Utility of intraoperative rotational thromboelastometry in thoracolumbar deformity surgery

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OBJECTIVE Blood loss during surgery for thoracolumbar scoliosis often requires blood product transfusion. Rotational thromboelastometry (ROTEM) has enabled the more targeted treatment of coagulopathy, but its use in deformity surgery has received limited study. The authors investigated whether the use of ROTEM reduces transfusion requirements in this case-control study of thoracolumbar deformity surgery.

METHODS Data were prospectively collected on all patients who received ROTEM-guided blood product management during long-segment (≥ 7 levels) posterior thoracolumbar fusion procedures at a single institution from April 2015 to February 2016. Patients were matched with a group of historical controls who did not receive ROTEM-guided therapy according to age, fusion segments, number of osteotomies, and number of interbody fusion levels. Demographic, intraoperative, and postoperative transfusion requirements were collected on all patients. Univariate analysis of ROTEM status and multiple linear regression analysis of the factors associated with total in-hospital transfusion volume were performed, with $p < 0.05$ considered to indicate statistical significance.

RESULTS Fifteen patients who received ROTEM-guided therapy were identified and matched with 15 non-ROTEM controls. The mean number of fusion levels was 11 among all patients, with no significant differences between groups in terms of fusion levels, osteotomy levels, interbody fusion levels, or other demographic factors. Patients in the non-ROTEM group required significantly more total blood products during their hospitalization than patients in the ROTEM group (8.5 ± 4.2 units vs 3.71 ± 2.8 units; $p = 0.001$). Multiple linear regression analysis showed that the use of ROTEM ($p = 0.016$) and a lower number of fused levels ($p = 0.022$) were associated with lower in-hospital transfusion volumes.

CONCLUSIONS ROTEM use during thoracolumbar deformity correction is associated with lower transfusion requirements. Further investigation will better define the role of ROTEM in transfusion during deformity surgery.

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KEY WORDS rotational thromboelastometry; spine surgery; thoracolumbar deformity; blood product management; blood transfusion; coagulation testing

SPINAL deformity surgery is often associated with a significant volume of blood loss.^{2,7} The need for blood transfusion to compensate for these losses is associated with a wide array of complications, including infection,¹¹ thromboembolic events,¹ and hemolytic reactions.¹⁷ In addition, patients requiring blood transfusion have been shown to have prolonged hospitalizations and higher surgery-related costs.²³ Because of these myriad deleterious effects, significant efforts have been made to

curtail the need for blood products intraoperatively and perioperatively.^{3,4}

Rotational thromboelastometry (ROTEM; TEM International GmbH) is a form of viscoelastic testing that allows rapid analysis of multiple coagulation parameters.⁶ Although significant questions remain regarding the interpretation and standardization of ROTEM,¹⁰ trauma and transplant surgeons have begun to use this technology in clinical practice to guide transfusion and improve outcomes.^{15,16,21}

ABBREVIATIONS BMI = body mass index; FFP = fresh-frozen plasma; INR = international normalized ratio; PRBC = packed red blood cell; ROTEM = rotational thromboelastometry; TXA = tranexamic acid.

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FIG. 1. ROTEM transfusion protocol. A20 = clot firmness after 20 minutes of clot formation; CBC = complete blood count; CFT = clot formation time; CT = clotting time; Hgb = hemoglobin; MCF = mean clot firmness; POC = point of care.

Investigations into the use of ROTEM for spine surgery (in general) and for deformity surgery (in particular) remain extremely limited. In this study, we investigated the use of ROTEM-guided transfusion in long-segment (≥ 7 levels) thoracolumbar fusions for adult deformity. We hypothesized that the use of ROTEM during surgery would reduce intraoperative and postoperative blood transfusion requirements.

Methods

Study Population

After obtaining approval from the institutional review board, we retrospectively reviewed a prospectively collected database to identify patients who underwent single-stage posterior thoracolumbar instrumented fusion procedures at our institution from April 1, 2015, to February 1, 2016. All patients undergoing fusions of 7 or more segments during this period who had ROTEM-guided intraoperative blood management were identified (Fig. 1). These patients were then matched based on age, surgical levels, osteotomy levels, interbody fusion levels, tranexamic acid (TXA) use, and revision status with historical controls operated on between March 1, 2012, and March 1, 2016, who had intraoperative blood management without ROTEM guidance (Fig. 2). All included ROTEM-guided operations were performed sequentially

FIG. 2. Non-ROTEM transfusion protocol.

over the study period with a single exception: 1 control case was performed during the ROTEM time frame because the ROTEM machine was not available when the surgery was being performed. Non-ROTEM procedures were not necessarily performed sequentially, as they were selected from cases performed during the study period based on our matching criteria.

A single experienced surgeon (A.T.D.) performed all surgical procedures, and all surgeries were performed with the assistance of a specialized neuroanesthesiology team. Transfusion guidelines (Figs. 1 and 2) were adhered to whenever possible, and any deviations were the result of discussions between the neurosurgeon and anesthesiologist based on the available data.

Data Collection

Preoperative data including age, sex, body mass index (BMI), preoperative hematocrit, preoperative platelet count, preoperative international normalized ratio (INR), and American Society of Anesthesiologists Physical Status Classification System grade were collected for all patients. Surgical data included whether the surgery was a revision, the number of levels fused, the number of osteotomy levels performed (pedicle subtraction, Smith-Petersen, or vertebral column resection), and the number of interbody fusions performed. Intraoperative variables included the total number of units of packed red blood cells (PRBCs), platelets, and fresh-frozen plasma (FFP) that were transfused during the procedure. The volume of autologous blood transfused was also recorded and converted to units according to the standard volume of 1 unit of PRBCs at our institution (1 unit of PRBCs = 250 ml blood). We also determined the estimated intraopera-

tive blood loss and amount of crystalloid/colloid solution infused. TXA was used in select cases at the discretion of the attending surgeon and anesthesiologist when significant blood loss was expected, and the use of TXA was recorded for each case. Data on cell-saver use for autologous blood transfusion for each case were also collected, as were operative duration and the percentage of surgery during which the patient was hypothermic (defined as body temperature $< 36^{\circ}\text{C}$).⁸

Postoperative variables included length of stay, drain output, postoperative hematocrit, postoperative platelet count, postoperative INR, and the number of postoperative PRBCs, platelets, and FFP units transfused during the remainder of the patient's hospitalization. The total amount of blood products used in each patient during hospitalization, which consisted of the total number of units of PRBCs, platelets, FFP, and autologous blood transfused intraoperatively and postoperatively, was also calculated. ROTEM data were collected after the placement of all pedicle screws and completion of the osteotomies, as well as during the final correction of the deformity through the placement of rods.

Statistical Analysis

Continuous variables were analyzed using the Student t-test, and categorical variables were analyzed using the chi-square test. Univariate analysis was performed to compare total in-hospital blood transfusion volumes between ROTEM and non-ROTEM patients. Multiple linear regression analysis was then performed to compare the 2 groups. Variables were selected for this model if we thought they would significantly impact transfusion volume. These variables included ROTEM use, number of levels fused, preoperative hematocrit, preoperative INR, and TXA use. In all analyses, $p < 0.05$ was considered statistically significant. The statistical analysis was performed using SPSS (version 20.0; IBM Corp.).

Results

Fifteen patients who received ROTEM-guided therapy and met the inclusion criteria were identified and matched with 15 non-ROTEM control patients. Our matched variables were not significantly different between the ROTEM and non-ROTEM groups, with similar ages, sex distributions, BMIs, fusion levels, osteotomy levels, interbody levels, revision rates, and TXA use rates in the 2 groups (Table 1). Preoperative and postoperative laboratory values were also similar in the groups. Patients in the non-ROTEM group received significantly higher volumes of PRBCs, FFP, and autologous blood transfusions intraoperatively compared with patients in the ROTEM group. Blood loss appeared to be greater in the non-ROTEM group, although this difference did not reach statistical significance. Postoperative blood transfusion requirements were similarly low in both groups. Total blood products transfused during hospitalization were significantly higher in the non-ROTEM group than in the ROTEM group. Of note, although we used mean values for our calculations, the median values for total blood transfusion were also significantly different between the 2 groups when ana-

TABLE 1. Univariate analysis of ROTEM versus non-ROTEM groups

Characteristic	Non-ROTEM	ROTEM	p Value
No. of patients	15	15	
Female, no. (%)	7 (47)	10 (67)	0.269
Age, yrs	65.6 $\pm$ 12.7	61.9 $\pm$ 11.1	0.400
BMI, kg/m ²	28.8 $\pm$ 4.6	27.7 $\pm$ 6.1	0.578
ASA PS grade, no. (%)			0.275
II	5 (33)	4 (27)	
III	8 (53)	11 (73)	
IV	2 (13)	0 (0)	
Preop hematocrit, %	39.0 $\pm$ 6.0	40.8 $\pm$ 5.9	0.410
Preop platelet count, platelets/ μl	245.7 $\pm$ 54.4	256.2 $\pm$ 96.0	0.718
Preop INR	1.10 $\pm$ 0.17	1.02 $\pm$ 0.06	0.114
Levels fused	11.5 $\pm$ 3.3	10.3 $\pm$ 3.2	0.317
Osteotomy levels	1.9 $\pm$ 2.0	2.3 $\pm$ 3.0	0.617
Interbody levels	0.20 $\pm$ 0.41	0.33 $\pm$ 0.62	0.493
Intraop PRBC, units	2.6 $\pm$ 2.0	0.93 $\pm$ 1.5	0.016
Intraop autologous blood, units	2.1 $\pm$ 1.0	0.97 $\pm$ 1.3	0.009
Intraop platelets, units	0.40 $\pm$ 1.06	0.07 $\pm$ 0.26	0.245
Intraop FFP, units	2.0 $\pm$ 1.7	0.53 $\pm$ 1.0	0.007
Estimated blood loss, ml	1880 $\pm$ 700	1347 $\pm$ 857	0.072
Crystalloid volume, ml	4606 $\pm$ 1890	5310 $\pm$ 1918	0.320
Colloid volume, ml	633 $\pm$ 581	800 $\pm$ 649	0.465
TXA use, no. (%)	3 (20)	3 (20)	1.000
Cell-saver use, no. (%)	13 (87)	10 (67)	0.195
Op time, mins	510.7 $\pm$ 118.1	484.7 $\pm$ 77.9	0.482
Op time spent hypothermic, %	36.8 $\pm$ 31.4	38.4 $\pm$ 25.2	0.881
Length of stay, days	10.7 $\pm$ 5.1	8.2 $\pm$ 2.7	0.099
Drain output, ml	1508 $\pm$ 786	1392 $\pm$ 454	0.480
Postop PRBC, units	1.1 $\pm$ 1.4	1.1 $\pm$ 0.9	0.881
Postop platelets, units	0.27 $\pm$ 0.70	0.07 $\pm$ 0.26	0.310
Postop FFP, units	0	0	NA
Postop hematocrit, %	28.8 $\pm$ 3.1	28.0 $\pm$ 3.9	0.575
Postop platelet count, platelets/ μl	175.3 $\pm$ 78.6	185.5 $\pm$ 69.4	0.707
Postop INR	1.31 $\pm$ 0.18	1.34 $\pm$ 0.11	0.706
Total blood products transfused, units	8.45 $\pm$ 4.2	3.71 $\pm$ 2.75	0.001

ASA PS = American Society of Anesthesiologists Physical Status; NA = not applicable.

Values are presented as the mean $\pm$ SD unless specified otherwise. Boldface type indicates statistical significance.

lyzed using the Mann-Whitney U-test (median 3.6 units [interquartile range 2–4.8 units] for the ROTEM group vs 8.0 units [interquartile range 3.6–11.2 units] for the non-ROTEM group; $p = 0.0035$).

There were no significant differences in the rates of cell-saver use ($p = 0.195$) or operative duration ($p = 0.482$) between the 2 groups. The percentage of time spent with a temperature less than 36°C was not significantly different when comparing the ROTEM group with the non-

TABLE 2. Multiple linear regression analysis of total blood transfusion volume

Characteristic	Beta	B	95% CI for B	p Value
ROTEM use	-0.487	-3.973	-7.109 to -0.838	0.016
Levels fused	0.408	0.501	0.022 to -0.981	0.022
Preop hematocrit	0.086	0.060	-0.200 to 0.321	0.633
Preop INR	0.103	3.485	-9.324 to 16.294	0.576
TXA use	-0.304	-2.883	-6.425 to 0.658	0.105

Boldface type indicates statistical significance.

ROTEM group ($38.4\% \pm 25.2\%$ vs $36.8\% \pm 31.4\%$; $p = 0.881$).

In our multiple linear regression model, only ROTEM use and number of levels fused remained significantly associated with an increase in total in-hospital transfusion (Table 2). According to the results of our multiple linear regression analysis, the incorporation of ROTEM-guided transfusion management decreased a patient's total in-hospital transfusion requirement by nearly 4 units (95% CI 0.8–7.1).

Examples of normal EXTEM (the measure of the extrinsic hemostatic system within ROTEM) (Fig. 3 upper) and FIBTEM (the measure of the platelet contribution to the clot within ROTEM) (Fig. 3 lower) readouts (subsections of the ROTEM study) are shown: this patient received no intraoperative blood products. Similarly, examples of abnormal EXTEM (Fig. 4 upper) and borderline FIBTEM (Fig. 4 lower) are provided, and this patient required intraoperative transfusion of FFP.

Discussion

With the progressively increasing number and com-

plexity of spinal surgeries performed, intraoperative blood loss has rapidly become a dilemma for both surgeons and anesthesiologists. In the adult deformity population, in whom older age can be associated with multiple risk factors for increased bleeding such as a thinner periosteum, wider vascular channels secondary to osteoporosis, and stiffer spinal columns that require more extensive osteotomies,⁹ this concern is further magnified. Reports of typical blood loss during posterior deformity procedures vary, with a range in the literature of < 1 L to nearly 5 L,^{5,13,14} representing between < 20% and nearly 100% of a typical adult's circulating blood volume being replaced.²⁵

Viscoelastic testing such as ROTEM is gaining increasing traction in a variety of surgical fields because of its relatively low cost, rapid turnaround time, and ability to offer a more nuanced picture of coagulopathy.^{18,22,24} Naik et al.²⁰ recently published their series examining the use of ROTEM in the deformity population, and to date that paper constitutes the entire body of literature investigating the use of ROTEM in complex spine surgery. They found that a reduction in blood loss was achieved in patients who received ROTEM-guided therapy, possibly leading to a reduction in overall cost. Although our study examines a modestly different patient group—thoracolumbar deformity patients who had fusions more than 7 levels in length and with fewer revision surgeries—our findings appear to support theirs.

Patients in our cohort who received ROTEM-guided blood transfusion management had significantly lower in-hospital blood transfusion needs. One possible explanation for this difference is the use of a more targeted or timely transfusion of blood products in the ROTEM group compared with the non-ROTEM group. For example, a patient who had ROTEM-guided therapy may have received FFP in the early stages of coagulopathy, whereas a patient in the non-ROTEM group might have received FFP only after a large volume of blood was lost and hemo-

FIG. 3. Upper: Example of a normal EXTEM readout that indicates no intervention is needed in this patient. **Lower:** Example of a normal FIBTEM readout that indicates no intervention is needed in this patient. ML = maximum lysis.

FIG. 4. Upper: Example of an abnormal EXTEM readout that would prompt transfusion of FFP in this patient. **Lower:** Example of a borderline FIBTEM readout that might prompt transfusion of FFP in this patient.

static derangement had worsened. This may also explain the trend toward lower overall intraoperative blood loss in our ROTEM cohort. Another explanation could be a reduction in the use of preemptive blood transfusion, which is possible because knowledge of a patient's coagulation profile allows better prediction of a patient's transfusion needs and reduces overtransfusion. As can be seen in the differences in the transfusion algorithms between our study and that described by Naik et al., one of the major challenges in the utilization of ROTEM is disagreement in the timing and interpretation of the results, a fact that was also highlighted in a recent Cochrane review.¹⁰ This is further complicated by the relative unfamiliarity of many practitioners in the use of ROTEM.

The reduction in blood transfusion and minimization of blood loss during spinal deformity surgeries is of vital importance for several reasons. High-volume transfusions increase patient risk for various adverse events, including infection, cardiac and renal dysfunction, and transfusion-related acute lung injury.⁹ Higher intraoperative blood loss is also associated with the dreaded complication of postoperative visual loss due to ischemic optic neuropathy.¹² From a socioeconomic standpoint, blood transfusions after spinal fusions are also associated with prolonged intensive care stays¹⁹ and longer hospitalizations overall.²⁶ Length of stay in the ROTEM group was slightly shorter, although not significantly so, possibly because of the known impacts of higher transfusion needs.²³

Our study has several limitations, the foremost of which are its retrospective nature and small sample size which increase its vulnerability to confounding factors such as non-ROTEM-related changes in technique or transfusion patterns that could influence transfusion use. The small number of patients also limits the power of our study. This may help to explain the fact that while there

was a trend toward decreased blood loss in our ROTEM group compared with our non-ROTEM cohort (on average > 500 ml less in the former compared with the latter), this difference did not reach statistical significance. Although a single surgeon performed all procedures and we limited our control cohort to a 4-year period, it is possible that changes in surgical technique or anesthesia staffing may have influenced transfusion practices. Because of the lack of data on the timing of blood transfusions during surgery in relation to the laboratory results, our study is unable to make definitive conclusions about how ROTEM influenced transfusion practices on a more granular level, although the majority of transfusions in our cohort occurred after correction of deformity. Future studies on this topic would likely benefit from the precise recording of both the time and stage of surgery during which the laboratory values are determined and transfusions occur, as well as the precise decision-making response to each laboratory value. Our study represents a limited initial study of the possible benefits of ROTEM use in long-segment thoracolumbar fusion for deformity. Further studies—preferably prospective, randomized controlled trials with multiple centers—are needed to better define the usefulness of ROTEM in deformity surgery and elucidate the optimal response to the results of ROTEM testing.

Conclusions

In long-segment posterior spinal fusion for deformity correction, the utilization of ROTEM-guided transfusion management may be associated with decreased in-hospital transfusion requirements. Our results suggest that further research is merited on the utility of ROTEM in this population (in particular) and spine surgery (in general). An additional goal of future research should be to better standardize the interpretation of ROTEM results.

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Disclosures

Dr. Dailey reports being a consultant for K2M and Zimmer/Biomet and receiving non-study-related clinical or research support from K2M.

Author Contributions

Conception and design: all authors. Acquisition of data: Guan. Drafting the article: Dailey, Guan. Critically revising the article: Dailey. Reviewed submitted version of manuscript: Dailey, Guan. Approved the final version of the manuscript on behalf of all authors: Dailey.

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