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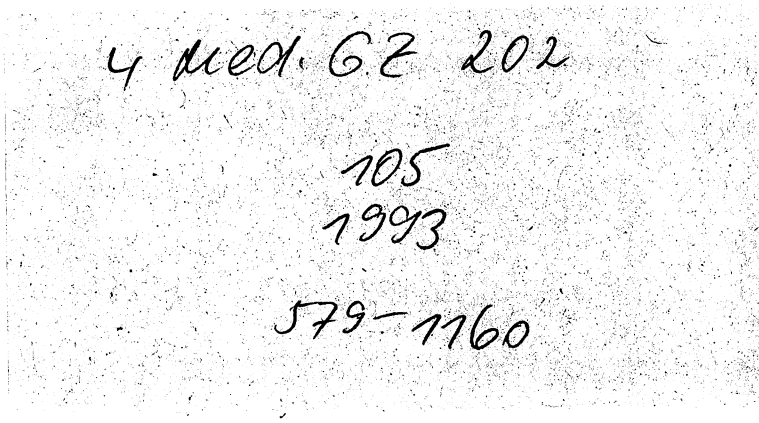

ı for reconstruction of a **580**

, MD, Peter E. Lange, MD, Alexander Bernhard, MD,

The functional behavior of monocuspid and bicuspid patches made from glutaraldehyde-treated porcine aortic roots for experimental repair of a surgically created hypoplastic pulmonary root was investigated. The function of the bicuspid design is superior to that of the monocuspid design and permits the construction of a competent and stenosis-free valve mechanism.

Intraventricular repair for Taussig-Bing anomaly **591**

Yasunaru Kawashima, MD, Hikaru Matsuda, MD (by invitation), Toshikatu Yagihara, MD (by invitation), Yasuhisa Shimazaki, MD (by invitation), Fumio Yamamoto, MD (by invitation), Kyoichi Nishigaki, MD (by invitation), Takuya Miura, MD (by invitation), and Hideki Uemura, MD (by invitation), Osaka, Japan

Ten patients with Taussig-Bing anomaly, mostly with a side-by-side relationship of the great arteries, underwent satisfactory intraventricular rerouting with no deaths and without late development of subaortic obstruction. This operation appears to be the method of choice for this subset of patients when care is paid to create an unobstructed left ventricular–aortic route during the operation.

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Computer simulation disclosed that the plasma leakage through the wall of an ePTFE vascular prosthesis depends on inner pressure, surface tension, and a mean distance between PTFE fibers in the direction of the circumferential axis of the vascular prosthesis.

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The right gastroepiploic artery graft: Clinical and angiographic midterm results in 200 patients **615**
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The GEA was used for CABG in 200 patients, with 6 early and 4 late deaths. Follow-up (6 to 70 months, mean 27 months) showed a GEA patency rate of 95% at both early (mean 2 months) and late (mean 2 years) angiography. Stress scintigraphy revealed satisfactory GEA function.

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IN MEMORIAM

Dr. E. Stanley Crawford died in Houston, Texas, on October 27, 1992. Dr. Charles Dubost, in attendance a few years ago at a surgical meeting in the United States, said that his real reason for coming to America was to pay his usual visit to "the greatest surgeon in your country." When pressed for his name, Dubost said, "Stanley Crawford."

Born in Evergreen, Alabama, on May 12, 1922, Stanley Crawford was a brilliant cardiovascular surgeon whose workload throughout his life was staggering, in spite of which his results were exemplary and set a standard for the rest of us to follow. While his early and richly rewarding writings stressed the drama of the domain in which he worked, in his later years his publications became precise and analytical. They too, in a different way, were richly rewarding to their readers. The perceptible transition was just one of the many remarkable and totally admirable characteristics of this lovable, gifted man. The readership of THE JOURNAL OF THORACIC AND CARDIOVASCULAR SURGERY surely joins the Editor in his loneliness for this productive, provocative, and genuinely unique and wonderful surgeon.

Hemostatic activation during cardiopulmonary bypass with different aprotinin dosages in pediatric patients having cardiac operations

The effect of high-dose aprotinin treatment on hemostatic activation during cardiopulmonary bypass in pediatric patients having cardiac operations was investigated. Sixty patients weighing less than 10 kg undergoing cardiac operations for different types of congenital heart diseases were studied: 20 patients were treated with aprotinin 2 × 15,000 KIU/kg, 20 patients with 2 × 30,000 KIU/kg, and 20 patients without aprotinin treatment served as the control group. Different split products of fibrinogen and/or fibrin and the fibrinolytic activity on fibrin plates were measured to assess fibrinolytic activation. F1/F2 prothrombin fragments, thrombin-antithrombin III–complex, and fibrin monomers were measured to estimate thrombin activation. There was a significant dose-dependent reduction in fibrin–fibrinogen split product formation during cardiopulmonary bypass: In the high-dose aprotinin group the concentration of the split products at the end of bypass was 1.5 ± 0.6 μg/ml, compared with 3.4 ± 3.0 μg/ml in the low-dose aprotinin group and 6.7 ± 3.5 μg/ml in the control group ($p < 00.5$). Fibrinolytic activation on fibrin plates was also significantly reduced by aprotinin. Fibrin monomer formation was significantly diminished at the end of cardiopulmonary bypass in the high-dose group: 9.2 ± 5.2 μg/ml compared with 21.6 ± 14 μg/ml in the control group ($p < 00.5$). Elastase in complex with α_1-protease inhibitor at the end of bypase was increased to the same amount in the three groups: 784 ± 278 ng/mL (control group), 693 ± 189 ng/ml (low-dose aprotinin), and 719 ± 270 ng/mL (high dose aprotinin) (no significant difference). Blood loss 6 hours postoperatively was significantly ($p < 00.5$) less in the high-dose group (99 ± 32 ml/m^2) than in the control group (164 ± 87 ml/m^2; low-dose group: 160 ± 106 ml/m^2). These observations suggest an attenuation of hemostatic activation during cardiopulmonary bypass with less plasmin formation and, because of inhibition of contact activation, less thrombin generation with aprotinin treatment. Thus the thrombotic-thrombolytic equilibrium is kept more balanced after cardiopulmonary bypass. High-dose aprotinin treatment is recommended for pediatric patients undergoing cardiac operations. (J THORAC CARDIOVASC SURG 1993;105:712-20)

W. Dietrich, MD,[a] H. Mössinger, MD,[a] M. Spannagl, MD,[b] M. Jochum, MD,[c] P. Wendt, MD,[d] A. Barankay, MD,[a] H. Meisner, MD,[e] and J. A. Richter, MD,[a] *Munich, Germany*

From the German Heart Center, Munich; the University Clinic, Munich; and the Technical University, Munich, Germany.

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Address for reprints: Wulf Dietrich, MD, German Heart Center Munich, Institute for Anesthesiology, Lothstrasse 11, D-8000 Munich 2, Germany.

[a]Institute for Anesthesiology, German Heart Center, Munich, Germany.

[b]Department of Hematology, University Clinic, Munich, Germany.

[c]Department of Surgery, Division of Clinical Chemistry, University Clinic, Munich, Germany.

Several recent studies[1-8] have demonstrated that the application of the protease inhibitor aprotinin during cardiac operations leads to a dramatic reduction of intraoperative and postoperative bleeding tendency. This reduc-

[d]Department of Experimental Surgery, Technical University, Munich, Germany.

[e]Department of Cardio-Thoracic Surgery, German Heart Center, Munich, Germany.

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tion is caused by an attenuation of the hemostatic activation during cardiopulmonary bypass (CPB). Although it is generally accepted that impaired platelet function is the most important factor of postoperative bleeding[9] and that platelet function is better preserved with aprotinin,[10-12] the precise mechanism underlying the action of aprotinin is still being discussed: A direct platelet protective effect,[12] inhibition of fibrinolysis,[2, 13] and inhibition of the contact phase of coagulation[4] are considered to be the main mechanisms of aprotinin action. However, there is strong evidence supporting the hypothesis that the inhibition of kallikrein and the resulting attenuation of contact phase activation is one important aspect of aprotinin action.

All these studies have been performed on adults having cardiac operations. With respect to coagulation, there are important differences between adults and infants or neonates: The vitamin K–dependent coagulation factors (II, VII, IX, and X) are lower in newborns and attain adult levels between 2 and 12 months of age.[14] The biologic activity of the contact factors (factor XI, factor XII, prekallikrein, high-molecular-weight kininogen) is depressed to variable degrees.[15] These differences are more pronounced in immature infants or infants with cyanotic heart disease than in adults. Data were published about the effect of a lower dosage of aprotinin on blood loss in repair of congenital heart defects.[16] However, no data are available in the literature so far concerning the impact of high-dose aprotinin on the coagulation system in infants and children.

The aim of the present study was to investigate the influence of different aprotinin dosages on the activation of hemostasis during CPB in pediatric patients having cardiac operations.

Methods

After institutional approval, 60 pediatric patients with a body weight less than 10 kg, undergoing cardiac operations for different congenital lesions, were enrolled in the protocol. Patients were excluded from the study if the expected duration of CPB exceeded 120 minutes. Patients were randomly assigned to one of three groups, each consisting of 20 patients. To twenty patients (group L, low-dose protocol) an aprotinin bolus of 15,000 kallikrein-inhibiting units per kilogram (KIU/kg) (Bayer AG, Leverkusen, Germany) was given after induction of anesthesia and an additional bolus of 15,000 KIU/kg was added to the pump prime of the heart-lung machine. In the high-dose aprotinin group (group H) 20 patients received an aprotinin bolus of 30,000 KIU/kg after induction of anesthesia and the same dose was given to the pump prime. The control group (group C) consisted of 20 patients without aprotinin treatment.

Anesthesia. Premedication consisted of morphine 0.2 mg/kg, flunitrazepam 0.04 mg/kg, and atropine 0.01 mg/kg given 1 hour before induction of anesthesia. For induction, halothane was applied via a face mask (0.5 to 1.0 vol %). Neuromuscular blockade was achieved and maintained with pancuronium (0.1 mg/kg). Fentanyl (10 to 20 μg/kg) and flunitrazepam (0.02 mg/kg) were given to deepen and maintain anesthesia. Patients' lungs were ventilated to mild hypocapnia with an air-oxygen mixture or 100% oxygen. After intubation an arterial catheter (radial artery) and a central venous line were inserted via the right internal jugular vein.

CPB. Mucosa heparin (375 U/kg, La Roche, Basle, Switzerland) was injected via the central venous catheter before aortic cannulation. The extracorporeal circuit consisted of a bubble oxygenator (High Flex D 700 S, Dideco, Mirandola, Italy), nonocclusive roller pumps, and polyvinyl tubing. Blood from the operating field was aspirated by the cardiotomy suction and reinfused to the oxygenator via a 40 μ filter (Dideco D 742). The oxygenator was primed in all patients with 500 ml homologous blood and 100 to 300 ml of crystalloid solution. Heparin 3000 U was added to this homologous blood unit. Two different techniques were applied: (1) Patients operated on with the aid of hypothermia were cooled during bypass to a rectal temperature of 26° C. The blood flow was kept to 2.4 L/min /m^2, being reduced under hypothermia to 1.2 L/min/m^2. (2) For deep hypothermic circulatory arrest (DHCA), patients were cooled until the rectal temperature was 20° C. Then perfusion was stopped and the venous cannula was removed from the right atrium. After the surgical procedure, the venous cannula was inserted again and the patients were rewarmed on CPB by means of the heat exchanger of the heart- lung machine and a warming blanket.

CPB was terminated in all patients when a rectal temperature of 32° C was attained. After completion of CPB, residual heparin was neutralized with protamine chloride in a ratio of 1.5 mg/125 U heparin (protamine; La Roche, Basle, Switzerland). One unit of fresh whole blood was available after CPB for all patients from which, depending on hemoglobin value and hemodynamics, different amounts were given. Mechanical ventilation was continued for at least 12 hours after the operation.

Blood samples. Blood samples were taken from the radial artery or, during CPB, from a port of the oxygenator at the following times: (1) after induction of anesthesia before aprotinin infusion, (2) 5 minutes after the onset of CPB, (3) 30 minutes after the onset of CPB or, in case of DHCA 15 minutes after the end of circulatory arrest, (4) at the end of CPB, and (5) at the end of the operation. After the first 5 ml of blood was discarded, blood was drawn into ethylenediaminetetraacetic acid tubes for assessment of hematocrit value, platelet count, and leukocyte count or into acid-citrate-dextrose (ACD) solution (4:1) for all other measurements. The ACD blood was centrifuged at 3000*g* for 10 minutes at room temperature and the plasma was separated from the cellular components. All plasma samples were frozen immediately at −40° C in aliquots and thawed only before testing.

Aprotinin plasma concentrations were quantified by means of a competitive enzyme-linked immunosorbent assay according to Müller-Esterl and associates.[17] The split products of the cross-linked fibrin were measured by two independent immunoassays, based on monoclonal antibodies to D-dimers (Boehringer, Mannheim, Germany) and to fibrin (Organon Teknika, Heidelberg, Germany). The degradation products of fibrinogen, the total degradation products (Organon Teknika, Heidelberg, Germany), the complex of thrombin with antithrombin III (Behringwerke, Marburg, Germany), F1/F2 prothrombin

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Table I. *Demographic data on patients*

Group	*Age (days)*	*Weight (gm)*	*Operation time (min)*	*CPB time (min)*	*CCHD (yes/no)*	*DHCA (yes/no)*
Control	211 ± 189	5477 ± 1838	168 ± 57	84 ± 31	10/10	14/6
Low dose	263 ± 189	6178 ± 1934	200 ± 47	100 ± 27	9/11	13/7
High dose	349 ± 305	6313 ± 2479	187 ± 47	98 ± 40	6/14	10/10

CPB, Cardiopulmonary bypass; *CCHD*, cyanotic congenital heart disease; *DHCA*, deep hypothermic circulatory arrest.

Table II. *Preoperative diagnoses*

	Control	*Low dose*	*High dose*	*Total*
VSD	6	1	8	15
TGA*	5	3	3	11
CAVSD	1	5	5	11
PA	3	1	2	6
TOF	1	2	1	4
SV	2	1	0	3
TAPVR	0	2	0	2
TA	0	2	0	2
TAC	1	1	0	2
other	1	2	1	4
Total:	20	20	20	60

VSD, Ventricular septal defect; *TGA*, transposition of the great arteries; *CAVSD*, complete artrioventricular septal defect; *PA*, pulmonary atresia; *TOF*, tetralogy of Fallot; *SV*, single ventricle; *TAPVR*, total anomalous pulmonary venous return; *TA*, tricuspid atresia; *TAC*, truncus arteriosus communis.

*Only atrial level repairs.

fragments (Behringwerke, Marburg, Germany), and elastase in complex with α_1-protease inhibitor (E. Merck, Darmstadt, Germany) were determined by sandwich enzyme-linked immunosorbent assays using polyclonal and monoclonal antibodies. The concentration of fibrin monomers was measured by an immunoassay using monoclonal antibodies directed against the N-terminal α-chain of human fibrin (Boehringer, Mannheim, Germany).

Spontaneous fibrinolytic activation in the native samples and in their euglobulin fraction was estimated by the use of plasminogen containing human fibrin plates.[18] Any development of a lysis area, regardless of its size, was considered to be an indication of extrinsic plasminogen activator(s) in the sample. The activated clotting time was determined according to the instructions of the manufacturer (Hemochron 400, International Technidyne Corp., Edison, N.J.). For global coagulation tests, routinely applied clotting methods were used. Blood loss through the chest tubes was measured in the intensive care unit 6, 12, and 24 hours after the operation. Because body weight varied substantially among patients, the blood loss was expressed as a function of the body surface area in milliliters per square meter.

Data analysis. Two-way analysis of variance was used to analyze normal distributed data. Whenever appropriate, significant differences among the three groups were explored with the Newman-Keuls test. Parametric data were given as mean ± standard deviation. If Shapiro's test of normality revealed that data did not conform to a normal distribution, comparison among the three groups was done with the Kruskal-Wallis test. The χ^2 test was used for categoric data. Stepwise multiple regression analysis was performed to assess the independent contributions of group allocation, cyanotic heart disease, or the application of DHCA to changes of hemostatic variables at the end of CPB. Linear regression analysis was applied to examine the relationship between the temperature 30 minutes after onset of CPB and the degree of fibrin formation and the concentration of the total degredation products. A p value less than 0.05 was considered statistically significant.

Results

All 60 patients admitted to the study were included to the subsequent analysis. Table I shows the demographic data for the three groups and Table II the preoperative diagnoses. No significant differences were found for any of the variables. The mean CPB times including circulatory arrest times were 84 ± 31 minutes (group C), 100 ± 27 minutes (group L), and 98 ± 40 minutes (group H), respectively. Fourteen (group C), 13 (group L), and 10 patients (group H) were operated on in DHCA. The circulatory arrest time was 34 ± 17 minutes in group C ($n = 14$) compared with 48 ± 17 minutes in group L ($n = 13$) and 55 ± 12 minutes in group H ($n = 10$) ($p < 0.05$, group C versus groups L and H). The mean CPB time, not including the arrest time for all infants with DHCA ($n = 37$), was 56 ± 25 minutes, whereas the CPB time was 81 ± 38 minutes in patients without DHCA ($n = 23$) ($p < 0.05$).

The highest aprotinin plasma concentrations were measured 30 minutes after the onset of CPB: 73 ± 30 KIU/ml in group L and 99 ± 25 KIU/ml in group H. At the end of CPB the concentrations were 63 ± 72 KIU/ml (group L) and 92 ± 20 KIU/ml (group H), respectively. Patients of group L received a total amount of 98,000 ± 42,000 KIU aprotinin, as compared with 180,000 ± 81,000 KIU in group H ($p < 0.05$).

The concentration of the F1/F2 prothrombin fragments and the thrombin–antithrombin III complex increased steadily during CPB. At the end of the operation the F1/F2 concentrations were 9.9 ± 4.9 ng/ml (group C), 11.2 ± 4.8 ng/ml (group L), and 6.3 ± 6.0 ng/ml (group H) ($p < 0.05$ versus groups C and L). In contrast, the thrombin–antithrombin III complex did not show significant differences. The course of the concentra-

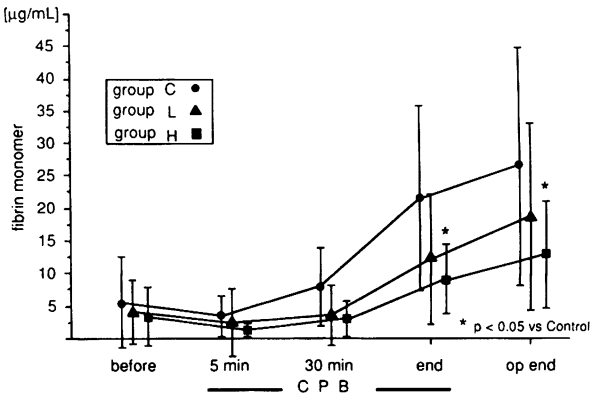

Fig. 1. Fibrin monomer concentration increased during CPB in all three groups. However, the increase in the high-dose aprotinin group (group H) was significantly attenuated by aprotinin. This indicates reduced clotting activation with aprotinin treatment.

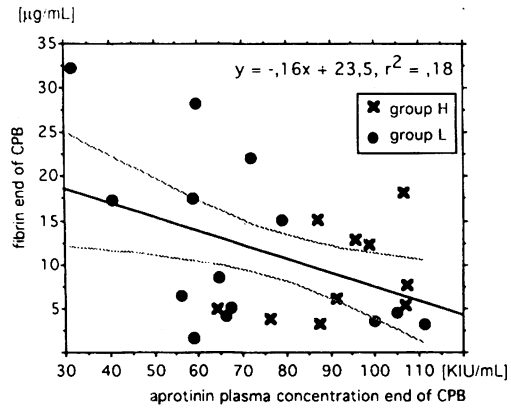

Fig. 2. Correlation of aprotinin plasma concentration at the end of CPB and fibrin monomer concentration. The higher the aprotinin plasma concentration the lower the fibrin generation.

tion of fibrin monomers is given in Fig. 1. The level was significantly higher in the control group (21.6 ± 14 µg/ml) than in groups L and H (12.2 ± 10 and 9.2 ± 5.2 µg/ml, respectively) ($p < 0.05$ versus group C). There was a significant correlation between the formation of fibrin monomers and the concentration of aprotinin in the plasma at the end of CPB (Fig. 2).

The course of the concentration of fibrin-fibrinogen split products is given in Fig. 3. Aprotinin showed a dose-dependent effect on the development of split products. At the end of CPB the concentrations of fibrin-fibrinogen split products were 6.7 ± 3.5 µg/ml in group C, 3.4 ± 3.0 µg/ml in group L, and 1.5 ± 0.6 µg/ml in group H ($p < 0.05$). The course of the concentration of D-dimers was nearly identical (D-dimer concentrations at the end of the operation: 1.2 ± 0.8 µg/ml, group C; 0.9 ± 0.9 µg/ml, group L; and 0.5 ± 0.4 µg/ml, group H) ($p < 0.05$ versus group C). The fibrin split products paralleled the course of the D-dimers (Fig. 4). Thirty minutes after the onset of CPB, the fibrin plates showed positive results in 75% of patients in group C, in 65% in group L, and in 35% in group H (the lysis areas were 15.8 ± 20.1 mm^2, 8.7 ± 8.5 mm^2, and 1.7 ± 3.8 mm^2 in groups C, L, and H, respectively; $p < 0.05$). There were no differences in the results on the fibrin plates at the end of CPB or the end of the operation.

No significant correlation could be found between rectal temperatures measured 30 minutes after onset of CPB and the formation of fibrin or fibrin degradation products. However, there was a tendency in all three groups toward a higher degree of activation of coagulation and fibrinolysis with lower body temperatures. Multivariate analysis

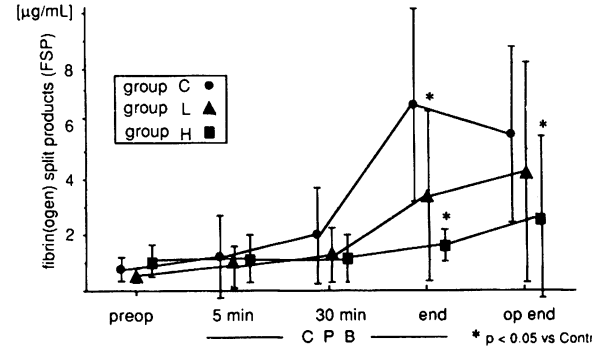

Fig. 3. The total split products of fibrinogen and fibrin *(FSP)* demonstrated a dose-dependent reduction during CPB with aprotinin treatment. This indicates less fibrinolytic activity with aprotinin treatment.

identified only the group allocation as being independently associated with a decreased clotting activation at the end of extracorporeal circulation. However, regardless of group allocation, all patients operated on in DHCA showed at the end of CPB increased concentrations of fibrin-fibrinogen split products (with DHCA, 4.6 ± 3.8 µg/ml; without, 2.7 ± 2.2 µg/ml; $p = 0.05$) and fibrin split products (with DHCA, 2.7 ± 2.9 µg/ml; without, 1.2 ± 1.4 µg/ml; $p < 0.05$) compared with patients without DHCA. On the other hand, there were no differences in regard to hemostatic activation between cyanotic and acyanotic patients.

A continuous increase of the concentration of the complex bound elastase over CPB time was noted. At the end of CPB these concentrations were 784 ± 278 ng/ml (group C), 693 ± 189 ng/ml (group L), and 719 ± 270

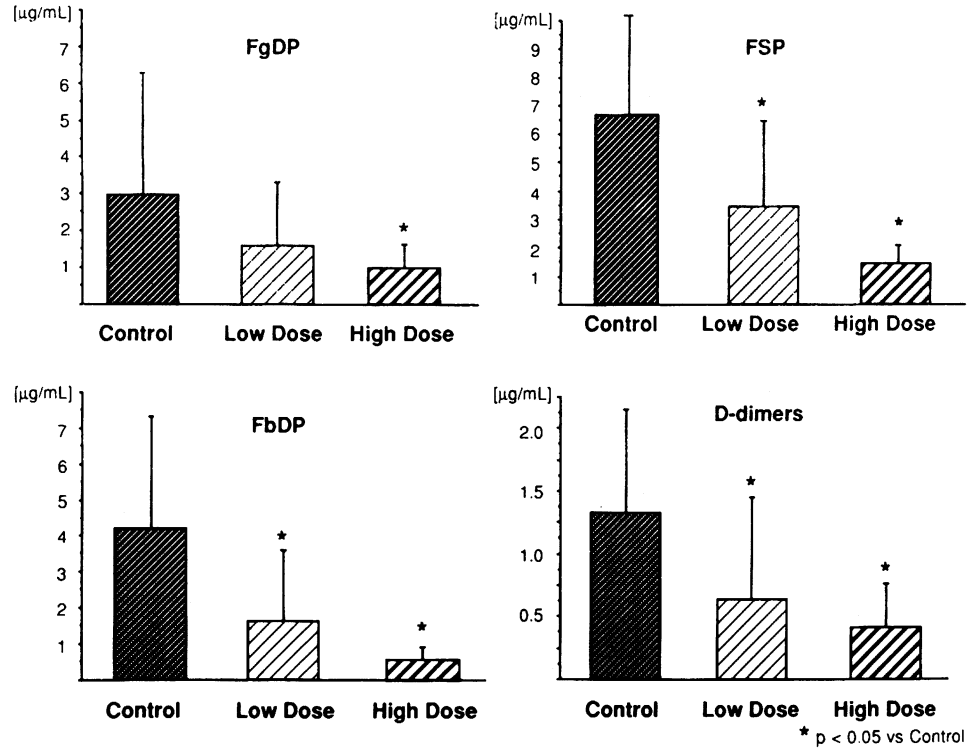

Fig. 4. Concentrations of different split products of fibrinogen or fibrin at the end of CPB. D-dimers and split products of fibrin *(FbDP)* were measured by different immunoassays. Total degradation products *(FSP)* are the split products of fibrin and fibrinogen, whereas fibrinogen degradation products *(FgDP)* were determined by monoclonal antibodies against fibrinogen split products. There was a dose-dependent reduction of all split products at the end of CPB, indicating reduced fibrinolytic activity with aprotinin treatment.

ng/ml (group H) (p = NS*). The platelet count did not reveal significant differences among the three groups. From normal preoperative values the counts dropped to 121 ± 36 × 10^9/L (group C), 93 ± 37 × 10^9/L (group L), and 102 ± 44 × 10^9/L (group H) at the end of the operation (p = NS). The preoperative hemoglobin concentration varied from 13.0 ± 2.3 gm/dl (group C) to 14.1 ± 3.4 gm/dl (group L) and 12.8 ± 2.1 gm/dl (group L) (p = NS). At the end of CPB hemoglobin values were 10.6 ± 1.4 gm/dl (group C), 10.9 ± 2.0 gm/dl (group L), and 10.9 ± 1.3 gm/dl (group H), respectively.

Blood losses 6 hours postoperatively were 164 ± 87 ml/m^2 (group C), 160 ± 106 ml/m^2 (group L), and 99 ± 32 ml/m^2 (group H) ($p < 0.05$, group H versus group C or L). However, there were no significant differences in 24-hour blood losses: 294 ± 148 ml/m^2 (group C), 278 ± 162 ml/m^2 (group L), and 199 ± 67 ml/m^2 (group H) (range, 78 to 603 ml/m^2, group C; 79 to 761 ml/m^2, group L; and 103 to 370 ml/m^2, group H). There were no differences in the required units of homologous blood among the groups. Two units of fresh whole blood were available for all patients. The oxygenator of the heart-lung machine was primed with the first unit, and different amounts from the second unit were given during and after the operation. In none of the patients was a third unit of bank blood necessary.

The activated clotting time was greater than 1000 seconds in all groups during CPB. None of the patients needed additional heparin to keep the activated clotting time above 400 seconds. After heparin reversal by protamine chloride, the activated clotting times were 139 ± 19 seconds (group C), 135 ± 23 seconds (group L), and 136 ± 23 seconds (group H) (p = NS). The times to control bleeding, that is, the intervals between end of CPB and thoracic closure, were between 60 ± 17 minutes (group H) and 63 ± 14 minutes (group C) (p = NS). No side effects attributable to aprotinin were observed. All patients survived the early postoperative period.

*NS = Not significant.

Discussion

This investigation corroborates the results of recent studies[2, 6, 19, 20] on the use of high-dose aprotinin in adults having cardiac operations. In the present study we found a dose-dependent attenuation of the deleterious effect of CPB on hemostatic activation, as well as a reduction of bleeding tendency, in our group of children undergoing cardiac operations with aprotinin compared with the control group without aprotinin treatment. Duration of operation and CPB, as well as preoperative hemoglobin concentration, were comparable among the groups, thus rendering negligible the influence of different surgical procedures on hemostatic alterations.

Several studies have shown that clotting activation and fibrinolysis takes place during CPB.[21, 22] This process starts with the activation of factor XII (Hageman factor) by the initial blood contact with the unphysiologic, nonendothelial surfaces of the circuit of the heart-lung machine. The contact activation with the conversion of prekallikrein to kallikrein launches the activation of the cascades systems of the body, including the intrinsic coagulation pathway, fibrinolysis, the classic complement pathway, and the kinin-kininogen system. Contact activation does not play a role in physiologic coagulation. The extracorporeal circuit, however, with its artificial surfaces, is a highly unphysiologic system. Therefore, under the condition of CPB contact activation contributes to the activation of hemostasis. Neutrophil activation takes place at the same time. Heparin treatment is supposed to inhibit only one component of this contact activation system, the formation of fibrin. Because thrombin already bound to fibrin is less inhibitable by heparin,[23] fibrin formation and polymerization take place despite heparin treatment during CPB.[24]

Platelets are activated either by contact with unphysiologic surfaces[25] by generated thrombin[26, 27] or plasmin,[28] which are both powerful platelet stimulators.[29] It is known that impaired platelet function is the main cause of bleeding after cardiac operations.[30] Thus the link between hemostatic and platelet activation is as follows: Less plasmin and thrombin formation causes less platelet activation. This assumption is corroborated by the results of several studies demonstrating better preservation of platelet function in patients with high-dose aprotinin treatment.[10-12]

Our study clearly proved a dose-dependent reduction in fibrinolytic activity with aprotinin: Patients in the high-dose group had the lowest concentrations of fibrin-fibrinogen split products, control patients the highest, and patients in the low-dose group had intermediate concentrations. The results of the fibrin plates also demonstrated less fibrinolytic activity. However, the given dosages of aprotinin were not able to suppress fibrinolytic activity on fibrin plates completely. Besides this antifibrinolytic effect, a less pronounced antithrombin effect was also evident: We found significantly less fibrin formation in the patient group with the highest aprotinin dosage, and the concentrations of the F1/F2 fragments were significantly reduced at the end of the operation. However, the thrombin-antithrombin III–complex concentrations were not different among the three groups. With respect to plasma levels of complexed elastase, we did not see any differences in neutrophil activation, which indicates that clotting and fibrinolysis products play a minor role in neutrophil stimulation.

Several studies have shown the antifibrinolytic effect of aprotinin treatment during CPB.[2, 13] Aprotinin is supposed to manifest its antifibrinolytic properties in plasma concentrations of about 50 KIU/ml,[31, 32] whereas kallikrein inhibition is achieved only with higher concentrations.[33] It seems to be of paramount importance that aprotinin not only acts as an antifibrinolytic agent but also inhibits thrombin generation,[4, 11] thus enhancing the anticoagulatory effect of heparin during CPB.[34] This is the pivotal difference to therapy with solely antifibrinolytic agents.[35]

The present data show some differences compared with results from adult patients treated with aprotinin. Recently, a reduction of the thrombin-antithrombin III–complex[4, 11] and fibrin formation[36] in adult patients undergoing myocardial revascularization could be demonstrated. The difference in these findings may be based on the different aprotinin plasma concentrations: The peak concentration found in adult patients was around 300 KIU/ml,[4] whereas in our study the peak aprotinin plasma concentration in the high-dose group was 99 ± 25 KIU/ml 30 minutes after the onset of CPB. According to the dosage introduced by Royston,[7] Bidstrup,[37] and their associates, adult patients received 5 to 6×10^6 KIU aprotinin during a cardiac operation. This represents approximately 60,000 KIU/kg body weight. Thus we calculated the dosage in the high-dose group according to this regimen with $2 \times 30{,}000$ KIU/kg. However, the relation between circulating blood volume and the pump prime differs when these small patients are compared with adults. Therefore the diluting effect of the pump prime is more pronounced, resulting in lower plasma concentrations of aprotinin during CPB. Consequently, the priming volume of the heart-lung machine should be included in the calculation of the aprotinin dosage. One might anticipate even more pronounced effects on hemostasis at aprotinin doses closer to those achieved in adults.

Another difference between infants and adults was the prolonged activated clotting time in our pediatric patients. Because of the immature hemostatic system, the prothrombin time and the partial thromboplastin time[14, 15, 38] in neonates and infants are prolonged. Furthermore, hepatic congestion with an impaired development of clotting factors and polycythemia with imbalance of cellular and plasmatic hemostatic components is common in congenital heart disease.[39] However, a more simple explanation for this difference may be based on the fact that our patients received 3000 U of additional heparin per unit of homologous blood during CPB. Therefore these patients were heparinized more effectively, because the total dosage of heparin per kilogram was higher than in adult patients.

A secondary result of this study was that the temperature reduction did not result in reduced hemostatic activation. In contrast, patients operated on under DHCA showed a tendency toward higher activation of the hemostatic system. Thus hypothermia does not seem to protect from activation of the hemostatic system.

The 6-hour postoperative blood loss was significantly lower in the high-dose aprotinin group than in the control group. Because postoperative blood loss is not the main predictor of transfusion requirement in patients with congenital heart disease, the homologous blood requirement was not significantly different among the groups. Moreover, in our institution homologous blood is available only in units containing 450 to 500 ml blood. Regardless of their group allocation, all patients received different amounts from 2 units of homologous blood during the operation and in the early postoperative period and therefore came into contact with the blood of two blood donors. However, because patients with an expected bypass time longer than 2 hours were excluded from the study (e.g., anatomic repair of transposition of the great arteries), we presumably deal with a bias toward lower intraoperative and postoperative blood loss. This exclusion was done for ethical reasons, because we did not want to withhold aprotinin in these longer operations in which the blood-saving effect of this drug was clinically obvious before this study. In our experience, after introduction of routine aprotinin treatment, a dry operative field is the rule, whereas during the time without aprotinin, surgical hemostasis was often a long-lasting endeavor.

What are the true merits of aprotinin treatment? Clearly, for adult patients with cardiac disease to date, aprotinin reduces bleeding tendency caused by CPB[40, 41] and thereby reduces homologous blood requirement. This reduction in bleeding is the consequence of better preservation of the hemostatic system. The present study demonstrated a statistically significant reduction of bleeding tendency also for pediatric patients. However, in terms of transfusion requirements it was clinically insignificant. This might be due to patient selection (patients with expected long bypass times were excluded) or to the setup of the heart-lung machine used in our institution (routine administration of 1 unit of blood to the pump prime. On the other hand, this study showed a significant reduction of clotting and fibrinolytic activation. Because contact activation during CPB leads to stimulation of other cascade systems,[42, 43] the attenuation of hemostasis found in this study is a favorable effect of aprotinin treatment.

The positive effect of aprotinin could be superseded by possible side effects. As a foreign protein, aprotinin has antigenic properties resulting in antibody formation. Whether this formation might cause severe sequelae during reexposure to aprotinin, which has to be anticipated in operations for congenital heart disease, has not yet been settled. Further studies will be necessary to clarify this issue.

In summary, the present data suggest that high-dose aprotinin treatment attenuates hemostatic activation during CPB in pediatric patients. The maintenance of a hemostatic equilibrium postoperatively caused by diminished clotting and fibrinolytic activity is the main effect of aprotinin treatment. The higher dosage of $2 \times 30{,}000$ KIU/kg was more effective than the dosage of $2 \times 15{,}000$ KIU/kg. Comparing these results with data gained in adults, one might postulate that an even higher aprotinin dosage would be desirable. Although it was not possible to demonstrate an overall saving of homologous blood in these small patients, the reduction of hemostatic activation and bleeding tendency is valuable. Therefore we recommend the routine use of aprotinin in pediatric patients having cardiac operations.

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