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Preoperative Haemostasis Testing Does Not Predict Requirement of Blood Products in Cardiac Surgery

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Abstract

Objective: Standard haemostasis screening tests are performed to reveal unknown congenital or acquired disturbances of plasma and/or platelet haemostasis. Since their diagnostic efficacy is often low, routinely performed haemostasis testing has been questioned. We investigated whether preoperatively assessed haemostasis testing can be used to predict the requirement of blood products.

Methods: We retrospectively assessed haemostasis parameters including platelet function testing by PFA 100 as well as the numbers of red blood cell (RBC) concentrates, fresh frozen plasmas (FFPs), and platelet concentrates (PCs) that were given peri-operatively and during the first two postoperative days in 2,831 cardiac surgery patients. Logistic regression analyses were used to select those parameters, which could predict blood product requirement.

Results: Of our study cohort, 56.5% needed RBCs, 15% FFPs, and 5% PCs. The need for RBCs was associated with significantly altered pre-operative values of most haemostasis parameters. However, by the use of logistic regression analysis fibrinogen was the only haemostasis parameter that was independently associated with the use of RBCs (odds ratio 1.56; 95% CI: 1.27-1.91; $P < 0.001$). The predictive value of other parameters such as age, body weight, haemoglobin, and haematocrit was however much higher in comparison to fibrinogen (odds ratios: 1.92-3.50; $P < 0.001$). It was not possible to develop a score based on haemostasis parameters to accurately identify patients at risk for RBC use. Moreover, we were unable to estimate the need for FFPs and PCs using preoperative haemostasis testing.

Conclusions: Our data demonstrate that preoperatively performed haemostasis testing is not predictive in estimating the need for blood products in cardiac surgery patients.

Key words: haemostasis testing, cardiac surgery, blood transfusion, platelet function

Abbreviations: aPTT: activated partial thromboplastin time; CABG: coronary artery bypass grafting; CI: confidence interval; CRP: C-reactive protein; Exp(B): exponent of the B-coefficient; FFP: fresh frozen plasma; MPV: mean platelet volume; PC: platelet concentrates; PDW: platelet distribution width; PT: prothrombin time; PFA 100: platelet function analyser 100; RBC: red blood cell; ROC: receiver operating characteristics

Introduction

It is well-established clinical practice to perform haematological analyses such as haemoglobin measurements, and haemostasis tests such as prothrombin time (PT), activated partial thromboplastin time (aPTT), platelet counts time prior to surgery, invasive diagnostic procedures, and therapeutic procedures, respectively. Sometimes bleeding time, fibrinogen measurement and in vivo platelet function testing is also performed. The primary goal of standard haemostasis screening is to reveal unknown congenital or acquired disturbances of plasma and/ or platelet haemostasis [1, 2]. However, severe and thus relevant defects are rarely detected. In contrast, there is a clear rationale to perform platelet function tests [3, 4], as platelet function defects such as von Willebrand's disease are far more prevalent than coagulation disturbances.

The diagnostic efficacy of the plasma haemostasis screening tests is often low [5, 6]. Although the usefulness of haemostasis screening tests has therefore been questioned [7, 8|, they may be helpful in order to predict bleeding intensity during surgery and other clinical procedures to estimate the need for blood products. Several studies have already investigated whether haemostasis testing is useful in order to predict the risk for bleeding. However, some of these earlier studies included a small number of patients [9-16], some were restricted to the intra-operative assessment of haemostasis parameters [9, 17] or to haemostasis testing in children [18], and others were performed in elective coronary artery bypass grafting surgery patients only [19].

We therefore aimed to investigative the clinical usefulness of preoperatively assessed haemostasis testing for the prediction of blood products requirement in a randomly selected large cohort of cardiac surgery patients.

Materials, Methods, and Statistics

Patients

This report summarizes data obtained from 2,831 cardiac surgery patients at the Heart Center North Rhine Westphalia, Bad Oeynhausen, Germany between January 2003 and October 2003. One thousand three hundred and ninety five patients underwent coronary artery bypass grafting (CABG), 432 patients isolated aortic valve replacement, 252 patients combined CABG and aortic valve replacement, 118 patients isolated mitral valve replacement, and 664 patients other single or combined cardiac procedures. All patients received a dose of 2 million KIU of the antifibrinolytic agent aprotinin intra-operatively (Bayer, Leverkusen, Germany). All patients had a complete haemostasis testing. Mean age of the study cohort was 65.6 years (range: 15 – 92 years). One thousand nine hundred six patients (69.3%) were males.

Methods

We used the medical records of the patients in order to assess age, sex, and anthropometric data. For haematological and clinical biochemical analysis, blood samples were collected 1 - 3 days before surgery (see below). In each patient we recorded the number of red blood cell concentrates (RBCs), fresh frozen plasmas (FFPs) and platelet concentrates (PCs) given during surgery and within the first two days at the intensive care unit. Data were obtained from our blood bank records.

Haematoligical and Haemostasis Analyses

We measured blood haemoglobin, haematocrit, mean red cell volume, and white cell counts, platelet counts, mean platelet volume (MPV), and platelet distribution width (PDW) in EDTA blood by automated procedures using the Abbott CellDyn 3500 haematology analyser (Abbott, Wiesbaden, Germany). For coagulation tests, we used citrate-anticoagulated blood. Immediately after smooth vein puncture, blood was gently mixed with anticoagulant by several inversions and analysed automatically in a CA6000 optical coagulation device from Dade Behring, Liederbach, Germany. Fibrinogen was determined using the coagulometric method. Activated partial thromboplastin time (aPTT) was analyzed using the reagent Actin FS, and for prothrombin time we used the reagent Innovin. All reagents were supplied by Dade Behring (Liederbach, Germany). Antithrombin activity was detected by a Dade Behring assay with a chromogenic peptide substrate via its ability to inhibit thrombin. Platelet function analysis was performed in whole blood that was anticoagulated by a tenth volume of 0.129 mol/l (3.8%) buffered sodium citrate solution pH 5.5 by the platelet function analyser 100 (PFA 100) also from Dade Behring (Liederbach, Germany). It consists of single-use cartridges with a blood reservoir, a membrane with a 150 μm central hole and a capillary of 200 μm inner diameter. The membrane was coated with collagen and either epinephrine or ADP as a platelet activator. The main difference to other devices for function testing is that adhesion and aggregation of platelets are tested under flowing high shear rate conditions [15]. Test results are closure times of the membrane hole at the end of a capillary tube. Serum concentrations of total protein and C-reactive protein (CRP) were determined by the standard biuret method on a Beckman Coulter LX20 clinical chemistry analyser (Krefeld, Germany) and by turbidimetry on a Dimension RxL analyser from Dade Behring (Liederbach, Germany), respectively.

Statistics

Continuous variables are expressed as mean and standard deviation. ANOVA was used to evaluate differences between multiple groups. Multiple regression analyses were performed to assess associations of haemostasis parameters and other blood parameters with the total number of RBCs, FFPs, and PCs that were needed. We used logistic regression analysis to develop a score estimating the need for each type of blood concentrate preoperatively. Based on the coefficients of the logistic regression analysis, score formulas were determined. All patients were scored using this formula. The area under the receiver operating characteristics (ROC) curve was used to assess how clearly the newly developed score could discriminate between two subgroups. A P value < 0.05 was considered statistically significant. We performed the statistical evaluations with SPSS, version 14 (Chicago, Illinois, USA).

Results

Of our study cohort, 1,234 patients (43.5%) needed no RBCs peri-operatively, whereas 41.8% needed up to 4 units and 14.7% more than 4 units, respectively. In Table 1, characteristics and laboratory parameters of these subgroups are presented. Patients who needed RBCs were older and had a lower body weight and height compared to patients who required no RBCs. Moreover, subgroups differed in almost all preoperatively assessed haematological and haemostasis data. As determined by multiple regression analysis, age, body weight, haemoglobin, haematocrit, leucocyte counts, platelet counts, PTT, throboplastin time, and CRP (dependent variables) were significantly associated with the number of RBCs (independent variable). The multiple R^2 was 0.178 ($P < 0.001$).

By the use of logistic regression analysis, fibrinogen was the only haemostasis parameter that was significantly associated with the use of RBCs (Table 2). Other parameters were age, body weight, blood leucocytes, haemoglobin, haematocrit, total protein, and CRP. The predictive value for some non-haemostasis parameters such as age, body weight, haemoglobin, and haemotocrit was much higher than for fibrinogen (Table 2).

In order to predict the need for RBCs, we used the data of the logistic regression analysis to calculate a risk score as follows: I (age >67 years) x 3.5 + I (body weight <76 kg) x 2.4 + I (leucocyte counts >6.500) x 1.3 + I (hemoglobin <14.2 g/dl) x 1.9 + I (hematocrit $<42.3\%$) x 2.7 + I (fibrinogen <336 mg/l) x 1.6 + I (total protein <6.9 g/dl) x 1.3 + I (CRP >0.5 mg/dl)

Table 1. Baseline characteristics of the study cohort according to red blood cell concentrate requirement.

Parameter	No concentrate N = 1234	2-4 concentrates N = 1182	> 4 concentrates N = 415	P-value
Age (years)	61.5 ± 10.7	68.6 ± 9.6	69.7 ± 11.3	0.001
Body weight (kg)	80.5 ± 11.8	73.6 ± 14.3	69.9 ± 13.7	0.001
Body height (cm)	173 ± 12	167 ± 17	167 ± 12	0.001
Haemoglobin (g/dl)	14.9 ± 1.1	13.7 ± 1.3	12.9 ± 1.8	0.001
Haematocrit (%)	44.3± 3.3	40.9 ± 3.7	39.6 ± 4.4	0.001
MCV (fl)	90.9 ± 3.8	90.3 ± 4.6	89.6 ± 5.5	0.001
White cell count (per µl)	6.73 ± 2.16	6.83 ± 2.23	7.24 ± 2.41	0.001
Platelet count (per µl)	229 ± 58	240 ± 67	237 ± 76	0.001
MPV (fl)	9.07 ± 2.70	19.16 ± 2.70	8.52 ± 3.53	0.001
PDW	16.6 ± 4.4	16.7 ± 4.3	15.5 ± 5.9	0.001
Prothrombin time (sec)	31.1 ± 12.6	32.5 ± 14.6	35.8 ± 18.8	0.001
Thromboplastin time (%)	91.9 ± 18.6	88.9 ± 23.3	80.8 ± 29.9	0.001
Fibrinogen (mg/dl)	322 ± 72	350 ± 74	371 ± 80	0.001
Antithrombin activity (%)	95.3 12.9	95.2 13.7	94.1 16.4	0.336
PFA time epinephrine (sec)	165 ± 71	186 ± 75	211 ± 73	0.001
PFA time ADP (sec)	155 ± 64	168 ± 63	179 ± 66	0.001
Total protein (g/dl)	6.86 ± 0.49	6.83 ± 0.54	6.79 ± 0.62	0.062
CRP (mg/dl)	0.53 ± 0.77	0.73 ± 1.29	1.35 ± 2.44	0.001

Table 2. Logistic regression analysis concerning predictors of the need of RBCs during and early after cardiac surgery.

Parameter	**Odds ratio**	**95% CI**	**P-value**
Age > 67 years (yes)	3.50	2.91-4.21	<0.0001
Body weight < 76 kg (yes)	2.36	1.97-2.84	<0.0001
Leucocyte counts > 6,500 per microlitre (Yes)	1.26	1.04-1.52	0.020
Haemoglobin < 14.2 g/dl (yes)	1.92	1.37-2.77	<0.001
Haematocrit < 42.3% (yes)	2.64	1.83-3.80	<0.001
Fibrinogen < 336 mg/dl (yes)	1.56	1.27-1.91	<0.001
Total protein < 6.9 g/dl (yes)	1.32	1.09-1.60	0.004
C-reactive protein > 0.5 mg/dl (yes)	1.30	1.03-1.64	0.027

x 1.3, whereas I (X) denotes the indicator function, being equal to 1 if X holds and 0 otherwise.

The probability to use RBCs during surgery was 88% in those patients who scored 10-12 points and 92% in those patients who scored more than 12 points. In patients with a score below 3 points, the probability for RBC use was 20% only. The area under the ROC curve was 0.81 (95%CI: 0.79-0.82). However, note that the contribution of plasma fibrinogen values to this score was modest (1.6 points if fibrinogen values were < 336mg/l). It was not possible to assess a formula that was able to separate those patients that needed more than four RBCs from those patients that needed four or less RBCs with sufficient accuracy (data not shown).

Approximately 15% of the patients needed FFPs (range: 1-128 units). As determined by multiple regression analysis, body weight, haemoglobin, haematocrit, TVB, PTT, fibrinogen, and CRP (dependent variables) were significantly associated with the use of FFPs (independent variable). The multiple R^2 was 0.177 ($P < 0.001$). By the use of logistic regression analysis, the haemostasis parameter antithrombin activity (values >95 %) and blood platelets counts <230,000 per microlitre predicted the need for FFP (Table 3). In addition, body weights <76 kg, total protein concentrations <6.9 g/dl, and CRP concentrations >0.5 mg/dl were associated with the need for FFPs (Table 3).

Again, we tried to use these data to calculate a score in order to predict the need for FFPs as follows: I(body weight <76 kg)x1.9 + I(thrombocyte counts >230,000 per microlitre)x1.6 +I(antithrombin >95 %)x1.4 + I(total protein <6.9 g/dl)x1.4 + I(CRP >0.5 mg/dl) x 1.7. However, the area under the ROC curve of 0.629 (95%CI: 0.60-0.66) was only modest. When a cut-off value of 3.5 points of the maximal possible 8 points of was used, sensitivity was only 61.6% and specificity was only 56.5%.

Table 3. Logistic regression analysis concerning predictors of the need of fresh frozen plasma during and early after cardiac surgery.

Parameter	Exp (B)	95% CI of Exp (B)	P-value
Body weight < 76 kg (yes)	1.83	1.44-2.36	<0.0001
Thrombocyte counts < 230,000 per microlitre (yes)	1.60	1.26-2.04	<0.001
Antithrombin activity > 95 % (yes)	1.38	1.10-1.75	0.007
Total protein < 6.9 g/dl (yes)	1.32	1.04-1.67	0.021
C-reactive protein > 0.5 mg/dl (yes)	1.65	1.28-2.12	<0.001

Table 4. Logistic regression analysis concerning predictors of the need of one or more platelet concentrates during cardiac surgery.

Parameter	Exp (B)	95% CI of Exp (B)	P-value
Body weight < 76 kg (yes)	2.25	1.46-3.47	<0.0001
Thrombocyte counts < 230,000 per microlitre (yes)	2.03	1.32-3.12	<0.0001
Prothrombibn time < 28%. (yes)	1.75	1.16-2.64	0.08
PFA time epinephrine > 230 sec. (yes)	2.30	1.48-3.56	<0.001
Antithrombin activity > 95% (yes)	1.71	1.12-2.62	0.014

Table 5. Blood product requirement per patient according to platelet function analysis.

PFA Closure times	N	Blood products required per patient					
		Red cell concentrates		Fresh frozen plasmas		Platelet concentrates	
		mean units ±s	max. units	mean units ±s	max. units	mean units ±s	max. units
Epinephrine <170 sec (normal value)	1475	2.26 ± 6.1	104	0.83 ± 4.1	58	0.10 ± 1.0	24
Epinephrine >170 sec and ADP < 110 sec (typical aspirin value)	271	2.7 ± 6.6	94	0.88 ± 3.1	28	0.15 ± 1.4	22
Epinephrine > 170 sec and ADP >110 sec (serious impairment)	1004	4.56 ±11.5*	176	2.3 ± 8.8*	128	0.32 ± 1.9*	37

Approximately 5% of the patients needed PCs (range 1-37 units). As determined by multiple regression analysis, body weight, haemoglobin, haematocrit, platelet counts, fibrinogen, and CRP (dependent variables) were significantly associated with the use of PCs (independent variable). The multiple R^2 was 0.096 ($P<0.001$). By use of logistic regression analysis, the 3 haemostasis parameters prothrombin time >28%, antithrombin activity >95 %, and blood platelet counts <230,000 per microlitre predicted the need for PCs (Table 4). In addition, body weights <76 kg, and PFA epinephrine times >230 sec, was significantly associated with the need for PCs (Table 4).

The calculated score to predict the need platelet concentrates is as follows: I (body weight in kg) x 2.25 + I (PFA epinephrine time >230 sec) x 2.3 + I (thrombocyte counts <per microlitre) x 2.0 + I (prothombin time < 28%) x 1.75 + I (antithrombin activity >95%) x 1.70. The area under the ROC curve of 0.73 (95% CI: 0.68-0.77) was moderate. When a cut-off value of 6 points of the 11 possible points was used, sensitivity was 67.6% and specificity was 64.9% only.

In Table 5, the amount of required blood products is given according to platelet function analysis with the epinephrine and ADP induced PFA closure time. Whereas a disturbed platelet function is associated with a higher requirement of blood products, it is also obvious that the differences are relatively small and the ranges in each subgroup are very wide.

Discussion

This large retrospective study demonstrates that preoperatively assessed haemostasis parameters cannot be used with satisfactory results to predict the need for RBCs during cardiac surgery. It was also not possible to estimate the need for FFPs and PCs using preoperative haemostasis testing.

Generally, cardiac surgery patients are an ideal study cohort in order to clarify the question whether or not

it is possible to use preoperative blood parameters for estimating the need for blood products. Because of very large wound surfaces, and challenges to the haemostasis system by hypothermia and extracorporeal circulation, a significant percentage of these patients need transfusion of blood products with highly variable amounts of transfused units. In our study group, RBCs were needed in almost every second cardiac surgery patient, whereas only a minority of patients needed FFPs and PCs, respectively. Thus, the preoperative assessment of the need for RBCs would be very valuable in these patients.

In our study, body weight and age were the strongest predictors of RBC demand (Table 2). This might be explained at least in part by the fact that body weight correlates directly with blood volume [20] and that advanced age may increase the risk of bleeding by reduced vessel integrity [16]. Haematocrit and haemoglobin concentrations also predicted the need for RBCs better than the haemostatic parameters. This is also not surprising since most haemostasis test results were normal or near normal, and one can expect that the need for a substitute product closely correlates with the products amount in the body of a human individual. Furthermore, low haematocrit means low blood viscosity which is also known to increase bleeding intensity. Haemostasis is vigorously influenced by several intra-operative factors such as extracorporeal circulation, oxygenation membranes, hypothermia, and anticoagulation [21, 22]. This may limit the usefulness of preoperative haemostasis testing for the calculation of peri-operative blood loss. In our patients, a fibrinogen concentration below 336 mg/l (median level of the study cohort) was the only haemostasis parameter associated with an elevated bleeding risk (56% higher risk than patients beyond this value). However, the risk is still relatively low compared with the higher bleeding risk of advanced age (+250%), low body weight (+136%), low haematocrit values (+164%), and low haemoglobin values (+94%). None of our patients had fibrinogen concentrations below 150 mg/l. Thus, the effect of fibrinogen deficiency, which would make intensive bleeding more likely, could not be investigated. Obviously, coagulation profile tests may only be useful to differentiate cardiac surgery patients with massive bleeding from those without massive bleeding, when they are performed intra-operatively [9, 17]. This assumption is in line with our findings and with the fact that other authors did not discover any significant interrelationship of preoperative coagulation test results with postoperative haemorrhage [9-12, 23]. Since the diagnostic efficacy of the plasma haemostasis screening tests to assess unknown congenital or acquired disturbances of plasma and/or platelet haemostasis is also often low [5, 6], routinely performed preoperative haemostasis testing in cardiac surgery is generally questionable.

Our study has the limitation that only few baseline characteristics of the study cohort were assessed. Others have included several additional preoperative factors of clinical relevance [24]. However, it was the aim of the present study to investigate whether haemostasis tests including routinely applicable platelet function tests can predict requirement of blood products and not to develop a score from extended patients' data with a high predictive value. It has recently been demonstrated that patients at low risk or high risk for massive blood transfusion can accurately identified by 12 variables including several preoperative clinical parameters [25].

Although body weight and some haemostasis parameters were also predictors of the need for FFPs and PCs, it was not possible to assess the need of these two blood products with the accuracy that is necessary to estimate their requirement preoperatively (Tables 3 and 4). There is some evidence that platelet function tests like PFA closure time and platelet activated clotting time correlate with patient's blood demand in certain situations [14, 17, 26]. However, our measurements of PFA closure time demonstrate that although the increase in PFA closure times is associated with the requirement of more blood products, the range of needed blood units is extremely wide. Consequently, results do not allow calculating the individual need for blood products from this preoperatively assessed parameter. Since we could not confirm the aforementioned earlier results [14, 17, 26], their clinical usefulness remains unclear. Our data support from a large, haemostatically challenged patient cohort supports earlier assumptions [27, 28] that conventional (plasma) haemostasis testing cannot accurately identify the need for FFPs and PCs, respectively.

The need for basic blood products usually depends on the intensity of blood loss during and after surgery. As we have shown, blood requirement cannot be predicted with sufficient accuracy by haemostasis testing. Such screening tests are questionable in cardiac surgery patients. The only rationale for these tests may be the detection of inborn or recently aquired severe haemostasis defects. These cases are, however, extremely rare in older cardiac surgery patients.

In conclusion, our results show that preoperatively performed haemostasis testing, including platelet function testing, cannot be used to predict the need for blood products during cardiac surgery.

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