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Can albumin as priming solution improve post cardiopulmonary bypass platelet quantity? A prospective randomized comparison between albumin and polygeline in patients having elective coronary artery bypass grafting surgery.

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Background : *Cardiopulmonary bypass has several adverse effects in many physiologic functions. One of the physiologic disturbances is platelet quantity. Decreasing in platelet quantity after CPB is one of major causes of post operative bleeding. Thrombocytopenia is partly caused by platelet absorbed to circuit surface. By theory, albumin coated surface may prevent platelet adsorbed on biomaterial.*

Objective : *To investigate the influence of albumin in priming solution with standard polygenline on the post cardiopulmonary bypass platelet quantity and post operative bleeding.*

Setting : *Division of Cardiovascularthoracic Surgery, Department of Surgery, Faculty of Medicine, Chulalongkorn University and Hospital Bangkok 10330, Thailand.*

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Research design : *A prospective randomized controlled clinical trial.*

Patients and Methods : *Forty two patients presenting for the first time coronary artery bypass grafting surgery were prospectively randomized into two groups, A and B. Twenty one patients in group A were designed to use normal serum human albumin as priming solution. The other twenty one patient B were designed to use polygeline (Haemaccel®) as priming solution. All patients, anesthetists, surgeons and intensive care unit personnel were blinded as to the solution type.*

Result : *Both groups were demographically and hemodynamically similarly. There were no difference in blood chemistry and operative technique among both groups. After cardiopulmonary bypass had finished, there were no difference in platelet quantity, hemoglobin level and white blood cell count. There were no differences in number and percent of platelet lost among both groups. One patient in polygeline group had reoperated because of massive bleeding. This bleeding episode did not relate to thrombocytopenia. There was no differences in reoperation rate among both groups. Excluding this bleeding case, there were no differences in platelet quantity, hemoglobin level and white blood cell count in the first 24 hours after arrival ICU. Excluding the bleeding case, there were no difference in postoperative bleeding and platelet transfusion among both groups.*

Conclusion : *There is no advantage in using albumin over polygeline for priming solution in hematologic point of view for the first 24 hours after operation. Because albumin is more expensive, polygeline priming solution is preferable to albumin priming solution.*

Key words : *Cardiopulmonary bypass, Priming solution, Albumin, Polygeline, Platelet.*

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สนธกิติ์ ลีลหานนท์, กิตติชัย เหลืองทวีบุญ, Jeffery Graeme Bennett, เสรี สิงหฉนัดกิจ, จุล นำชัยศิริ, บังอร เนียมอินทร์, สมพงษ์ ตั้งสุภาชัย, สกลสุภา เวชวิฐาน, อำพล คำยอด. การใช้อัลบูมินเป็น priming solution สามารถช่วยเพิ่มจำนวนเกร็ดเลือดหลัง cardiopulmonary bypass ได้หรือไม่? การศึกษาแบบสุ่มตัวอย่างไปข้างหน้าระหว่างอัลบูมินและโพลีจีลีนในผู้ป่วยที่ได้รับการผ่าตัดบายพาสเส้นเลือดโคโลนารี. จุฬาลงกรณ์เวชสาร 2541 พ.ย;42(11): 1013-25

ปัญหา : *Cardiopulmonary bypass มีผลข้างเคียงมากมายในทางสรีระวิทยา หนึ่งในนั้นคือการลดลงของจำนวนเกร็ดเลือดซึ่งเป็นสาเหตุหนึ่งของการเสียเลือดจำนวนมากหลังการผ่าตัด จำนวนเกร็ดเลือดที่ต่ำลงสาเหตุหนึ่งเกิดจากเกร็ดเลือดเกาะตัวกับผิวของอุปกรณ์การทำ cardiopulmonary bypass โดยทฤษฎีแล้ว อัลบูมินสามารถเคลือบพื้นผิวของอุปกรณ์และสามารถ ป้องกันเกร็ดเลือดไม่ให้มาเกาะพื้นผิวได้*

วัตถุประสงค์ : *เพื่อศึกษาถึงผลของการใช้อัลบูมินเป็น priming solution เทียบกับโพลีจีลีน ซึ่งเป็นสารที่ใช้เป็น priming solution อยู่ในปัจจุบันในแง่ของจำนวนเกร็ดเลือดและการเสียเลือดหลังผ่าตัด*

สถานที่ที่ทำการศึกษา : *หน่วยศัลยศาสตร์ทรวงอก ภาควิชาศัลยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย*

รูปแบบการวิจัย : *การศึกษาแบบไปข้างหน้า แบบสุ่มตัวอย่าง*

ผู้ป่วยที่ได้รับการศึกษา : *ผู้ป่วยจำนวน 42 คนที่ได้รับการผ่าตัดบายพาสเส้นเลือดโคโลนารี เป็นครั้งแรกแบบไม่ฉุกเฉิน จะถูกแบ่งออกเป็น 2 กลุ่มแบบสุ่ม คือกลุ่มเอและบี ผู้ป่วย 21 คนในกลุ่มเอจะใช้อัลบูมินเป็น priming solution ขณะที่ผู้ป่วยอีก 21คนในกลุ่มบีจะใช้โพลีจีลีน (ฮีแมกเซล®) เป็น priming solution ผู้ป่วยทุกคน, ศัลยแพทย์ และเจ้าหน้าที่ในหอผู้ป่วยหนักจะไม่ทราบว่า ผู้ป่วยใดได้รับสารใดเป็น priming solution*

ผลการศึกษา : *ผู้ป่วยทั้งสองกลุ่มมีข้อมูลพื้นฐานและข้อมูลทางด้านการสรีระวิทยาไม่แตกต่างกัน ไม่พบว่ามีความแตกต่างกันในด้านเคมีในเลือดและวิธีการผ่าตัด หลังจากที่กระบวนการ cardiopulmonary bypass เสร็จสิ้นแล้ว ไม่พบว่ามีความแตกต่างกันในจำนวนของเกร็ดเลือด ระดับฮีโมโกลบิน และจำนวนเม็ดเลือดขาว ไม่พบว่ามีความแตกต่างกันในจำนวนและร้อยละของเกร็ดเลือด ที่สูญเสียระหว่างผู้ป่วยทั้งสองกลุ่ม ผู้ป่วยคนหนึ่งในกลุ่มที่ใช้โพลีจีลีน มีการเสียเลือดหลังผ่าตัดมากจนต้องได้รับการผ่าตัดใหม่ แต่สาเหตุของการเสียเลือดนี้ไม่ได้เกิดจากจำนวนเกร็ดเลือดต่ำ ไม่มีความแตกต่างกันในจำนวนผู้ป่วยที่ได้รับการ*

ผ่าตัดใหม่เนื่องจากการเสียเลือด โดยไม่พิจารณาผู้ป่วย 1 รายที่ได้รับการผ่าตัดใหม่ พบว่าไม่มีความแตกต่างกันในจำนวนเกร็ดเลือด ระดับฮีโมโกลบิน และจำนวนเม็ดเลือดขาวใน 24 ชั่วโมงแรก และไม่พบว่ามีความแตกต่างกันในจำนวนเลือดที่สูญเสีย หรือจำนวนของการใช้เกร็ดเลือดระหว่างผู้ป่วยทั้งสองกลุ่ม

วิจารณ์และสรุป : ไม่พบว่ามีข้อได้เปรียบในการใช้อัลบูมินเป็น *priming solution* เมื่อเทียบกับการใช้โพลีจีลีน ในแง่ของโลหิตวิทยาใน 24 ชั่วโมงแรกหลังผ่าตัด เนื่องจากอัลบูมินมีราคาแพงกว่าโพลีจีลีนมาก ดังนั้นโพลีจีลีนน่าจะเหมาะสมกว่าในการใช้เป็น *priming solution*

Cardiopulmonary bypass (CPB) is a method that temporarily substitutes for pumping and ventilatory functions of the heart and the lung. However, CPB also has several adverse effects in physiologic functions. One of the physiologic disturbances is platelet quantity and this effect has been well documented. Decreasing in platelet quantity after CPB is one of major causes of postoperative bleeding. [1, 2] Thrombocytopenia is partly caused by platelet adsorption to circuit surface. Also, albumin and other plasma proteins are adsorbed on the surface of circuit. By theory, albumin coated surface may prevent platelet adsorption on biomaterial. [3] At Chulalongkorn hospital, using of polygeline as colloid priming solution is widely accepted. This study is designed to investigate the influence of albumin as priming solution compared with polygeline on the post cardiopulmonary bypass platelet quantity and postoperative bleeding.

Patients and Methods

Forty-two adult patients who had coronary artery disease were selected in this study. They were undergoing to be operated their first-time elective coronary artery bypass grafting surgery (CABG) at Chulalongkorn hospital between 1st November 1997 and 28th February 1998. Exclusion criteria were as followed: (1) patients who had hematologic disease that disturbed coagulation and bleeding tendency, (2) patients who stopped heparin or glyceryl trinitrate infusion less than one day before operation, (3) patients who had renal failure which interfered platelet function (serum creatinine level more than 6.7 mg/dl [4]), (4) patients who had previous history of cardiac or pulmonary surgery, (5) patients who had unstable hemodynamic condition, (6) patients who stopped taking aspirin less than 3 days before operation, (7) patients who had ejection fraction less than 20%, (8) patients who used aprotinin and (9) patients who had history of allergy to human albumin, polygeline, mannitol and ampicillin. Preoperative basic data included sex, age, weight, height, associated disease, New York Heart Association (NYHA) functional class, ejection fraction. Preopera- tive blood chemistry included hemoglobin level, white blood cell (WBC) count with differential (polymorphonuclear cell: PMN, lymphocyte: LYM), platelet quantity, fasting blood sugar (FBS), blood urea nitrogen (BUN), creatinine, electrolyte (sodium, potassium, chloride, bicarbonate), total bilirubin, direct bilirubin, SGOT, SGPT, alkaline phosphatase (ALP), albumin, globulin, cholesterol, triglyceride, high density lipoprotein (HDL), prothrombin time (PT) and partial thromboplastin time (PTT).

Cardiopulmonary bypass machines and equipments were selected by perfusionist before randomization. There were two cardiopulmonary bypass machines used in this study. Both were roller pump machines. These included (1) Polystan® Ballerup Denmark Type modular No 1128 and (2) Stockert® S3 roller pump. CPB tubes were Chulalongkorn adult pack model made of polyvinylchloride (PVC) from Biosensors international®, size 1/4 x 1/16 inch, 3/8 x 3/32 inch and 1/2 x 3/32 inch. Cardiotomy reservoirs (Braile biomedica® company) made of rigid biocompatible plastic were used in this study. They also composed with 120 μm filter and defoaming polyurethane cellular filter 150 μm of porosity. Three type of oxygenators were used in this study. All of which were membrane oxygenators include (1) Oxymaster® from braile biomedica, (2) Bard® William Harvey® HF-5701 membrane oxygenator and (3) Capiox® SX 18 from Terumo® corporation. Bubble

trappers were Capiox® bubble trap from Terumo® corporation.

Patients were prospectively randomized into two groups, A and B. Group A were designed to use priming solution with 20% Normal Human Serum Albumin (Thai Red Cross) 100 ml. + 7.5% Sodium bicarbonate 100 ml. + 15% Potassium chloride 10 ml. + 20% Mannitol 100 ml. + Ampicillin 2 gm diluted in sterile water 20 ml. and lactated Ringer's solution until total volume reached 1530 ml. Group B was designed to use priming solution with 3.5% polygeline (Haemaccel®) (Behring, Heochst Thailand) 500 ml. + 7.5% Sodium bicarbonate 100 ml. + 15% Potassium chloride 10 ml. + 20% Mannitol 100 ml. + Ampicillin 2 gm diluted in sterile water 20 ml. and lactated Ringer's solution until total volume reached 1530 ml. All patients, anesthetists, surgeons and intensive care unit personnel were blinded as to the solution type. Only the perfusionists who primed the pump knew to what group each patient belong. During operation, two blood samples were collected (first just before heparinization with 3 mg / kg of heparin before CPB, and second was collected after CPB had been stopped and the patient was reversed with protamine sulfate). These blood samples were analyzed for hemoglobin level, white blood cell count and platelet quantity by the same laboratory. During CPB, no platelets were transfused to any patients. Intraoperative parameters included CPB time, aortic cross clamping time, number of coronary bypass grafts and type of coronary bypass grafts.

After the operation, all patients were admitted to the cardiovascularthoracic surgical ICU. Postoperative parameters included platelet quantity, hemoglobin level and white blood cell count upon ICU arrival, 12 hours and 24 hours after ICU admission. Amount of platelet transfusion, amount of bleeding from chest tube drainage in the first 24 hours and bleeding episode that required second operation were observed.

Statistic

Data were shown as mean ± standard deviation. Testing statistical comparison, X^2 analysis was applied for discrete variables and Student's unpaired t-test was applied for continuous variables. SPSS program for Windows version 7.5.1 (standard version) from SPSS Inc. was used to calculate the significant difference in data.

Result

Forty two patients were randomized into group A (albumin, 21 patients) and group B (polygeline, 21 patients). Basic preoperative data were shown in Table 1. There were no differences in age, sex, weight, height, associated disease, New York Heart Association (NYHA) functional class and ejection fraction between both groups. Preoperative blood chemistries were shown in Table 2. Also, there were no significant differences in hematologic parameters, renal function, liver function, blood sugar, electrolyte and lipid metabolism. There were no significant differences in platelet quantity, prothrombin time and partial thromboplastin time. Intraoperative basic data were shown in Table 3. No significant differences between two groups were detected in number of bypass grafts, bypass time, cross clamp time and amount of cardioplegia.

Before CPB started, complete blood count was checked. No significant differences between two groups were detected in hemoglobin level, white blood cell count, differential polymorphonuclear cell, differential lymphocyte and platelet quantity. (Table 3).

Table 1. Basic preoperative data.

	Albumin (n=2)	Polygeline (n=21)	p Value
Male : Female	13:8	14:7	NS
Age (Year)	62.43 ± 9.40	62.86 ± 7.62	NS
Weight (Kg)	63.45 ± 8.42	63.80 ± 6.52	NS
Height (cm)	160.69 ± 7.90	159.81 ± 7.91	NS
Associated disease			
Diabetes mellitus	7	6	NS
Hypertension	9	9	NS
Functional class			NS
FC 1	5	4	
FC 2	12	12	
FC 3	4	5	
Ejection fraction	0.53 ± 0.19	0.51 ± 0.14	NS

Table 2. Preoperative blood chemistry.

	Albumin (n=21)	Polygeline (n=21)	p Value
Complete blood count			
Hemoglobin (g/dl)	12.56 ± 1.97	13.18 ± 1.95	NS
WBC (cell / mm^3)	7643 ± 2773	8812 ± 3449	NS
PMN (%)	51.20 ± 14.02	55.85 ± 11.78	NS
LYM (%)	30.26 ± 12.45	29.84 ± 9.95	NS
Platelet (cell / mm^3)	261,143 ± 77,327	213,143 ± 53,717	NS
BUN (mg/dl)	17.95 ± 10.21	20.52 ± 14.68	NS
Creatinine (mg/dl)	1.32 ± 0.54	1.28 ± 0.42	NS
Fasting blood sugar (mg/dl)	115.81 ± 38.14	132.38 ± 81.43	NS
Electrolyte			
Sodium (mEq/L)	140.49 ± 3.52	139.60 ± 3.26	NS
Potassium (mEq/L)	4.34 ± 0.47	4.07 ± 0.43	NS
Chloride (mEq/L)	105.67 ± 4.91	106.24 ± 3.96	NS
Bicarbonate (mEq/L)	25.13 ± 3.17	24.00 ± 2.92	NS

Table 2. (ต่อ)

	Albumin (n=21)	Polygeline (n=21)	p Value
Liver function test			
Total bilirubin (mg/dl)	0.58 ± 0.41	0.66 ± 0.34	NS
Direct bilirubin (mg/dl)	0.13 ± 0.13	0.18 ± 0.11	NS
SGOT (unit/dl)	31.43 ± 42.34	27.95 ± 14.77	NS
SGPT (unit/dl)	32.00 ± 49.00	2.52 ± 26.34	NS
ALP (unit/dl)	157.81 ± 72.56	187.38 ± 82.96	NS
Albumin (g/dl)	4.53 ± 0.51	4.42 ± 0.58	NS
Globulin (g/dl)	2.81 ± 0.32	3.06 ± 0.53	NS
Cholesterol (mg/dl)	228.43 ± 52.68	215.14 ± 29.91	NS
Triglyceride (mg/dl)	181.43 ± 79.43	212.52 ± 138.23	NS
HDL (mg/dl)	40.62 ± 10.95	39.81 ± 12.77	NS
PT (mean value / mean control)	12.95 / 13.21	13.10 / 12.95	NS
PTT (mean value / mean control)	30.87 / 30.12	33.63 / 32.57	NS

Table 3. Intraoperative pre-bypass data.

	Albumin (n =21)	Polygeline (n =21)	p Value
Total number of bypass grafts	67	64	
Internal mammary artery grafts	15	12	NS
Radial artery grafts	2	2	NS
Saphenous vein grafts	50	50	NS
Grafts / patient	3.19 ± 0.51	3.05 ± 0.50	NS
Bypass time (minute)	95.81 ± 25.57	90.05 ± 34.23	NS
Cross clamp time (minute)	57.14 ± 14.46	52.24 ± 15.80	NS
Amount of cardioplegia (ml)	1,104.76 ± 419.20	1,080.95 ± 508.79	NS
Hemoglobin level (g/dl)	11.56 ± 1.68	11.97 ± 2.02	NS
WBC count (cell/mm^3)	5,821 ± 1,488	7,180 ± 2,372	NS
Platelet quantity (cell/mm^3)	250,810 ± 92,504	215,286 ± 63,245	NS

Platelet quantity after CPB were measured to compare effect of CPB and priming method. CPB decreased platelet quantity significantly in both groups. In Polygeline group, platelet quantity before CPB was 215,286 ± 63,245 and after CPB was 135,376 ± 45,082 (p = 0.00004). Also, In albumin group, platelet quantity before CPB was 250,810 ± 92,504 and after CPB was 164,843 ± 70,409 (p = 0.0017).

Comparing effect of different type of priming solution to platelet quantity, data were compared between two groups after CPB finished. No significant differences in platelet quantity between polygeline and albumin group was detected (135,376 ± 45,082 and 164,843 ± 70,409 respectively). Also, there were no significant differences in amount of platelet lost and percent of platelet lost (polygeline group: 79,910 ± 41,194, 36.33% and albumin group 85,967 ± 53,661, 33.33%) (Table 4).

Table 4. Comparing effect of priming to platele quantity.

	Albumin (n=21)	Polygeline (n=21)	p Value
Pre-bypass platelet quantity	250,810 ± 92,504	215,286 ± 63,245	NS
Post-bypass platelet quantity	164,843 ± 70,409	135,376 ± 45,082	NS
Comparing pre and post bypass			
difference (cell / mm^3)	85,967 ± 53,661	79,910 ± 41,194	NS
difference (%)	33.33 ± 16.37	36.33 ± 12.95	NS

Platelet quantity, hemoglobin level and white blood cell count were measured again at ICU arrival. Also, no differences between two groups were detected (Fig 1, 2, 3).

In the third hour after ICU arrival, one patient in polygeline group developed bleeding and required second operation. He was a 75-year old male patient with NYHA functional class 2 before operation and had ejection fraction 51%. Quadruple coronary bypass grafting was performed using saphenous veins only. Proximal anastomosis of all grafts were at ascending aorta and distal anastomosis were at (1) obtuse marginal artery, (2) first diagonal artery, (3) left anterior descending artery and (4) right coronary artery. Bypass time was 92 minutes, cross clamp time was 53 minutes and total cardioplegia used was 800 ml. Platelet quantity before CPB was 206,000 and after CPB was 127,000. Upon ICU arrival, his platelet quantity was 171,000 cell/mm^3. He experienced bleeding of 460 ml per hour in the third hour. He was resuscitated by intravenous fluid, blood transfusion both with whole blood and fresh frozen plasma but no platelet was given to him. In the next hour, massive bleeding did not stop, so he was taken for emergency reoperation. Total blood loss in ICU until reoperation was 1,060 cc. Bleeding site was identified at proximal anastomosis of saphenous vein graft to ascending aorta (it was a graft to diagonal branch). After reoperation, his bleeding was stopped. This patient finally recovered and could be discharged home without any more complications.

Excluding this bleeding case, hemoglobin, white blood cell count and platelet quantity were measured again in 12 hours and 24 hours after admission in ICU. Again, no significant differences were detected between two groups (Fig 1, 2, 3). No patient in this study required platelet transfusion. Amount of bleeding was not significantly different between two groups (Table 5)

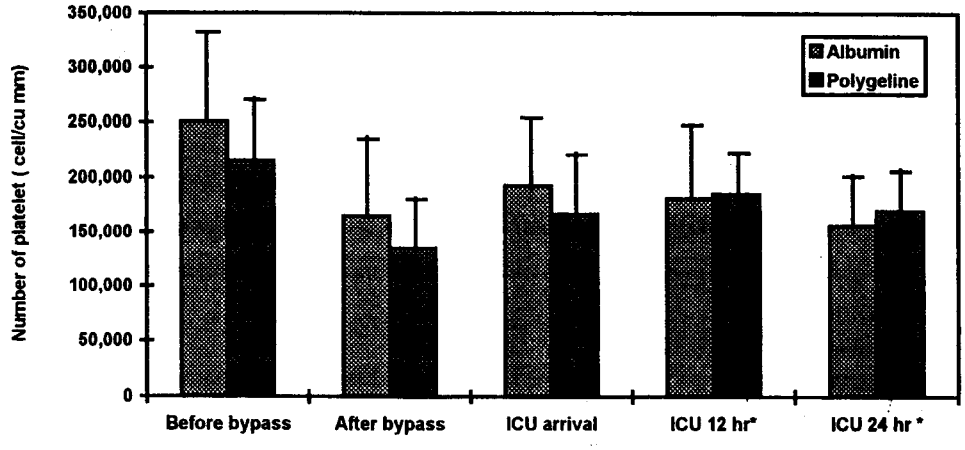

Figure 1. Change in platelet quantity (* = Bleeding case was not included).

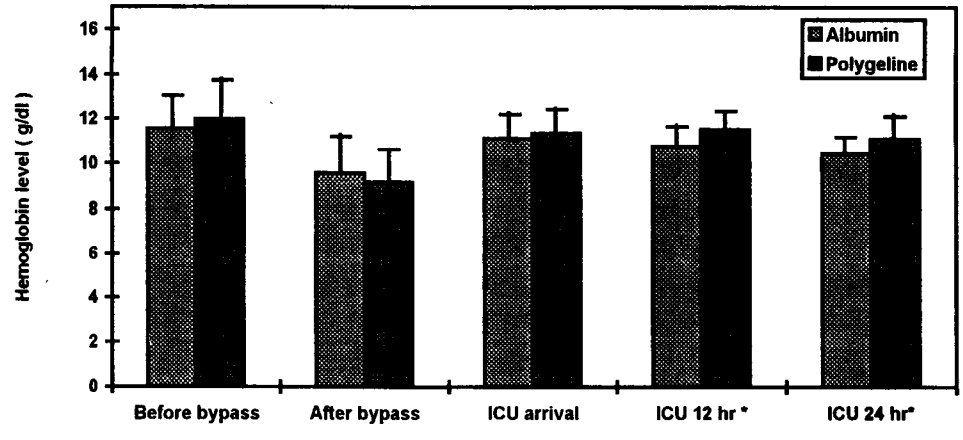

Figure 2. Change in hemoglobin level (* = Bleeding case was not included).

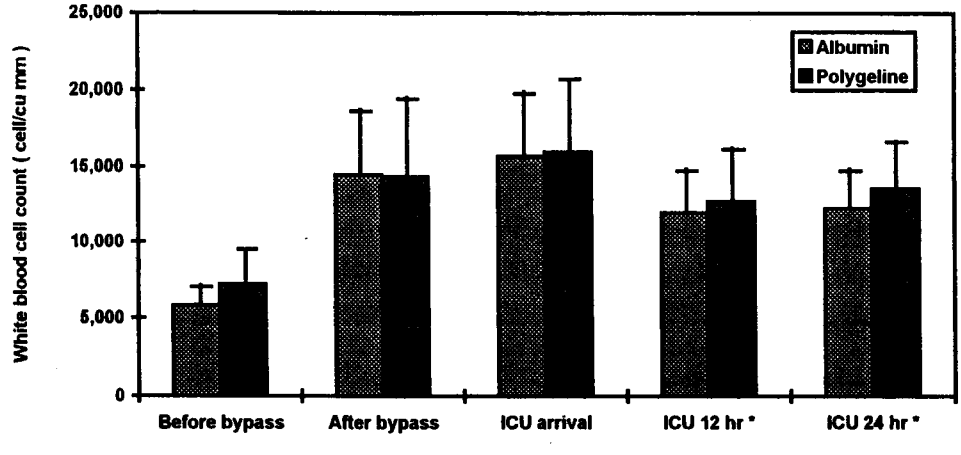

Figure 3. Change in white blood cell count (* = Bleeding case was not included).

Table 5. Postoperative amount of bleeding and platelet transfusion (* = Bleeding case was not included).

	Albumin (n=21)	Polygeline (n= 21)	p Value
Bleeding case require second operation	0	1	NS
Amount of bleeding in 24 hr (ml)*	550.00 ± 288.51	436.50 ± 224.34	NS
Amount of platelet transfusion (unit)*	0	0	NS

Discussion

Since no standard priming solution protocol has been established in clinical practices, there are many types of priming solutions and additives used in CPB. Hemodilution was introduced in the technique of cardiopulmonary bypass (CPB) more than 30 years ago, and today non blood priming solutions are routinely used.[5,6] Survey in priming solutions used in 35 National Health Service centers in the UK in 1994 showed that there were 54% of CPB using crystalloid priming solution and 46% using colloid priming solution.[7] Different priming solutions for cardiopul- monary bypass were extensively studied by many medical centers. Colloid priming solution is preferable to crystalloid priming solution because of less effect in pulmonary fluid accumulation.[8,9] Crystalloid priming solution also impaired cardiac functions.[10] Effect of cardiopulmonary bypass to platelet quality and quantity were well documented. Kestin AS, et al[11] had shown that cardiopulmonary bypass could induce platelet dysfunction. Cardiopulmonary bypass decreased platelet quantity through the process of platelet adhesion, platelet aggregation and blood dilution.[12,13] Thrombocytopenia increased risk of postoperative bleeding. There were a few studies about the effects of albumin and polygeline in hematologic response. Different types of colloid therapy in patients undergoing CPB by Boldt J et al[14] and Wahba A et al[15] did not show any different influences made by albumin and polygeline to hemodynamic effects and platelet quantity. These studies did not use solutions to prime the pump, so they could not tell the effect of platelet adsorption to CPB tubing. Another study by Scott DA et al[16] studied effect of stable plasma protein solution (SPSS - albumin 4.6% with globulin 0.4%) compared with polygeline to hemodynamic and hematologic parameters. No differences between two groups were detected in postoperative bleeding and platelet quantity. Because stable plasma protein solution could produce profound hypotension on rapid infusion by effect of Pre-Kallikrein Activator (PKA)[17], So, many centers had used pure serum albumin instead. Because stable plasma protein solution had the component of globulin, it could not interpret the exact result of the recently used normal serum albumin on platelet quantity. Roohk HV et al[3] showed that albumin coated surface can prevent platelet adsorption on biomaterial in vitro. As a result, the aim of this study is to determine whether normal serum albumin is more effective than polygeline in preventing the loss of platelets during CPB.

Result of this study showed that, there was no differences in platelet quantity, hemoglobin level, postoperative bleeding, platelet transfusion after cardiopulmonary bypass and in the first 24 hour after operation between two groups. Also, there was no difference in reoperation case. Only one case in polygeline group experienced postoperative bleeding. There was

no evidence of thrombocytopenia during bleeding. He did not want any platelet transfusion for bleeding control. The cause of bleeding was surgical technical problem. So, It seemed to us that bleeding was not relevant to the platelet effect.

This study was designed for healthy coronary arterial disease patients. For the other groups of patients who were excluded from this study (e.g. hemodynamic instability, low ejection fraction, require reoperation or emergency operation), we hope that this study will increase confidence in using polygeline from the hematologic point of view.

In conclusion, It seems that there is no advantage in using albumin over polygeline as priming solution from the hematologic point of view for the first 24 hours after operation. Talking into consideration albumin's expensiveness, polygeline is superior to albumin for priming the solutions.

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