Application of thrombo-elastography in clinical practice and how to control quality

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Rotational thromboelastometry (ROTEM) and thromboelastography (TEG) are dynamic, visco-elastic coagulation tests, which represent the coagulation process from the initiation of the clot formation to fibrinolysis. The tests are performed in citrated whole blood instead of plasma, which saves time and gives a quick glance at the interaction between cellular and plasmatic clotting factors. The use of ROTEM or TEG in massive bleeding is widely practiced and has been proven to be cost effective (1). Literature and guidelines (2,3,4,5, 6) for the treatment of massive hemorrhage in bleeding patients recommend the use of TEG or ROTEM. Assessment of coagulation status in bleeding patients is complex. Global coagulation tests activated partial thromboplastin time (aPTT) and prothrombin time (PT) have been used for a long time. However, their ability to reflect *in vivo* hypocoagulability accurately is questioned since aPTT and PT reflect only a small part of the plasmatic coagulation system and do not provide information on the full balance between coagulation and anticoagulation. Rotational thromboelastography (TEG) and thromboelastometry (ROTEM) are developed as point-of-care tests (POCT). The devices are usually operated by a member of the operating team and not by a laboratory technician. Worldwide the ROTEM or TEG testing and performance is often not laboratory controlled. Quality control is required to ensure reliable results. The Maastricht University Medical Centre (MUMC+) decided to use thromboelastometry to monitor hemotherapy in massive bleeding in 2008. The implementation project lasted a couple of years. During the project, decisions were made on the type of equipment (ROTEM), the technical validation procedures (reproducibility)of the devices, the comparability between 3 devices and determination of normal values in healthy volunteers (7) and in pregnant women (8, 9). Routine tests (aPTT, PT, fibrinogen and platelet counts) were clinically compared with ROTEM parameters and turnaround time of our concept was validated (10). In the MUMC+ the clinical chemist is responsible for all laboratory devices in the hospital (central laboratory and all POCT devices) according to Dutch guidelines on POCT(11) and based on literature (12,13,14,15,16). The choice of the location of the ROTEM devices, the central laboratory or the operating theatre, was made in close collaboration with the anesthesiologists and surgeons. In case of massive, life-threatening bleeding, paramedics and medical staff are engaged with life-saving procedures, and processing of blood samples for ROTEM analysis may be delayed. Execution of ROTEM in a central laboratory was in our situation desirable to decrease reliance on nurse and medical staff and improve quality of test results. Analysis by qualified laboratory personnel assures high quality results and the performance of daily quality control according to ISO 15189. If ROTEM analysis is performed in a central laboratory, it is necessary to rapidly transport blood samples into the laboratory and transmit the results to the emergency and/or operating rooms as soon as they are available. Pneumatic tube mailing systems reduce workload and turnaround time and are used for transport of blood specimens. These transport systems have to be validated for coagulation assays depending on tube length and speed in your hospital. The tube transport in the MUMC+ did not affect ROTEM results (17) and transmission of “live” ROTEM graphic curves to the anesthesiologist in the operating theatre, emergency department or ICU was realized without time delay. ROTEM results transmission on-line using local area network is of greatly advantage and a prerequisite for centrally performed ROTEM analysis. In the implementation process in the MUMC+ the education and training of anesthesiologists in interpretation ROTEM results and the use of a ROTEM based treatment algorithm was very important. Finally, external quality assessment surveys are needed to control and compare test results with other users. For laboratories in the Netherlands it is necessary to participate in proficiency testing for all laboratory tests.(centrally performed testing ánd POCT devices). The UK National External Quality Assessment Scheme (NEQAS) for Blood Coagulation had already undertaken a series of exercises evaluating the provision of External Quality Assessment (EQA) material for these devices in 2010 (18). They showed that regular EQA/proficiency testing is needed for these devices especially when used as POCT devices in operating theatres. A series of studies took place in the UK using lyophilized plasmas as the test material. Up to 18 TEG users and 10 ROTEM users were involved testing different samples (normal plasmas, factor VIII or XI deficient samples, or normal plasmas spiked with heparin). The precision of the tests varied greatly for both devices, with coefficients of variances ranging from 7.0 to 83,6 %. Some centers returned results that were sufficiently different from those obtained by other participants to predict alterations in patient management decisions. In 2013 ECAT decided to start a first pilot for proficiency testing for ROTEM and TEG in The Netherlands with 9 pilot hospitals and 16 devices using 5 different plasma samples. The pilot was used to select the ROTEM or TEG parameters that were suitable for external quality control. In 2014 a second pilot survey was performed with 10 participants, 17 devices and 3 plasma samples. Results of the two pilot surveys will be presented during this ECAT meeting.

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