Original Research Article

Comparison study of Routine Coagulation Tests and Thromboelastography for Detection of Hypocoagulable State in Patients Undergoing Cardiac Surgery on Cardiopulmonary Bypass

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Abstract

Background & Aims: Excessive bleeding occurs after cardiac surgeries on cardiopulmonary bypass (CPB) due to various nonsurgical causes. Finding these causes, and correction using appropriate blood product therapy, conventionally routine coagulation tests (RCT) were used, but recently point of care test Thromboelastography being used. We want to compare different RCT with TEG and their value with postoperative blood loss for correlation. **Methods:** This prospective study was done on patients undergoing cardiac surgery on CPB to correlate between different RCT (PT/INR, aPTT, Fibrinogen level, platelet and Hct) and thromboelstography parameters before heparinization and after reversal with protamine and their correlation with chest-tube output at 24 hours after surgery. **Result:** We found most RCT parameters changed significantly after cardiopulmonary bypass, but only prebypass platelet count and postbypass PT and fibrinogen level were significantly correlated with the postop blood loss at 24hr. In TEG parameters only MA was changed significantly after bypass but alpha angle and k-time after bypass was significantly correlated with postop blood loss. Routine lab-based coagulation tests and TEG parameters correlation was found in both prebypass and postbypass samples except in few pair. **Conclusion:** In our study different RCT and TEG parameters correlate and PT and fibrinogen level derangement after bypass and their corresponding part in TEG, k-time and alpha angle correlate significantly with amount of blood loss, so TEG can be used to guide blood component therapy postoperatively in ICU rather than providing empirically due to non-availability of routine coagulation test due to long turnaround time.

Keywords: Thromboelastography, TEG, CPB, Routine coagulation test

Introduction

Excessive bleeding after cardiac surgeries on cardiopulmonary bypass (CPB) is still a major concern. That contributes to a major extent of morbidities and mortalities postoperatively[1].

There are many factors considered responsible other than surgical control of bleeding, like decrease in various coagulation factors, acute acquired platelet dysfunction, decrease platelet count and fibrinolysis etc. for bleeding after CPB[1]. During CPB haemodilution, contact of platelets to artificial surface of CPB circuits, platelet destruction and sequestration, high dose of heparin and hypothermia trigger haemostatic disturbances that leads to nonsurgical bleeding[1]. This suggests inquiring the possible causes of hypo-coagulable state, so that correction can be made using appropriate blood and blood product therapy. That will decrease the incidence of excessive nonsurgical bleeding and will prevent unnecessary re-explorations without surgical cause.

Conventionally in laboratory, plasma-based tests like prothrombin time/international normalised ratio (PT/INR), activated partial thromboplastin time (aPTT), fibrinogen levels along with platelet counts and in operation theatre activated clotting time (ACT) are being used after administration of heparin and protamine. The main drawback of laboratory-based tests is the long time-duration required to give results, so empirically blood product therapy was being practiced[2].

After recent advances point of care, viscoelastic in vitro coagulation profile testing devices (like Thromboelastograph Hemostasis Analyzer or TEG®) are being used. They use whole blood as sample and analyze cellular and plasmatic components interaction in vitro and give a coagulation profile from clot formation to fibrinolysis in the form of different parameters (r-time, k-time, α-angle, MA and LY-30 etc.) within few minutes[2].

There are some studies which states that TEG predicts better who will bleed[3–5]. While some other studies did not find TEG as a better predictor of bleeding[6–10]. Metanalysis concluded that TEG remains invalidated compared to routine coagulation tests and large studies are needed involving haematology input to confirm so that results can be extrapolated to all kind of cardiac surgeries[11].

This prospective study was done on 100 patients to determine the accuracy of routine coagulation tests against thromboelastography for prediction of hypocoagulable state, to determine the correlation between different routine coagulation test and thromboelstography parameters and their correlation with chest tube output at 24 hours in patients undergoing cardiac surgery on cardiopulmonary bypass.

Methods

Study design: hospital based prospective observational study.

Eligible participants were all adult patients with ASA grade II and III undergoing cardiac surgery on cardiopulmonary bypass whom anticoagulants and antiplatelets therapy were stopped as per standard surgery protocol 5 days before surgery and with normal coagulation profile at the time of surgery with informed and written consent. Study was conducted in cardiac surgery Operation theatre S.M.S. Medical College, Jaipur after due permission from institution ethics committee from April to July 2021.

Standard induction, anaesthetic management and surgical protocols were followed during cardiac surgeries. Blood samples were collected

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at two time points from central venous catheter after flushing them with crystalloid and discarding initial few ml of blood (a.) after internal jugular vein cannulation using central venous catheter before giving heparin (b.) after CPB weaning and heparin neutralization with protamine.

Heparin 4mg/kg was given to achieve ACT>400sec after 5 min of heparin. Extracorporeal circuit were primed with 1700 ml of crystalloid solution which contains 5000unit heparin before going on bypass, Perfusion flow rate kept at 2.0 to 2.5L/min/m^2 (MAP>50-70 mm Hg) with temp of 28^{0}C to 30^{0}C with use of membrane oxygenation. Myocardial protection was done by cardioplegia. After completion of intra cardiac repair, rewarming and weaning from CPB done and residual heparin were neutralized by injection protamine sulphate (1.5mg x total heparin given) to achieve ACT<120 sec, after 5min second blood sample collected. Collected blood samples transferred to (a.) K_3 EDTA vial for complete blood count (b.) Tri sodium citrate vial for PT/INR, aPTT and Fibrinogen level (c.)1 ml non anticoagulated blood in kaolin vial for kaolin activated TEG using TEG® 5000 Thrombelastograph® Hemostasis Analyzer System (Haemonetics Corporation U.S.).

Blood sample collected for laboratory tests transferred at room temperature to lab for routine coagulation test and haematological parameters (PT/INR, aPTT, Fibrinogen level platelet and complete blood count).

Blood sample from kaolin vial 360microlitre collected using micropipette within 5minute for TEG before heparinization and after weaning from CPB in clear and heparinase cups respectively for different TEG parameters (r-time, k-time, α-angle and MA).

After completion of surgery, patient shifted to ICU where chest drain output was recorded hourly as per protocols.

Patients with abnormal r time and MA value grouped into two, whether FFP and Platelet transfused according to manufacturer guideline[12] (group A)and empirically (group B).

Sample size

Study included 100 cases at 95%confidence interval and 10% absolute allowable error to verify the expected 51% accuracy of Routine coagulation tests against Thromboelastography for detecting haemostatic abnormalities in cases of cardiac surgery on CPB.

Statistical analysis

For statistical analysis MS Excel 2016 and IBM SPSS version 21.0 (IBM Corporation New Orchard Road Armonk, NY) was used. The data were expressed in the form of the mean, standard deviation and range. The correlation between TEG-derived blood clotting parameters and those from routine coagulation tests were obtained using correlation analysis. Mean values of Hct, routine coagulation tests, and TEG parameters in pre and post bypass samples were compared by using paired t-test. To determine whether routine lab-based coagulation tests correlate with TEG parameters, regression analysis and Pearson's correlation coefficient used. Pearson's correlation coefficient was also used to determine significant correlation between blood loss at 24 h and routine coagulation tests, as well as TEG parameters. Groups with abnormal r value and MA post bypass were compared using unpaired t Test for blood loss and amount of blood transfusion units. P value< 0.05 were used to consider correlations statistically significant.

Results

Baseline characteristics

Out of 100 patients the mean age of patients undergoing cardiac surgery was 45.62 ±16.57 yrs. The mean Aortic cross clamp time, mean CPB time and mean chest tube output in 24 hours were 62.86 ± 35.71 min, 106±41.95 min. and 432.11±297.87ml (Table 1).

Table 1: Demographics and surgical procedure characteristics of study subjects

Patient demographics	Mean value± SD (range)
Age (years)	45.62±16.57 (12-82)
Sex (male/ female)	64/36
Height (cm)	161.61±9.53(139-181)
Weight (kg)	51.87±12.63(25-81)
BSA (m2)	1.52±0.22 (1.0-1.98)
Surgical procedures	
Mitral valve replacement (MVR)39	
Double valve replacement (DVR)13	
Aortic valve replacement (AVR)	19
ASD closure	3
TOF repair	2
CABG	7
CABG+ASD closure	1
CABG+ AVR	1
CABG+DVR	2
CABG+LA Myxoma	1
CABG+MVR	4
EBSTAIN REPAIR	1
ICR	3
FONTON REPAIR	1
LA Myxoma	1
MVR+TVR	2
ACC time (min)	62.86±35.71 (0-168)
CPB time (min)	106.48±41.95 (30-243)
Chest tube output at 24 h (ml)	432.11±297.87(80-1800)

SD: standard deviation, BSA: body surface area, ASD: atrial septal defect, TOF: tetralogy of fallot, CABG: coronary artery bypass grafting, LA: left atrial, ICR: intracardiac repair, TVR: tricuspid valve repair, ACC: aortic cross clamp, CPB: cardiopulmonary bypass

Hematological parameters (Table 2)

The mean values of baseline CBC parameters were within normal range. The **hematocrit** values at baseline was 39.13±8.05%, which decreased significantly after bypass to reach 31.65±6.10%. The mean **hemoglobin** at baseline was 13.12±2.79 g/dl, which decreased significantly to 10.56±2.04 g/dl after bypass surgery. **RBC count** at baseline was 4.87±0.56x10^{12}/l, and post-surgery it decreased significantly to 4.03±0.48x10^{12}/l. The **platelet count** decreased significantly from 191.85±56.99x10^9/l at baseline to 106.96±42.52x 10^9/l after surgery. The mean **TLC levels** at baseline was 7.6±2.2x10^9/l, and it increased significantly (p<0.01) to 13.6±3.6x10^9/l after surgery [Table 2].

Laboratory based coagulation tests parameters [Table 2]

Coagulation tests parameters baseline values (pre -bypass) were within normal range.

ACT*:* Activated clotting time pre-bypass value was113.42±22.17sec, and it increased slightly after bypass to 115.83±15.40sec, this difference was however not found to be statistically significant (p=0.44)

PT: Baseline PT value was 15.70±2.18sec and after bypass it increased significantly (P< 0.01) to 24.11±4.15 sec.

aPTT: Baseline value was 33.78±4.72sec and it increased significantly (P<0.01) after bypass value to 41.45 ±7.64 sec

Fibrinogen

Baseline value was 390.62±132.64mg/dl and after bypass it decreased to 254.48 ±102.49mg/dl, this difference was found to be statistically significant (P<0.01).

Thromboelastography parameters [Table 2]

R time (or reaction time): Baseline value was 6.65±6.92 min and it increased post bypass to 7.37±4.46 min. This increase in R time was however not found to be statistically significant (p=0.43).

k-Time (or clot formation time): time taken from r-time to reach amplitude of 20mm, measure of clot formation kinetics(13,14). Baseline value was 1.88 ± 2.09 min and post bypass value increased to 1.98±1.12 sec. This difference was also not statistically significant (p=0.68)

alpha angle: it is angle of trace formed by tangential line drawn to the curve starting from split point of trace, measures speed of clot formation(13,14). Baseline value was 65.50±14.0 degrees and post bypass value decreased slightly to 62.87±11.32. This decrease was however not found to be statistically significant (p=0.16).

MA (maximum amplitude): it is maximum amplitude reached on trace and represent maximum clot strength. Baseline value was 77.44±14.0mm, and after bypass MA values decreased significantly to 70.16±15.59 (p<0.01).

Table 2: Baseline and post bypass complete blood count, coagulation, and thromboelastography parameters

Test parameters	After induction Mean± SD	After bypass Mean ±SD	P -value
RCT			
Hct(N=36-51%)	39.13±8.05	31.65±6.10	P<0.01(S)
ACT(sec)	113.42±22.17	115.83 ± 15.40	0.44(NS)
PT(N=11-16sec)	15.70±2.18	24.11 ± 4.15	P<0.01(S)
aPTT(N=24-36sec)	33.78±4.72	41.45 ±7.64	P<0.01(S)
Platelet count(N=150-400x10^9/l)	191.85±56.99	106.96 ±42.52	P<0.01(S)
Fibrinogen(N=200-400mg/dl)	390.62±132.64	254.48 ±102.49	P<0.01(S)
TEG			
r-time(N=4-8min)	6.65±6.92	7.37 ±4.46	0.43
k-time(N=0-4min)	1.88±2.09	1.98 ±1.12	0.68
α-angle(N=47^0-74^0)	65.50±14.00	62.87 ±11.32	0.16
MA(N=52-72mm)	77.44±14.00	70.16 ±15.59	P<0.01(S)

SD: standard deviation, Hct: hematocrit, ACT: activated clotting time, PT: prothrombin time, aPTT: activated partial thromboplastin time, S: significant, NS: nonsignificant, RCT: routine coagulation tests, TEG: thromboelastography.

Correlations of thromboelastography parameters with routine coagulation tests [Table 3]

Before bypass PT showed moderate positive correlation with r-Time (r=0.57), however after bypass weak positive correlation was seen (r=0.28).

Similarly PT showed moderate positive correlation with k-Time before bypass (r=0.49), however post bypass only weak positive correlation was seen (r=0.36).

aPTT showed moderate positive correlation with r-Time in pre bypass sample (r=0.41).

aPTT showed weak positive correlation with k time in post bypass sample (r=0.25).

Similarly platelet count showed weak positive correlation with MA in post bypass sample (r=0.26).

Fibrinogen showed weak positive correlation with alpha angle (r=0.28) and MA (r=0.31) in pre bypass sample.

Table 3: Correlation between thromboelastography parameters and corresponding routine coagulation tests Parameters

	Before bypass		After bypass	
	r-value	p-value	r-value	p-value
PT/r-time	0.57	P<0.01(S)	0.28	0.02(S)
PT/k-time	0.49	P<0.01(S)	0.36	P<0.01(S)
aPTT/r-time	0.41	P<0.01(S)	0.19	0.11(NS)
aPTT/k-time	0.22	0.06(NS)	0.25	0.04(S)
Platelet/MA	0.22	0.06(NS)	0.26	0.03(S)
Fibrinogen/α-angle	0.28	0.02(S)	0.19	0.12(NS)
Fibrinogen/MA	0.31	P<0.01(S)	0.20	0.10(NS)

PT: prothrombin time, aPTT: activated partial thromboplastin time,
MA: maximal amplitude, S: significant, NS: nonsignificant.

Correlation of routine coagulation test and thromboelastography parameters with postoperative blood loss at 24hour. (Table 4)

In routine coagulation test, Platelet count before bypass showed weak negative correlation with blood loss at 24hour (r=-0.28), i.e. patients with lower platelet count had higher blood loss. After bypass, Fibrinogen level showed weak negative correlation with blood loss at 24hour (r= -0.30) whereas weak positive correlation was seen between PT and blood loss (r= 0.25) [Figure 1a].

Among TEG parameters alpha angle showed weak negative correlation (r= -0.34) while k-time showed weak positive correlation (r=0.29) with blood loss at 24hour. [Figure 1b].

Table 4: correlation between different parameters and blood loss at24hour (CTO)

	Before bypass		After bypass	
Parameters	**r-value**	**p-value**	**r-value**	**p-value**
CPB Time	0.26	**0.03(S)**		
ACC Time	0.09	0.45(NS)		
Hct	0.07	0.59(NS)	-0.03	0.78(NS)
ACT	0.11	0.36(NS)	0.09	0.45(NS)
PT	0.03	0.77(NS)	0.25	**0.03(S)**
aPTT	0.07	0.54(NS)	0.16	0.18(NS)
Platelet	-0.28	**0.02(S)**	-0.23	0.06(NS)
Fibrinogen	-0.10	0.41(NS)	-0.30	**0.01(S)**
r-time	-0.02	0.88(NS)	0.09	0.43(NS)
k-time	-0.03	0.77(NS)	0.29	**0.01(S)**
α-angle	-0.07	0.54(NS)	-0.34	**0.00(S)**
MA	-0.05	0.66(NS)	-0.20	0.10(NS)

Hct: hematocrit, ACT: activated clotting time, PT: prothrombin time, aPTT: activated partial thromboplastin time, S: significant, NS: nonsignificant, RCT: routine coagulation tests, TEG: thromboelastography, ACC: aortic cross clamp, CPB: cardiopulmonary bypass

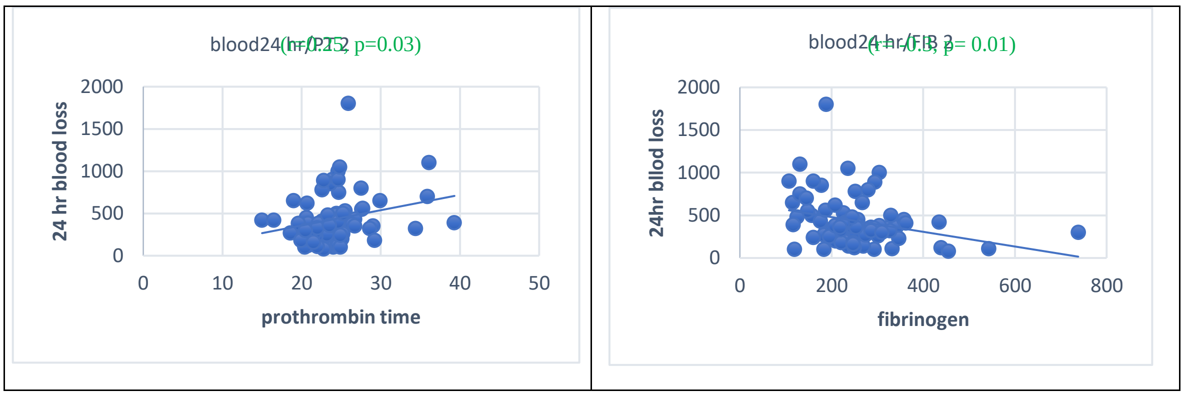

Fig. 1a: statistically significant correlation between 24hr blood loss and RCT post bypass

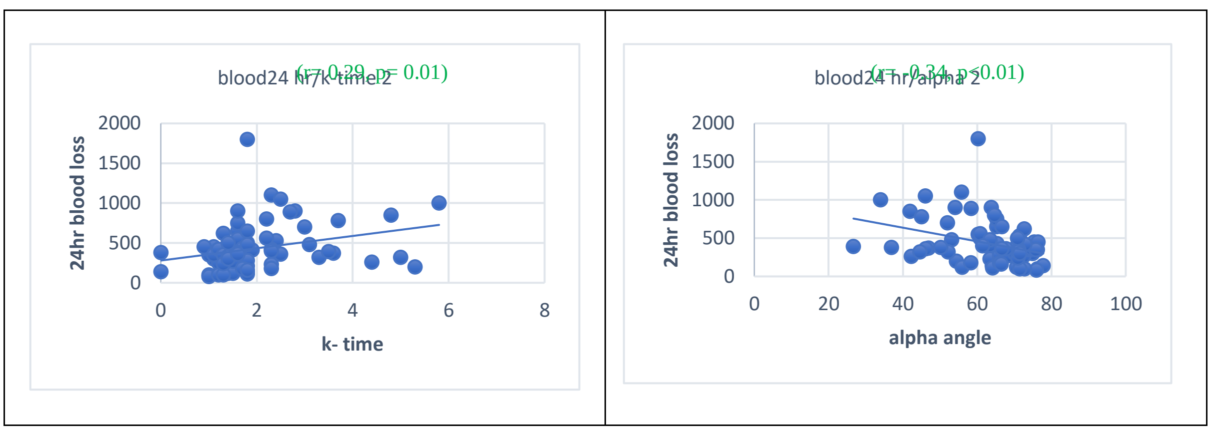

Fig. 1b: statistically significant correlation between 24hr blood loss and TEG parameter post bypass

RCT: routine lab-based coagulation test, TEG: thromboelastography, PT: Prothrombin time, k-time: kinetic time, FIB: fibrinogen level, alpha: alpha angle, 1: pre bypass sample,2: post bypass sample

Comparison of blood loss amount and blood transfusion units in both group

In 14 patients post bypass values of either r time or MA or both were deranged. Out of 14, 6 patients (Group A) were transfused FFP and platelets according to manufacturer guidelines (12) and remaining 8 patients (Group B) were transfused empirically. Post bypass mean blood loss at 24hour in group B (523.75±251.28ml) was more than group A (396.67±156.55ml), the difference was however not statistically significant (p=0.30). Mean packed red blood cell units transfused were more in group B (1.5±0.76) than group A (1.0±0.63), this difference was also not statistically significant (p=0.21). No significant difference was seen in mean FFP and Platelet units transfused (p>0.5).

Discussion

The result of our study showed that among the hematological parameter Hb, RBC and platelet count decrease because of hemodilution when the patient taken on bypass and TLC increase because of blood component come into contact of CPB circuit.

The lab-based coagulation tests showed an increase in PT, aPTT and decrease in fibrinogen.The TEG parameter showed an increase in r-time, k-time from baseline and alpha angle decrease post bypass from baseline and MA showed a decrease in value which was significant.

Routine coagulation test showed a relation with postop blood loss at 24hour by showing a negative correlation of fibrinogen and a weak positive correlation between PT and blood loss while among TEG parameter alpha angle and k time showed a weak negative and weak positive correlation with blood loss at 24hour. Duration of CPB was also a significant factor correlated to the blood loss.

Only alpha angle after bypass among the TEG parameters found to be associated with bleeder.

Due to multifactorial derangement in hemostatic parameters following cardiopulmonary bypass finding specific diagnosis and therapy to guide treatment is complex, theoretically thromboelastography provide more information than RCTs as TEG measure whole clotting process in vivo from initial fibrin formation to clot lysis while most RCT are useful only in initial part of coagulation.

PT and aPTT reflect coagulation factors status used in intrinsic, extrinsic or common pathways of coagulation cascade, fibrinogen level and platelet count are individual values affecting clot formation and its strength. While in TEG r time, k time reflect initial part of coagulation cascade like PT and aPTT and alpha angle related to fibrinogen activity and MA maximum strength of clot related to platelets.

In the present study, we found most routine hematological and lab-based coagulation test parameters changed significantly after cardiopulmonary bypass. These result findings are similar to Wang et al.[7], Sharma et al.[15], Welsh et al[16],. But only pre bypass platelet count and after bypass PT and fibrinogen level were significantly correlated with the postoperative blood loss amount at 24 hr.In TEG parameters only MA was changed significantly after bypass but alpha angle and k-time in after bypass sample was significantly correlated with post op blood loss. After bypass TEG parameters changes were not consistent in different studies, no significant change in TEG parameters found by Sharma et al.[15], and r-time and k-time changes was found by Wang et al[7].

Routine lab-based coagulation tests and TEG parameters correlation was found in both preoperative and postoperative samples but in few pair (pre bypass; aPTT/k-time, Platelet/MA, post bypass; aPTT/r-time, Fibrinogen/α-angle, Fibrinogen/MA) correlation was not statistically significant. These result findings are similar to Welsby et al.[4], Sharma et al.[15],Welsh et al.[16], Ozolina et al.[17], a significant correlation of alpha angle and MA with fibrinogen and strong correlation between MA and platelet count in postoperative samples was found by Sharma et al[15]. Most of RCT and TEG parameters corelation was found by Welsh et al[16]. Contrary to these and our study, Dorman et al[8]. have shown that there is no correlation between preoperative and postoperative TEG and RCT parameters. Narani et al[18]. has reported that it is not possible to correlate TEG parameters with conventional coagulation profile as both techniques are different.

Discrepancies in results may be due to the lack of a standardized technique for TEG, differences in study populations such as cardiac pathology, CPB technique(machine, prime solution, duration)used, ongoing antiplatelet therapy, sex, age and the multiple TEG modifications such as tissue factor, kaolin, or celite activation or plain and heparinase cups for samples[11,19]. These were limitations in our study.

Conclusion

In our study different RCT and TEG parameters correlate among themselves and PT and fibrinogen level derangement after bypass and their corresponding part in TEG k-time and alpha angle correlate significantly with amount of blood loss. We conclude that TEG can be used to guide blood component therapy postoperatively in ICU rather than providing empirically due to non-availability of routine coagulation test due to long turnaround time.

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