Point-of-Care Viscoelastic Coagulation Monitor Identifies Coagulopathic Phenotypes during Mechanical Circulatory Support

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Introduction

- Comprehensive coagulation monitoring during mechanical circulatory support (MCS) traditionally requires clinical laboratory support.
- Coagulation monitoring during MCS is particularly important in populations at high risk for coagulopathic complications – such as trauma.
- The Viscoelastic Coagulation Monitor (VCM; Entegrion, Inc. Durham, NC, USA) was designed for point-of-care coagulation monitoring (850 g, 13x18x5 cm), to include outside of the hospital setting
- We previously demonstrated in a translational polytrauma swine model that VCM is comparable to a conventional laboratory-based viscoelastic coagulation test, TEG 5000 (Haemonetics; Waltham, MA, USA), and can identify coagulopathic phenotypes (Roberts, et al. *Mil Med.*2025; 190 (5-6):e994-e1003.
- VCM uses a native whole blood sample applied directly to a shelf-stable cartridge (~350 µL blood volume required) at the bedside. This is in contrast to TEG 5000 which requires citrate anticoagulation for sample transport to the laboratory, addition of $CaCl_2$ to sample before analysis, and trained laboratory personnel and pipettes for operation **(Figure 1).**
- We conducted a follow-on study to evaluate VCM in polytrauma injured swine that received rapid intervention with extracorporeal life support (ECLS) and 72-hours follow-up with systemic heparin anticoagulation.
- This work is a part of an ongoing international collaborative study involving observational clinical assessment of VCM during MCS at the Heart Institute of the Ministry of Health of Ukraine (HIMHU) (target enrollment N=25).

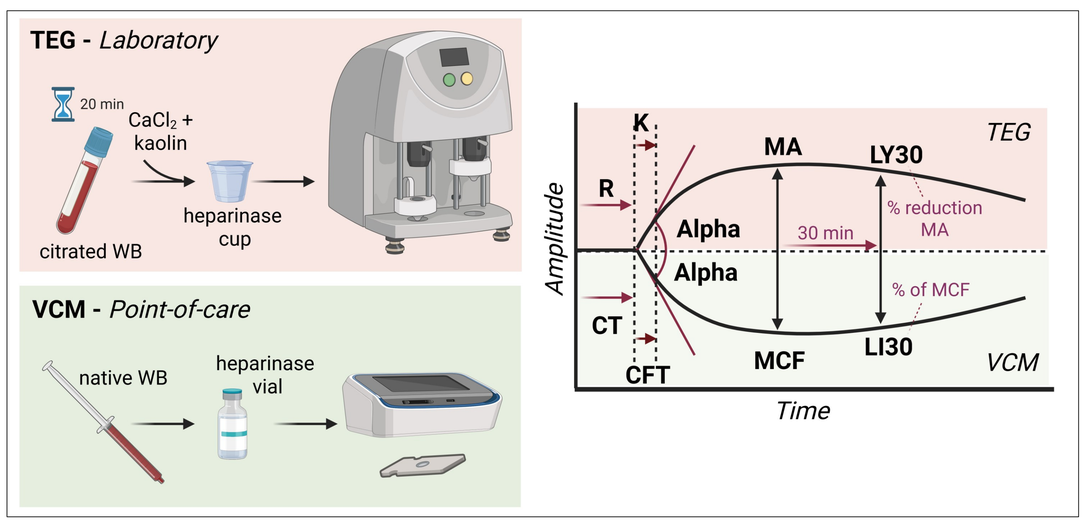

Figure 1: Comparison of TEG and VCM heparinase tests, and outcome metrics

Objective

- Evaluate diagnostic accuracy of VCM to predict common coagulopathic phenotypes during MCS with systemic heparin anticoagulation. Evaluate VCM in clinical setting in heparinized MCS patients at HIMHU. **Hypothesis:** VCM variables identify common coagulopathic phenotypes.

Methods

- Blood for VCM testing was acquired from anesthetized mechanically ventilated Yorkshire swine (*sus scrofa domesticus,* N=22; 46-65 kg*)* enrolled in the following studies: 1) ECLS in absence of injury (n=5); 2) ECLS following pulmonary contusion and controlled hemorrhage either with (n=6) or without (n=12) traumatic brain injury.
- Timepoints: baseline, post-injury + ECLS initiation, 6-, 24-, 48-, and 72-hr follow-up.
- For all studies, ECLS modality was extracorporeal carbon dioxide removal ($ECCO_2R$) with blood flow rate initiated at 1.5 L/min and sweep gas flow rate of 3-14 L/min depending on animal condition.
- For VCM use in heparinized subjects, 1 mL native whole blood was withdrawn from indwelling line. 350 µL blood was transferred to vial of lyophilized heparinase, gently mixed, and transferred to the VCM cartridge to initiate the test at point-of-care.
- Logistic regression and receiver operating characteristic (ROC) curves were used to examine predictiveness of VCM to identify the following coagulopathic phenotypes: low platelets (PLT ≤ 150 x 10^3/µL), low hematocrit (HCT ≤ 24 %), low fibrinogen (FIB ≤ 150 mg/dL), and high fibrinogen (FIB ≥ 400 mg/dL).
- At HIMHU, VCM heparinase test was conducted following the same methods at pre-cannulation, post-cannulation, 24-, 48-, and 72-hours follow-up in heparinized patients during MCS for various indications. Results compared in context of clinical labs. Representative results from the first n=6 patients are presented.

Results

- Summary of logistic regression and ROC curves with AUC > 0.7 in **Table 1.**
  1. Both CT and MCF showed good diagnostic accuracy for low hematocrit.
  2. CT showed excellent diagnostic accuracy for low fibrinogen.
  3. MCF showed excellent diagnostic accuracy for high fibrinogen; CT/CFT/Alpha showed good diagnostic accuracy for high fibrinogen.

Table 1

	AUC	Sensitivity	Specificity	Odds Ratio	95% Confidence Interval
Low Platelet Count					
VCM CFT	0.730	0.621	0.839	2.049	1.225-3.426
Low Hematocrit					
VCM CT	0.762	0.662	0.862	1.799	1.292-2.505
VCM MCF	0.799	0.688	0.910	0.836	0.761-0.918
Low Fibrinogen					
VCM CT	0.885	0.794	0.948	0.318	0.183-0.551
High Fibrinogen					
VCM CT	0.785	0.687	0.884	1.683	1.260-2.249
VCM CFT	0.764	0.659	0.868	1.959	1.201-3.193
VCM Alpha	0.772	0.668	0.876	0.919	0.874-0.965
VCM MCF	0.824	0.725	0.922	1.212	1.104-1.332

CFT, clot formation time; CT, Clotting time; MCF, maximum clot firmness; Alpha, rate of clot formation

- Pilot results for the first 6 patients receiving VCM during MCS with heparin anticoagulation at HIMHU are shown in **Figure 2** along with fibrinogen concentration, platelet count, and activated partial thromboplastin time at matched timepoints. All patients received systemic unfractionated heparin.

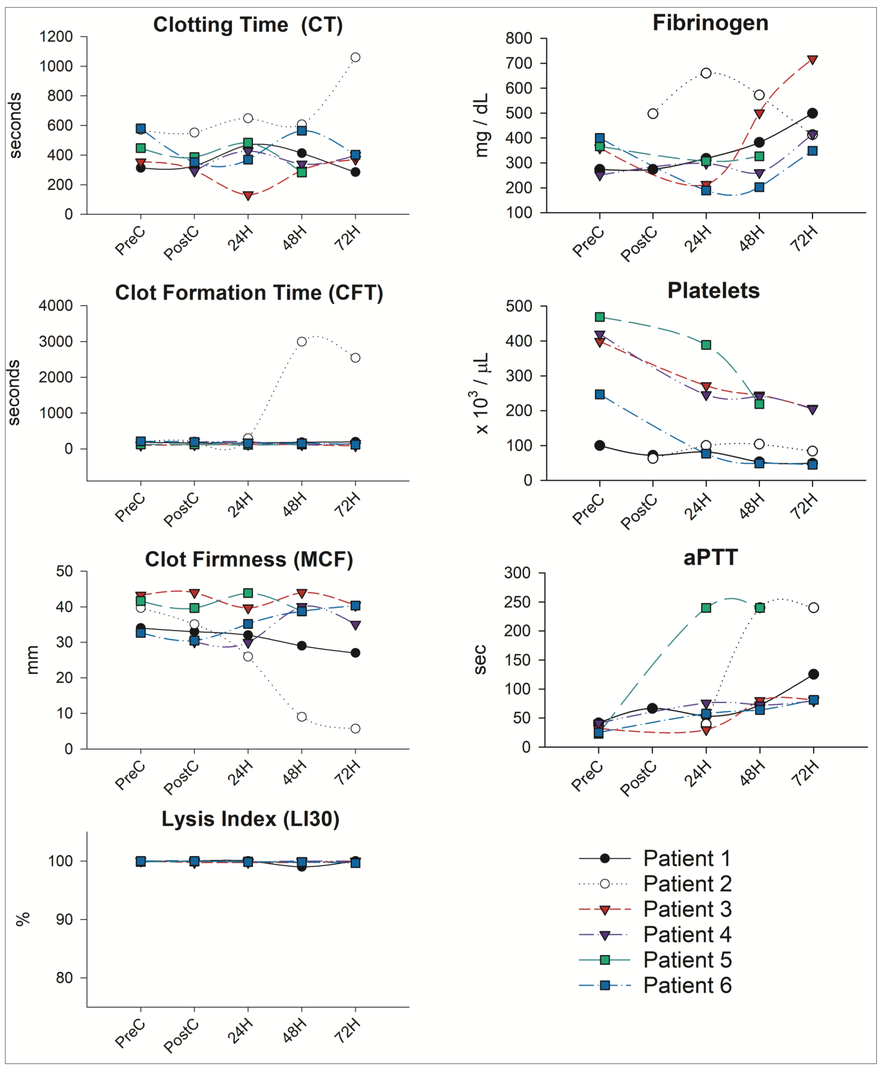

Figure 2: VCM results from 6 patients in HIMHU ECLS pilot study

Table 2

Patient	ECLS Indication	ECLS Type	Hemostatic Complication Encountered?
1	Heart Failure	VA-ECMO	N
2	ARDS	VV-ECMO	Y – tracheostomy site
3	Dilated Cardiomyopathy	VA-ECMO	Y – surgical bleed during heart transplant, 2x oxygenator replacement for clotting
4	ECPR	VA-ECMO	N
5	ECPR	VA-ECMO	Y- pericardial tamponade after stenting
6	ECPR, Intraoperative MI	VA-ECMO	Y-surgical bleeding

Conclusions

- VCM identified coagulopathic phenotypes during ECLS in heparinized swine both with and without trauma.
- VCM with heparinase in clinical setting at HIMHU during MCS is feasible.
- Data collection continues in our collaborative observational study at HIMHU.

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