The use of viscoelastic hemostatic tests in pregnancy and puerperium: review of the current evidence - communication from the Women's Health SSC of the ISTH

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INTRODUCTION

Recent years have shown increasing interest in the use of thromboelastography (TEG) (Haemonetics, Braintree, MA) and thromboelastometry (ROTEM; Munich, Germany). These are established point-of-care global viscoelastic hemostatic techniques with several advantages. They use whole blood samples, which are more physiological compared with conventional plasma-based tests, require small volumes, and provide comprehensive and real-time data on coagulation/fibrinolysis. Many successful applications have been reported, including hepatobiliary/cardiovascular surgeries, transfusion therapy, and trauma; however, the routine use of these tests remains surprisingly low in relation to pregnancy and puerperium.

Systemic reviews of literature and meta-analyses¹² have not shown the routine use of viscoelastic point-of-care tests to improve important clinical outcomes except in cardiac surgery; this was validated by The UK National Institute for Health and Care Excellence (https://www.nice.org.uk/guidance/dg13). Although the TEG and ROTEM assays and the technology itself have been analytically validated³ it is perhaps the clinical validation, applications, and recommendations in relation to pregnancy that still require perfection as future large studies are now available.

The effectiveness of TEG and ROTEM as point-of-care tests, in reducing and guiding transfusion therapy is most studied in trauma and postpartum hemorrhage (PPH).⁴‑⁶ Other pregnancy-related bleeding or thrombotic disorders are much less studied.

Literature shows limited uptake among clinicians regarding the use of TEG/ROTEM during pregnancy,⁷‑⁹ which is likely from a perceived lack of evidence. Indeed, there are currently no clinical guidelines on indications of these assays and the strength of available evidence regarding clinical correlates or efficacy remains unknown, with several contradictory opinions reported. A major barrier to improving the application of this technology in obstetrics remains the lack of studies that improve patient outcomes, and an international consensus (at least in key obstetric conditions beyond PPH is lacking).

The aim of this project was to systematically review current evidence for the use of TEG/ROTEM in pregnancy and pregnancy-related complications and examine the existing scope of utilization in this context. We would like to clarify that this incorporates not only the use of these tests in assessing PPH and bleeding conditions, but also hypercoagulability and thrombosis risk. For basics about the assay and technology, refer to our previous publications.¹⁰,¹¹

SEARCH METHODS FOR LITERATURE REVIEW

A systematic 10-year critical literature review was performed by searching OVID versions of MEDLINE and EMBASE for all records between 2007 and 2017. Inclusion criteria were human studies published in English, presented as full manuscripts, with TEG/ROTEM...
performed during pregnancy, labor, or peripartum, either solely or part of a bigger study. We excluded studies in which TEG/ROTEM were not used, other global hemostatic tests were used, and if non-peripartum studies or neonates were instead tested. The full text of 45 articles were examined and data extracted. The flow chart for literature review is provided in Figure 1.

### 3 | Objective Review of the Evidence

A detailed summary of all 39 articles is provided in Table S1; however, the following major points have been extracted and are discussed here.

1 TEG/ROTEM parameters confirm the hypercoagulable state of pregnancy. Thromboelastography parameters correlate with duration of pregnancy, with hypercoagulability increasing toward the third trimester, labor, and up to 6 weeks postpartum.\(^8,12-16\) There is evidence that these tests can reflect the higher risk of venous thromboembolism (VTE), particularly in the postpartum period.\(^13,14\)

2 The TEG/ROTEM profile is known in normal pregnancy in all trimesters, during labor, and in the puerperium. Formal reference ranges are available and have been recommended for use in clinical practice.\(^13,14,17-20\) Furthermore, profiles (pre- and postoperative) for women undergoing cesarean delivery are also available.\(^19\)

3 TEG/ROTEM-guided transfusion during PPH has been a focus of many studies. A significant correlation, although only moderate, between fibrinogen levels and fibrin-based extrinsically activated test with tissue factor and the platelet inhibitor cytochalasin D (FIBTEM) was found.\(^4,17,21-23\)

4 TEG/ROTEM-based transfusion algorithms have been developed to provide goal-directed transfusion therapy during massive obstetric and severe hemorrhage. Although these algorithms are being used, they have not been formally validated.\(^24,25\)
5 There is sufficient evidence from multiple prospective observational studies that TEG/ROTEM shows strong correlation with conventional coagulation parameters in normal, hypocoagulable, and hypercoagulable states; however, there is a debate about the sensitivity of the assays in relation to pregnancy-related hyperfibrinolysis. Although overall, these assays may be less sensitive to fibrinolysis, the tPA TEG challenge test was shown to increase the sensitivity and specificity of defining clinically significant fibrinolysis and in vitro studies showed potential. It is not certain why pregnancy-related fibrinolysis may not be shown on TEG or ROTEM, perhaps because fibrinolysis is often localized to the placental bed rather than occurring systemically. Although the administration of the antifibrinolytic agent tranexamic acid is used widely for resuscitation of postpartum hemorrhage, there is not sufficient evidence that fibrinolysis detected by TEG/ROTEM can guide the drug use.

6 TEG/ROTEM have the potential to guide safe anesthesia in obstetric emergencies. It was reported that patients with platelet counts as low as 56,000/mm³ can safely receive spinal regional anesthesia during parturition, provided TEG results are normal and thus rendering more patients eligible to benefit from such anesthesia. According to some studies, TEG/ROTEM parameters correlate well with platelet count and function in all gestational weeks, which suggests platelet counts may be sufficient. Despite this, a safe cutoff in platelet counts may not be easily extrapolated from clinical situations. In addition, assessment of platelet function requires specialized tests that may not be readily available or feasible in clinical practice. Larger studies regarding the utility of TEG/ROTEM and/or platelet count to guide safe anesthesia in conditions such as immune thrombocytopenic purpura (ITP) and are still needed.

7 Given their higher sensitivity compared with conventional tests such as fibrinogen levels, and the added value of being a whole blood test, TEG/ROTEM can detect hypercoagulability in various pregnancy-related conditions, including gestational diabetes, preeclampsia, and hemolysis, elevated liver enzymes, and a low platelet count (HELLP) syndrome. Pathological changes of coagulation parameters including fibrinolysis using TEG/ROTEM have been reported in patients with antiphospholipid antibody syndrome. TEG changes were also seen in association with recurrent pregnancy loss.

8 Some studies reported TEG/ROTEM can be used to monitor the effect of low-molecular-weight heparin (LMWH) during pregnancy and puerperium to guide treatment of thrombophilia patients. Although some reported correlation to standard plasma anti-Xa assays for monitoring LMWH therapy in those patients, much of the data on LMWH are ex vivo or the result of very small cohorts. This also requires validation in larger studies.

4 | DISCUSSION

Postpartum hemorrhage remains the most common pregnancy condition for which TEG/ROTEM are currently used, with both fibrinogen and ROTEM FIBTEM being established as markers for predicting the progression of PPH and guiding transfusion needs. The results of one randomized control trial, regarding fibrinogen transfusion in PPH protocol, is now available and provides supportive evidence for usefulness of ROTEM FIBTEM in management of PPH. This randomized, controlled trial (RCT) showed infusion of fibrinogen concentrate triggered by FIBTEM A5 ≤15 mm did not improve outcomes in PPH and suggested fibrinogen replacement is not required if the FIBTEM A5 is >12 mm or fibrinogen >2 g/L, but an effect below these levels cannot be excluded.

Apart from this RCT, studies provided little outcome TEG/ROTEM data and were cautious regarding the generalized use of these tests in obstetrics. Recently published guidelines indicated that coagulation factors replacement to the level of normal range at term, during PPH may not be required and that raising them to the nonpregnant normal range may be sufficient. It is important to note that UK guidelines on the use of TEG/ROTEM in various conditions including PPH, trauma, guiding transfusion, and hemostatic therapy have just been published. In this regard, we would also refer readers to other useful documents/guidelines.

Clinicians who object to the utilization of the TEG/ROTEM in the obstetric population believe the problem is absence of large RCTs. Currently, the only available RCT to justify the use of the TEG/ROTEM is to guide blood products therapy in PPH. RCTs are also needed to assess hypercoagulability and risk stratification in pregnant women who may need VTE prophylaxis and similarly RCTs to assist in guidance of blood products therapy in patients with complex pathologies such as HELLP and other coagulopathies. The relative lack of knowledge of the TEG/ROTEM and thus the relative infrequency of use appear to have led to the resistance by Cochrane Reviewers to recommend the TEG/ROTEM for bleeding trauma and obstetric patients.

Studies that promote the utilization of the TEG/ROTEM to evaluate clinically significant fibrinolysis in obstetrics are lacking. Those available, mostly in trauma studies, suggest that improvement of these tests is needed as they are not sufficiently sensitive to guide the use of tranexamic acid. The definition of clinically significant fibrinolysis using the TEG/ROTEM remains unclear in literature. Further research, for better defining clinically significant fibrinolysis and guiding the use of tranexamic acid, and TEG/ROTEM is needed in obstetrics and other fields.

In our views, the major advantages of TEG/ROTEM are (a) being a whole blood global assay providing comprehensive picture on hemostasis and (b) their real-time, rapid assessments, compared with other plasma-based conventional tests. Additionally, enabling serial testing to closely monitor evolving clinical situations is a major advantage of TEG/ROTEM.

We also believe that much more attention needs to be given to assessment of hypercoagulability (compared with bleeding) during pregnancy, particularly in placenta-mediated complications with complex coagulopathies such as preeclampsia, gestational diabetes, or recurrent miscarriage. Indeed, extensive evidence for the effectiveness of TEG/ROTEM in identifying...
hypercoagulability has been demonstrated in various clinical conditions, including cancer and preeclampsia. TEG/ROTEM applications in hypercoagulability and thrombosis in pregnancy remain to be expanded.

Individualized therapy is an important principle in goal-directed treatment of coagulopathy. Individualization has the potential to reduce risk of iatrogenic complications or under-treatment. TEG/ROTEM, rather than conventional tests, may provide sufficiently detailed or sensitive results to enable this.

Interestingly, aside from PPH, most studies used data in comparison to conventional tests to validate TEG/ROTEM use; however, the clinical community often used these same results to justify continued use of conventional tests, potentially ignoring additional information provided by TEG/ROTEM. We believe that directly validating the usefulness of such information, improving the quality of hypercoagulability and/or fibrinolysis assessment (both underappreciated analyses when using TEG/ROTEM), while proving clinical efficacy/correlates would be rather valuable.

Finally, we highlight a few additional key points regarding practical use of TEG/ROTEM. Pregnancy reference ranges should always be used when assessing results of TEG/ROTEM in pregnancy/puerperium. It is essential that laboratories ensure high quality control is implemented. Clinicians who potentially manage such patients should be trained; training is easy and available. It is important to note new versions of the technology, including TEG6s (http://teg. haemonetics.com/en-gb) and ROTEM Sigma (https://www.rotem.de/en/products/rotem-sigma/) are now available. These tests are likely to provide higher reproducibility and easier applications and any treatment algorithm derived for earlier models may not apply to the new analyzers.

5 | SUMMARY AND FUTURE DIRECTIONS
A comprehensive 10-year literature review of objective evidence regarding the use of TEG/ROTEM in pregnancy is presented. In addition to the established evidence for using TEG/ROTEM in PPH, the literature has identified several potential areas for use in obstetrics, including detecting hypercoagulability and prediction of thromboembolism, assessment of coagulopathy in gestational diabetes, antiphospholipid syndrome, recurrent pregnancy loss, preeclampsia, and HELLP syndrome. In addition, the assessment of bleeding risk, provision of appropriate hemostatic cover at delivery for preexisting bleeding phenotypes, better assessment of the effect of LMWH during pregnancy and, finally, a more permissive safe threshold for spinal anesthesia.

There remains a need for further large, multicenter, perhaps randomized, and, certainly, more high-powered obstetric studies to generate evidence regarding clinical outcomes. We would hope to see some of these studies directed toward assessment of pregnancy-related hypercoagulable states and thrombosis risk stratification, with important clinical impacts such as VTE prophylaxis and LMWH therapies.

CONFLICTS OF INTERESTS
The authors declare no conflicts of interests.

AUTHOR CONTRIBUTIONS
M. Othman designed the project, reviewed all articles, analyzed data, and wrote manuscript. M. Elbatarny assisted with the project design, conducted the literature review, analyzed data, and wrote manuscript. K. Han, reviewed all the articles, tabulated, and analyzed data. R. Kadir designed the project, analyzed data, and wrote the manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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