Thromboelastography Analysis after Autologous Transfusion in Patients Undergoing Coronary Artery Bypass Surgery

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Abstract

Background- Acute normovolemic hemodilution (ANH) includes the removal of blood from a patient either immediately before or shortly after the induction of anesthesia and the simultaneous replacement with an appropriate volume of plasma substitute to maintain normovolemia. Thromboelastography (TEG) is a non-invasive diagnostic approach designed to monitor and analyze the coagulability state of a blood sample in order to assist clinical assessment of the haemostatic condition of the patient. The aim of this study was to use the ANH technique in patients requiring coronary artery bypass graft (CABG) surgery and to confirm the advantages of the ANH technique along with TEG.

Method- A controlled randomized clinical trial was conducted in 130 patients (32 females, mean age 57 ± 9.0 years, range 38 to 79 years) who were scheduled for CABG surgery with cardiopulmonary bypass (CPB). They were equally divided into two equal-sized ANH and control groups (n = 65). Patients in group A underwent ANH with an average of 500 ml whole blood removal after the induction of anesthesia and their removed blood was replaced with crystalloid solution; blood was not removed in the subjects of the control group. Serum levels of hemoglobin and platelets, TEG parameters analysis, homodynamic changes before and after the operation, and the amount of blood transfused during surgery and in the ICU were checked in both groups. Statistical analysis was performed using repeated measures ANOVA models.

Results- After the surgery, there were significant decreases in hemoglobin and platelets levels ($p < 0.005$), but the decrease was less in the ANH group. However, no difference was found in the amount of platelets decrease between the two groups. Changes in TEG parameters - K, ANGLE, EPL and CI – in the ANH group were statistically significant before and after the surgery (all p-values <0.05). Also, there were significant differences in MA, EPL, and CI parameters between the ANH and control groups (all p-values <0.05).

Conclusion- Use of ANH in patients undergoing CABG surgery results in greater preservation of coagulation factors and platelets that may reduce the amount of bleeding ***(Iranian Heart Journal 2009; 10 (4):19 -27).***

Key words: coronary artery bypass graft ■ thromboelastography ■ hemostasis

Autologous transfusion was first reported in 1917.[1]

Acute normovolemic (isovolemic) hemodilution (ANH), also referred to as

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intraoperative hemodilution, was introduced in the early l970s.[2] The advantages and disadvantages, applications, and complications vary with the techniques being used. The two primary reasons for employing autologous transfusion are avoidance of complications associated with allogenic transfusion and conservation of blood resources. Patients with rare blood phenotypes can benefit from autologous transfusion because compatible allogenic blood may not always be available.

Potential complications of allogenic transfusion that can be eliminated or minimized when autologous blood is administered include acute and delayed hemolytic reactions, alloimmunization, allergic and febrile reactions, transfusion–transmitted infectious disease, and immunosuppression.[3]

ANH should be considered for patients with acceptable initial hematocrit levels, when they are expected to lose more than two units of blood (900 to 1000 ml) during surgery. This technique is better suited to healthy young adults, although it has also been successfully employed in younger children and the elderly. Operation settings in which ANH is appropriate include vascular, orthopedic, and some general surgical procedures.

ANH is contraindicated in the following settings:

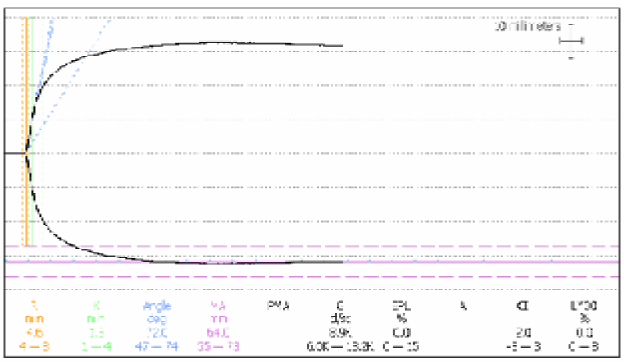
1. Cardiac diseases; since the main compensatory mechanism for the induced anemia is an increase in the cardiac output. However, the decreased blood viscosity associated with the induced anemia may have cardioprotective effects in some cardiac surgical settings.[4, 5]
2. Impaired renal function; since large amounts of infused fluids need to be excreted.
3. Baseline hemoglobin below 11g/dL.
4. Low concentrations of coagulation proteins.
5. Inadequate vascular access.
6. Absence of appropriate monitoring capability.

Performing ANH by withdrawing blood and replacing it with fluid is accompanied by normovolemic anemia (decrease of arterial oxygen content and hemoglobin level), which causes physiologic effects on the circulation and cardiovascular system, including: i) redistribution of blood flow and increase in the myocardial and cerebral blood flow (increase of tissue oxygen extraction); ii) a decrease in blood viscosity and reflex vasodilatation, hence a decrease in peripheral vascular resistance (SVR) and decrease in afterload; iii) an increase in cardiac output (CO) due to increase in stroke volume and heart rate; and iv) enhancement in the microvascular blood flow and more efficient oxygen utilization due to increase of CO and decrease of SVR, and an extreme shifting of oxygen-dissociation curve to the right.[6]

It is important to note that compensatory mechanisms during ANH are independent of age and left ventricular ejection fraction.[7] Furthermore, during ANH tissue O_2 extraction increases until a hematocrit level of 17% is preserved.[8] Patients with decreased renal function and significant restrictive or obstructive pulmonary disease or preexisting coagulopathy with a reduction in coagulation factors, thrombocytopenia, or impaired platelet function are contraindicated for ANH technique.[3]

The thrombelastograph (TEG) is a non-invasive diagnostic instrument designed to monitor and analyze the coagulability state of a blood sample in order to assist the assessment of patients' clinical haemostatic conditions. Coagulation evaluations are commonly used to assess clinical conditions such as postoperative hemorrhage and/or thrombosis during and following surgery.[9, 10.16] Cardiac surgery with CPB is accomplished by complex alterations of hemostasis, including acquired dysfunction of platelets, consumption coagulopathy, and increased fibrinolysis. Despite major advances in blood conservation methods and perioperative care of the patients, transfusion rates in cardiac surgery remain high. Thromboelastography has an ability to assess almost all components of the haemostatic system globally. Currently, thromboelastography is used with standard coagulation tests to decrease the microvascular bleeding and homologous blood transfusion in cardiac surgery with cardiopulmonary bypass.[15]

The overall coagulability profile can be quantitatively or qualitatively interpreted in terms of the hypocoagulable, normal, or hypercoagulable state of the sample and the degree of lyses.[11]



R= Time to initial fibrin formation
K= Speed to reach clot strength
ANGLE = Rapidity of fibrin build-up and clot strengthening
MA= Dynamic properties of fibrin and platelet bonding, i.e., ultimate strength of the clot.

Fig.1. Thromboelastography components (with permission).

The aim of this prospective and randomized study was to determine the benefits of ANH in patients undergoing CABG surgery using thromboelastography as the end-point.

Methods

This randomized controlled trial study was approved by the RHC Review Board and Ethics Committee. Among the patients scheduled for CABG with CPB, 130 patients were enrolled in the study. Patients with renal failure, significant restrictive or obstructive pulmonary disease, or pre-existing coagulopathy or hepatic disease were excluded.

Participants signed written informed consent, and then they were randomly assigned to one of the ANH or control groups. Randomization was performed by using the balanced block randomization (block of four) technique. The results of randomization were sealed in an envelope. After the registration of each patient, the envelope was opened by the anesthesiologist at the first visit and the participants were assigned to the defined group.

Similar inductions of anesthesia with midazolam (0.1-0.15 mg/kg), atracurium (0.1mg/kg) and fentanyl (10-30 µg/kg) were carried out on patients before performing the ANH technique. Maintenance of anesthesia was performed with 100% oxygen and infusion of atracurium, midazolam, and fentanyl.

Through the induction of ANH, 450 ± 50 ml of blood was extracted from the subjects, which was then returned to them after the surgery; the ANH technique was not performed in the control group.

Isovolemia was maintained by the infusion of crystalloids. Serum levels of hemoglobin and platelets and as well as TEG profile (R, K, MA, angle, CI, LYS 30%, and EPL) were measured by the thromboelastograph machine V4.1 from Heamoscope. The amount of transfusion in the operating room and differences in systolic, mean, and diastolic blood pressure were also checked.

TEG profile was checked in all the patients after the induction of ANH, after termination of CPB in group B, and after the return of ANH blood to the subjects in group A. The amount of blood transfusion during CPB and in the ICU, and the amount of chest tube drainage at 6 and 12 hours after the operation were also checked.

Statistical Analysis

Data were classified as mean ± standard deviation for the quantitative and count (%) for the qualitative variables. Statistical analysis was performed by SPSS 15 for Windows (SPSS Corporation, Chicago, Illinois). Student's t-test and repeated measures ANOVA models were used for statistical analysis. P-values < 0.05 were considered statistically significant.

Results

Baseline data

One hundred thirty patients (30 females, mean age 57 ± 9.0 years, range 38 to 79 years) were enrolled in the study. Background information is shown in Table I. No important difference existed between the patients in the two groups.

Table I. Baseline data in ANH and control groups

	ANH group (n = 65)	Control group (n = 65)	P value
Age (*years*)	56 ± 8.9	58 ± 9.2	0.46
Weight (*kg*)	68 ± 9.1	68 ± 8.2	0.79
Platelets count (*10^3/ml*)	222 ± 53.2	215 ± 42.2	0.37
Systolic BP (*mmHg*)	126 ± 16	126 ± 12.2	0.98
Diastolic BP (*mmHg*)	72 ± 7.2	69 ± 8	0.24
Hemoglobin (*g/dL*)	14 ± 1.2	12.7 ± 1.2	0.33
Female Male	16 (23%) 49 (77%)	15(26%) 50(74%)	0.61

TEG Parameters and their Changes

Different parameters of TEG were measured before and after intervention, and the results were compared between the two groups (Table II).

Table II. Comparison between TEG parameters in the ANH and control groups before and after CABG

	Before CABG		After CABG		P Value		
Parameter	ANH Group (n= 65)	Control Group (n = 65)	ANH Group (n= 65)	Control Group (n = 65)	Parameter main effect	Group main effect	Parameter – Group Interaction
R *min*	5.19 (3.08) †	3.07 (2.69) †	2.87 (1.28)‡	4.98 (1.25)‡	0.44	0.97	< 0.001
K *min*	2.92 (2.23)	2.92 (2.56)	1.79 (0.67)	1.64 (0.40)	< 0.001	0.74	0.74
Angle *deg*	56.63 (13.43)	58.60 (10.47)	65.41 (10.13)	64.17 (5.96)	< 0.001	0.52	0.75
MA *mm*	62.74 (7.82) †	67.90 (9.05) †	64.14 (5.03)	63.80 (6.54)	0.70	0.02	< 0.001
G *d/sec*	8.32 (2.80)	8.38 (2.80)	8.73 (1.60)	8.45 (2.24)	0.31	0.75	0.40
EPL *%*	0.25 (0.58)	0.32 (0.64)	0.25 (0.45) ‡	0.77 (1.25) ‡	0.03	0.005	0.03
LY30 *%*	0.57 (0.90)	0.74 (1.03)	0.47 (0.69) ‡	0.87 (1.35) ‡	0.91	0.96	0.27
CI	- 0.37 (4.35) †	1.99 (2.70) †	1.78 (2.27)	1.68 (1.29)	0.01	0.001	0.001
A *mm*	59.63 (7.88) †	63.74 (8.90) †	61.93 (6.29)	62.37 (6.29)	0.61	0.29	0.04

* R: time of initial fibrin formation, K: speed to reach clot strength, ANGLE: rapidity of fibrin build-up, MA: maximum amplitude, G: strength of the clot, EPL: estimated percent of lysis, LY30: lysis percent after 30 minutes, CI: coagulation index, A: amplitude.
† and ‡ : Statistically significant differences between two study groups

Time of initial fibrin formation (R)

The results showed that no difference existed in the mean R before and after the operation between the ANH group and control group. However, there was a significant parameter-group effect modification (p<0.001), i.e. the values of the parameter "R" had different changes in the two groups. Data revealed that before surgery, the mean of R was greater in the ANH group but after surgery, it became significantly greater in the control group (p<0.001, Fig. 2-a).

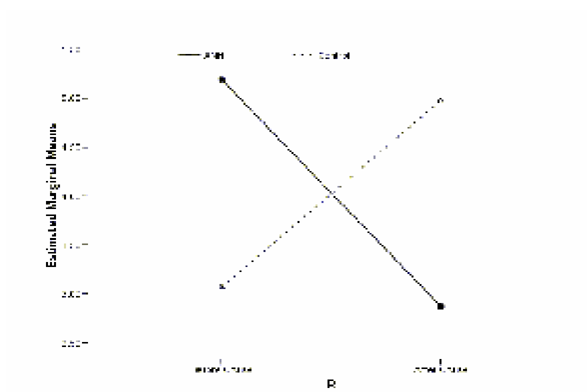


Fig. 2-a. Parameter R in the two groups before and after CABG.

Speed to reach clot strength (K)

Table II shows that the means of this parameter were similar in the two study groups. On the other hand, the mean of "K" is significantly higher in the preoperation state ($p<0.001$). It means that after surgery, the time for reaching strong clot is significantly shorter. No important parameter – group interaction was found.

Rapidity of fibrin buildup (ANGLE)

Like the speed, the acceleration of fibrin formation was higher in the postoperative rather than preoperative status (Table II; $p<0.001$). Neither any important difference nor parameter–group interaction was observed between the two groups (Fig. 2-b).

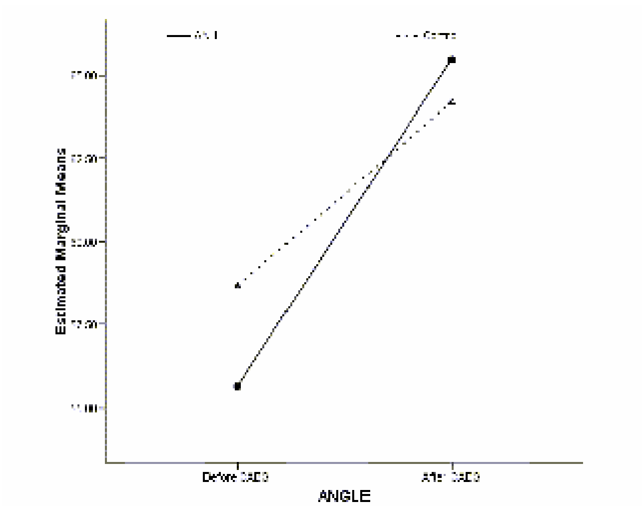


Fig. 2-b. Parameter ANGLE in the two groups before and after CABG

Maximum amplitude (MA)

It was observed that the mean MA was higher in the control group ($p=0.02$). On the other hand, the main effect of this parameter was not statistically significant ($p=0.07$). It means that the mean MA was not different before and after the surgery, but the parameter–group modification of effect was significant ($p<0.01$). It can be explained with the fact that the mean MA was different in the ANH and control groups before CABG ($p=0.03$); however, after the procedure, the mean MA is similar in the two groups. In other words, there was an obvious reduction in maximum amplitude in the control group; but no important changes were shown in the ANH group (Fig. 2-c).

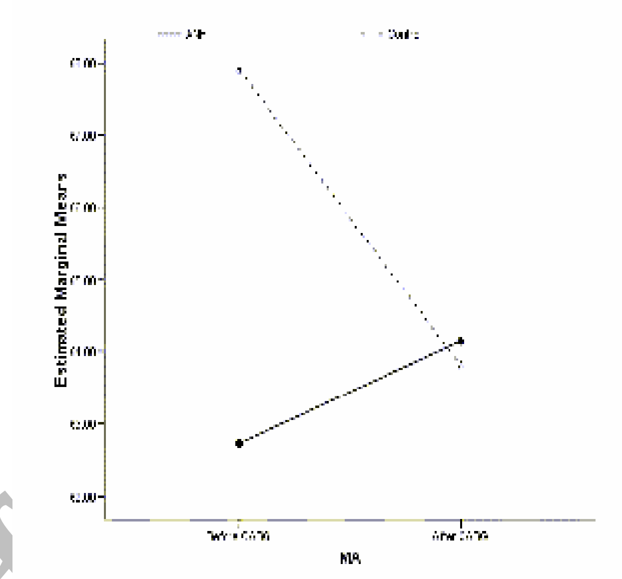


Fig. 2-c. Parameter MA in the two groups before and after CABG

Strength of the clot (G)

No significant differences were observed in the strength of the clot before and after surgery and between the groups. No effect modification of this parameter was present between the two groups (Table II, Fig. 2-d).

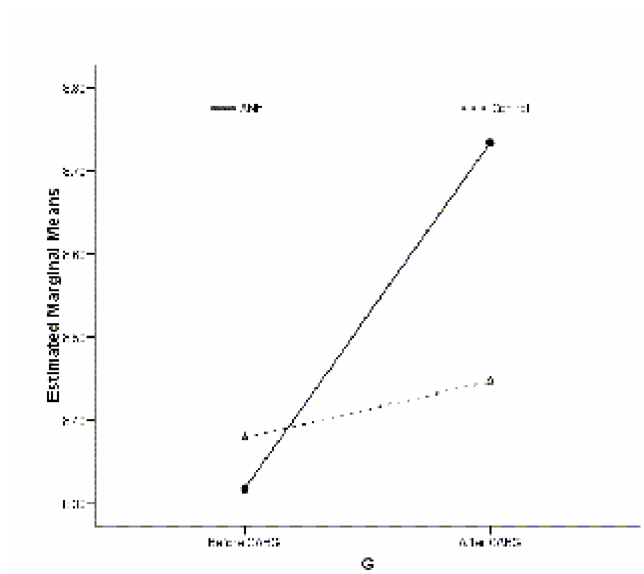


Fig. 2-d. Parameter G in the two groups before and after CABG

Estimated percent of lysis (EPL)

As presented in Table II, the estimated percent of lysis was significantly higher in the control group (p=0.005) and greater after surgery (p=0.03). Also, a parameter – group interaction was found. Actually, there was no change in the lysis of the ANH group before and after the procedure. Indeed, the percentage of the lysis had a significant rise in the control group after surgery (Fig. 2-e).

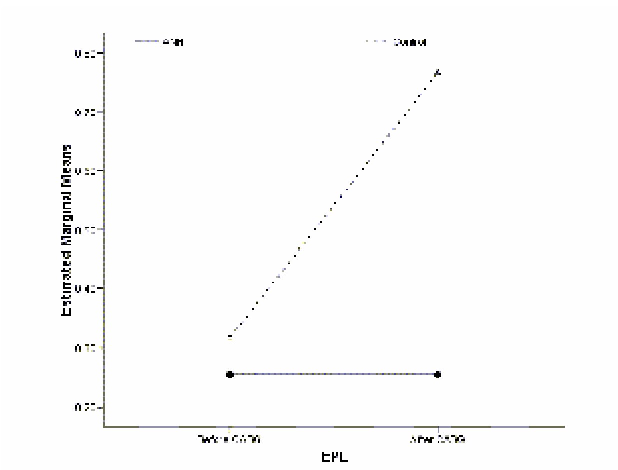


Fig. 2-e. Parameter EPL in the two groups before and after CABG

Lysis percent after 30 minutes (LY30)

There were no differences in LY30, neither between ANH and control groups nor between the preoperation and postoperation status (Fig. 2-f).

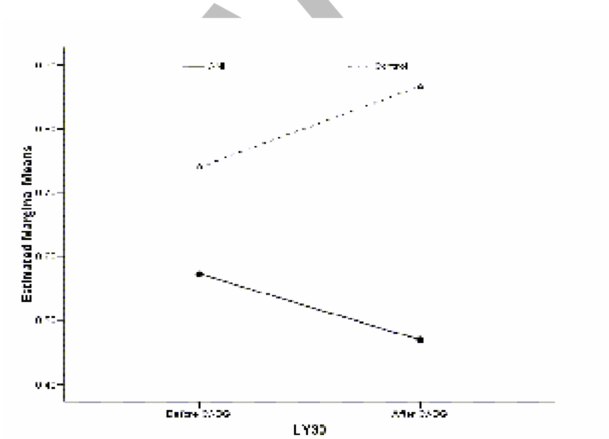


Fig. 2-f. Parameter LY30 in the two groups before and after CABG

Coagulation index (CI)

The results showed that the mean CI was significantly lower in the ANH group (p=0.001) and in the preoperation status (p=0.01). Before surgery, the mean coagulation index was lower in the ANH group (p<0.001), but after that, CI in the two groups was similar. It means that CI had an obvious rise after the procedure, which was not observed in the control group and this proposed an interaction (p=0.001, Table II, Fig. 2-g).

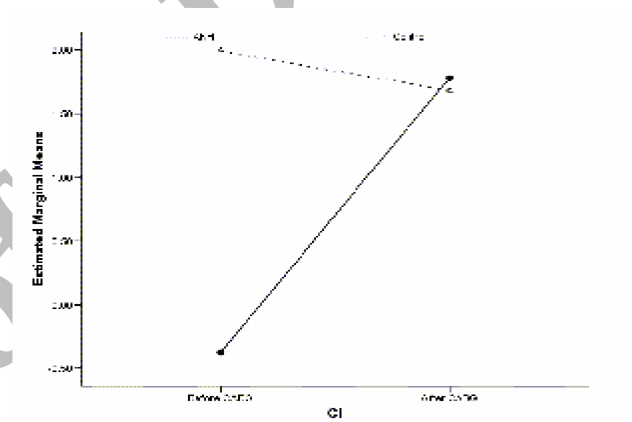


Fig. 2-g. Parameter CI in the two groups before and after CABG

Amplitude (A)

It was observed that the mean parameter "A" was similar in the two groups of patients before and after surgery. However, a parameter – group effect modification was found (p=0.04). It can be explained that before CABG, the mean A was significantly lower in the ANH group; but after the operation, the values of the parameter were about equal to each other. However, it seems that these findings had limited clinical importance (Fig. 2-h).

Hemoglobin and Platelet Count

The results of the comparisons are presented in Table III. Before surgery, the mean concentration of Hb was 14.0 (1.2) in the ANH

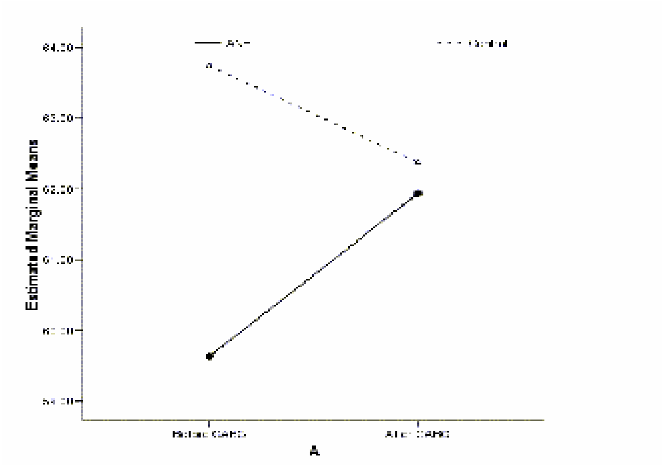


Fig. 2-h. Parameter A in the two groups before and after CABG

group and 12.7 (1.2) in the control group. After the procedure, the values declined. The mean Hb in the ANH and control groups reached 11.1 (1.4) and 9.3 (1.1), respectively.
The results suggested that the decrease of Hb was significant (p<0.001). Also, there was a significant difference between the two groups (p<0.001) and the interaction of parameter – group was also significant. It means that the fall in Hb was more severe in the control group than that of the ANH group (p=0.005). The average platelet count was 222 (53.2) x10^3/ml in the ANH group and 215 (42.2) x10^3/ml in the control group before CABG. After that, a significant decrease was observed. The count was 185 (37.8) x 10^3/ml in the ANH and 173 (46.6) x 10^3/ml in the control group (p<0.001). No significant difference was found between the two groups and no interaction was found either. In this study the difference in the amount of blood transfusion in the operating room between the ANH and control groups was statistically significant (p=0.0001), as well as in the ICU (p= 0.0001). Also, time to initial fibrin formation (R) and coagulation index (CI) between the ANH and control groups was statistically significant (p=0.0001). In this study, the difference between the amounts of drainage in the first 6 hrs and second 6 hrs postoperation between the two groups was significant (p=0.0001). Also, postoperative hemoglobin and hemoglobin gradient between the two groups were statistically significant (p=0.0001). Also, a comparison of postoperative diastolic blood pressure between the two groups was statistically significant (p=0.0001, Table=III).

Table III. Comparison of parameters between of ANH and control groups

Parameter	ANH	Control	P-value
Age	56.4±8.8	57.6±9.2	0.40
Weight	68±9.1	67.6±8.2	0.78
Hemoglobin	12.6±4.4	12.7±1.2	0.0001
Platelet count	219.0±60.0	214.7±42.2	0.43
Time to initial fibrin formation (R)	5.2±3.0	3.0±2.7	0.0001
Speed to reach clot strength (K)	2.9±2.2	3.9±8.9	0.76
Rapidity of fibrin buildup (ANGL)	54.8±15.4	58.6±10.4	0.46
Maximum amplitude (MA)	62.7±7.8	67.9±9.0	0.008
Predefined maximum amplitude (PMA)	0.11±0.31	0.19±0.39	0.22
Strength of the clot (G)	8.3±2.8	9.4±6.0	0.48
Estimated percent of lysis (EPL)	0.25±0.58	0.32±0.64	0.96
Lysis percent after 30 min (LY30)	0.57±0.89	0.74±1.0	0.32
Coagulation index (CI)	0.22±6.8	1.9±2.7	0.0001
Alpha (A)	166.7±844	63.7±8.8	0.013
Systolic blood pressure (mmHg)	126.4±16	126.4±12	0.97
Diastolic blood pressure (mmHg)	72.0±7.2	69.5±8.0	0.17
Mean arterial pressure	84.8±10.5	80.3±7.9	0.004
Intraoperative transfusion	1.9±0.27	1.5±0.5	0.0001
Postop. hemoglobin	11.0±1.4	9.3±1.08	0.0001
Postop. platelet count	184.8±37.8	173.4±46.6	0.019
Postop. time to initial fibrin formation	2.87±1.27	4.97±1.24	0.0001
Postop. speed to reach clot strength	1.7±0.6	1.6±0.4	0.58
Postop. rapidity of clot strengthening	65.5±10	64.2±5.96	0.008
Postop. strength of the clot	64.0±5.0	63.8±6.5	0.99
Postop. maximum altitude	0.00±0.00	0.03±0.17	0.17
Postop. strength of the clot	8.7±1.5	8.4±2.2	0.18
Postop. estimated percent of lysis	0.25±0.45	2.8±9.1	0.12
Postop. lysis	0.47±0.68	2.9±9.1	0.21
Postop. coagulation index	1.7±2.2	1.6±1.3	0.037
Postop. alpha index	61.9±6.3	62.3±7.9	0.27
Postop. systolic blood pressure	123.5±19	121.7±8.0	0.38
Postop. diastolic blood pressure	74.2±9.1	66.8±8.8	0.0001
Drainage in 1st 6hrs	193.5±105.7	294.8±189.7	0.0001
Drainage in 2nd 6hrs	146±100.8	239.7±97.9	0.0001
Transfusion in ICU	1.8±0.31	1.4±0.5	0.0001
Hemoglobin gradient	3.6±0.69	2.9±0.67	0.0001
Platelet gradient	2.9±1.1	2.7±0.89	0.70

The change in the mean of diastolic blood pressure pre- and post-surgery in the ANH group (p=0.047) and change in the mean of systolic and diastolic and mean blood pressure pre- and post-surgery with p=0.001, p=0.037, p=0.000, respectively, were statistically significant.

Discussion

In this study, we used thromboelastography (TEG), which can non-invasively determine the changes in patients' coagulation factors such as fibrinogen and the level or function of platelets and also the presence of fibrinolysis in the circulation using 0.36 ml of their blood. This study shows that the Hb level in the ANH group (A) was greater than that in control group (B) after CABG. This result may be obvious because of the return of the blood to patients in the ANH group. In another study, similar results were reported with the use of ANH technique.[12]

On the other hand, previous studies show that hemodilution was tolerated in patients undergoing CABG until Hb level reached 8.8 ± 0.3 g/dl and lower.[13]

This study revealed that with similar initial platelet levels in both groups, the ANH group showed less decrease in platelet levels after CABG compared to the control group, suggesting preservation of platelets in the ANH group and fewer effects of CPB on platelets.

The R component of the TEG profile indicates the enzymatic system activity and the level of coagulation factors (time to initial fibrin formation). After CABG, there was a decline in R value in the ANH group, showing greater preservation of coagulation factors in this group (Figs. 2 and 3). The K component of the TEG profile shows the speed to reach clot strength. After CABG, there was a decline in the speed of decrease in the ANH group, showing greater speed of clot formation in this group.

The angle component of the TEG profile shows rapidity of fibrin build-up and clot strengthening and fibrinogen level. This component showed no significant difference and no parameter-group interaction between the two groups.

The MA component of the TEG profile shows dynamic properties of fibrin and platelet bonding, i.e. the level and function of platelets. This parameter was not decreased significantly in the ANH group, showing better preservation of platelet and platelet function in this group.

The G component of the TEG profile shows clot strength, and LYS 30% and EPL components of TEG show fibrinolysis level. These parameters along with coagulation index (CI) were not significantly different between the two groups, showing that patients do not have significant fibrinolysis after CPB.

This study demonstrates that the changes in diastolic blood pressure after CPB *per se* were significant in the ANH group but changes in systolic, mean, and diastolic blood pressure after CPB were significant in the control group, which shows that there was less hemodynamic stability in the control group.

In a prospective study by Helm et al. on CABG patients, an obvious decline in the transfusion of blood products was seen in the ANH group.[14]

In a study by Ruel et al., the decrease in blood transfusion in the ANH group in CABG patients was also statistically significant.[12]

In other studies, the amount of transfusion in the operating room and the ICU was not statistically significant between both groups, but the ANH group generally had less blood transfusion in the ICU compared to control groups (non-ANH).[2,17]

In previous studies, the amount of blood products transfused such as platelets, fresh frozen plasma, and packed red blood cells was significantly less in the ANH group.[18]

Conclusion

Hemodilution in selected patients is a strategy to avoid allogenic transfusions. Anesthetic technique (primarily hemodilution) and the physicians' growing tolerance for euvolemic anemia have reduced the exposure of patients to allogenic blood.

Because patients entering cardiac surgery are typically hypercoagulable, ANH may serve the function of providing a more normalized coagulation profile, i.e., from hyper toward normal coagulability. Furthermore, in CPB, patients may be prone to bleeding diathesis so the use of the ANH technique and TEG profile together can more precisely detect disorders in haemostatic condition, for example; fibrinogen deficiency, factor deficiency, thrombocytopenia or platelet dysfunction, and heparin excess.

This strategy decreases the amount of transfusion and reoperation and also prevents the imposition of excess risks on patients.

Conflict of Interest

No conflicts of interest have been claimed by the authors.

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