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Utility of rotational thromboelastometry in total hip replacement revision surgery (case-control study)

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Abstract

Total hip replacement revision surgery is accompanied by significant blood loss. Using rotational thrombelastometry (ROTEM) perioperatively to diagnose coagulopathy may help to provide rapid aimed therapy and thus decrease blood loss and the consumption of transfusion products. The aim of this case-control study was to find out whether point of care using of ROTEM may reduce blood loss and the consumption of blood transfusion products in hip replacement revision surgery.

Data were prospectively collected from patients who underwent hip replacement revision surgery in the period 2017 to 2018 when the management of bleeding and coagulopathy was based on the results of ROTEM. Data were compared with a group of historical controls for the period 2015 to 2016 when bleeding and coagulopathy management was not based on ROTEM results. The consumption of blood transfusion products and perioperative blood loss were compared between the groups.

The total number of analyzed patients was 90. Forty five patients were analyzed in the ROTEM group and the same number of patients were analyzed in the non-ROTEM group. Significantly decreased perioperative consumption of fresh frozen plasma and packed red blood cells was found in the ROTEM, as well as decreased perioperative blood loss comparing to non-ROTEM group. All data were statistically different with $P < .05$.

Perioperative management of bleeding and coagulopathy based on the results of ROTEM during hip replacement revision surgery seems to help to decrease perioperative blood loss and the consumption of blood transfusion products, especially fresh frozen plasma.

Abbreviations: CFT = clot formation tme, CT = clotting time, FFP = fresh frozen plasma, IQR = interquartile range, MCF = maximum clot firmness, POC = point of care, PRBC = packed red blood cells, ROTEM = rotational thromboelastometry.

Keywords: fresh frozen plasma, haemostasis management, perioperative bleeding, rotational thrombelastometry, total hip replacement revision surgery

1. Introduction

Major hip surgery such as total hip replacement revision surgery is usually associated with significant blood loss and a need for allogenic transfusions.[1] Perioperative haemostasis management is often provided empirically by administering blood transfusion products i.e., packed red blood cells (PRBC) and fresh frozen plasma (FFP), which may be associated with numerous risks, especially in the case of FFP.[2–4]

Standard coagulation tests such as prothrombin time (PT) and activated partial thromboplastin time (aPTT) are plasma tests commonly used to assess the haemocoagulation status. The results of these methods are usually not available within 45 minutes of blood sampling, which is not practical for perioperative use. Moreover, according to the cell-based model of haemocoagulation,[5] a whole blood sample seems to be more suitable for haemocoagulation status assessment. Thus, rotational thromboelastometry (ROTEM) could be the method of choice for assessing blood clotting in the perioperative period.

ROTEM is a viscoelastic method used for assessing the haemocoagulation status by evaluating the mechanical properties of clots in a whole blood sample. In contrast to the conventional tests (PT, aPTT) that measure the time until the generation of the first fibrin fibres in the blood plasma, ROTEM also evaluates the effect of blood cells (platelets, erythrocytes) on haemocoagulation. Moreover, ROTEM provides valuable information about fibrinolysis. ROTEM can be used as a point of care method (POC) and because its clinically important results are available within 5 to 10 minutes, this method seems to be suitable for perioperative use and enables a rapid diagnosis of coagulopathy and the subsequent aimed therapy.[6,7] The use of viscoelastic methods such as POC tests is also recommended in current

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The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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European guidelines for the treatment of traumatic bleeding with Grade 1C.[8]

FFP is frequently either used in the perioperative period empirically or to correct laboratory coagulopathy of prolonged PT/aPTT. However, this approach does not seem to decrease perioperative blood loss.[9–11] Moreover, the use of FFP may be associated with significant health risks such as TRALI – transfusion related acute lung injury, TACO – transfusion-associated circulatory overload, haemolytic reactions, febrile non-haemolytic reactions, allergic and anaphylactic reactions, erythrocyte alloimmunization, prolonged hospital stays, postoperative complications including wound infections and a need for revision surgery. Even more, the use of FFP may be associated with increased morbidity and mortality in patients.[2,3,12,13] A study investigating the development of multiple organ failure (MOF) and acute respiratory distress syndrome (ARDS) in trauma patients describes an increased risk of MOF and ARDS by 2.1% and 2.5%, respectively, with each administered FFP unit.[3] Another study investigating the use of FFP in trauma patients who do not require massive transfusions (using 10 or more PRBC units with FFP units in a 1:1 ratio in 12 hours), indicates that the incidence of MOF, ARDS, pneumonia and sepsis is increased 12 times, 6 times, 4 times and 4 times, respectively, when patients receive more than 6 FFP units.[12] A study investigating the risk of postoperative infections after cardiovascular surgery reveals the correlation between the transfusion rate and the incidence of sepsis and superficial and deep sternal wound infections.[13]

The aim of this study was to find out whether perioperative management of bleeding and coagulopathy based on the results of ROTEM in total hip replacement revision surgery may be associated with decreased blood loss as well as decreased consumption of FFP and PRBC compared to an approach not based on ROTEM results.

2. Methods

The study was approved by the Ethics Committee for Multi-Centric Clinical Trials of the Motol University Hospital in Prague, Czech Republic on 4th February 2015, Ref. No. EK-28/15.

Data from adult patients who underwent total hip replacement revision surgery for instability or the mechanical loosening of primary total hip arthroplasty from 2015 to 2018 were analyzed in this study. In the first group (the ROTEM group), where the management of perioperative bleeding and coagulopathy was based on the results of POC ROTEM, data were collected prospectively. These patients were then matched with historical controls and managed without the use of ROTEM (the non-ROTEM group).

The aim of this study was to compare the total FFP and PRBC consumption as well as blood loss during surgery and 24 hours after surgery in the 2 aforementioned groups of patients.

Rotational thromboelastometry was used as the POC test for the evaluation of perioperative haemostasis (ROTEM delta machine, Tem International GbmH, Germany). Coagulation profile in each patient was assessed by ROTEM before surgery, then repeatedly after blood loss of 10% to 15% (500–750 ml) of calculated blood volume during surgery and at the end of surgery. Practically, ROTEM tests were performed 3 times during surgery. The following tests of ROTEM were performed and evaluated: EXTEM (contains recombinant tissue factor activating extrinsic coagulation pathway), INTEM (contains partial thromboplastin activating intrinsic coagulation pathway), and FIBTEM (contains cytochalasin D inhibiting platelets function; it evaluates the level of functional fibrinogen). HemoCue point of care devices were used in this study for the perioperative measurement of haemoglobin levels (HemoCue AB, Ängelholm, Sweden).

The following parameters were evaluated in EXTEM and INTEM assays: CT (clotting time; time from the start of measurement until the first fibrin formation is detected in an amplitude of 2 mm; represents the initiation phase of clotting), CFT (clotting formation time; the time from CT until the clot firmness is 20 mm; represents fibrin polymerization and clot stabilization with platelets and fibrinogen), the alpha angle (the angle between the time axis and the ROTEM curve; along with CFT it represents the propagation phase of clot formation and its kinetics), A5, A10, and A20 (amplitude in the 5th, 10th, and 20th minutes; represents clot firmness in each minute from CT time), MCF (maximum clot firmness), LI30 and LI60 (lysis index; represents a reduction in the clot firmness in relation to MCF in the 30th and 60th minutes from CT time). A5, A10, and MCF parameters were evaluated in the FIBTEM assay.

The first clinically important information is available within 5 to 10 minutes after the beginning of a ROTEM examination. This includes parameters such as $A5_{EXTEM}$, $A10_{EXTEM}$, $A5_{FIBTEM}$, and $A10_{FIBTEM}$, which have strong and linear correlation with MCF_{EXTEM} and MCF_{FIBTEM} parameters and are thus very useful in rapid diagnoses and therapy of coagulopathy.[14,15]

In the ROTEM group, a specialized protocol was used to guide coagulation therapy and it is schematically shown in Figure 1. This protocol was made on the base of ROTEM pioneers articles such as Görlinger and Schöchl, who used very similar protocol in management of bleeding during liver surgery and in traumatic bleeding.[14,15] In the non-ROTEM group, the transfusion of FFP was indicated together with PRBC in a 1:1–1:1.5 ratio.

2.1. Statistics

The GraphPad Prism 8 statistical program was used for the statistical analysis of the data. Because data did not follow a normal distribution, statistical assessment of the significance of differences between the compared groups was performed using the nonparametric unpaired Mann–Whitney test. Median with interquartile range was evaluated (IQR). A P value of $<.05$ was considered statistically significant.

3. Results

A total of 90 patients were analyzed in this study; 45 patients in the non-ROTEM group and 45 in the ROTEM group. The characteristics of the subjects are shown in Table 1. Both groups do not differ in age, gender or body weight.

Figure 2 shows blood loss during the perioperative period. There was significant decrease of blood loss in ROTEM group comparing to non-ROTEM group in all phases of perioperative period namely during surgery with $P<.01$, during 24 hours after surgery with $P<.05$ and in total perioperative blood loss with $P<.01$.

The haemoglobin concentration preoperatively and postoperatively, including the difference between these values, is shown in Table 2.

Perioperative FFP consumption is shown in Table 3. There was significant decreased consumption of FFP in ROTEM group

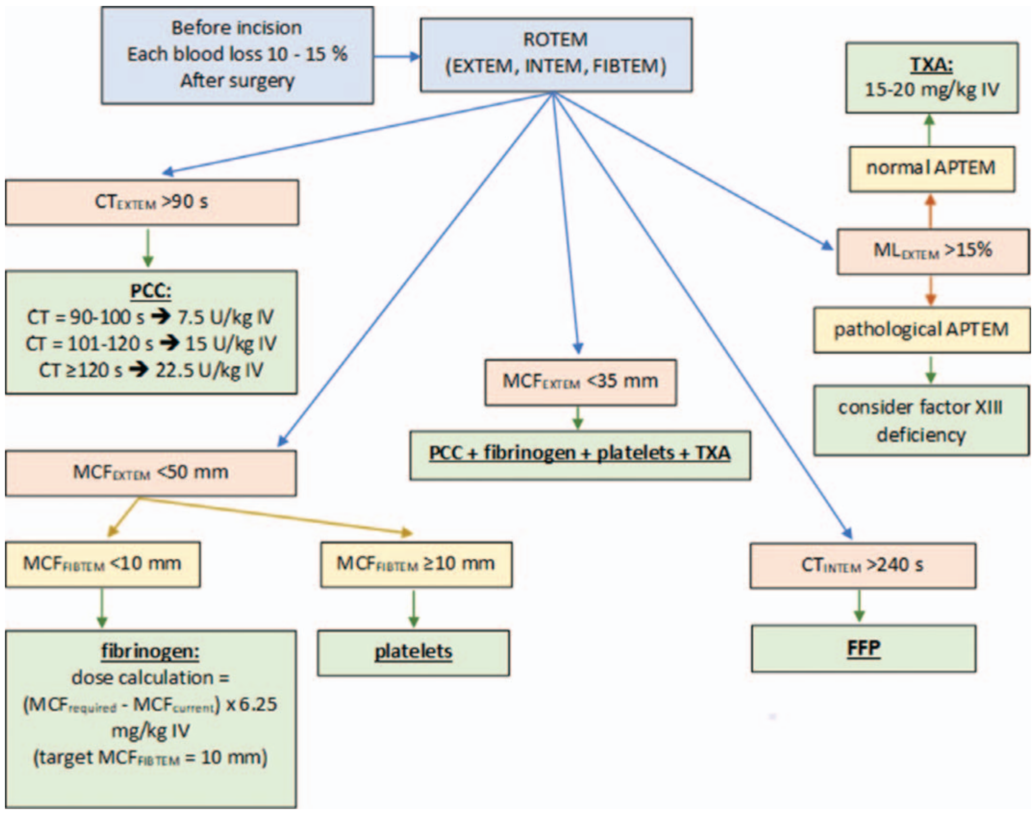

Figure 1. Examination and therapy schema. Schematic protocol for diagnosis and therapy of coagulopathy. FFP = fresh frozen plasma, PCC = prothrombin complex concentrate, TXA = tranexamic acid.

during surgery with $P < .0001$ and in total perioperative FFP consumption with $P < .05$ although consumption of FFP in 24 hours postoperatively did not differ significantly ($P > .05$).

Perioperative PRBC consumption is shown in Table 4. There was significant decreased consumption of PRBC in ROTEM group during surgery with $P < .01$ and in total perioperative PRBC consumption with $P < .01$ although consumption of PRBC in 24 hours postoperatively did not differ significantly ($P > .05$).

There was no death in any patient or a severe complication requiring surgical revision during the study.

4. Discussion

The results of our study suggest that the use of ROTEM has a place in perioperative bleeding and coagulopathy management, especially in extensive surgical procedures such as major hip revision surgery. Implementation of the ROTEM method as a point of care method in the perioperative period during total hip replacement revision surgery enables a rapid diagnosis of coagulopathy which leads to early and adequate therapy. This approach seems to decrease perioperative blood loss and the consumption of FFP and PRBC.

Our findings are similar to the work of Bonnet et al who performed a study in patients undergoing orthotopic liver transplantations. They describes that a ROTEM-guided transfusion algorithm reduces perioperative blood product consumption during liver transplantations, mainly FFP.[16]

Similarly, the authors Li et al performed a meta-analysis of nineteen studies with a total of 15,320 adult patients undergoing cardiac surgery with cardiac pulmonary bypass and also found that ROTEM-guided transfusion algorithms reduce blood loss and transfusion rates.[17]

Although the use of FFP was lower in the ROTEM group, ROTEM parameters were not worsened, no clinically significant coagulopathy was noted and the blood loss did not increase either, even though there was a lower concentration of preoperative haemoglobin in the ROTEM group. This finding might be explained by a POC coagulation profile assessment with rapid aimed therapy of coagulopathy. Perioperative bleeding and coagulopathy may be worsened by the potential haemodilutional effect of IV fluids and the unnecessary administration of FFP, both of which are routinely used in the perioperative period. This adverse effect leads to a decrease in haematocrit, a decreased level of coagulation factors and thrombocytopenia, which results in increased bleeding and PRBC consumption. The administration of PRBC further dilutes coagulation factors and a vicious circle begins. All of this may result in a worsening of the clinical outcome with increased morbidity and prolonged hospitalization.[18,19]

Table 1

Characteristics of subjects.

	non-ROTEM	ROTEM	*P* value
Subjects (n)	45	45	
Male (n, %)	15 (33.3%)	17 (37.8%)	>.05
Female (n, %)	30 (66.7%)	28 (62.2%)	
Age (years) [median (Q1–Q3)]	69 (63–74)	69 (63–74)	>.05
Body weight (kg) [median (Q1–Q3)]	75 (66–93)	72 (64–83)	>.05

Data are expressed as median with interquartile interval (Q1–Q3).

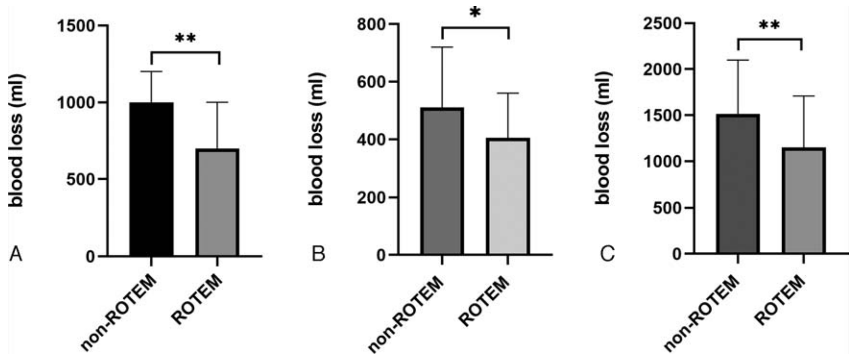

Figure 2. Perioperative blood loss. A–blood loss during surgery; B–blood loss during 24 hours after surgery; C–total perioperative blood loss; $^{*}P<.05$; $^{**}P<.01$.

Another factor contributing to perioperative coagulopathy is a type of intravenous fluid therapy. According to studies investigating the effect of IV fluids on haemocoagulation, balanced crystalloid solutions appear safe when followed by gelatin, but hydroxyethyl starch (HES) impairs the propagation phase of clot formation and clot strength and decreases the functional fibrinogen level.[20–22]

All of the aforementioned factors that potentially lead to coagulopathy and increased blood loss become even more critical during surgeries such as hip replacement revision surgery, which itself is accompanied by significant blood loss. In our study we found that the ROTEM-based administration of FFP and coagulation factors lead to decreased perioperative blood loss and decreased consumption of PRBC and FFP.

Although the use of coagulation factor concentrates (PCC – prothrombin complex concentrate and fibrinogen) are generally recommended in ROTEM-guided bleeding management,[13,14] we also included the use of FFP in our therapy scheme in case of prolonged CT INTEM. Pathologically prolonged CT INTEM is usually caused by deficiency of coagulation factors of intrinsic pathway of coagulation (under the condition that there is no heparin present) and PCC contains only factors II, VII, IX, and X (not VIII, XI, XII, and V). Therefore PCC in case of prolonged CT INTEM would not be appropriate therapy but FFP is justified in this case.

The limitation of the study might be its retrospective design. However, as a case-control study done on 90 patients, it brings forth interesting findings which may serve as a pilot study for future randomized studies.

In conclusion, the perioperative use of ROTEM during extensive hip surgeries such as total hip replacement revision surgery seems to be justified. A rapid assessment of the coagulation status helps to provide aimed therapy of coagulopathy and to prevent unnecessary administration of FFP. Management of bleeding and coagulopathy based on ROTEM results seem to reduce perioperative blood loss as well as the consumption of PRBC and FFP.

Table 2

Preoperative and postoperative haemoglobin concentration.

	e	ROTEM [median (Q1–Q3)]	*P* value
Preoperative Hb (g/L)	135 (118–140)	122 (110–133)	<.05
Postoperative Hb (g/L)	108 (99–119)	104 (93–118)	>.05
Δ Hb (g/L)	25 (16–32)	16 (4–25)	<.05

Data are expressed as median with interquartile interval (Q1–Q3).
Δ Hb = difference between pre- and postoperative haemoglobin concentration, Hb = haemoglobin concentration.

Table 3

Perioperative FFP consumption.

	e	ROTEM [median (Q1–Q3)]	*P* value
FFP consumption during surgery (ml)	440 (0–558)	0 (0–0)	<.0001
FFP consumption in 24 hours after surgery (ml)	0 (0–0)	0 (0–270)	>.05
total perioperative FFP consumption (ml)	488 (0–711)	0 (0–389)	<.05

Data are expressed as median with interquartile interval (Q1–Q3); FFP = fresh frozen plasma.

Table 4

Perioperative PRBC consumption.

	e	ROTEM [median (Q1–Q3)]	*P* value
PRBC consumption during surgery (ml)	527 (0–560)	0 (0–515)	<.01
PRBC consumption in 24 hours after surgery (ml)	250 (0–573)	0 (0–411)	>.05
Total perioperative PRBC consumption (ml)	577 (254–1131)	296 (0–586)	<.01

Data are expressed as median with interquartile interval (Q1–Q3); PRBC = packed red blood cells.

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Author contributions

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