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APPLICATION OF ROTEM TECHNOLOGY IN EARLY DIAGNOSIS OF DISSEMINATED INTRAVASCULAR COAGULATION SYNDROME

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Abstract

Disseminated intravascular coagulation (DIC) is a life-threatening coagulopathy characterized by simultaneous widespread activation of coagulation and fibrinolysis, leading to microvascular thrombosis and severe bleeding. Early diagnosis is crucial to improve patient outcomes, yet conventional laboratory tests often fail to capture the dynamic nature of this syndrome in real time. This study aimed to evaluate the diagnostic utility of rotational thromboelastometry (ROTEM) in detecting early-stage DIC and to compare its performance with standard coagulation tests including prothrombin time (PT), activated partial thromboplastin time (aPTT), fibrinogen levels, and D-dimer.A prospective observational study was conducted at a tertiary care center over 24 months. A total of 148 critically ill patients at risk for DIC were enrolled. ROTEM analysis (EXTEM, INTEM, FIBTEM, APTEM) was performed alongside conventional coagulation tests at admission and at 6, 12, and 24 hours. DIC was scored using the International Society on Thrombosis and Haemostasis (ISTH) scoring system. ROTEM detected hemostatic abnormalities significantly earlier than conventional tests. Sensitivity of ROTEM for overt DIC was 91.3% versus 74.6% for standard laboratory tests ($p < 0.01$). Clot formation time (CFT), clot amplitude at 10 minutes (A10), and maximum clot firmness (MCF) in the FIBTEM assay were the most sensitive ROTEM parameters, showing significant changes up to 4.2 hours earlier than conventional coagulation parameters.

Keywords: Rotational thromboelastometry (ROTEM); Disseminated intravascular coagulation (DIC); viscoelastic hemostatic assay; point-of-care testing; coagulopathy; critical care; early diagnosis; hemostasis; fibrinolysis; clot formation.

Introduction

Disseminated intravascular coagulation (DIC) is one of the most challenging and life-threatening complications encountered in intensive care medicine. It is not a disease entity per se but a syndrome that complicates numerous serious underlying conditions, including sepsis, major trauma, obstetric complications, malignancies, and severe burns. The pathophysiology of DIC involves a dysregulated activation of coagulation cascades, leading to the simultaneous formation of microthrombi throughout the vasculature and consumption of coagulation factors and platelets, which paradoxically results in bleeding tendencies. The global incidence of DIC among hospitalized patients ranges from 1% to 9%, with dramatically higher rates in specific clinical contexts. In patients with septic shock, DIC is reported in up to 35% of cases, while in patients with major trauma or obstetric emergencies, the incidence may reach 40–50%. Despite

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advances in critical care medicine, the mortality associated with DIC remains unacceptably high, ranging from 30% to 80% depending on the underlying etiology and severity of the syndrome. The timely diagnosis of DIC represents a major clinical challenge. Conventional laboratory coagulation tests — including prothrombin time (PT), activated partial thromboplastin time (aPTT), fibrinogen concentration, platelet count, and D-dimer levels — are widely used in clinical practice. However, these static, plasma-based assays fail to reflect the global hemostatic status, do not account for the contribution of cellular components (particularly platelets and red blood cells), and have significant turnaround times that delay clinical decision-making. Viscoelastic hemostatic assays (VHA), including thromboelastography (TEG) and rotational thromboelastometry (ROTEM), offer a compelling alternative. These point-of-care (POC) devices analyze whole blood and provide a comprehensive, real-time picture of the entire coagulation process — from clot initiation and propagation to fibrinolysis. ROTEM, in particular, has gained significant traction in perioperative and trauma settings, and emerging evidence suggests its potential utility in DIC diagnosis and management. Given the critical need for rapid and reliable diagnostic tools in DIC, this study was designed to assess the diagnostic performance of ROTEM in identifying early-stage DIC, compare its utility with conventional coagulation assays, and explore its potential to guide hemostatic therapy in critically ill patients.

Objective: The primary aim of this study was to evaluate the clinical diagnostic accuracy of ROTEM for the early detection of DIC in critically ill patients. The secondary objectives were: to identify the most sensitive ROTEM parameters for DIC detection. To compare the diagnostic performance of ROTEM with conventional coagulation tests (PT, aPTT, fibrinogen, platelet count, D-dimer) using the ISTH DIC scoring system as the reference standard. To assess the time advantage of ROTEM over conventional laboratory methods in detecting hemostatic abnormalities.To evaluate the correlation between ROTEM parameters and DIC severity score and patient outcomes.

Materials and methods

A prospective, observational, single-center study was conducted at the Department of Anesthesiology, Resuscitation, and Intensive Care of a tertiary university hospital over a 24-month period (January 2021 – December 2022). The study was approved by the Institutional Ethics Committee (protocol No. 2021-047) and conducted in compliance with the Declaration of Helsinki. Written informed consent was obtained from all patients or their legal representatives.Inclusion criteria: (1) adult patients (≥18 years) admitted to the ICU; (2) presence of at least one recognized underlying condition associated with DIC risk (sepsis/septic shock, major trauma, obstetric complications, hematological malignancy, solid tumor, or massive transfusion); (3) available baseline coagulation parameters within 1 hour of ICU admission.Exclusion criteria: (1) pre-existing coagulation disorders (hemophilia, thrombocytopenia of non-DIC origin); (2) current anticoagulant or thrombolytic therapy; (3) liver failure (Child-Pugh class C); (4) pregnancy at time of enrollment; (5) incomplete data sets; (6) patient or next-of-kin refusal to participate. Blood samples were collected simultaneously for ROTEM and conventional laboratory tests at four time points: admission (T0), and 6 (T6), 12 (T12), and 24 (T24) hours thereafter. ROTEM analysis was performed using the ROTEM delta analyzer (Tem Innovations GmbH, Munich, Germany) with four standard assays: EXTEM (extrinsic pathway activation with tissue factor), INTEM (intrinsic pathway activation with phospholipid and ellagic acid), FIBTEM (EXTEM with platelet inhibitor cytochalasin D, reflecting fibrin-based clot formation), and APTEM (EXTEM with aprotinin, for fibrinolysis detection). Key ROTEM parameters analyzed included: clotting time (CT), clot formation time

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(CFT), alpha angle (α), maximum clot firmness (MCF), clot lysis index at 30 minutes (CLI30) and 60 minutes (CLI60), and maximum lysis (ML). FIBTEM-MCF was used as a surrogate for functional fibrinogen levels.

Results

A total of 148 patients were enrolled in the study (mean age 54.3 ± 16.8 years; 58.1% male). The most common underlying diagnoses were sepsis/septic shock (n=61, 41.2%), major trauma (n=38, 25.7%), hematological malignancy (n=22, 14.9%), obstetric complications (n=15, 10.1%), and solid tumors (n=12, 8.1%). Overt DIC (ISTH score ≥5) was identified in 72 patients (48.6%), non-overt DIC (score 3–4) in 41 patients (27.7%), and 35 patients (23.6%) did not develop DIC during the observation period. Significant differences between overt DIC and non-DIC patients were observed across multiple ROTEM parameters. In the EXTEM assay, patients with overt DIC showed markedly prolonged CT (median 89 vs. 52 seconds; $p<0.001$) and CFT (median 187 vs. 98 seconds; $p<0.001$), with a significantly reduced MCF (median 34 vs. 58 mm; $p<0.001$) and decreased alpha angle (median 42° vs. 67°; $p<0.001$). FIBTEM-MCF, reflecting functional fibrinogen, was critically reduced in overt DIC patients (median 5 vs. 16 mm; $p<0.001$). In the APTEM assay, 31 of 72 overt DIC patients (43.1%) demonstrated evidence of hyperfibrinolysis, compared with 2 of 35 non-DIC patients (5.7%). ROC analysis demonstrated that ROTEM parameters offered superior diagnostic accuracy for overt DIC compared to individual conventional tests. The combined ROTEM index (incorporating EXTEM-CT, FIBTEM-MCF, and APTEM-ML) achieved an AUC of 0.941 (95% CI: 0.891–0.975), significantly outperforming the best individual conventional parameter, D-dimer (AUC 0.812; 95% CI: 0.740–0.871; $p=0.003$). The overall sensitivity of the ROTEM-based approach for overt DIC was 91.3% with specificity of 88.6%, compared with 74.6% sensitivity and 80.0% specificity for the ISTH score-based conventional panel. For early (non-overt) DIC, the diagnostic advantage of ROTEM was even more pronounced. FIBTEM-MCF <10 mm demonstrated a sensitivity of 78.0% and specificity of 85.7% for detecting non-overt DIC (AUC 0.834; $p<0.001$), whereas conventional fibrinogen levels at the same threshold showed a sensitivity of only 51.2% ($p=0.02$). Among patients in whom ROTEM-guided therapy was implemented (n=88), the total volume of blood product transfusions was significantly lower compared to patients managed by conventional coagulation monitoring alone (n=60): fresh frozen plasma 3.2 ± 1.1 vs. 5.8 ± 1.9 units ($p<0.001$); fibrinogen concentrate 2.8 ± 0.9 vs. 4.1 ± 1.3 g ($p=0.004$). ICU mortality in the ROTEM-guided group was 28.4% compared with 41.7% in the conventional group ($p=0.08$), though this difference did not reach statistical significance.

Conclusion

Rotational thromboelastometry (ROTEM) represents a significant advancement in the bedside diagnosis and monitoring of DIC. Compared to conventional coagulation assays, ROTEM provides earlier, more sensitive, and more comprehensive detection of hemostatic disturbances characteristic of DIC, with particular strength in identifying hypofibrinogenemia and hyperfibrinolysis — two critical and often underappreciated components of DIC pathophysiology. The approximately 4-hour diagnostic lead time over conventional tests is clinically meaningful in the ICU setting, where timely intervention is paramount. The integration of ROTEM into standardized DIC diagnostic and management protocols has the potential to reduce transfusion requirements, rationalize hemostatic therapy, and ultimately improve patient survival. Future multicenter randomized controlled trials are warranted to definitively establish ROTEM-guided management protocols in DIC and to determine whether the early diagnostic advantage translates into a statistically significant mortality benefit. Additionally, the

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development of ROTEM-integrated DIC scoring systems may provide a more dynamic and accurate diagnostic framework than current plasma-based scoring tools.

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