Multicenter Evaluation of the Quantra QPlus System in Adult Patients Undergoing Major Surgical Procedures

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BACKGROUND: The management of perioperative bleeding and the optimization of the available therapies are subjects of significant clinical interest. Clinical guidelines recommend the use of whole blood viscoelastic testing devices to target the utilization of blood products during major surgical procedures. The Quantra QPlus System is a new cartridge-based viscoelastic testing device based on an innovative ultrasound technology. The aim of this study was to evaluate this new system in a surgical population.

METHODS: Two hundred seventy-seven adult subjects were enrolled in a multicenter, prospective observational study consisting primarily of patients undergoing cardiac and major orthopedic surgeries. Samples were obtained at multiple time points for testing on the Quantra QPlus System, the rotational thromboelastometry (ROTEM) delta, and standard coagulation tests. Quantra measurements included Clot Time (CT), Heparinase Clot Time (CTH), Clot Time Ratio (CTR), Clot Stiffness (CS), Fibrinogen (FCS), and Platelet (PCS) Contributions to CS. Data analyses included assessment of the concordance of Quantra parameters with a series of clinical composite indexes formed on the basis of standard coagulation tests in 3 domains representing increased, decreased, and normal/subclinical coagulation function. Linear regression and receiver operator characteristic (ROC) analyses of Quantra parameters with corresponding parameters from ROTEM assays were also performed.

RESULTS: The accuracy (overall percent agreement or ratio of true positives and true negatives over the entire population) between the Quantra and the composite indexes was between 72% and 98% depending on the specific parameter. Linear regression analysis indicated that the correlation between ROTEM delta and Quantra was very strong with r values ranging between 0.84 and 0.89. Results from ROC analysis demonstrated sensitivities and specificities in the 80%–90% range when QPlus parameters were used to discriminate ROTEM threshold values currently used in goal-directed treatment algorithms.

CONCLUSIONS: This study demonstrated that the Quantra QPlus System is strongly correlated with a well-established viscoelastic testing device and its parameters effectively represent the results from multiple standard laboratory assays. The Quantra has been designed to operate at the point of care with the potential to provide rapid and comprehensive results to aid in the management of coagulopathic patients. (Anesth Analg 2020;130:899–909)

KEY POINTS

• Question: Can the Quantra QPlus System be used to monitor coagulation status in patients undergoing cardiac or major orthopedic surgeries?
• Findings: Metrics from the Quantra are strongly correlated with current viscoelastic testing devices and can integrate the information generated from laboratory tests of coagulation.
• Meaning: The Quantra QPlus System can be used as alternative to current viscoelastic testing devices to monitor coagulation function in the perioperative settings.

Reprints will not be available from the authors.
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GLOSSARY

ADP = adenosine diphosphate; aPTT = activated partial thromboplastin time; AUC = area under the curve; CCI = clinical composite index; CAP = College of American Pathologists; CE = Conformité Européenne; CLIA = Clinical Laboratory Improvement Amendments; CPB = cardiopulmonary bypass; CS = Clot Stiffness; CT = Clot Time; CTH = Heparinase Clot Time; CTR = Clot Time Ratio; EDTA = ethylenediaminetetraacetic acid; FCS = Fibrinogen Contribution; FDA = Food and Drug Administration; hPa = hectoPascals; ICU = intensive care unit; INR = international normalized ratio; IUO = Investigational Use Only; NL-NH = not low and not high; NPV = negative predictive value; PCS = Platelets Contribution; PT = prothrombin time; ROC = receiver operating characteristics; ROTEM = rotational thromboelastometry; SI = Système Internationale; TEG = thromboelastography; VET = viscoelastic testing

Patients undergoing major surgical procedures often develop coagulopathy due to extensive hemodilution, coagulation factor consumption, worsening of preexisting platelet defect(s), or coagulation disorder(s).1–5 Although various allogeneic blood components and pharmacological agents are available to treat coagulopathic bleeding, accurate and timely tests to determine their indications and doses are important to avoid unnecessary and incorrect transfusions as well as potential complications while reducing overall costs.

Cardiac bypass surgery has often been associated with significant intra- and postoperative blood loss. In addition to tissue injury and presurgical utilization of antithrombotic therapies, the use of heparin anticoagulation and protamine, the exposure to the surfaces of the bypass machine, hypothermia, and the invasiveness of the procedures further contribute to perioperative coagulopathic states.2–6 It has been estimated that roughly 20% of all allogeneic blood products are transfused to this patient population.2,3

Major spine surgery has also been reported to result in blood loss as high as 100%–150% of the circulating blood volume.7,8 The number of osteotomies required for surgical correction, wide surgical exposure, and the inability to obtain mechanical compression of bleeding surfaces are some of factors associated with this complication. This large volume blood loss precipitates a number of changes in the hemostatic pathways including platelet impairment, coagulation factor consumption, hemodilution, and fibrinolysis.9,10

Clinical guidelines on patient blood management recommend the use of viscoelastic testing (VET) devices in conjunction with goal-directed treatment algorithms to aid in the management of coagulopathic bleeding.11–14 Several prospective randomized studies in cardiac surgery have demonstrated the effectiveness of VET in reducing postoperative hemorrhage and certain blood product transfusions.15,16 Two technologies have emerged at the forefront of whole blood VET: thromboelastography (TEG System; Haemonetics Corporation, Braintree, MA) and rotational thromboelastometry (ROTEM; Instrumentation Laboratory, Bedford, MA). Both use an adaptation of the classic methodology first reported by Hartert that involves a pin suspended in a cup containing a blood sample.17 Recently, cartridge-based versions of these devices have been developed with only the TEG 6S having received Food and Drug Administration (FDA) approval.18

The Quantra QPlus System (HemoSonics, LLC, Charlottesville, VA) is a cartridge-based VET system that uses a novel ultrasound technology.19,20 The system is Conformité Européenne (CE) marked, and it has been granted de novo marketing authorization by the FDA. The performance of the system was previously reported in a number of single-center observational studies.21–25 In this article, we present the results of a multicenter, prospective, observational study aimed at evaluating the Quantra QPlus System as compared to the ROTEM delta and standard laboratory assays of coagulation in patients undergoing cardiac or major orthopedic surgeries. We hypothesized that this system would show a strong correlation with comparable ROTEM parameters and demonstrate a strong concordance with a series of clinical composite indexes (CCIs) based on laboratory assays.

METHODS

This was a multicenter, prospective, observational study with adult patients undergoing major cardiac and/or vascular procedures or major orthopedic surgery (primarily complex spine reconstructions). The 4 participating clinical sites were the University of Virginia Health System (Charlottesville, VA), Duke University Medical Center (Durham, NC), the University of Maryland Medical Center (Baltimore, MD), and the Medical University of South Carolina Health (Charleston, SC). The study was approved by each site’s local institutional review board and registered under Clinical Trial number NCT03152461. The primary objectives of the study were as follows: (1) to assess the clinical agreement between the QPlus parameters and a series of CCIs formed on the basis of standard coagulation tests in 3 domains representing increased, decreased, and normal/subclinical coagulation function and (2) to assess the correlation of the
Quantra parameters with corresponding metrics from the ROTEM delta.

**Study Population**

The subjects enrolled were scheduled for elective cardiac surgery with cardiopulmonary bypass (CPB) or multilevel thoracolumbar spine surgery between May 2017 and February 2018. A small number of subjects presenting with acute bleeding in a postsurgical unit after cardiac, vascular, or orthopedic surgery were also enrolled. Exclusion criteria included pregnancy, imprisonment, and inability to obtain consent. Preoperative use of anticoagulant or antiplatelet medications did not preclude enrollment in the study. Furthermore, to ensure there were sufficient samples to cover the measurement range for each QPlus parameter, additional samples were obtained from subjects outside the clinical population with an abnormal coagulation profile or by manipulating whole blood samples from normal volunteers (Supplemental Digital Content, Tables S1–S2, http://links.lww.com/AA/D9). Written informed consent was obtained from all enrolled subjects.

**Study Protocol**

For subjects undergoing cardiac surgery involving CPB, testing was performed at 4 time points: (1) preoperatively after the induction of anesthesia before surgical incision (baseline); (2) during surgery before the end of CPB (while the patient was still fully anticoagulated with heparin) (bypass); (3) after heparin reversal with protamine (postbypass); and (4) postoperatively, within 1–24 hours after arrival in the intensive care unit (ICU). For subjects undergoing major orthopedic surgery, testing was performed at 3 time points: (1) preoperatively before surgical incision (baseline); (2) during surgery (1 or 2 time points) (intraoperative); and (3) postoperatively, within 1–24 hours after arrival in the ICU.

At each time point, venous whole blood samples were collected by venipuncture or from an existing line into 3 citrated tubes (3.2% citrate) and 1 ethylenediaminetetraacetic acid (EDTA) tube. The citrated tubes were analyzed with the Quantra System; the ROTEM delta with the INTEM, HEPTEM, EXTEM, and FIBTEM assays; and a series of coagulation assays that included the prothrombin time (PT/international normalized ratio [INR]), activated partial thromboplastin time (aPTT), and fibrinogen level. The EDTA tube was utilized for analysis of platelet count. PT/INR, aPTT, fibrinogen level, and platelet count were performed by each clinical site’s College of American Pathologists (CAP)– and Clinical Laboratory Improvement Amendments (CLIA)–certified central laboratory and were interpreted based on the locally established reference ranges. Note that the PT/INR and aPTT assays were not performed during CPB due to the presence of high levels of heparin. Figure 1 shows a schematic representation of the study protocol.

The Quantra analyzers and QPlus cartridges used in the study were labeled for Investigational Use Only (IUO). The results generated by the Quantra QPlus Systems were blinded to the perioperative study team, and clinical decisions were solely based on each institution’s standard of care and were not influenced by the study. Quantra analyzers were located either directly outside the operating rooms (near patient), in the laboratory servicing the operating rooms, or in clinical research laboratories and were operated by the hospital staff according to the manufacturer-recommended guidelines.

All 4 clinical sites used automated fluorescent flow cytometry to measure platelet count (XN or XE analyzer with Fluorcell reagents; Sysmex North & South Americas, Lincolnshire, IL). Measurements of aPTT, PT/INR, and fibrinogen (Clauss assay) were performed using 2 different types of multiparameter analyzers with different reagents, both of which are used interchangeably in coagulation laboratories worldwide. Two sites used an automated photo-optical clot detection system (ACL TOP with HemosIL reagents; Instrumentation Laboratory, Bedford, MA) and 2 used an electromagnetic mechanical clot detection system (STA-R Evolution with STA reagents; Diagnostica Stago, Parsippany, NJ). ROTEM delta assays were performed by each site’s local laboratory by trained laboratory personnel.

All data were documented in an electronic Case Report Form using electronic data capture software (IBM Clinical Development, Armonk, NY).

**Quantra QPlus System**

The Quantra QPlus System is a new cartridge-based VET device consisting of an instrument (the Quantra Hemostasis Analyzer; HemoSonics, LLC, Charlottesville, VA), a single-use disposable cartridge, and external quality control materials. The Quantra QPlus System is fully automated and designed to operate at the point of care and in critical care environments by nonlaboratory personnel. The device measures the clot viscoelastic properties (ie, the shear modulus, an absolute measure of elasticity) using an ultrasound technology that does not require moving mechanical parts or direct contact with the sample. A detailed description of the device and its principles of operation are presented elsewhere.19,20

The QPlus Cartridge is a multichannel single-use component designed to assess the coagulation status of a patient’s whole blood sample in the perioperative settings. The measured parameters are as follows: Clot Time (CT) (reference range: 104–166 seconds), Heparinase Clot Time (CTH) (reference range: 103–153 seconds), Clot Stiffness (CS) (reference range: 13.0–33.2
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Clinical Composite Indexes
A series of CCIs were formulated to describe the coagulation status of the patient on the basis of routine coagulation test results. The development of the CCIs included an in-depth review of scientific and clinical literature, guidelines from the American and European Societies of Anesthesiologists, and consultation with physicians from anesthesia, hematology, and pathology departments across multiple institutions in the United States. Each CCI was classified to 1 of the following 3 categories, based on a set of specific definitions:

- High (H)—representative of increased coagulation function
- Low (L)—representative of decreased coagulation function
- Not low and not high (NL-NH)—coagulation function within normal and subclinical ranges

A detailed description of the CCIs definitions and the concordance analysis performed is provided in Supplemental Digital Content, Tables S3 and S4, http://links.lww.com/AA/D9.

Statistical Analysis
All data analyses presented here were performed using either SAS version 9.4 or higher (SAS Institute Inc, Cary, NC) or R Version 3.2.1 or higher (https://www.r-project.org/). Data analyses were performed by Precision For Medicine (PFM, Bethesda, MD).

For the analysis of concordance with the CCIs, each QPlus parameter result was classified as “low (L),” “NL-NH,” or “high (H)” based on its specific reference interval. For example, a short CT below the normal reference interval was classified as high (H) to denote increased coagulation function. Likewise, a high CS value above the normal reference interval was also classified as high (H). To assess concordance between each CCI and QPlus parameter pair, a 3 × 3 confusion matrix was constructed to depict the assignment of samples into L, NL-NH, and H categories based on CCI versus QPlus criteria. The agreement in each category, the overall agreement, and Cicchetti and Allison weighted κ statistics of the classification order L, NL-NH, or H were calculated and the corresponding

Figure 1. Schematic representation of the study design. Citrated venous whole blood samples were obtained at baseline, intra-surgery, and postsurgery in patients undergoing cardiac bypass and major orthopedic surgeries. aPTT indicates activated partial thromboplastin time; CS, Clot Stiffness; CT, Clot Time; CTH, Heparinase Clot Time; CTR, Clot Time Ratio; FCS, Fibrinogen Contribution; INR, international normalized ratio; PCS, Platelets Contribution; PT, prothrombin time; ROTEM, rotational thromboelastometry.
Figure 2. Dial-screen used on the Quantra Hemostasis Analyzer. Numerical results of specific parameters are displayed relative to a reference range (green segment on the dial). A, The representative dials from a cardiac bypass patient at baseline with coagulation function within normal reference values for each QPlus parameter are shown. The corresponding laboratory assay values and the ROTEM values were also within the respective normal reference ranges. B, The dials from a cardiac bypass patient after protamine reversal of heparin anticoagulation. In this case, a CTR value >1.4 denotes the presence of potential heparin residual. The coagulopathic state of this patient is further demonstrated by a decreased CS, decreased fibrinogen and platelet contributions. The corresponding laboratory assays indicated an aPTT of 73.8 s, Clauss fibrinogen level of 121 mg/dL, and platelet count of 57,000/μL. ROTEM showed an INTEM CT of 243 s, HEPTEM CT of 217 s, EXTEM A20 of 27 mm, and FIBTEM A20 of 5 mm. aPTT indicates activated partial thromboplastin time; CS, Clot Stiffness; CT, Clot Time; CTH, Heparinase Clot Time; CTR, Clot Time Ratio; FCS, Fibrinogen Contribution; PCS, Platelets Contribution; ROTEM, rotational thromboelastometry.
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95% confidence intervals were generated using a non-parametric bootstrap approach\(^3\) (ie, resampling of the sample data multiple times) at a patient level to account for repeated measurements taken for each subject.

Linear regression analysis was performed to characterize the correlation between the QPlus parameters and the corresponding ROTEM delta outputs. The following comparisons were performed: CT versus INTEM CT, CTH versus HEPTEM CT, CS versus EXTEM A20, and FCS versus FIBTEM A20. There are no ROTEM delta corresponding parameters for PCS and CTR. A Passing–Bablok regression analysis was also performed on rank-transformed Quantra and ROTEM delta data. The strength of the concordance and the correlation (\(r\) value) was interpreted according to common definitions: 0.00–0.19 “very weak,” 0.20–0.39 “weak,” 0.40–0.59 “moderate,” 0.60–0.79 “strong,” and 0.80–1.0 “very strong.”22,23

Finally, logistic regression models were used to assess the ability of QPlus parameters to discriminate a series of ROTEM-based values. Areas under the curves of the receiver operating characteristic (ROC) plots were created for each model, and optimal QPlus cutoff values were obtained by using the Youden \(J\) value.

Sample Size Calculation

To calculate sample size, a bootstrap resampling approach was used that relied on data from previous similar studies. Based on these results, 500 studies were simulated across a range of sample sizes. A sample size of 250 subjects, each with data from a minimum of 3 time points, was determined to provide a lower bound of the 95% confidence interval of the agreement in each of the 3 subcategories of the concordance analysis of at least 60% with an 80% power.

RESULTS

The eligible patient set consisted of 250 surgical subjects, 166 undergoing cardiac bypass surgery, 79 undergoing major orthopedic surgery, and 5 that presented with acute bleeding in a postsurgical unit after cardiac surgery. After closure of the study, 3 patients were excluded from data analysis due to issues with data collection that precluded comparison with the Quantra. These subjects were supplemented with samples obtained from 12 patients identified within the hospital or outpatient clinic with an abnormal coagulation profile, and 18 nonsurgical volunteers whose samples were artificially contrived to achieve various hypo- or hypercoagulation profiles. Patient demographic data and surgical details are summarized in Table 1, and Supplemental Digital Content, Tables S1 and S2, http://links.lww.com/AA/D9, describe the specific characteristics of the nonsurgical samples. From these, a total of 886 samples were obtained with each having data from a successful QPlus cartridge run enabling one or more comparisons of QPlus parameters to the CCIs or to the ROTEM delta. The failure rate of the Quantra System was just below 1.5%. In each of these cases, the failure was captured by the system’s internal quality control checks. Across the study, final QPlus results were available 12.6 ± 1.5 minutes after the test was initiated. The results of the analyses performed are summarized below.

### Concordance Agreement With CCIs

A detailed table with results of the concordance analysis is presented in Supplemental Digital Content, Table S5, http://links.lww.com/AA/D9. These data demonstrate strong and very strong concordance of the QPlus parameters with the CCIs formed from laboratory assays. The overall agreements ranged between 72% and 98%. The agreements in each of the 3 subcategories of the concordance analysis of at least 60% with an 80% power.

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<th>Table 1. Study Demographics</th>
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Values are expressed as mean ± standard deviation or number (%).

Abbreviations: CABG, coronary artery bypass graft; FXa, factor Xa; N/A, not applicable; TXA, tranexamic acid; VAD, vascular assist device; V-K, vitamin K.
Correlation With ROTEM Delta

The results from the linear regression analysis are summarized in Figure 3A–C, which shows the scatter plots of the 4 paired parameters: CT versus INTEM CT, CTH versus HEPTEM CT, CS versus EXTEM A20, and FIBTEM A20. The QPlus CT is compared to INTEM CT because both parameters are derived via activation of the intrinsic pathway. The ROTEM delta-based clot amplitude parameters from EXTEM and FIBTEM are plotted both in units of millimeters and after transformation into Pascals. Table 2 includes estimates of the slope and intercept, their 95% confidence intervals, and the Pearson correlation coefficients. The best fit equation utilized for the comparison of CS to EXTEM A20 and FCS to FIBTEM A20 corresponds to the published ROTEM conversion formula to transform clot amplitude from units of millimeter to units of Pascals.32,33 These data demonstrate a very strong correlation of QPlus parameter to corresponding metrics obtained from various ROTEM delta assays, accepting the presence of an inherent bias associated with the differences in measurement principles.

To mitigate the effects of the bias, we performed a Passing–Bablok regression analysis using rank-transformed Quantra and ROTEM delta values. The rank transformation replaces each device’s actual test value with its corresponding rank with the smallest value receiving a rank of 1, the second smallest value a rank of 2, etc. Using the rank-transformed data, the best fit line obtained via Passing–Bablok regression had estimated slopes of 1.0 with intercept estimates close to 0 for all 4 matching QPlus/ROTEM parameters. The estimated Pearson correlation coefficients of rank-transformed data also demonstrated very strong correlation between the paired variables, with $r$ values (Pearson correlation) between 0.82 and 0.9 (data not shown).

ROC Analysis

The results of the ROC analyses are presented in Table 3, which indicates the ability of QPlus
parameters to discriminate specific values of corresponding ROTEM assays. The ROTEM values represent threshold values typically used in goal-directed treatment algorithms for managing coagulopathic bleeding in cardiothoracic surgery. Therefore, for this analysis, only data from the cardiac patients were utilized. Note that for some comparisons between CT versus INTEM CT and CTH versus HEPTEM CT, there were only a limited number of occurrences with prolonged CTs, thus generating artificially low cutoff values for CT and CTH parameters.

**DISCUSSION**

This article describes the results of a multicenter study aimed at characterizing the performance of the Quantra QPlus System, a fully automated cartridge-based VET device, in patients undergoing major surgical procedures. This also represents the first report of a market-ready version of the system. In agreement with the results from previously published single-center studies in cardiac and spine reconstruction patients, the data presented here confirm that the QPlus parameters are very strongly correlated with corresponding metrics obtained from the ROTEM delta, a well-characterized VET system. Furthermore, the results also demonstrated the concordance of the QPlus parameters with a series of laboratory-based CClIs in the clinically relevant spectrum of coagulopathic dysfunctions.

The concordance analysis of QPlus parameters versus the CClIs demonstrated that in the majority of cases, samples were similarly classified as L, NL-NH, or H coagulation function at least 80% of the time, thus indicating not only very strong concordance but also the ability of the QPlus parameters to integrate the results from multiple standard laboratory assays.

The results from the linear regression analysis using raw values from each device highlighted the differences in technologies and reported parameters. While the Quantra directly measures the clot shear modulus and thromboelastometry, the results from previously published single-center studies in cardiac and spine reconstruction patients, the data presented here confirm that the QPlus parameters are very strongly correlated with corresponding metrics obtained from the ROTEM delta, a well-characterized VET system. Furthermore, the results also demonstrated the concordance of the QPlus parameters with a series of laboratory-based CClIs in the clinically relevant spectrum of coagulopathic dysfunctions.

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output CS, FCS, and PCS in units of hPa, the ROTEM delta indirectly measures the shear modulus and instead outputs clot amplitude on arbitrary units of millimeters. Shear modulus is a well-known and objective parameter that describes the elastic properties of a solid material and is expressed in Système Internationale (SI) units of Pascals. Figure 3C, D demonstrates that the QPlusses’ CS and FCS parameters are nonlinearly related to EXTEM A20 and FIBTEM A20, respectively (data shown as filled blue dots). This result is expected due to the nonlinear, polynomial relationship between Pascals and millimeters.32,33 When the nonlinear transformation is applied to the ROTEM data, linearity is established albeit in the presence of measurement bias caused primarily by differences in reagents and technologies utilized by the 2 devices (data shown as orange-filled diamonds in Figure 3C, D). This bias, however, does not introduce concerns regarding the comparison of these devices since measured results are interpreted in relation to the respective reference intervals.

The differences in technology and physical properties measured by the Quantra as compared to conventional VET systems have important implications regarding the measurement of CS and other derived parameters. Solomon et al33 recently demonstrated that calculation of the platelet component to CS should be based on measurements of elasticity and not on measurements of clot amplitude as currently done in thromboelastography (TEG) and thromboelastometry devices. Because the Quantra System directly measures the shear modulus and the elastic properties of the clot, it can correctly quantify the contribution of platelets to clot stiffness. In a recent study in cardiac surgery, PCS was independently associated with platelet count and adenosine diphosphate (ADP)-dependent platelet function as measured by multiple electrode aggregometry, thus demonstrating an association between a VET test result and a nonviscoelastic or platelet count–related measure of platelet function.25

Additionally, the direct measurement of the clot stiffness properties using the shear modulus may result in output parameters that more accurately reflect the cross-functional interactions between the main coagulation components. While fibrinogen generates a stiff 3-dimensional fibrin structure, the functional interaction of platelets removes “slack” from this structure, resulting in a multiplicative effect on the overall viscoelastic property. In the data presented here, the platelet contribution to clot stiffness measured with the Quantra shear modulus was on average 7.8 ± 2.6 times greater than the stiffness generated by fibrinogen alone. The nonlinear transformation that governs the relationship between shear modulus and clot amplitude results in a form of data compression. At low values, changes in shear modulus and clot amplitude are roughly proportional, but with larger values, the same differences in millimeters correspond to progressively larger differences in shear modulus. Effectively, this translates to a reduced dynamic range for clot stiffness measurements and in a bias toward the fibrinogen component when clot amplitude measurements in millimeters are used. Because platelets contribute to the majority of the measured clot stiffness,26,32 this effect is more pronounced with the assessment of the platelet contribution as demonstrated by Solomon et al33 and Ranucci et al. Multiple regression analysis indicated that fibrinogen explained 43.4% of the variability in the QPlus CS values and 46.6% of the variability in the EXTEM values, hence, fibrinogen alone was a slightly better predictor of the EXTEM A20 value than the QPlus CS value. However, when knowledge of the platelet count was added to the model, fibrinogen and platelets explained 64.4% of the QPlus CS value and 60.3% of the EXTEM A20 value. As a result, knowledge of the platelet count provided an additional 21.0% to the explanation of the variability of QPlus CS and 13.7% to the explanation of the variability of EXTEM A20.

The results of the ROC analysis between the Quantra and the ROTEM delta further demonstrate the relationship between corresponding metrics from these devices. QPlus parameters can accurately discriminate clinically relevant ROTEM values that are often utilized in goal-directed transfusion algorithms. The derived QPlus threshold values could be used as an initial starting point in the development of an algorithm for use in cardiac surgery which includes information related to a patient’s coagulation status provided by the Quantra QPlus System.

The study was limited because it was observational, and the clinical impact of the Quantra System should be evaluated in future interventional studies. The definitions of the CCIs did not include the results of additional assays such as platelet function testing or factor XIII assays, for example, because those were not routinely available. Additionally, not all the QPlusses and ROTEM delta parameters were compared because each system parameter was not available across both platforms.

In conclusion, this work demonstrates the clinical performance of a new FDA-approved device that is based on a novel technology with the potential to enable unique capabilities. Like conventional TEG and thromboelastometry devices, the Quantra calculates and displays parameters that can be directly associated with potential interventions utilized in major surgical procedures, but with the addition of 2 potential unique parameters: PCS and CTR. Output parameters are displayed using dial display instead of shape recognition of curves. These features have the potential to allow the development of more simplified treatment algorithms for the clinical implementation
of the Quantra and therefore to enable rapid and comprehensive results to aid in the management of coagulopathic patients.

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DISCLOSURES

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Contribution: This author helped design and conduct the study and write the manuscript.
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Contribution: This author helped design and conduct the study and write the manuscript.
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Contribution: This author helped design and conduct the study.
Conflicts of Interest: None.
Name: Charles S. Greenberg, MD.
Contribution: This author helped design and conduct the study.
Conflicts of Interest: None.
Name: Deborah A. Winegar, PhD.
Contribution: This author helped design the study, analyze the data, and write the manuscript.
Conflicts of Interest: D. A. Winegar is an employee of HemoSonics, LLC, a medical device company that is commercializing the Quantra QPlus System.
Name: Francesco Viola, PhD.
Contribution: This author helped design the study, analyze the data, and write the manuscript.
Conflicts of Interest: F. Viola is an employee of HemoSonics, LLC, a medical device company that is commercializing the Quantra QPlus System.
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REFERENCES


