Original Article

Application of Polygeline in Pediatric Cardiac Surgery

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ABSTRACT

The purpose of this study was to determine the effect of using polygeline as part of the cardiopulmonary bypass solution in pediatric cardiac surgery.

A total of 40 cases were divided into two groups, a polygeline group (H group, n=20) and a plasma group (P group, n=20). Operations were performed under routine extracorporeal circulation. The dose of polygeline or plasma used was calculated to maintain the patient's plasma colloid oncotic pressure at 10-12 mmHg.

The results showed that in the polygeline group, no patient developed allergic or coagulation disorders even after large volumes of polygeline were used (45 ml/kg). At the initiation and completion of cardiopulmonary bypass (CPB), the concentrations of calcium were higher in the H group (1.38 ± 0.19, 1.21 ± 0.11) than those (0.72 ± 0.11, 0.95 ± 0.10) in the P group. There were no other statistically significant differences between the two groups. There were no organ problems in the patients included in the study.

This study demonstrated that polygeline could be used as part of prime solution instead of plasma to keep an ideal plasma colloid oncotic pressure, reduce infections caused by blood product transfusions and lower the cost to the patients.

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INTRODUCTION

Recently, with the increasing number of open heart operations in China, the availability of blood is decreasing, and the risk of bloodborne infections, such as hepatitis and HIV, is increasing (1). Thus, the technique of using minimal or no blood during cardiopulmonary bypass (CPB) has become a common practice (2). However, the lowering of plasma colloid oncotic pressure (COP) after hemodilution results in complications postoperatively (3). Application of polygeline as a substitute for plasma has been successfully used in cardiac surgery of adults for many years (4, 5).

Haemaccel[a], made of polygeline, is a type of plasma substitute. It is a good volume expander and does not interfere with coagulation or accumulate in the body. Its clinical effect has been reported (6-8). However, experience in pediatric heart surgery was limited. In this study, we evaluated its use in pediatric cardiac surgery.

MATERIALS AND METHODS

The study protocol had been approved in advance by the ethical committee of Xin-hua Hospital. Forty patients undergoing open heart surgery with CPB for correction of congenital heart defects were sequentially allocated into two groups. Polygeline (Haemaccel) group (n = 20, H group) and plasma group (n=20, P group). The two groups were comparable in terms of age, weight, sex, and diagnoses (Table 1). Standard anesthetic and surgical techniques were used in all cases.

All patients underwent CPB with moderate systemic hypothermia (25-27°C). Flows were maintained at 2.2–2.4 L/min/m^2. For flow rates of <2,000 ml/min, a Minimax Plus[b] membrane oxygenator was used; for flow rates >2,000 ml/min, a Univox[c] membrane oxygenator was employed. Alpha-stat blood gas management was used in all patients. Crystalloid cardioplegia (modified St. Thomas' Hospital solution) was routinely employed.

PRIMING SOLUTION

The priming solution was a mixture of Lactated Ringer's solution, packed red blood cells, and Haemaccel/plasma in a ratio calculated to achieve a hematocrit of 20% to 22%. For maintaining COP at 10-12 mmHg (normal 20-25 mmHg), Haemaccel/plasma was added in the priming solution according to the formula below:

PD/FFP = [TPV-(AHH+PPV/2)]/2

where PD = polygeline dose; FFP = fresh frozen plasma; TPV = total prime volume; ABB = added bank blood; PPV = patient's plasma volume.

a Haemaccel, Hoechs, United Kingdom
b Medtronic, Inc., Anaheim, CA
c Baxter Healthcare, Bentley Division, Irvine, CA

SAMPLING

Indwelling arterial cannulas were inserted as per routine clinical practice. Blood samples were obtained at the following intervals: (1) preoperative; (2) after induction of anesthesia; (3) 15 minutes after onset of CPB; (4) completion of CPB; (5) two minutes after skin closure; (6) two hours after transfer to intensive care unit; and (7) 24 hours after transfer to intensive care unit. The tests performed included liver and renal functions, plasma calcium, platelet count, and COP.

RESULTS

All children in the study survived their cardiac surgery and were discharged home in good condition. There were no sig-

Table 1: Summary of patient data

Variable	H group (n = 20)	P group (n = 20)
Sex (M/F)	11/9	9/11
Age (yr)	3.9 ± 2.8	4.6 ± 2.26
Body Weight (kg)	16.23 ± 5.47	14.32 ± 4.53
Procedure		
ASD	2	9
VSD	11	10
TOF	4	6
DORV	1	3
L-TGA	1	0
D-TGA	0	1
SAS	1	0

Note: Where applicable, data are shown as the mean ± standard deviation. In all data, there were no significant differences between the groups. ASD = atrial septal detect; VSD = ventricular septal defect; TOF = Tetralogy of Fallot; DORV = double outlet right ventricle; L-TGA = levotransposition of great artery; D-TGA = dextrotransposition of great artery; SAS = subaortic stenosis.

Table 2: Intra and post-operation data

Variable	H group (n = 20)	P group (n = 20)
Aortic time (min)	45.5 ± 35.5	48.7 ± 27.9
Bypass time (min)	88.8 ± 65.7	84.8 ± 35.2
Chest drainage[a] (ml)	147 ± 52	165 ± 65
Ventilator time (hrs)	19.9 ± 16.3	23.3 ± 23.8
ICU stay time (days)	4.0 ± 1.8	4.2 ± 2.0
Urine output intraoperation (ml)	258 ± 354	405 ± 561
Urine output[a] (ml)	700 ± 241	937 ± 425
Spontaneous cardiac activity	95% (19/20)	90% (18/20)
Inotropic drug use	40% (8/20)	60% (12/20)

Note: Where applicable, all data are shown as the mean ± standard deviation. In all data, there were no significant differences between the groups.
[a]In the first 24 hours postoperatively

Figure 1: Change of COP between two groups

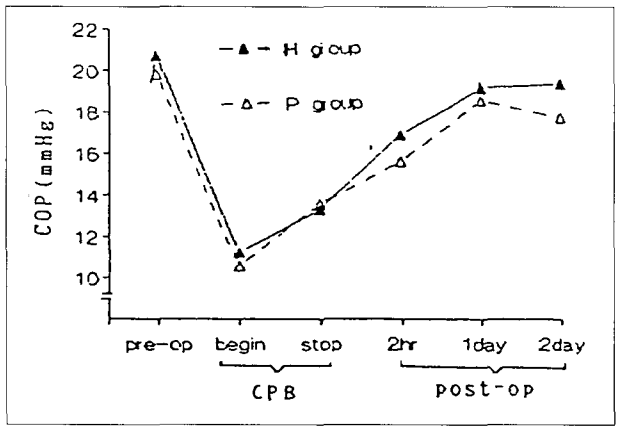


Figure 2: Change of platelet count between two groups

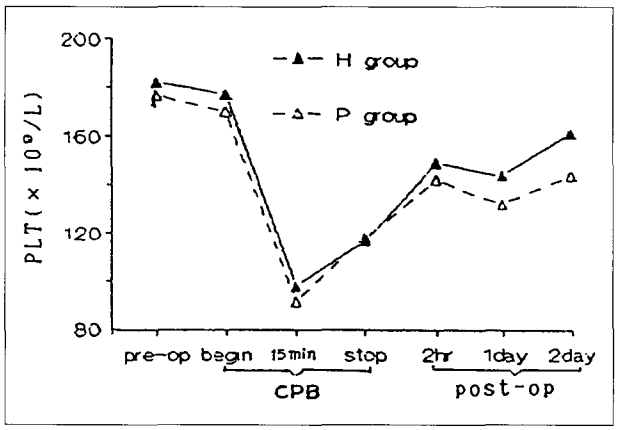


Figure 3: Change of kaolin partial thromboplastin time (KPTT) between two groups

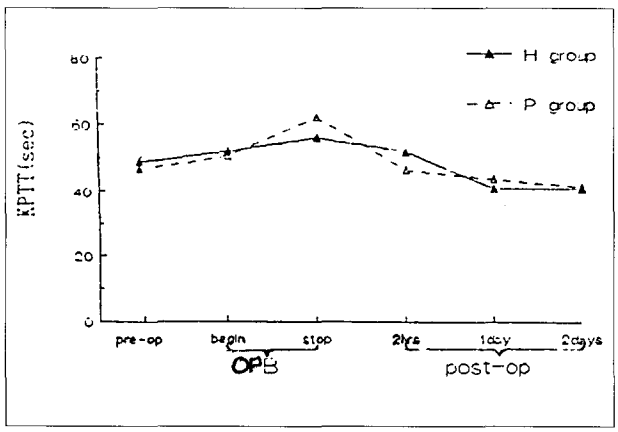


Figure 4: Change of prothrombin time (PT) between two groups

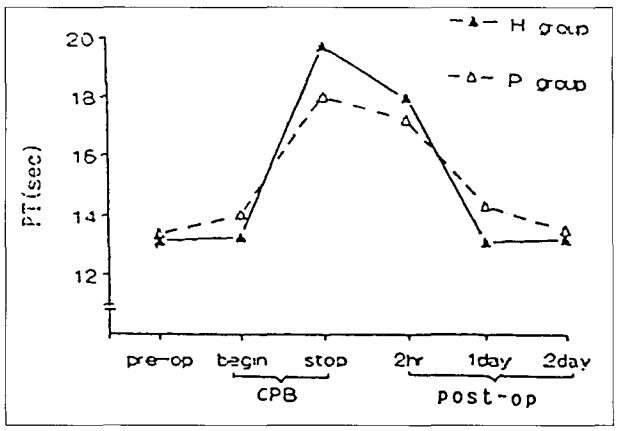
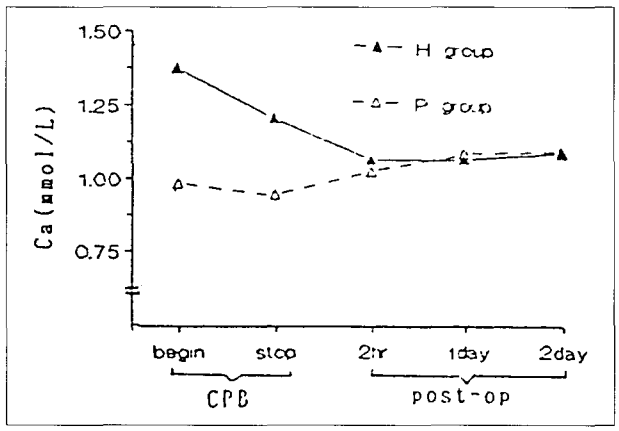


Figure 5: Change of plasma Ca^{++} between two groups



nificant differences in terms of aortic clamp time, bypass time, the duration of artificial ventilation after operation and stay in the intensive care unit. There were also no significant differences in the first 24 hours of postoperative chest drainage and urine output between the two groups. Regarding the number of patients developing spontaneous cardiac activity, H group was higher than P group, 95% versus 90% (not statistically significant). Also, positive inotropic drug use (e.g., dopamine, dobutamine) was higher in the P group, but these differences were not significant (Table 2).

Following CPB, none of the children had observable edema. By using the formula in this study, the volume of Haemaccel used in CPB was 24.9 ± 9.2 ml/kg. No allergic response was observed in the patients of the H group.

COP changes in each group were similar (Figure 1). After initiating CPB, the COP decreased to approximately half of its preoperative value ($p<0.01$). Postoperatively, it increased slowly.

The platelet count decreased during CPB and increased af-

Figure 6: Change of SBPT between two groups

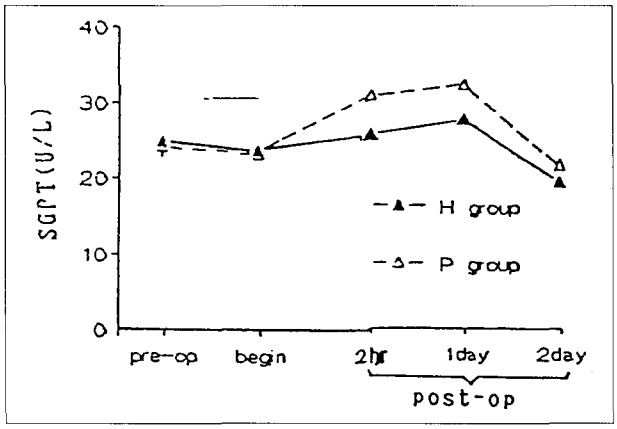


Figure 7: Change of SGOT between two groups

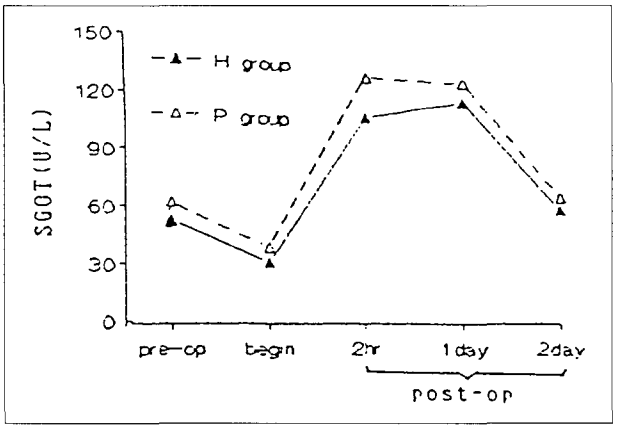


Figure 8: Change of alkaline phosphatase (AKP) between two groups

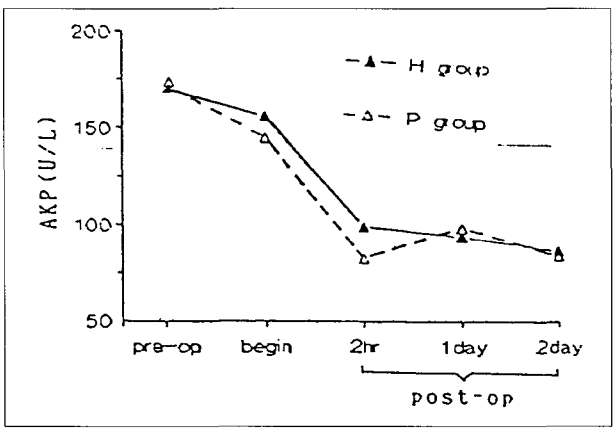
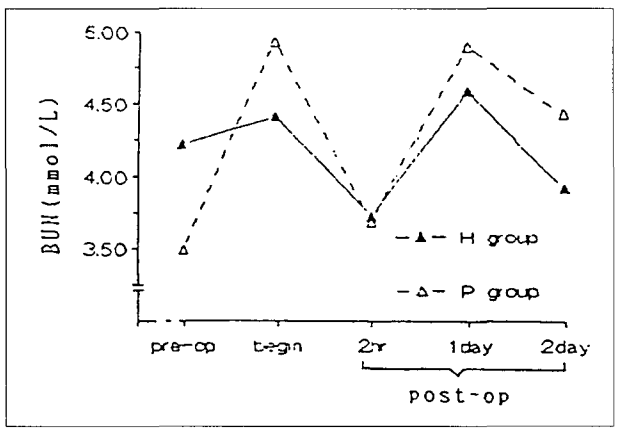


Figure 9: Change of blood urea nitrogen (BUN) between two groups



ter CPB (Figure 2). Forty-eight hours after operation, the platelet count was lower than the preoperative level.

There were no differences in kaolin partial thromboplastin time (KPTT) or prothrombin time (PT) between the two groups. KPTT and PT recovered to postoperative levels after two hours and 24 hours, respectively (Figures 3, 4).

The concentration of Ca^{++} was lower in the P group and higher in the H group ($p<0.01$). After adding $CaCl_2$ in the P group Ca^{++} levels were normal in both groups after terminating CPB (Figure 5).

The other data (SGPT, SGOT, AKP, BUN, Cr) (Figures 6-10) were all normal in this study and there were no significant differences between the two groups.

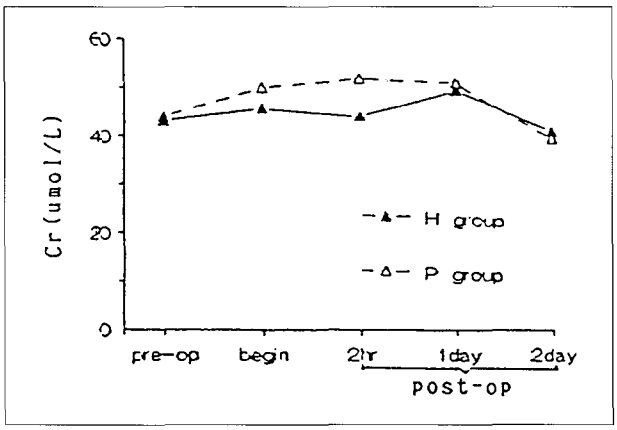
DISCUSSION

Haemaccel, which is made of polygeline, is a type of plasma substitute. It has a stable physiochemical quality, is a good volume expander, does not interfere with coagulation or accumulate in the body. Its clinical effect has been reported (6-8). However, experience in pediatric heart surgery was limited. In this study we evaluted its use in pediatric cardiac surgery.

It is important to maintain an appropriate COP during CPB for adequate tissue perfusion and supply of oxygen. Haemaccel has an oncotic pressure equal to plasma's. We used it as a substitute in the priming solution to maintain COP in children undergoing CPB. During CPB, we succeeded in perfusing the tissue adequately, maintaining normal acid-base balance, and didn't observe any periorbital or peripheral edema. There were no significant differences in the functional recovery of important organs, the time spent on the ventilator or the duration of stay in the intensive care unit.

In the past, we had used other substitutes for plasma (e.g., hydroxyethyl starch) (9). It can maintain plasma oncotic pressure too, but its dose is limited and it has the possibility of affecting coagulation (10). In this study, an average of 24.9 ml/kg

Figure 10: Change of creatinine (Cr) between two groups



Haemaccel was used, with the largest volume being 45 ml/kg. This is equivalent to 33%-53% of the patients' total blood volume. However, no allergic reaction or adverse effects on coagulation were found. The concentration of Ca^{++} in Haemaccel is high (6 mmol). According to studies on myocardial protection, a lower concentration of Ca^{++} before reperfusion of the heart is beneficial to cardiac function (11). Thus, we worried that the Ca^{++} in Haemaccel would be harmful to the myocardium (12). In the present study, we did not biopsy or examine myocardial cells by electron-microscope, and therefore could not analyze for any cellular or molecular changes in the myocardium after using Haemaccel. Because the ratio of spontaneous cardiac activity and the rate of positive inotropic drugs used postoperatively were similar between groups, using Haemaccel in the priming solution appears to be safe.

CONCLUSION

Using Haemaccel as a substitute in the priming solution in pediatric CPB can maintain COP during the operation to improve tissue perfusion. No allergic reaction was found. The functional recovery of major organs, the time spent on the ventilator, and the duration of stay in the intensive care unit for the Haemaccel group proved similar to that of the plasma group. Haemaccel can be used in pediatric open heart surgery without limitation. The high Ca^{++} in the Haemaccel group and its potential effect on myocardial function should be studied.

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