Clinical application of vacuum-assisted cardiopulmonary bypass with a pressure relief valve

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Abstract

Objectives: Hemodilution induced by cardiopulmonary bypass (CPB) often prevents open heart operations without blood transfusion because of a large CPB-priming volume. A vacuum-assisted venous drainage system appears to overcome this problem and our previous experimental study demonstrated the beneficial effect of a vacuum-assisted CPB with a pressure relief valve. In this study, we clinically applied this novel system, and evaluated its efficacy by comparing it with the results of a conventional siphon-dependent drainage system.

Methods: Sixty patients undergoing open heart operation were divided into Group V (vacuum-assisted system, n = 30) and Group S (siphon-dependent system, n = 30). The vacuum-assisted system contains a powerful vacuum generator and a pressure relief valve to keep the negative pressure in the reservoir constant when the blood suction is used.

Results: The CPB-priming volume was significantly smaller in Group V (V vs. S: 1071 ± 88 vs. 1405 ± 137 ml; P < 0.01), resulting in the lower hemodilution in Group V evidenced by the minimum hemoglobin level (V vs. S: 6.83 ± 1.06 vs. 5.78 ± 0.79 mg/dl; P < 0.01) and blood transfusion rate (V vs. S: 9 vs. 20%; P < 0.01). There were no significant differences in the plasma free hemoglobin level and the reduction ratio of plasma haptoglobin between the groups.

Conclusions: These data demonstrate that this vacuum-assisted CPB can provide simplification of the CPB circuit, resulting in a smaller CPB-priming volume and lower hemodilution. This vacuum-assisted CPB may attenuate the negative effect of CPB by minimizing hemodilution and appears to be a useful modification to accomplish no blood-requiring open heart operations. © 2001 Elsevier Science B.V. All rights reserved.

Keywords: Cardiopulmonary bypass; Vacuum-assisted venous drainage; Circuit priming volume; Blood transfusion; Hemolysis

1. Introduction

Cardiopulmonary bypass (CPB) is a necessary procedure in a certain cardiac operations. On the other hand, CPB induces several negative effects affecting perioperative morbidity [1–6]. Hemodilution, one of the CPB-induced negative effects, often prevents open heart operations without the outflow of donor blood components when it is severe [7–9]. A siphon-dependent venous drainage system in a conventional CPB requires a sufficiently long circuit line for obtaining an appropriate negative pressure in case of unexpected poor venous drainage, resulting in a large amount of CPB-priming volume and excess hemodilution. The improvement of CPB systems by shortening the bypass circuit line leads to a reduction in CPB-priming volume, which is thought to be essential for the spread of no blood-requiring open heart operations.

The vacuum-assisted CPB system enables sufficient venous drainage by shortening a venous line to reduce the CPB-priming volume, as we previously described in the experimental perfusion [10]. In clinical circumstances, however, two possible negative effects induced by vacuum-assisted CPB remain to be evaluated. When the blood suction is used, the pressure in the venous reservoir changes, which may prevent sufficient and stable venous drainage. From this point of view, we have developed a vacuum-assisted CPB circuit using a pressure relief valve and have reported its efficacy in an experimental study [10]. Another possible negative effect is the influence on hemolysis, an important element in CPB [11–13]. Vacuum-assisted venous drainage may enhance CPB-induced hemolysis in clinical situations, although our experimental study demonstrated that it did not adversely affect hemolysis [10].

In the present study, we applied this vacuum-assisted...
CPB system to clinical situations to evaluate its efficacy in terms of hemodilution and hemolysis.

2. Materials and methods

2.1. Study population

The subjects of this clinical study were 60 patients who underwent elective open heart operation between 1997 and 1998 in our institution. The same type of CPB circuit was used in this study, and re-do operation was not included. The diagnoses were: aortic valve disease in nine, mitral valve disease in 19, coronary artery disease in 27 and congenital heart disease in five patients. Thirty-one patients were men and 29 were women, and their ages at operation ranged from 15 to 82 years with a mean of 57.1 ± 14.1 years. All patients gave their informed consent to participate in this study, and we followed the guidelines of our internal review board.

Patients were randomly divided into two groups according to the CPB system for venous drainage: the vacuum-assisted CPB group (Group V, n = 30) and the siphon-dependent CPB group (Group S, n = 30).

2.2. CPB system and management

The CPB circuit for either group comprised a centrifugal pump (BioPump, BP-80, Medtronic, BioMedicus, Anaheim, CA), a membrane oxygenator (SARNS; Sarns, Inc./3M, Ann Arbor, MI), an arterial filter, a venous hard-shell reservoir, and tubing lines (1/2 inches), which were primed without blood components. The surfaces of the CPB circuit used in this study were not heparin-coated.

The venous line and suction lines of the CPB circuit were connected to the venous reservoir in both groups. In the conventional siphon-dependent CPB system used for Group S, the negative pressure in the venous reservoir was regulated by the pressure gradient between the pressure at the operating table (the central venous pressure) and the pressure at the reservoir level. To obtain an appropriate negative pressure in case of unexpected poor venous drainage, a sufficiently long drainage line was used and the height between the operating table and the venous reservoir was kept at about 100 cm. In the vacuum-assisted CPB system used for Group V, the negative pressure in the venous reservoir was regulated by a novel vacuum system, as previously described [10]. This system contains a powerful vacuum generator (Surgical/Free-Flow Vacuum Regulator, Mera Co. Ltd., Tokyo, Japan) and a pressure relief valve to easily maintain the negative pressure in the venous reservoir constant whether the blood suction was used or not (Fig. 1) [10]. The residual tubing line was cut down in this vacuum-assisted system and the height between the operating table and the venous reservoir was kept at about only 20 cm.

Our preliminary study demonstrated the relationship between the vacuum pressure and the drainage flow (Fig. 2). In the early period for clinical application of this vacuum-assisted CPB system, both ‘20 + 24 French’ and ‘24 + 24 French’ showed an increasingly linear relationship between drainage flow and vacuum pressure. At 30 mmHg of negative pressure in the venous reservoir, they provided the same drainage flow (approximately 4.0 l/min) as ‘28 + 28 French’ did in the conventional siphon drainage system. Thus, the vacuum pressure was set at −30 mmHg.

Heparin at a dose of 3 mg/kg was infused, and CPB was instituted in the following fashion. A venous cannula was placed directly into the superior vena cava and another into the inferior vena cava, and venous drainage was carried out. Two 28 French venous cannulae were used in Group S. In Group V, a 20 or 24 French cannula was inserted into the superior vena cava, and a 24 French cannula was inserted into the inferior vena cava. An arterial cannula (21 French) was positioned directly into the ascending aorta in both groups. To reduce the CPB-induced inflammatory response, nafamostat mesilate (FUT-175; Torii Pharmaceutical Co., Tokyo, Japan), which is a serine protease inhibitor, was added at a dose of 1 mg/kg into the venous reservoir at the initiation of CPB, and was administered continuously during CPB at a dose of 0.5 mg/kg per h [14]. CPB was controlled on the basis of α-stat management with blood-flow rates of 2.2–2.6 l/min per m² to maintain the mean arterial pressure between 60 and 80 mmHg with the use of vasoactive agents such as chlorpromazine hydrochloride and norepinephrine if necessary. The temperature of blood was measured in the arterial line just after it passed through the heat exchanger which controlled it at 34°C. Myocardial protection during aortic cross-clamping was done by the method using cold blood cardioplegia, as previously described [15].

The patient characteristics are shown in Table 1 according to their distribution in the two groups. Both preoperative and perioperative variables are included.

2.3. Measurement

To evaluate the effects on hemodilution, CPB-priming volume, the minimum hemoglobin level during CPB (before transfusion), and the transfusion rate were compared between the two groups. The CPB-priming volume was considered as the sum of the initial priming volume and the additional volume infused until the stable perfusion was achieved. Donor blood was transfused when the circulating blood hemoglobin level was below 6.0 g/dl even after the use of preoperatively stocked autologous blood.

Arterial blood samples were obtained at the following six times: (1) just before the initiation of CPB; (2) 10; (3) 30; (4) 60; (5) 90; and (6) 120 min after the initiation of CPB. To evaluate the effects on hemolysis, the plasma free hemoglobin level (F-Hb) and the reduction ratio of plasma haptoglobin (R-Hp) were measured and compared between the two groups.
2.4. Statistical analysis

All data are expressed as means ± standard deviation (SD). Comparisons between the groups were analyzed by χ² test for independence and the unpaired Student’s t-test. Repeated measures analysis of variance (ANOVA) was used to test the time-dependent changes in F-Hb and R-Hp. All statistical analyses were performed with the Statview v5.0 statistical package (Abacus Concepts, Inc., Berkeley, CA). A P value of less than 0.05 was considered statistically significant.

3. Results

3.1. Clinical outcome

All patients enrolled in this study tolerated the surgical procedures and were discharged from hospital. No complications related to the CPB system for venous drainage, such as neurological complications, air contamination and air embolization, were observed in either group during their hospitalization.

3.2. The size of venous cannulae

In Group V, a 28 French venous cannula was not used because with the smaller venous cannulae (20 or 24 French) initially inserted, poor venous drainage flow was not observed. In Group S, a sufficient venous drainage flow...
was obtained with the use of 28 French venous cannulae, although poor venous drainage was observed at times and the height between the operating table and the venous reservoir was frequently controlled.

3.3. CPB-priming volume and effect on hemodilution

The CPB-priming volume was significantly smaller in Group V than in Group S. Regarding the effect on hemodilution, the minimum hemoglobin level during CPB was significantly higher in Group V than in Group S, and the transfusion rate was significantly lower in Group V (Table 2).

3.4. Effect on hemolysis

In both groups, the F-Hb level increased and the R-Hp value decreased gradually during CPB. Between the two groups, there were no significant differences in both F-Hb (Fig. 3) and R-Hp at each sampling point (Fig. 4).

4. Discussion

The results of our present study demonstrated that this vacuum-assisted venous drainage system provided a significantly smaller CPB-priming volume by shortening the residual tubing, resulting in a significantly higher hemoglobin level and lower transfusion rate. Furthermore, hemolysis was observed in cases with the vacuum-assisted CPB system only to the same degree as that observed with the siphon-dependent CPB system, as evidenced by the changes in plasma free hemoglobin and haptoglobin levels during CPB. These findings suggest that our vacuum-assisted venous drainage system can effectively simplify CPB equipment, and may minimize CPB-induced hemodilution without increasing CPB-induced negative effects such as hemolysis.

The requirement of donor blood transfusion is heavily influenced by the following three issues: the preoperative hemoglobin level, the amount of autologous blood stocked preoperatively, and the degree of CPB-induced hemodilution. The degree of hemodilution is mainly determined by the CPB-priming volume [7–9]. Furthermore, hemodilution caused by CPB-priming volume is thought to enhance the CPB-induced inflammatory response, as well as to prevent no blood-requiring open heart operations [16,17]. Thus, the reduction of the CPB-priming volume is a critical step in diminishing the perioperative morbidity associated with CPB-induced negative effects, and seems to be one of the most important factors for improving the outcome of open heart operations. With the use of siphon-dependent venous drainage, however, a sufficient height between the operating table and the venous reservoir should be kept to cope with unexpected poor venous drainage. The siphon-dependent venous drainage system is limited to overcome these issues.

The vacuum-assisted venous drainage system may resolve this problem, although it can make the management of CPB more troublesome while controlling the negative pressure in the venous reservoir when blood suction is used. Precautions against the positive pressure in the reservoir resulting in venous back-flow should be taken under

Table 2
Comparison of CPB-priming volume, minimum hemoglobin level and blood transfusion rate

<table>
<thead>
<tr>
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<th>Group V (n = 30)</th>
<th>Group S (n = 30)</th>
<th>P-value</th>
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<tbody>
<tr>
<td>CPB-priming volume (ml)</td>
<td>1071 ± 88</td>
<td>1405 ± 137</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Minimum hemoglobin level (g/dl)</td>
<td>6.83 ± 1.06</td>
<td>5.78 ± 0.79</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Blood transfusion rate (%)</td>
<td>9 (30)</td>
<td>20 (67)</td>
<td>&lt;0.01</td>
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vacuum-assisted CPB when blood suction is used. A pressure relief valve in our vacuum-assisted venous drainage system, whose efficacy was demonstrated previously in our experimental CPB [10], appears to be suitable for clinical applications without complicated management of CPB. Actually, in the present clinical examination, our vacuum-assisted venous drainage system significantly reduced the CPB-priming volume without complicating the management of CPB. To reduce a larger amount of CPB-priming volume, however, further improvements of CPB equipment, such as an oxygenator, centrifugal pump and arterial filter, are also needed.

Our vacuum-assisted venous drainage system enabled the use of smaller venous cannulae (20 or 24 French) as well as a reduction of the CPB-priming volume. However, it is possible that a higher shear stress imposed on the fluid when it passes through a smaller diameter by forced vacuum pressure may enhance CPB-induced hemolysis. The present study indicates that there is no significant difference in the degree of hemolysis during CPB between the vacuum and siphon systems, and thus, these findings suggest that the clinical effect of our vacuum-assisted venous drainage system on hemolysis is within acceptable levels compared with the conventional siphon-dependent system.

The recent popularity of minimally invasive cardiac surgery (MICS) requires the improvement of operative procedures, such as a less invasive CPB system and an avoidance of full-sternotomy [18–21]. The present study demonstrates that our vacuum-assisted venous drainage system provides a smaller CPB-priming volume and enables the use of smaller venous cannulae than the siphon-dependent system does, which is essential for successful MICS. Thus, our vacuum-assisted venous drainage system appears more practicable, safe and effective for MICS procedure than a conventional CPB with a siphon-dependent venous drainage system.

In summary, this vacuum-assisted venous drainage system with a pressure relief valve provides simplification of the CPB circuit, resulting in a smaller CPB-priming volume and lower hemodilution in patients undergoing open heart operations in comparison with the conventional siphon-dependent venous drainage system. This novel system may attenuate the negative effect of CPB by minimizing hemodilution and may be suitable for more practicable and safer MICS procedures, as well as being a useful modification to accomplish no blood-requiring open heart operations.

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References


