

Prospective comparison of viscoelastic coagulation monitor (VCM) and rotational thromboelastometry (ROTEM) in the assessment of cirrhosis coagulopathy

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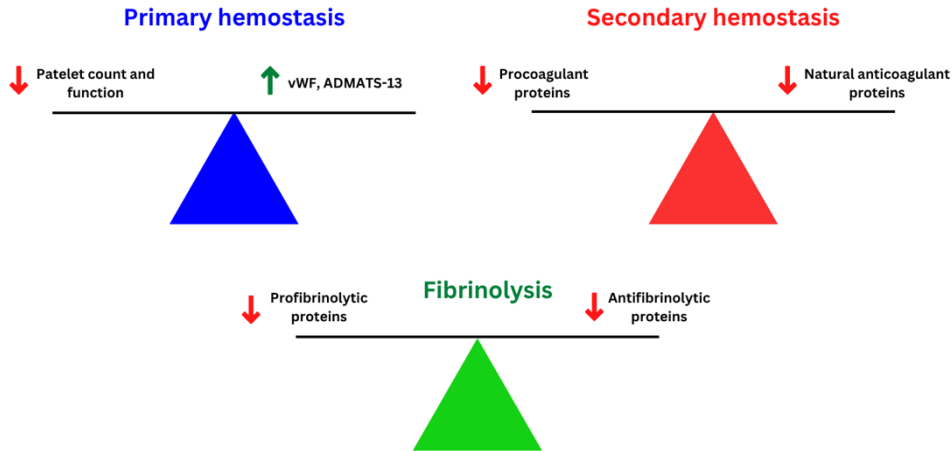
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Background



- INR and platelet count do NOT reflect hemostatic capacity
- Viscoelastic tests (VET) such as ROTEM and TEG enable real-time whole-blood clot analysis and are increasingly used in hepatology

Background



ROTEM relies on exogenous activators, potentially masking subtle hemostatic changes, especially in early-stage disease



VCM™ (Entegriion): new cartridge-based, activator-free device, 3 mL non-citrated whole blood, contact activation via glass discs

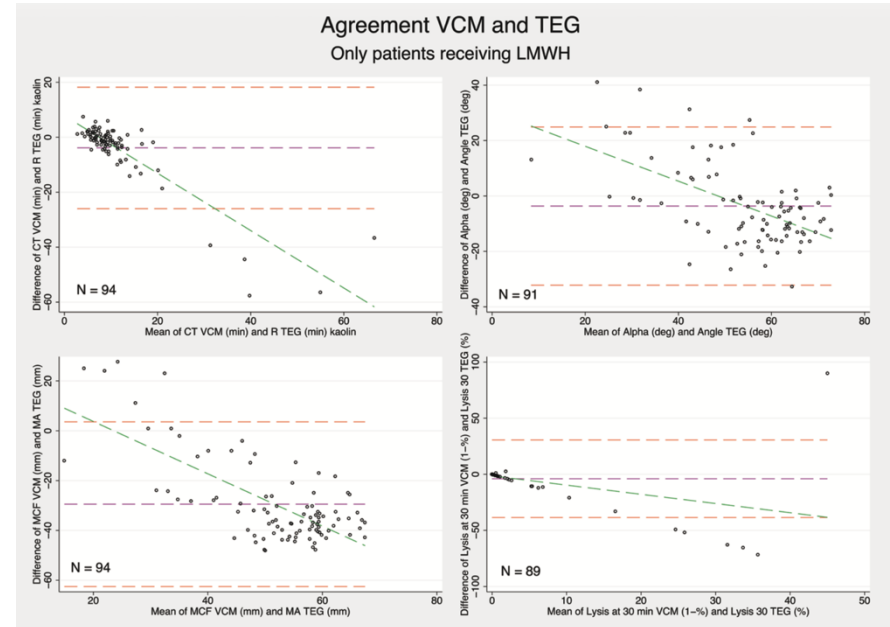
Background



Hemostatic Evaluation With Viscoelastic Coagulation Monitor: A Nicu Experience

Giacomo Simeone Amelio¹, Genny Raffaelli^{1,2}, Ilaria Amodeo¹, Silvia Gulden¹, Valeria Cortesi^{1,2}, Francesca Manzoni^{1,2}, Nicola Pesenti^{1,2}, Stefano Ghirardello^{1,4}, Fabio Mosca^{1,2} and Giacomo Cavallaro^{1*}

- VCM validated in surgical/ICU settings: strong correlation with TEG ($r^2=0.75-0.92$) and ROTEM ($\rho=0.70-0.80$)
- No study has yet assessed VCM™ in cirrhosis patients



Aim

- To evaluate VCM™ and ROTEM concordance
- To assess how each test tracks hemostatic changes depending on liver disease severity
- To verify whether VCM or ROTEM predict further decompensation or liver-related mortality

Methods



1. Anamnesis and clinical exploration



2. Blood samples including:

- Liver function
- Kidney function
- Albumin
- Blood count
- ROTEM



3. VCM samples collection



4. VCM analysis



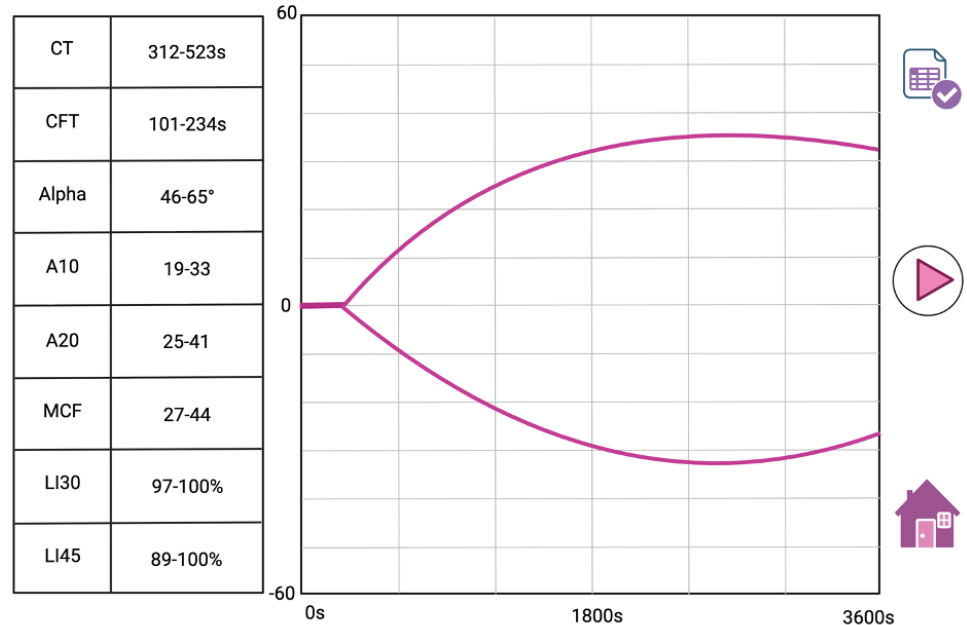
110 patients with cirrhosis admitted to Gastroenterology Unit of Padua University Hospital

Exclusion criteria:

- HCC
- Coagulation disorders
- Patients who received transfusions within 7 days

VCM™ : How It works

- **3 mL** of fresh whole blood, no preparation, no reagents
- Cartridge inserted in **< 4 minutes**: glass discs initiate clotting via contact activation (Factor XII), no chemical accelerants
- Results **within ~1 hour** directly at bedside

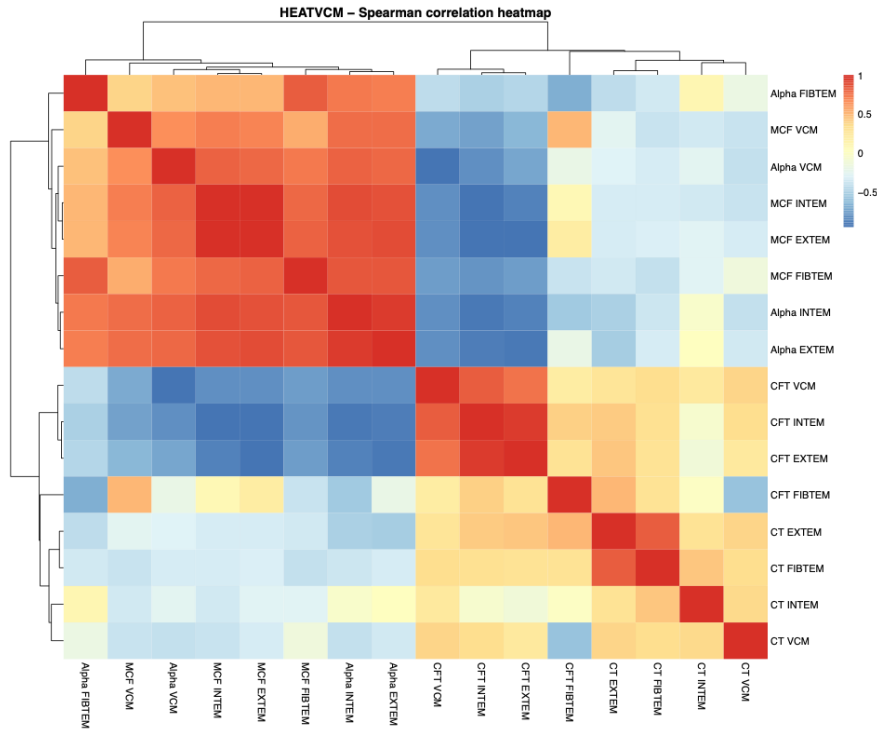


Results: Baseline Characteristics

Variable	Median (IQR)/ n (%)
Age	61.00 (54.00–68.00)
Sex	
Male	75 (68.2)
Etiology	
Alcohol-related	49 (44.5)
Viral	12 (10.9)
MASLD	10 (9.1)
Other	39 (35.5)
PLT (10⁹/L)	89.00 (56.00–139.00)
INR	1.56 (1.32–1.99)
Child-Pugh	
A	32 (29.1)
B	43 (39.1)
C	35 (32.7)
MELD	17.00 (12.75–23.00)
Esophageal/gastric varices*	81 (73.6)
Ascites*	53 (48.2)
PVT*	15 (13.6)
AKI*	25 (22.7)
Infection*	21 (19.1)

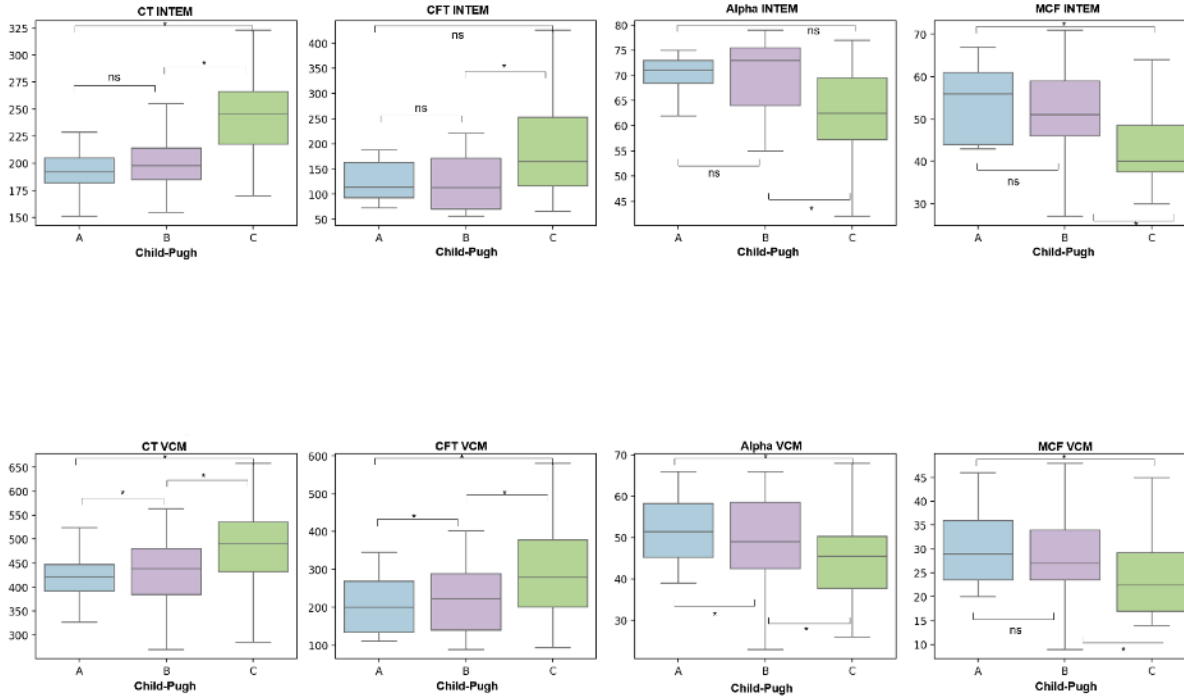
**at the time of sample*

Results: VCM and ROTEM concordance



- The **strongest** associations were observed for **alpha angle** ($\rho=0.80$; $p<0.0001$) and **MCF** ($\rho=0.71$; $p<0.0001$)
- Correlations with INTEM were similar: CT ($\rho=0.37$), CFT ($\rho=0.84$), alpha angle ($\rho=0.81$), and MCF ($\rho=0.73$; all $p<0.0001$).
- Concordance with **FIBTEM** was **weaker**

Results: Disease Severity



ROTEM

- Significant differences only in Child C
- Child A and B largely overlapping
- Limited early-stage discrimination

VCM™

- Progressive changes
A → B → C

Results: VCM across Child-Pugh CLASSES

Parameter	Child-Pugh A median (IQR)	Child-Pugh B median (IQR)	Child-Pugh C median (IQR)	p
CT (s)	421 (391.5–447)	439 (384.5–480.5)	491.5 (432.2–536.2)	0.0033
CFT (s)	200.5 (134–269)	223 (139.5–289)	279 (200.8–378.8)	0.0195
Alpha (°)	51.5 (45.2–58.2)	49 (42.5–58.5)	45.5 (37.8–50.2)	0.0297
MCF (mm)	29 (23.5–36)	27 (23.5–34)	22.5 (17–29.2)	0.0368

Activator-free VCM better approximates in vivo coagulation under low tissue factor exposure?

Results: Clinical Outcomes

0 non-portal hypertensive bleeding events

0 portal vein thrombosis development

Follow-up: median
11 months

Further decompensation: 30 patients
(27.2%)

Liver-related death: 16 patients (14.5%)

Results: Clinical Outcomes

No VCM parameter was associated with further decompensation/liver-related mortality in univariate or multivariate analysis (all $p > 0.05$)

Variable	Univariable		Multivariable	
	HR (95% CI)	p	HR (95% CI)	p
Sex			-	-
Male	1	0.511	-	-
Female	0.81(0.43-1.51)			
Age	1.06 (1.03-1.09)	<0.001	1.05 (1.01-1.09)	0.0282
Etiology				
Alcohol	1	-	-	-
Viral	1.01(0.40-2.55)	0.990		
MASLD	2.37 (0.868-6.49)	0.092		
Other	1.20 (0.62-2.33)	0.597		
MELD	1.04 (0.998-1.082)	0.0631	1.05 (0.994-1.10)	0.0859
Child-Pugh				
A	1	-	-	-
B	1.07 (0.43-2.63)	0.888		
C	1.98 (0.828-4.73)	0.124		
CT INTEM	0.99 (0.994 -1.01)	0.822	-	-
CFT INTEM	1.00 (0.999 1.01)	0.301	-	-
MCF INTEM	0.99 (0.962 -1.02)	0.583	-	-
Alpha angle INTEM	0.97 (0.942 -1.00)	0.0826	-	-
CT EXTEM	1.03 (1.01-1.05)	0.009	0.98 (0.950-1.02)	0.465
CFT EXTEM	1.00 (0.998-1.00)	0.520	-	-
MCF EXTEM	0.99 (0.966-1.02)	0.666	-	-
Alpha angle EXTEM	0.98 (0.948-1.01)	0.123	-	-
CT FIBTEM	1.01 (1.00-1.02)	0.00345	1.01 (1.00-1.02)	0.0132
CFT FIBTEM	1.01 (0.994-1.02)	0.369	-	-
MCF FIBTEM	0.96 (0.912-1.01)	0.142	-	-
Alpha angle FIBTEM	0.95 (0.880-1.04)	0.265	-	-
CT VCM	1.00 (0.998-1.00)	0.589	-	-
CFT VCM	1.00 (0.999-1.00)	0.565	-	-
MCF VCM	0.98 (0.95-1.01)	0.159	-	-
Alpha angle VCM	0.99 (0.971-1.02)	0.649		

Conclusions

- **VCM™** shows **good technical agreement with ROTEM** for key viscoelastic parameters in cirrhosis
- **VCM™** demonstrates more **gradual hemostatic changes across Child-Pugh stages**, possibly reflecting its activator-free, physiological activation kinetics
- **Neither VCM nor ROTEM** had independent **prognostic value**

Conclusions

- VCM's **portability** and **ease of use** make it a promising **point-of-care** alternative where accessibility matters
- Further prospective interventional studies are needed to define VCM-guided clinical protocols in cirrhosis



Thank you