruskal-Wallis Test. None of the variables were significantly different between healthy pregnant and hypertensive pregnant patients. Both were significantly different from non-pregnant patients, with the exception of R Time. The second p-value is a Chi-Square Test based on the proportion of patients above or below the normal range (unidirectional).
Abbreviations: **MA CFF**-maximum amplitude of citrated functional fibrinogen; **MA CRT**-maximum amplitude of citrated rapid TEG; **FLEV**-functional fibrinogen of TEG.

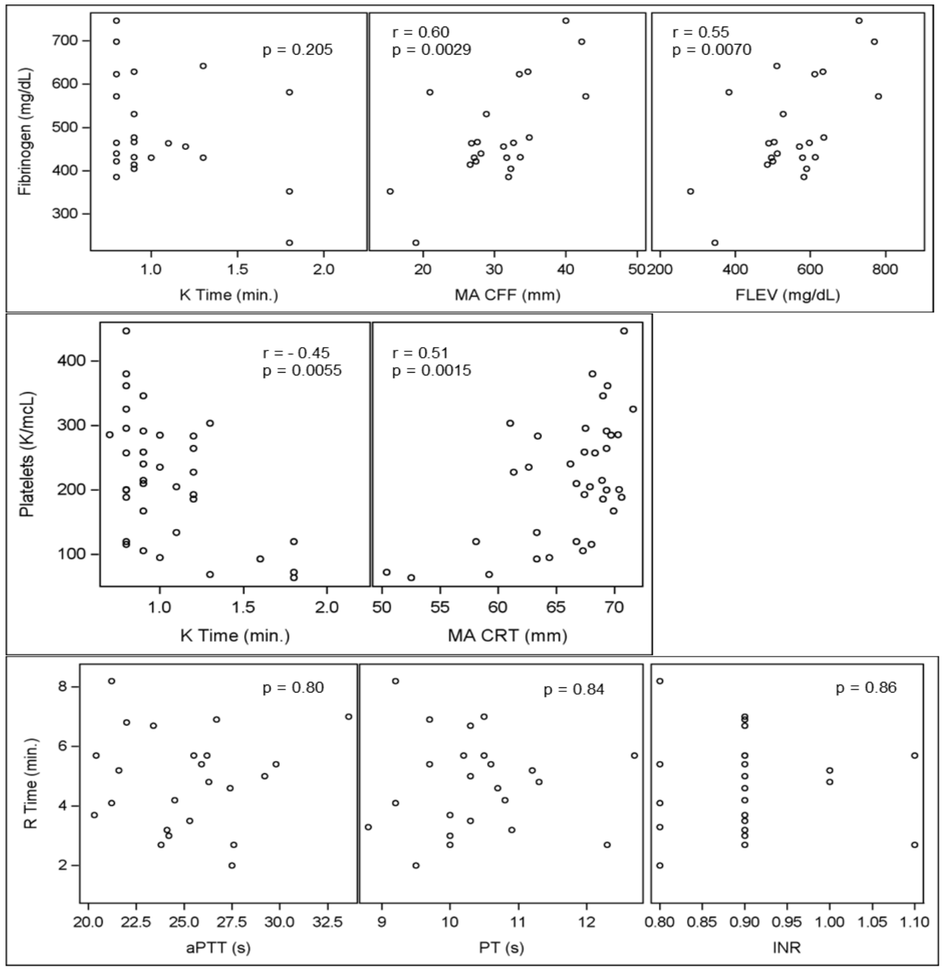


Figure 3: Comparison of Blood Labs to TEG 6S Values
Scatterplots comparing platelet, fibrinogen , coagulation blood labs to four of the TEG 6S variables for hypertensive pregnant patients. P-values and correlation (r) reflect Spearman Rank Correlation. Sample sizes are n=36 for platelets and n=23 for other blood labs. R time any coagulation variable. Positive correlation was seen between platelets and MACRT and fibrinogen and MACFF and FLEV. Abbreviations: **MA CFF**-maximum amplitude of citrated functional fibrinogen; **MA CRT**-maximum amplitude of citrated rapid TEG; **FLEV**-functional fibrinogen of TEG.

Discussion and conclusion

- TEG applications in obstetrics have been vast include evaluating neuraxial anesthesia safety, fluid preloading effects, thrombotic risk, anticoagulant dosing, and guiding therapy in postpartum hemorrhage
- Goettalwela incorporated the monoclonal antibody ReoPro in TEG for healthy pregnant women to independently assess the contributions of fibrinogen and platelets to clot strength (maximum amplitude, MA) [Goettalwela].
- Huang et al. reported that parturients with platelet counts below 100,000/μL may safely undergo neuraxial anesthesia during delivery if their platelet count is above 56,000/μL and their TEG profile remains within normal limits
- However, prior studies utilized earlier TEG models, and clinical adoption remains limited due to insufficient robust evidence supporting routine use of TEG in obstetric anesthesia [Amagalan].
- Our study used the TEG6s model and validates its use in pregnant patient for coagulation status. The TEG6s is portable and faster than earlier competitors and is easily available

Study Limitations

- Lack of data in patient with Thrombocytopenia and or low fibrinogen
- Sample size not enough to predict abnormal coagulation in HTN group compared to main labs

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