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Association of Primary Hemodilution and Retrograde Autologous Priming with Transfusion in Cardiac Surgery: Analysis of the Perfusion Case Database of the Japanese Society of Extra-Corporeal Technology in Medicine

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Abstract: It is important to avoid unnecessary blood cell transfusion. However, the associations of hemodilution and retrograde autologous priming with red blood cell transfusion during and after cardiopulmonary bypass (CPB) in cardiac surgery in Japan are currently unclear. We analyzed these associations using data for 3,090 adults from the Perfusion Case Database of the Japanese Society of Extra-Corporeal Technology in Medicine. Percent hemodilution was calculated by total priming volume and weight. Logistic regression models were used to adjust for covariates including type of surgery, gender, age, hemoglobin concentration before CPB, CPB time, urine volume during CPB, and institution. The percentages of red blood cell transfusions during CPB for patients with <15, 15 to <20, 20 to <25, 25 to <30, and ≥30% hemodilution were 43.0, 51.5, 68.9, 77.3, and 87.7%, respectively. This increase in line with increasing dilution was significant after adjusting for covariates. The percentage of red blood cell transfusion after CPB also increased slightly between 39.0 and 49.4% with percent hemodilution, but the trend after adjusting for covariates was not significant. Use of retrograde autologous priming was significantly associated with blood cell transfusion during CPB after adjusting for covariates, but was not significantly related to blood cell transfusion after CPB. These results suggest that optimizing the percent hemodilution and use of retrograde autologous priming might reduce the use of red blood cell transfusion during CPB in clinical practice in Japan. **Keywords:** hemodilution, blood transfusion, cardiac surgery, cardiopulmonary bypass, extracorporeal circuit. *J Extra Corpor Technol. 2018; 50:231–6*

It is important to avoid unnecessary blood cell transfusion during cardiac surgery with cardiopulmonary bypass (CPB) (1–3). Blood cell transfusion is related to complications such as infections and renal damage (3–5). Although bleeding blood is returned to the CPB circuit, blood cell transfusions are still frequently performed during and after weaning from CPB (4,6).

The CPB circuit is filled with priming fluid, which results in hemodilution, although excessive hemodilution may be associated with the need for red blood cell transfusion (7,8). Retrograde autologous priming is used to replace the priming fluid with the patient's own blood after priming of the CPB circuit and may thus reduce the degree of hemodilution and the consequent need for red blood cell transfusions (9,10). The effects of hemodilution and retrograde autologous priming on intraoperative red blood cell transfusion have been examined in many studies in the United States and Europe, including analyses of data from a large multi-institution perfusion database (4,7–12). In addition, the Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists Blood Conservation Clinical Practice Guidelines stated "Minicircuits (reduced priming volume in the minimized CPB circuit) reduce hemodilution and are indicated for blood conservation" and "Retrograde autologous priming of the CPB circuit may

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be considered for blood conservation" (13). However, few studies have examined hemodilution and retrograde autologous priming in Japan, and their effects on red blood cell transfusion in clinical practice thus remain unclear (14,15).

Analysis of data for perfusion cases would allow us to clarify the current status of intraoperative transfusion and its related factors in cardiac surgery in clinical practice. Several transfusion-related factors have been reported: type of surgery, gender, age, and CPB time (7–12). The extents and magnitudes of those effects may vary according to the timing of transfusion (2,16). Intraoperative transfusion is divided into three periods: before, during, and after CPB. Such analysis would, therefore, require methods of adjusting for covariates and accounting for the timing of transfusion, using data including the necessary information.

Perfusion case registration was recently initiated in Japan by the Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) (17). Analysis of this database may improve our understanding of the current status of cardiac surgery with CPB in Japan and thus allow international comparisons to be made (17,18).

We aimed to investigate the association of percent hemodilution and retrograde autologous priming with red blood cell transfusions during and after CPB in Japan, using the Perfusion Case Database of the JaSECT.

MATERIALS AND METHODS

The Perfusion Case Database of the JaSECT

The Perfusion Case Registration of the JaSECT has been described elsewhere (17,18). It aims to progress extracorporeal circulation techniques in Japan and contribute to the promotion of national medical care and health. The database registry was started in 2013, and the number of institutions has since increased to 24, with 3,800 registered cases between January 1, 2014, and December 31, 2015. The database targets adult patients aged 16 years or older and collects information for six fields comprising a total of 243 items: basic patient information, circuit and filling fluid, extracorporeal circulation, in-and-out management, test data management, and outcome management. The data manager in charge of the case registry at each institution is required to be a full member of JaSECT. The managers receive aggregated results for their own data and overall aggregated results at twice yearly data manager meetings.

Subjects

Among 3,800 subjects registered in the Perfusion Case Database of the JaSECT, we excluded 577 who received red blood cell transfusion before CPB, eight who received preserved autologous blood transfusion at the time of circuit priming, and 125 with missing values for the data used in our analysis. A total of 3,090 subjects were, therefore, analyzed.

Data

We used the following data from the Perfusion Case Database of the JaSECT: institution, gender, age at surgery (years), weight (kg), type of surgery, total priming volume (mL), CPB time (minutes), urine volume during CPB (mL), use of retrograde autologous priming, hemoglobin concentration value (g/dL), and red blood cell transfusion. Hemoglobin concentration was measured shortly before the start of CPB (before CPB) and at weaning (after CPB). Information on red blood cell transfusion was obtained from the start of CPB to just before weaning (during CPB), and from weaning of perfusion to the completion of surgery (after CPB). We did not obtain information on red blood cell transfusion after surgery.

Percent hemodilution (%) was calculated using the following equation:

$$\frac{\text{total priming volume [mL]}}{\text{weight [kg]} \times 80 + \text{total priming volume [mL]}} \times 100.$$

Statistical Analysis

To describe and estimate the effects of percent hemodilution, we categorized it into five levels: <15, 15 to <20, 20 to <25, 25 to <30, and $\geq 30\%$. The types of surgery were classified as follows: isolated coronary artery bypass graft, isolated valve surgery, coronary artery bypass graft and valve surgery, and other (e.g., aorta surgery and surgery for congenital disease).

We calculated the distributions of red blood cell transfusions during and after CPB and of each covariate (as shown in Table 1) in relation to the percent hemodilution among 2,883 subjects without retrograde autologous priming. The distributions were compared by analysis of variance or χ^2 tests. We estimated the odds ratios (ORs) and 95% confidence intervals (CIs) for red blood cell transfusion during and after CPB in relation to percent hemodilution using a logistic regression model. Other independent variables were type of surgery, gender, age, hemoglobin concentration before CPB, CPB time, urine volume during CPB, and institution. Red blood cell transfusion during CPB and hemoglobin concentration after CPB were added as independent variables for the analysis of red blood cell transfusion after CPB. When trends in ORs for percent hemodilution were tested, a logistic regression model with the mean values of the categories of percent hemodilution as an independent variable was used.

Among the 3,090 subjects, the distributions of red blood cell transfusions during and after CPB and of each covariate (as shown in Table 1) in relation to the use of retrograde autologous priming were calculated and analyzed using t tests or χ^2 tests. The ORs and 95% CIs for red blood cell transfusion during and after CPB in relation to

Table 1. Characteristics of subjects according to use of retrograde autologous priming and percent hemodilution.

Characteristic	Total	Retrograde Autologous Priming			Percent Hemodilution*					
		Use	No Use	*p* Value†	<15%	15 to <20%	20 to <25%	25 to <30%	≥30%	*p* Value†
Number of subjects	3,090	207	2,883	–	249	1,065	1,099	397	73	–
Gender, %										
Male	63.3	67.6	63.0	.181	80.7	72.9	61.8	36.5	20.5	<.001
Female	36.7	32.4	37.0	–	19.3	27.1	38.2	63.5	79.5	–
Age, years	68.1 (12.0)	68.0 (10.6)	68.1 (12.1)	.911	64.3 (12.6)	66.2 (12.2)	69.3 (11.5)	71.4 (11.5)	74.1 (10.1)	<.001
Type of surgery, %										
Isolated coronary artery bypass graft	13.2	32.9	11.8	<.001	19.7	15.6	9.9	2.8	5.5	<.001
Isolated valve surgery	44.3	26.1	45.6	–	46.2	45.6	43.9	50.4	43.8	–
Coronary artery bypass graft and valve surgery	9.3	4.8	9.6	–	6.4	8.9	10.7	10.8	9.6	–
Other	33.2	36.2	33.0	–	27.7	29.9	35.6	36.0	41.1	–
Hemoglobin concentration before CPB, g/dL	11.9 (1.9)	12.8 (1.9)	11.8 (1.9)	<.001	12.4 (2.1)	12.3 (2.0)	11.6 (1.7)	11.1 (1.6)	10.4 (1.5)	<.001
Hemoglobin concentration after CPB, g/dL	9.1 (1.3)	8.6 (1.3)	9.1 (1.3)	<.001	9.1 (1.2)	9.0 (1.3)	9.2 (1.3)	9.1 (1.4)	9.6 (1.4)	.002
CPB time, minute	187.0 (82.0)	193.8 (72.2)	186.5 (82.6)	.215	196.2 (95.7)	184.5 (82.6)	186.3 (81.1)	187.2 (76.0)	180.6 (91.5)	.350
Urine volume during CPB, mL	659.4 (742.5)	421.3 (514.6)	676.5 (753.4)	<.001	650.9 (723.4)	669.0 (776.5)	688.4 (744.4)	683.7 (721.6)	655.1 (830.8)	.944
Hemodilution percent, %										
<15%	14.4	94.2	8.6	<.001	100.0	.0	.0	.0	.0	–
15 to <20%	34.7	3.9	36.9	–	.0	100.0	.0	.0	.0	–
20 to <25%	35.7	1.9	38.1	–	.0	.0	100.0	.0	.0	–
25 to <30%	12.8	.0	13.8	–	.0	.0	.0	100.0	.0	–
≥30%	2.4	.0	2.5	–	.0	.0	.0	.0	100.0	–
Use of retrograde autologous priming, %	6.7	100.0	.0	–	.0	.0	.0	.0	.0	–
Red blood cell transfusion during CPB, %	59.6	28.5	61.9	<.001	43.0	51.6	68.9	77.3	87.7	<.001
Red blood cell transfusion after CPB, %	46.1	73.9	44.1	<.001	39.0	39.3	49.4	45.8	43.8	<.001

Mean (SD).
*The analysis of percent hemodilution did not include subjects with the use of retrograde autologous priming.
†*p* value obtained by *t* test, analysis of variance, or χ^2 test.

the use of retrograde autologous priming were estimated using a logistic regression model. Independent variables were percent hemodilution and those used for the analysis of ORs of percent hemodilution. All analyses were performed using JMP® 12 (SAS Institute, Inc., Cary, NC), and a $p < .05$ was considered statistically significant.

This research was approved by the Epidemiology and Clinical Research Ethical Review Committee of Fujita Health University (date of approval: July 18, 2017).

RESULTS

This study analyzed data for a total of 3,090 subjects from 24 institutions. The mean (SD) number of subjects per institution was 128.8 (96.4). The characteristics of the subjects according to the use of retrograde autologous priming and percent hemodilution are shown in Table 1. The overall distribution of type of surgery was isolated valve surgery in 44.3%, isolated coronary artery bypass graft in 13.2%, and coronary artery bypass graft and valve surgery in 9.3%. The percentage of males was 63.3%, and the mean age was 68.1 years. The percentage of patients in each hemodilution category was <15, 14.4; 15 to <20, 34.7; 20 to <25, 35.7; 25 to <30, 12.8; and ≥30, 2.4%. Retrograde autologous priming was used in 207 cases (6.7%) and two institutions (8.3%). Overall, 1,843 patients (59.6%) received red blood cell transfusion during CPB and 1,425 (46.1%) received it after CPB, including subjects with red blood cell transfusions in both periods (938 [30.4%]).

Among the subjects without retrograde autologous priming, gender, age, type of surgery, and hemoglobin concentration before and after CPB differed significantly according to the percent hemodilution. The percentages of red blood cell transfusions during CPB for patients with <15, 15 to <20, 20 to <25, 25 to <30, and ≥30% hemodilution were 43.0, 51.5, 68.9, 77.3, and 87.7%, respectively, which were significantly different. The percentages of red blood cell transfusions after CPB ranged from 39.0 to 49.4% according to percent hemodilution, which also differed significantly.

Type of surgery, hemoglobin concentration before and after CPB, urine volume during CPB, and percent hemodilution differed significantly between patients with and without retrograde autologous priming. The percentages of red blood cell transfusion during CPB in patients with and without retrograde autologous priming were 28.5 and 61.9%, respectively, and the percentages of transfusion after CPB were 73.9 and 44.1%, respectively (both $p < .001$).

The ORs and 95% CIs for red blood cell transfusion in relation to percent hemodilution are shown in Table 2. The OR (95% CI) for red blood cell transfusion during CPB for patients with 15 to <20, 20 to <25, 25 to <30, and ≥30% hemodilution increased significantly compared with the lowest group, from 1.24 (.81–1.88), 1.90 (1.20–3.02), 2.35 (1.33–4.19), and 2.60 (.98–7.45). The OR (95% CI) for red blood cell transfusion after CPB ranged from .97 (.65–1.44) to 1.19 (.77–1.94), with no significant trend in relation to percent hemodilution.

The ORs and 95% CIs for red blood cell transfusion in relation to retrograde autologous priming are shown in Table 3. The OR (95% CI) for red blood cell transfusion during CPB in patients with compared with those without retrograde autologous priming was .25 (.07–.81), which was significantly <1. However, the OR (95% CI) for red blood cell transfusion after CPB was 1.22 (.06–8.68), which was not significant.

DISCUSSION

The results of this study represent the first analytical use of the Perfusion Case Database of the JaSECT (17,18). Percent hemodilution among Japanese patients undergoing cardiac surgery with CPB varied widely from <15 to ≥30%, and the percentage of red blood cell transfusion during CPB was high (59.6%). The Society of Thoracic

Table 2. Odds ratios of percent hemodilution for red blood cell transfusions during and after CPB.

	Dependent Variable of Red Blood Cell Transfusion during CPB*			Dependent Variable of Red Blood Cell Transfusion after CPB*		
Hemodilution Percent	OR	95% Confidence Interval	*p* Value†	OR	95% Confidence Interval	*p* Value†
<15%	1.00	–	.003	1.00	–	.616
15 to <20%	1.24	.81–1.88	–	.97	.65–1.44	–
20 to <25%	1.90	1.20–3.02	–	1.19	.77–1.84	–
25 to <30%	2.35	1.33–4.19	–	1.16	.68–1.99	–
≥30%	2.60	.98–7.45	–	1.09	.45–2.74	–

*Independent variables except percent hemodilution were type of surgery, gender, age, hemoglobin concentration before CPB, CPB time, urine volume during CPB, and institution. Red blood cell transfusion during CPB and hemoglobin concentration after CPB were added as independent variables in the analysis with red blood cell transfusion after CPB as a dependent variable.
†*p* value obtained by tests in logistic regression model with mean values of categories of percent hemodilution as independent variables.

Table 3. Odds ratios of retrograde autologous priming for red blood cell transfusions during and after CPB.

	Dependent Variable of Red Blood Cell Transfusion during CPB*			Dependent Variable of Red Blood Cell Transfusion after CPB*		
Retrograde Autologous Priming	OR	95% CI	*p* Value	OR	95% CI	*p* Value
No use	1.00	–	.025	1.00	–	.862
Use	.25	.07–.81	–	1.22	.06–8.68	–

*Independent variables except retrograde autologous priming were percent hemodilution, type of surgery, gender, age, hemoglobin concentration before CPB, CPB time, urine volume during CPB, and institution. Red blood cell transfusion during CPB and hemoglobin concentration after CPB were added as independent variables in the analysis with red blood cell transfusion after CPB as a dependent variable.

Surgeons and the Society of Cardiovascular Anesthesiologists Blood Conservation Clinical Practice Guidelines state the following: "With hemoglobin levels below 6 g/dL, red blood cell transfusion is reasonable because this can be lifesaving. Transfusion is reasonable in most postoperative patients whose hemoglobin is less than 7 g/dL but no high level evidence supports this recommendation" (13). Although the strategies for red blood cell transfusion in cardiac surgeries used by Japanese clinicians were unknown, these results may help clarify some aspects and issues relating to the current status of perfusion and blood management practice in Japan. The percent hemodilution was strongly associated with red blood cell transfusion during CPB after adjusting for other factors, including type of surgery, gender, age, and hemoglobin concentration before CPB. These associations in Japanese patients were in accord with observations in previous studies in the United States (7,8). The American Society of Extra-Corporeal Technology Standards and Guidelines for Perfusion Practice has three standards as follows: "The Perfusionist shall participate in efforts to minimize hemodilution and avoid unnecessary blood transfusions"; "The Perfusionist shall minimize the CPB circuit size to reduce prime volume"; and "The Perfusionist shall calculate and communicate to the surgical team prior to initiating CPB, a patient's predicted post-dilutional hemoglobin or hematocrit" (1,19). Our results confirmed the importance of these standards for clinical practice in Japan and suggested that optimizing the degree of hemodilution might greatly reduce the use of red blood cell transfusion during CPB (7,8).

We observed that retrograde autologous priming was only used in 8.4% of institutions and in 6.7% of total cases, supporting the idea that retrograde autologous priming is not currently common in clinical practice in Japan. The present study also showed that the use of retrograde autologous priming was significantly associated with a decrease in red blood cell transfusion during CPB. Previous studies also reported that retrograde autologous priming led to low priming volume, low hemodilution, and reduced red blood cell transfusion and was a relatively safe and easy method (9,10,20,21). The current results confirmed this association and indicated the importance of expanding the use of retrograde autologous priming in clinical practice in Japan.

The present study found no significant association between the degree of hemodilution or use of retrograde autologous priming and red blood cell transfusion after CPB, after adjusting for covariates. This was not unexpected, given that percent hemodilution and retrograde autologous priming are related to the volume of the CPB circuit, although red blood cell transfusion after CPB occurs after weaning from CPB. However, we observed a high percentage of red blood cell transfusion after CPB (46.1%), suggesting that this may have been affected by factors other than hemodilution and retrograde autologous priming (6,12).

The Perfusion Case Database of the JaSECT has been closely related to the activities of the International Consortium for Evidence-Based Perfusion (17,22). The present and further studies and analyses of this database may provide scientific evidence for improving clinical extracorporeal circulation techniques and the development of relevant guidelines in Japan (17,18).

This analysis had some limitations. First, we used data from the Perfusion Case Database of the JaSECT, which is the only nationwide perfusion database in Japan; however, the coverage of registered cases is still low (17,18), with the registered medical institutions only accounting for 5% of those that perform cardiac surgery with perfusion in Japan (17). Our results may, therefore, not be representative of nationwide cardiac surgery cases in Japan. Although the database included many items related to perfusion, not all information was available; e.g., information on the amount of fluid given by anesthesia was not included in the database and was, therefore, not available for our analysis (8). Second, this was an observational study of the associations of hemodilution and retrograde autologous priming with red blood cell transfusion, and the results might have been affected by different strategies for red blood cell transfusion in cardiac surgeries adopted by different Japanese clinicians (2,23). Third, although we adjusted for type of surgery, gender, age, hemoglobin concentration before CPB, and institution based on previous reports, possible residual confounding cannot be ruled out (7–12). Furthermore, we did not examine interactions between those

factors and hemodilution and retrograde autologous priming, and further advanced analysis is required to investigate such interactions. Fourth, only two institutions used retrograde autologous priming with cases in 2014 and 2015, and more data after 2016 need to be analyzed to understand the trend in retrograde autologous priming year over year. Fifth, we did not examine inter-institution differences in hemodilution, retrograde autologous priming, and transfusion in the present study (23). Sixth, we focused on red blood cell transfusion during or after CPB and did not analyze red blood cell transfusion after surgery. In addition, information on outcomes, including prognosis and complications, was not available (17).

CONCLUSION

Our results suggest that optimizing the percent hemodilution and use of retrograde autologous priming might greatly reduce the use of red blood cell transfusion during CPB in clinical practice in Japan.

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