

Comparison of Thromboelastography Devices TEG[®] 6S Point of Care Device vs. TEG[®] 5000 in Pediatric Patients Undergoing Cardiac Surgery

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Abstract: Thromboelastography (TEG) can predict bleeding in pediatric patients undergoing cardiac surgery. We hypothesized that results obtained from TEG[®]5000 correlate with the new point-of-care TEG[®]6S system and that TEG[®]6S rewarming maximum amplitude (MA) is associated with surrogate endpoints for perioperative bleeding in pediatric patients who underwent complex cardiac surgery. We describe a retrospective study of pediatric (≤ 18 years) patients who underwent complex cardiac surgery on cardiopulmonary bypass. Citrate whole-blood samples were used to compare TEG[®]5000 vs. TEG[®]6S and TEG[®]6S-FLEV (with fibrinogen measurement) vs. Clauss-fibrinogen methods. TEG[®]6S parameters obtained during rewarming were compared to the surrogate endpoints for perioperative bleeding using linear regression analysis. Among 100 patients, 225 TEG[®]5000 vs. TEG[®]6S comparisons and 54 TEG[®]6S-FLEV were analyzed. Good correlation was observed for all parameters comparing TEG[®]5000 to TEG[®]6S and TEG[®]6S-FLEV to the Clauss-fibrinogen method (Pearson $r \geq .7$). Similar to rewarming

TEG[®]5000 MA, rewarming TEG[®]6S MA was the only parameter independently associated with risk for perioperative bleeding (median [interquartile range {IQR}] in bleeding vs. nonbleeding patients: 35 [29, 48] vs. 37 [32, 55]; $p = .02$). A platelet transfusion calculator was developed based on TEG[®]6S results by determining the relationship between platelet transfusion volume (mL/kg) and percent change in MA using linear regression analysis. TEG[®]6S is a good alternative point-of-care method to analyze a patient's coagulation profile and it is comparable to TEG[®]5000 in pediatric patients undergoing cardiac surgery on cardiopulmonary bypass. Lower TEG[®]6S MA during rewarming is associated with increased risk for perioperative bleeding. TEG analysis during rewarming may be useful in customizing platelet transfusion therapy by reducing the risk of bleeding while minimizing excessive blood product transfusions. **Keywords:** pediatric cardiac surgery, thromboelastography (TEG), fibrinogen, anticoagulation, congenital heart disease. *J Extra Corpor Technol.* 2022;54:42-9

Postoperative bleeding is a major complication leading to morbidity and mortality in pediatric patients undergoing complex cardiac surgery requiring cardiopulmonary bypass (CPB) (1). Blood product transfusions are generally used as a first line of therapy in high-risk patients to

minimize perioperative bleeding and prevent adverse outcomes (2). Thromboelastography (TEG) to guide perioperative blood transfusions in high-risk patients can help minimize the risk of postoperative bleeding and reduce excess use of blood products (3,4). In a recently published article, we have shown an association of low rewarming TEG maximum amplitude (MA) measured on TEG[®]5000 (Haemonetics Inc., Braintree, MA) device with increased risk for bleeding in pediatric patients undergoing high-risk cardiac surgery (5).

An advancement in viscoelastic testing is the availability of TEG[®]6S, a point-of-care (POC) testing alternative

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to TEG[®]5000, with several benefits including ease of use (no need for pipetting), ability to perform multiple tests, and ease of maintenance. Apart from that, the TEG[®]6S analysis is more valuable in pediatric patients than in adults due to the small sample volume (340 μ L for four tests including a test for detecting fibrinogen levels [TEG-FLEV] on TEG[®]6S compared to 1,000 μ L for two tests on TEG[®]5000) required for testing. The user-friendly nature of this semiautomated TEG[®]6S system makes it more accessible to healthcare professionals as there is less need for extensively trained laboratory technicians, currently required for operating the TEG[®]5000 system. Because of the need for such advanced skill levels for operating TEG[®]5000, samples cannot be tested in the operating room (OR) and have to be sent out for analysis unlike TEG[®]6S. Furthermore, the TEG[®]6S system minimizes operator variability and technical errors. Additionally, unlike TEG[®]5000, the TEG[®]6S can be used as POC system as it can be moved around easily to test at the bedside, in the OR, or other patient care sites. Of note, TEG[®]6S has been approved by the Food and Drug Administration (FDA) for POC testing in adults, but is yet to be validated in pediatric patients.

Given the many advantages of TEG[®]6S, we sought to better understand its applicability in the pediatric population. To facilitate intraoperative workflow in use of rewarming TEG analysis for clinical decision-making, we examined the correlation between TEG[®]6S and TEG[®]5000 results for all major TEG parameters (R-time, K-time, Angle, and MA). In addition, we compared TEG-FLEV obtained from TEG[®]6S to the gold standard Clauss-fibrinogen method for detecting functional fibrinogen levels. We hypothesized that rewarming TEG[®]6S MA is associated with the composite endpoints of perioperative bleeding. Based on TEG[®]6S results at rewarming, we developed a platelet transfusion calculator that can estimate the change in MA associated with platelet transfusion volume indexed to patient weight.

MATERIALS AND METHODS

Study Design

Inclusion and exclusion criteria. Pediatric patients (age \leq 18 years) who underwent clinical testing with TEG[®]5000 at Boston Children's Hospital (BCH), who also underwent TEG[®]6S analysis between September 2017 and June 2020 were included in this study. Inclusion criteria for this cohort: 1) neonatal operation (age \leq 30 days), 2) single ventricle physiology, 3) reoperative sternotomy with greater than two previous operations, 4) complex cardiac reconstruction with prolonged duration of CPB $>$ 200 minutes. Also, patients were

included in this study only if TEG analysis was performed at both time points (during rewarming phase of CPB [32°C] and upon arrival to intensive care unit [ICU]) on both TEG devices. The patients who underwent clinical testing with TEG[®]5000 also underwent testing by TEG[®]6S only if sufficient remaining sample was available. Patients were excluded if they received blood product transfusion prior to TEG analysis in the OR. Institutional Review Board approved waiver of consent for this retrospective study.

TEG testing protocol and sample collection. Under our institution clinical TEG protocol, patients undergoing complex cardiac surgical procedures and presumed to be at high risk for bleeding/thrombotic complications were identified. Citrated whole-blood samples were collected during rewarming on CPB at 32°C and upon arrival to the cardiac ICU (following any blood product administration in the OR). TEG analysis was performed on all samples using TEG[®]5000 in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory. After the completion of testing on TEG[®]5000, any remaining citrated whole-blood sample was analyzed on the TEG[®]6S device. Citrated whole-blood samples drawn during rewarming phase were tested in the presence of heparinase on TEG[®]5000 and TEG[®]6S devices to neutralize excess heparin. Also, the testing was not affected by the presence of low levels of calcium in the circuit blood as the sample is collected in the sodium citrate tubes, which neutralizes the effect of calcium.

Study Endpoints. Several hypotheses were tested in this study. First, we hypothesized that TEG[®]6S values correlate with TEG[®]5000 values, and correlation was determined as outlined below. Second, we hypothesized that TEG[®]6S values correlate with clinical endpoints of bleeding following cardiac surgery, and that TEG[®]6S results can be used to risk stratify patients. Finally, as a secondary analysis, a platelet transfusion calculator was developed based upon TEG[®]6S data prior to and following platelet transfusion.

Transfusion practice at our center. Platelets are commonly transfused after CPB at our institution. Fresh frozen plasma (FFP), packed red blood cells (pRBC), recombinant Factor VIIa (rFVIIa), and cryoprecipitate are also available for transfusion during the perioperative period. Extended transfusion in this study was defined as the administration of one or more of these blood products in addition to platelets. Our primary outcome was a "composite endpoint" that was used as a surrogate for perioperative bleeding and included 1) need for extended transfusion in the perioperative period (OR), and/or 2) surgical reexploration for

bleeding. This intraoperative composite endpoint has been previously described and validated (5,6).

No standardized transfusion protocol for bleeding was present during the study period. Although general practice for blood product transfusions in the OR at our center includes a few guidelines: all patients irrespective of bleeding status in the OR receive cell saver processed or Blood Bank pRBC as indicated by hemodynamic status and hemoglobin levels. Platelets are used as first-line therapy following administration of protamine in patients with subjective bleeding. If the patient continues to bleed, cryoprecipitate or FFP are used as second line of therapy, followed by rFVIIa in patients with refractory severe bleeding persisting after second line of therapy.

Information on patient characteristics, blood product transfusions, and clinical laboratory data including all TEG[®]5000 parameters were collected from the electronic medical record.

Blood product transfusions calculator. Using Python libraries, the relationship between MA and perioperative platelet transfusion was modeled by performing least-squares regression analysis (<https://ipython.org>). Various prediction models were generated based on the Pearson correlation *r* test and the best-fit model was found to be linear.

Relation between 1) percent difference in MA before and after platelet transfusion vs. volume in milliliters/kilogram (mL/kg) of platelet transfusion and 2) percent difference in fibrinogen levels before and after platelet transfusion vs. the volume in milliliters/kilogram (mL/kg) of platelet transfusion was determined using the selected linear regression model.

A web-based formula that outputs the ideal and minimum platelet transfusion volume based upon user inputs (TEG[®]6S MA and patient weight) for nonneonates was designed based on the developed platelet calculator.

Statistical methods Median with interquartile range (IQR) was used to describe continuous data and number with frequency was used for categorical data. Univariate (polynomial, piecewise linear) regression analysis was used to determine the association between TEG[®]6S parameters and composite endpoints for bleeding in the OR. Bland–Altman plots were constructed by plotting average values of both measurements on X-axis against difference between the measurements for all comparisons on Y-axis. K nearest neighbors' method and polynomial regression were used to determine the relationship between MA and the probability of reaching the composite bleeding endpoint. For nonlinear fits, piecewise linear models were used to evaluate the association with probability of reaching the composite bleeding endpoint, as a means of categorizing the continuous

Table 1. Patient demographics and characteristics (n = 100).

Patient Characteristic	Median (IQR) or N (%)
Age at surgery (years)	.9 (.02, 4)
Neonates	27 (27%)
Weight (kg)	7.7 (3.6, 15.2)
Male	53 (53%)
Composite endpoint reached in OR	38 (38%)

Median (IQR) or number (%) are represented in the table. IQR, interquartile range; OR, operating room.

predictor. Python libraries (NumPy) and GraphPad Prism version 8.0 (San Diego, CA) were used for analysis. A *p*-value < .05 was considered statistically significant for all comparisons.

RESULTS

Patient Characteristics and Outcomes

One hundred patients (Table 1) met the inclusion criteria and were analyzed with both TEG analyzers. Of the 100 patients, 38 reached the composite endpoint for intraoperative bleeding (Table 1).

TEG[®]5000 and TEG[®]6S Comparisons

Among 100 patients yielding 225 comparisons, on samples tested from rewarming time point and the ICU, linear regression analysis revealed good correlations (Pearson *r* ≥ .7) for all TEG parameters (R-time, K-time, angle, and MA) comparing TEG[®]5000 to TEG[®]6S (Figure 1A–D). Bland–Altman plots were constructed by plotting average values of both time points against difference (TEG[®]5000 – TEG[®]6S) for all TEG parameters. Figure 2A–D and Table 2 show the Bland–Altman parameters including bias values, limits of agreement (LOA), and percent coefficient of variation (%CV) for all TEG parameters. The %CV between TEG[®]5000 and TEG[®]6S was <15% for R-time and K-time, and <10% for angle and MA, suggesting good agreement between the devices.

Fibrinogen Level Comparisons—TEG[®]6S-FLEV vs. the Clauss-Fibrinogen Method

TEG[®]6S-FLEV obtained after surgery in the ICU was compared to the gold standard Clauss-fibrinogen method used for quantifying fibrinogen levels. The mean TEG[®]6S-FLEV (321 ± 106 mg/dL) was significantly higher compared to the Clauss-fibrinogen levels (278 ± 93 mg/dL) (paired *t* test; *p* < .001). There was good correlation between TEG[®]6S-FLEV and the Clauss-fibrinogen levels (Pearson *r* = .84) (Figure 3A). Bland–Altman plots were constructed by plotting average values of both methods against difference (Clauss-fibrinogen method – TEG[®]6S-FLEV)

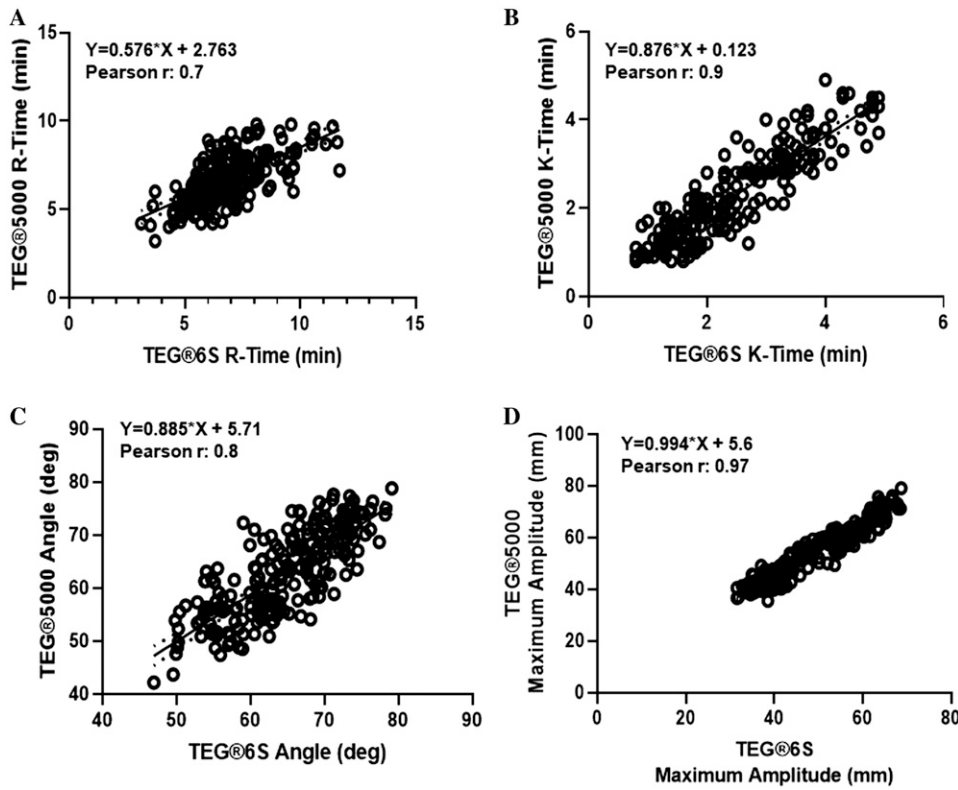


Figure 1. Linear regression plots (A–D) for all thromboelastography (TEG) parameters comparing TEG®5000 vs. TEG®6S from n = 100 patients yielding 225 comparisons analyzed from samples collected from rewarming and intensive care unit (ICU) time points. The solid line represents the best-fit linear regression line and the dotted lines represent 95% confidence interval of the best-fit line. Regression formula and Pearson r values for the best-fit of the slope are represented.

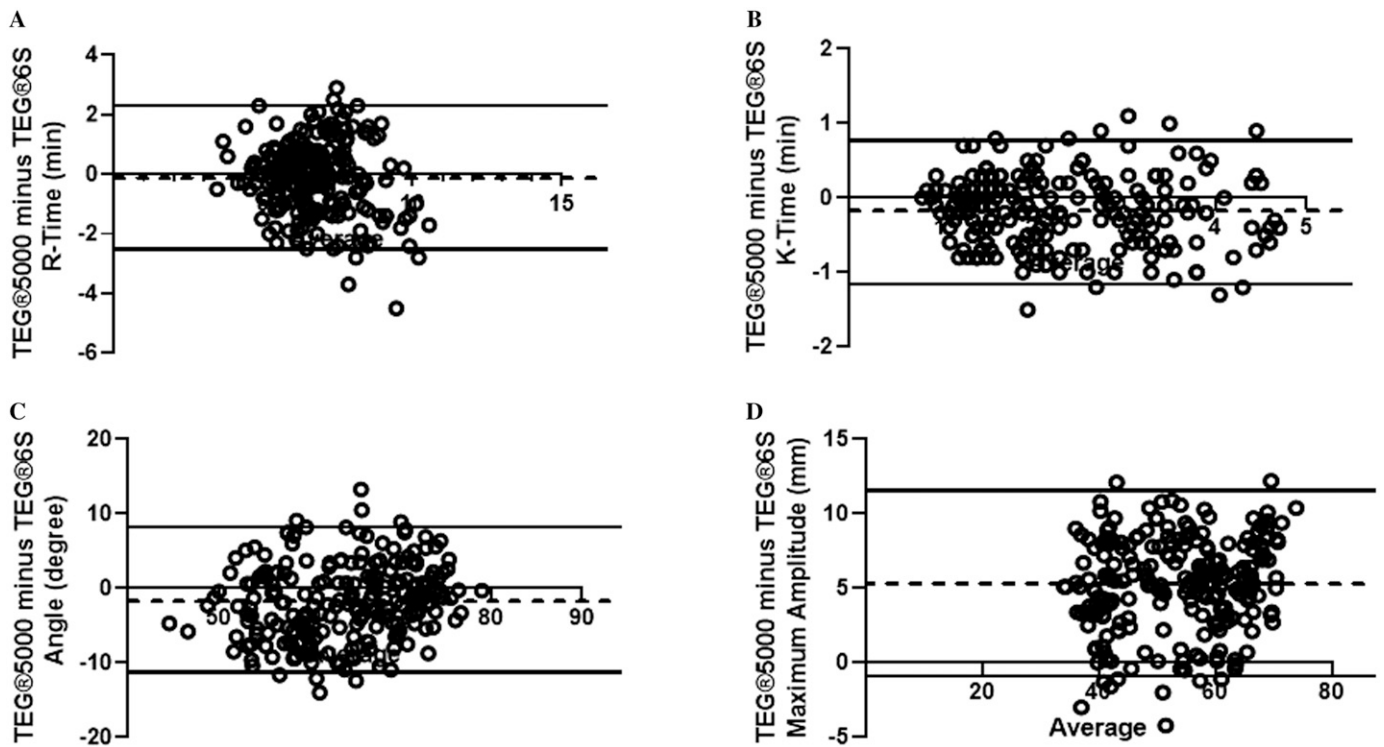


Figure 2. Bland–Altman plots (A–D) for all thromboelastography (TEG) parameters (R-time, K-time, angle, maximum amplitude [MA]) (n = 225). Average of the TEG parameters from both methods (TEG®5000 and TEG®6S) on X-axis was plotted against difference between the TEG parameters from both methods (TEG®5000 – TEG®6S) on the Y-axis. The solid line represents 95% limits of agreement and the dashed line represents the bias.

Table 2. Bland–Altman parameters for agreement of limits: TEG[®] 5000 vs. TEG[®] 6S (n = 225) and TEG[®] 6S-FLEV vs. Clauss-fibrinogen (n = 54).

TEG Parameter	Bias	SD of Bias	95% LOA	% CV
R-Time (minutes)	-.14	1.22	-2.5 to 2.3	10.05
K-Time (minutes)	-.18	.47	-1.1 to .75	12.11
Angle (degrees)	-1.75	5.13	-11.8 to 8.31	4.89
Maximum Amplitude (mm)	5.3	3.14	-.86 to 11.46	7.19
TEG [®] 6S-FLEV (mg/dL)	-42.75	57.55	-155.5 to 70.04	14.5

TEG[®] 6S-FLEV, thromboelastography-based functional fibrinogen; LOA, limits of agreement; CV, coefficient of variance.

(Figure 3B). Although there was good correlation between the methods, there was a consistent bias with an average of 42.8 mg/dL higher values being obtained from TEG[®]6S-FLEV compared to the Clauss-fibrinogen method (%CV: 14.5) (Figure 3B and Table 2).

Association Between TEG[®] 6S Parameters and Bleeding

By univariate analysis, TEG[®]6S MA during rewarming was the only parameter significantly associated with risk of perioperative bleeding (median MA [IQR] 34.7 [28.5, 48.3] in bleeding patients vs. 37.3 [32.2, 55] in nonbleeding patients; $p = .02$). The median (IQR) R-time in minutes (7.8 [7.1, 9.2] vs. 8.2 [7, 10]; $p = .4$), K-time in minutes (4.4 [3.7, 6] vs. 3.9 [3.2, 5.8]; $p = .3$), and angle in degrees (55.3 [48.3, 59.3] vs. 55.5 [48.9, 59.6]; $p = .8$) were not significantly different between patients in the bleeding and nonbleeding groups. Analysis of TEG[®]6S MA at rewarming demonstrated that a significantly higher proportion of patients reached the composite bleeding endpoint in the OR with an MA < 40 mm as

compared to MA \geq 40 mm (31/70 [44.3%] vs. 7/30 [23.3%], $p = .04$). The estimated probability of bleeding in the OR as the function of TEG[®]6S rewarming MA is shown in Figure 4. Similar trend of results was previously published on the estimated probability of bleeding in the OR as the function of TEG[®]5000 rewarming MA (5).

Effect of Platelet Transfusion on TEG[®] 6S MA and FLEV

In this study cohort, 25/100 (25%) patients received platelets intraoperatively as their only blood product prior to transfer to ICU. Based on the values of TEG[®]6S MA measured before and after platelet transfusion in patients who exclusively received only a platelet transfusion intraoperatively, a linear regression model was used to develop a relationship between volume of platelet transfusion and percent change in MA (Figure 5A). Using the linear regression analysis, a platelet transfusion calculator was developed to help predict intraoperative platelet transfusion volume. Similarly, based on TEG[®]6S-FLEV values before and after platelet transfusion, linear regression equation was generated to calculate the amount of fibrinogen in a given volume/kg of platelet transfusion (Figure 5B).

The link to the online TEG[®]6S platelet calculator is available at <https://platelettransfusioncalc-6s.000webhostapp.com/>.

DISCUSSION

Although there have been validation studies comparing TEG[®]5000 and TEG[®]6S results, most of the

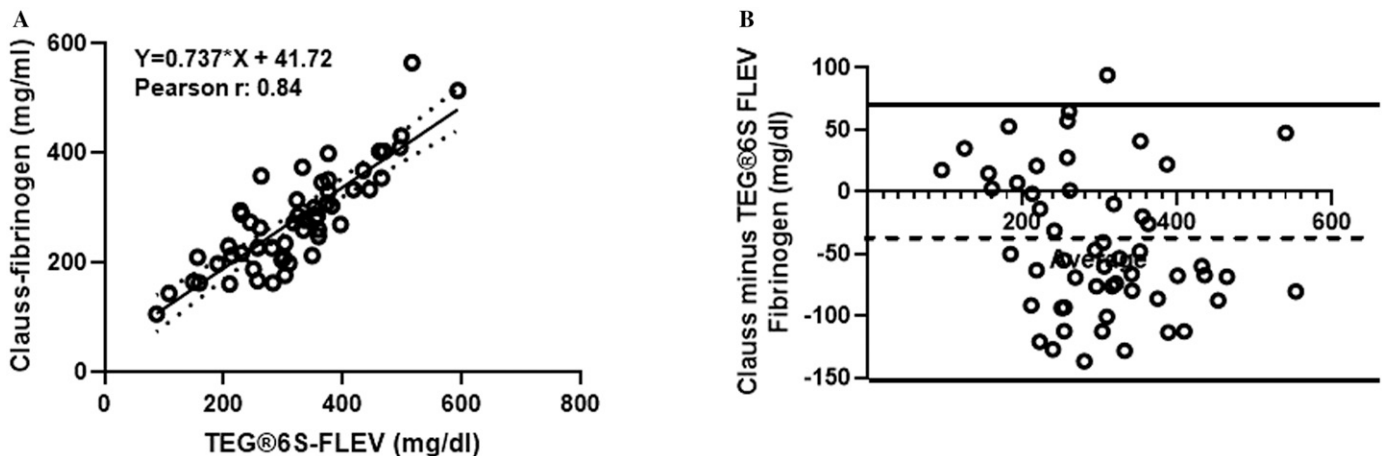


Figure 3. Linear regression analysis and Bland–Altman plots comparing TEG[®]6S-FLEV and Clauss-fibrinogen (mg/dl) method (n = 54). (A) For linear regression analysis plots, solid line represents the best-fit linear regression line and the dotted lines represent 95% confidence interval of the best-fit line. Regression formula and Pearson r values for the best-fit of the slope are represented. (B) For Bland–Altman plots, average of the TEG parameters from both methods (TEG[®] 5000 and TEG[®] 6S) on X-axis was plotted against difference between the TEG parameters from both methods (TEG[®] 5000 – TEG[®] 6S) on the Y-axis.

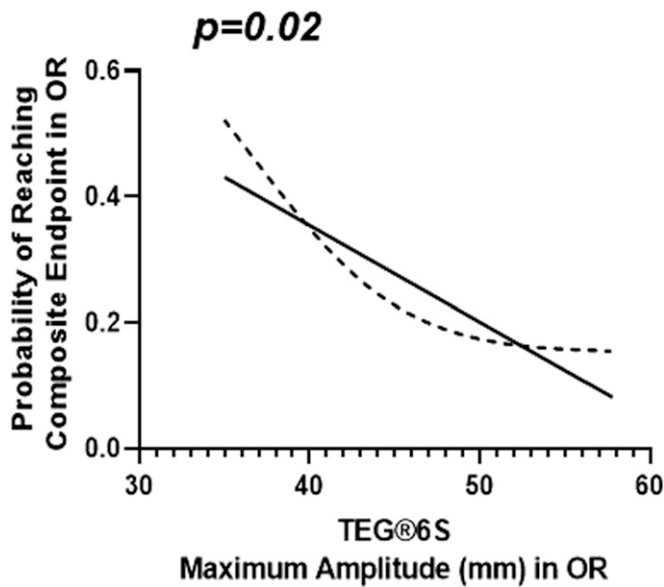


Figure 4. Estimated probability of reaching the composite bleeding endpoint in the operating room (OR) as a function of rewarming TEG®6S maximum amplitude (MA) (n = 100). The solid line indicates the estimated probability based on a linear regression fit. The dashed line indicates the estimated probability based on a nonlinear regression curve fit.

published data is from adult studies with only a few including pediatric patients (7–9). This study specifically focused on pediatric cardiac surgery patients who are at a higher risk for perioperative bleeding. In this study, we demonstrated a good correlation (Pearson $r \geq .7$) between results obtained from TEG®5000 when compared to TEG®6S. $CV \leq 20\%$ is generally considered acceptable for method comparisons (CLIA guidelines) and our results show all TEG parameter (R-time, K-time, angle, and MA) comparisons below 15% CV. However, there exists some bias in the values obtained between the methods especially for MA, with TEG®6S producing lower values for MA than TEG®5000. The

observed bias is clinically insignificant and thus allowing for the interchangeable use of these devices in various settings (OR, ICU, other in-patient and outpatient settings). Additionally, TEG®6S produces testing error messages in the presence of a few interfering anticoagulant drugs in the sample, unlike TEG®5000, which provides a result (as the test is based on a mechanical principle). In such situations when TEG®6S analysis need to be replaced by TEG®5000, the interchangeable nature of these devices would be necessary.

Previous data has shown that viscoelastic testing can help risk stratify for bleeding (5,6,10). In this study, we demonstrated that TEG®6S can be used to risk stratify

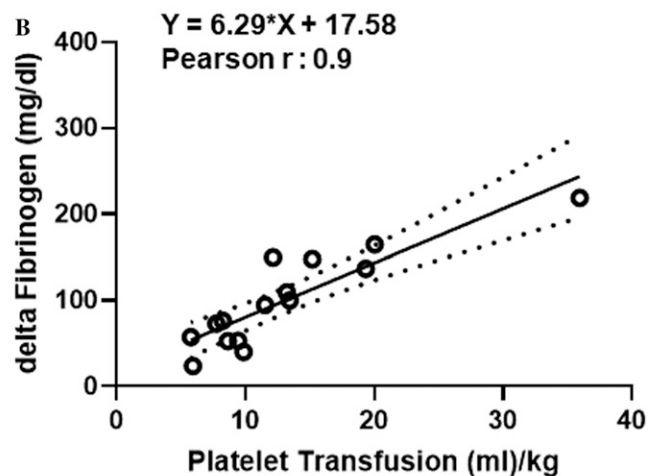
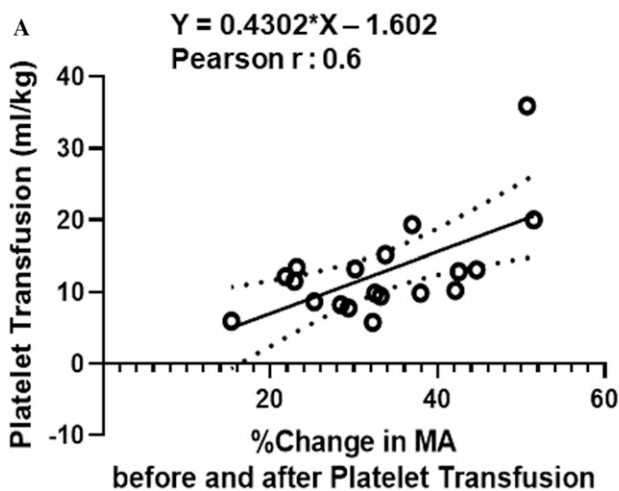


Figure 5. Linear regression models comparing percent increase in TEG®6S maximum amplitude (MA) from before and after transfusion vs. volume of platelet transfusion (ml/kg) (n = 25) or volume of platelet transfusion (ml/kg) vs. difference in fibrinogen levels (n = 25) from before and after transfusion as measured by TEG®6S (TEG-FLEV, mg/dl).

pediatric cardiac patients for bleeding endpoints. We validated the findings of our prior work demonstrating an association between rewarming MA (obtained during rewarming on CPB at $\geq 32^{\circ}\text{C}$) as measured by TEG[®]5000 and surrogate endpoints of perioperative bleeding (5). Similar to our previous findings established with a large data set of patients ($n > 500$) using the TEG[®]5000 system, this study demonstrates that rewarming TEG[®]6S MA was the only parameter associated with bleeding. These findings suggest that platelet dysfunction induced by CPB is the major contributor to perioperative bleeding. Interestingly, no other rewarming TEG[®]6S parameters were associated with perioperative bleeding. One of the major reasons for normal coagulation factor levels except for platelet dysfunction after CPB may be due to the pump priming protocols followed at our institution. As the CPB circuit in all patients in this cohort was primed with reconstituted whole blood (one unit of pRBCs and one unit of FFP), our pump prime results in relatively normal coagulation factors and fibrinogen levels during CPB. Thus, some of these findings may be institution specific and may differ from other centers that do not routinely prime the CPB circuit with FFP.

Rewarming time point was chosen for this TEG[®]6S analysis as it seemed to be an ideal time point to predict the risk of postoperative bleeding based on the data from our previous TEG[®]5000 analysis (5). Also, the results can be obtained in time to be acted upon for estimating ideal blood product transfusions to reduce bleeding in the postoperative period. Thus based on this study and our previously published data (5), rewarming TEG analysis from both devices can be used to evaluate risk of postoperative bleeding in patients undergoing complex heart surgeries, except that because of the consistent bias between MA from both devices, the values chosen as discriminator for bleeding risk and platelet calculator thresholds may vary.

Additionally, using lower sample volume (340 μL for four tests vs. 1,000 μL for two tests on TEG[®]5000), TEG[®]6S provides a larger panel of results compared to TEG[®]5000, which includes fibrinogen levels. This is particularly important, as abnormally low fibrinogen levels are associated with unfavorable perioperative outcomes in pediatric cardiac surgery patients (11). However, it is important to note that although there was a good correlation between TEG[®]6S-FLEV and the gold standard Clauss-fibrinogen method (Pearson $r = .9$), there is a clinically significant bias of approximately 45 mg/dL with TEG[®]6S consistently producing higher reported values for fibrinogen compared to the Clauss-method. This bias should be accounted for during clinical interpretation of TEG[®]6S fibrinogen levels.

Although the median TEG[®]6S rewarming MA values for bleeding group and nonbleeding group were 34.7

and 37.3 mm, respectively, the various rewarming TEG[®]6S MA values when subjected to iterative analysis suggested 40 mm as an optimal cut-off to discriminate bleeding patients from nonbleeding patients. Based on the findings of this study, a TEG[®]6S specific intraoperative platelet transfusion calculator has been developed for determining volumes of perioperative blood products transfusions that can prevent bleeding while minimizing thrombosis. Although TEG[®]6S rewarming MA of 40 mm was the inflection point to discriminate bleeding from nonbleeding patients, 50 mm was determined as an approximate target value beyond which the risk of perioperative bleeding plateaued (Figure 4). Importantly, the rewarming target MA of 50 mm indicated by the TEG[®]6S analysis corresponds with the previously reported target TEG[®]5000 MA of 55 mm, confirmed by approximately 5 mm bias between TEG[®]6S vs. TEG[®]5000 MA results in this study (5). Therefore, rewarming TEG[®]6S MA of 50 mm was selected as the target MA for the calculator to estimate the approximate volume of platelets to transfuse. A guided blood product transfusion may be helpful in reducing over transfusions known to be associated with higher risk of perioperative thrombosis (12).

One of the limitations of the developed web-based platelet calculator in its current iteration is that it is not intended for use in neonates to determine platelet transfusion volumes, because the study population used in generating this calculator included only a few neonates (2/25 patients, 8%). As, neonates at our center typically receive more than one type of blood product, data from neonates were excluded when developing the calculator. There is an ongoing effort to develop a neonate-specific calculator that will include additional factors that are key components of perioperative management of coagulopathy in neonates.

Limitations

This is a single-center study and the guidelines may be more center specific rather than a generalized approach to the management of perioperative blood transfusions in other pediatric populations. Although a relatively rigid definition of bleeding was used in this study, the true incidence of bleeding may be underestimated. The rewarming TEG[®]5000 parameters were clinically reported and were available for review, which may have impacted the decision-making in transfusion of blood products. To compensate for this confounder, we defined bleeding as the need for more than one type of blood product (e.g., platelets + cryoprecipitate). The main limitation is the sample size, data from 25 patients who received platelets as their only blood product was used to develop the platelet transfusion calculator. Additional data from patients who meet this strict

criterion is being collected to further validate the TEG[®]6S-based platelet transfusion calculator before it can be considered for clinical use. While our study included common measurable factors, the bleeding risk in this population may be influenced by other unaccounted factors not included in the analysis.

Conclusions

In conclusion, TEG[®]6S is a good alternative POC device that is comparable to the TEG[®]5000, and the results from both devices can be interchangeably used for clinical diagnostics. Low rewarming TEG[®]6S MA (<40 mm) is associated with increased risk for bleeding in pediatric patients undergoing high-risk cardiac surgery on CPB. Furthermore, a multicenter clinical validation of the TEG[®]6S platelet calculator would be necessary for designing a more accurate bleeding management algorithm in this patient population.

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