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Comparison of Transfusion Requirements for Conventional and Miniaturized Extracorporeal Circuits

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ABSTRACT

Objective. Hemodilution is a well-recognized phenomenon of cardiopulmonary bypass (CPB). The degree of hemodilution has attendant risks. As the degree of hemodilution increases, red blood cell transfusions may be necessary, and the risks of blood transfusions are becoming very well recognized. Blood-conservation programs are being developed worldwide to establish strategies to reduce transfusions. Miniaturized extracorporeal circuits (MECs) are associated with less hemodilution than conventional CPB circuits. The use of MECs can be expected to be associated with fewer red blood cell transfusions.

Methods. The first 250 patients who underwent coronary artery bypass grafting, aortic valve replacement, or both with the use of a MEC were compared with 200 consecutive patients who had similar comorbidities and types of surgery but underwent their operations on a conventional bypass circuit. These surgeries were completed between April 2004 and September 2005 under the care of the same surgical team. The minimum acceptable hematocrit on bypass was 22%. Intra- and postoperative transfusion rates were measured and compared.

Results. For conventional bypass, the intraoperative transfusion rate was 36.5%, whereas the rate for the MEC was 23.3%. The postoperative transfusion rate was 55% for operations performed with conventional bypass and 26% for the MEC. The overall in-hospital transfusion rate for conventional bypass was 63% and 36% for the MEC.

Conclusions. The data indicate that use of MECs leads to a lower transfusion rate than in surgeries in which conventional CPB is used.

INTRODUCTION

Hemodilution is a widely recognized and documented consequence of cardiopulmonary bypass (CPB). In an effort to reduce hemodilution and it consequences, miniaturization of the extracorporeal circuit has been introduced. Blood transfusions have been shown to increase morbidity and mortality after cardiac surgery [Engoren 2002]. Blood transfusions are associated with negative effects on health-related quality-of-life indicators after cardiac surgery [Koch 2006]. Transfusions have been related to increases in wound infections, pneumonia, renal dysfunction, and many other problems [Ranucci 1994; Zacharias 1996; Michalopoulos 1998; Leal-Noval 2000]. The Society of Thoracic Surgeons blood conservation guideline task force recommends the use of devices that conserve blood [Ferraris 2004]. Blood conservation strategies are recognized to have a positive impact on outcomes in cardiac surgery.

Miniaturization of the CPB circuit is expected to substantially reduce hemodilution associated with CPB compared with conventional CPB (CCPB). The miniaturized extracorporeal circuit (MEC) requires a smaller priming volume than conventional systems because of its closed system design, tubing length, and volume.

Our investigation was intended to evaluate differences in transfusion rates between the 2 systems.

MATERIALS AND METHODS

From April 2004 to September 2005, we evaluated 250 consecutive patients who were maintained on a MEC after we excluded an initial experience with 20 patients. We compared these 250 patients with 200 consecutive patients who were maintained on a CCPB circuit for similar surgeries during the same study period, and we evaluated patient characteristics with respect to their preoperative characteristics (Table 1). This retrospective study compared rates of red blood cell transfusions for these 2 groups of patients. After comparing the overall transfusion rates for the 2 groups, we divided the patient groups into 2 groups on the basis of preoperative hematocrit values (>35% or ≤35%).

The MEC consists of a tip-to-tip Carmeda-coated circuit, including cannulae, tubing, oxygenator, and centrifugal-pump head (Table 2). There was no venous reservoir or cardiotomy suction. The system is closed, has an active air-removal device, and uses kinetic venous drainage. The MEC requires a net priming volume of only 400 mL after retrograde

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Table 1. Preoperative Characteristics of the Patients*

	CCPB (n = 200)	MEC (n = 250)	*P*
Age, y	64 ± 11.89	65 ± 10.73	.147
Body surface area, m^2	2.03 ± 0.26	2.005 ± 0.23	.304
Preoperative creatinine, mg/dL	1.0 ± 0.27	1.1 ± 0.58	.322
Male sex, %	72	72	1.00
Diabetes, %	30	36	.153
Tobacco use, %	47	51	.423
Anticoagulant use, %	28	29	.780
Pre-bypass hematocrit, %	35 ± 5.4	35 ± 5.3	.989

*Data are presented as the mean ± SD where appropriate. CCPB indicates conventional cardiopulmonary bypass; MEC, miniaturized extracorporeal circuit.

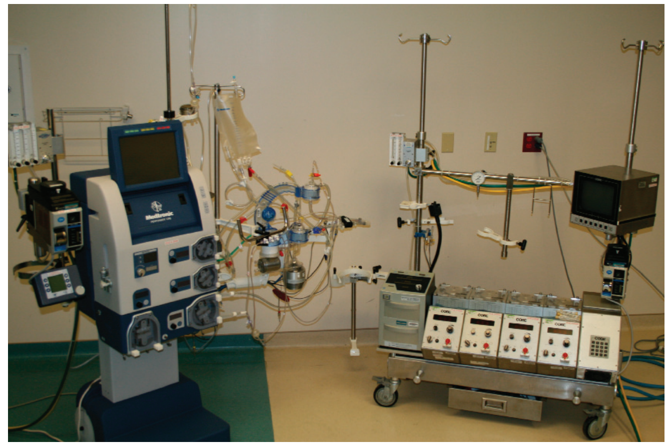

Figure 1. Miniaturized extracorporeal circuit and conventional cardiopulmonary bypass machines.

autologous priming. For the MEC Resting Heart System (Medtronic, Minneapolis, MN, USA), we used a triple-stage 29F cannula in patients who weighed <100 kg. For heavier patients, we used an oval 29/37F 2-stage cannula until the bulgy-basket 29/29/37F 3-stage cannula became available, at which time it became our cannula of choice. There was always an aortic root vent, and it was connected directly to the inflow line to the venous air-removal device. A cell saver was used for the entire surgery.

In comparison, the CCPB system has Carmeda-bonded tubing and an oxygenator and has an uncoated open venous reservoir (Table 2). The net priming volume for the CCPB is 1.4 L. Cardiotomy suction was available during the cross-clamp period only, and the cell saver was used for the entire surgery. We used a 36/46F 2-stage cannula for venous cannulation for CCPB in patients weighing <100 kg and used a 36/51F cannula in patients weighing >100 kg. Venous drainage was by gravity (Figure 1).

Heparin was administered intra-atrially in preparation for CPB at a dose of 2.0 mg/kg. Aprotinin was administered before

Table 2. Comparison of Conventional Cardiopulmonary Bypass (CCPB) and the Miniaturized Extracorporeal Circuit (MEC)

	CCPB	MEC
Priming volume, mL	1400	400
Open cardiotomy	Open noncoated	None
Oxygenator	Trillium-coated Affinity*	Carmeda-coated
Centrifugal head	Biomedicus	Biomedicus
Arterial filter	38 µm, coated	38 µm, coated
Cardiotomy suction	Available	Not available
Aortic root vent	Available	Available
Venous tubing	½ in, Carmeda-coated	⅜ in, Carmeda-coated
Arterial tubing	⅜ in, Carmeda-coated	⅜ in, Carmeda-coated
Venous drainage	Gravity	Kinetic
Air-removal device	None	Available

*Medtronic.

(2 million IU) and during (2 million IU) CPB. CPB was initiated when the activated clotting time reached 400 seconds. Indexed pump outputs were maintained at 2.4 L/min per m^2. The bladder temperature was maintained at 34°C.

Surgeries included for this study were coronary artery bypass, aortic valve surgery, and combined aortic valve/coronary artery bypass surgery. They were completed through a standard sternotomy except for the isolated aortic valve surgeries, which were performed through an upper sternotomy from the sternal notch to the third or fourth interspace. Mitral surgeries were not included because of the potential for venous air, the need for a reservoir, and the expected differences in technical complexity. All surgeries were performed by the same operating team. Coronary artery bypass surgery accounted for 78% of the surgeries in each group (156/200 in the CCPB group and 195/250 in the MEC group). Aortic valve surgery accounted for 14% (35/250) of the surgeries in the MEC group and 10% (20/200) of the surgeries in the CCPB group. Combined aortic valve/coronary artery bypass surgery accounted for 8% (20/250) of the surgeries in the MEC group and 12% (24/200) of the surgeries in the CCPB group (Figure 2).

The activated clotting time was checked every 15 minutes and maintained at >400 seconds. The surgeries followed routine procedures. Patients were warmed to 36°C prior to weaning from CPB. Once CPB had been terminated, all venous blood was directly reinfused for MEC patients. For heparin reversal, protamine was administered intra-aortically at a ratio of 0.7:1 (protamine to heparin). The arterial blood was reinfused at this time. Hematocrit levels were checked via point-of-care testing after the induction of anesthesia and every 15 minutes thereafter until termination of bypass. The hematocrit was checked again at incision closure.

Intraoperative transfusion was triggered by a hematocrit value of 21% or as part of a cerebral oximetry protocol [Goldman 2004]. Once the patient had been transferred from the operating room to the postoperative care areas (intensive care unit and telemetry), our transfusion criteria were related to the treatment of hypotension and oxygen-delivery issues.

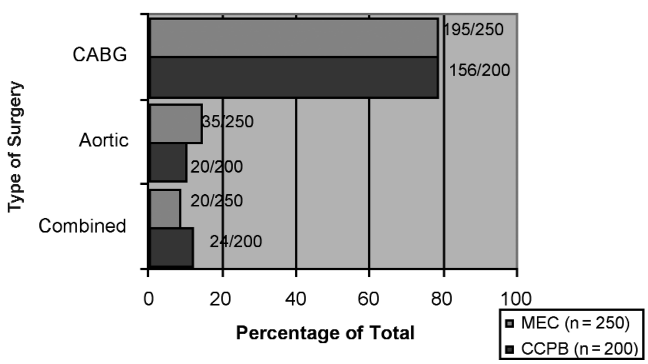

Figure 2. Type of surgery. CABG indicates coronary artery bypass grafting; MEC, miniaturized extracorporeal circuit; CCPB, conventional cardiopulmonary bypass.

Two-sample Student *t* tests were used for statistical analysis. In this study, we compared red cell transfusion rates independent of the use of other products; our purpose was to evaluate red cell transfusion requirements for patients maintained on 2 different CPB systems—a conventional circuit and a MEC.

RESULTS

Transfusion data were examined for both MEC and CCPB patients and were first analyzed with respect to intraoperative, postoperative, and overall transfusion rates (Figure 3).

With equal preoperative hematocrit levels, the 2 groups exhibited a statistically significant difference in transfusion rates. Intraoperatively, 37.5% (75/200) of the CCPB patients received transfusions, whereas only 23.3% (58/250) of MEC patients received transfusions. Postoperatively, 55% (110/200) of CCPB patients received transfusions, whereas only 26% (65/250) of MEC patients received transfusions. Sixty-three percent (127/200) of CCPB patients received a transfusion either during or after surgery, whereas 36% (93/250) of MEC patients received a transfusion during or after surgery (Table 3).

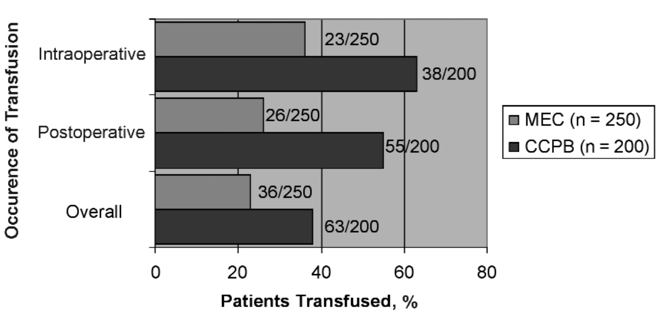

Figure 3. Comparison of transfusion rates. MEC indicates miniaturized extracorporeal circuit; CCPB, conventional cardiopulmonary bypass.

Table 3. Comparison of Transfusion Rates*

	CCPB (n = 200), % (n)	MEC (n = 250), % (n)	*P*
Intraoperative	38 (75)	23 (58)	<.001
Postoperative	55 (110)	26 (65)	<.001
Overall	63 (127)	36 (93)	<.001

*CCPB indicates conventional cardiopulmonary bypass; MEC, miniaturized extracorporeal circuit.

Subdividing the groups on the basis of pre-CPB hematocrit values revealed a trend toward a reduction in transfusion rates. We used a pre-CPB hematocrit value of 35% to separate the 2 groups. This value was based on the expected hematocrit reaching the transfusion trigger after the initiation of bypass [Helm 1998].

Patients with hematocrit values ≤35% also had a reduction in the transfusion rate (Table 4). Intraoperatively, 63% (62/98) of CCPB patients received transfusions, whereas only 32% (40/124) of MEC patients received transfusions. Postoperatively, 69% (68/98) of CCPB patients were transfused, and only 33% (41/124) of MEC patients were transfused. For CCPB patients, Eight-five percent (83/98) of CCPB patients received a transfusion either intraoperatively or postoperatively, whereas only 48% (60/124) of MEC patients received a transfusion during or after surgery (Figure 4).

Patients who had pre-bypass hematocrit levels >35% had the following transfusion characteristics (Table 5): Intraoperatively, CCPB patients had a transfusion rate of 13% (13/102), and MEC patients had a transfusion rate of 14% (18/126). Postoperatively, 41% (42/102) of the CCPB patients were transfused, whereas only 19% (24/126) of the MEC patients were transfused. Forty-three percent (44/102) of CCPB patients received a transfusion during or after surgery, whereas 26% (33/126) of MEC patients received a transfusion during or after surgery (Figure 5).

Of the 200 patients in the CCPB group, 127 received a total of 642 units of red blood cells for an overall rate of 3.2 units per patient. In the MEC group, however, 93 of the 250 patients in the MEC group received a total of 296 units of red blood cells, for an overall rate of 1.2 units per patient. A considertion of the transfused patients alone reveals that the 127 transfused patients in the CCPB group who received a total of 642 units received transfusions at a rate of 5.1 units per transfused patient and that the 93 transfused patients in

Table 4. Transfusion Rates for Patients with Hematocrits ≤35%*

	CCPB (n = 98), % (n)	MEC (n = 124), % (n)	*P*
Intraoperative	63 (62)	32 (40)	<.001
Postoperative	69 (68)	33 (41)	<.001
Overall	85 (83)	48 (60)	<.001

*CCPB indicates conventional cardiopulmonary bypass; MEC, miniaturized extracorporeal circuit.

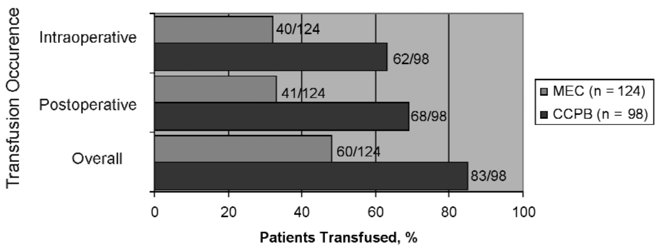

Figure 4. Transfusion rates for patients with hematocrits ≤35%. MEC indicates miniaturized extracorporeal circuit; CCPB, conventional cardiopulmonary bypass.

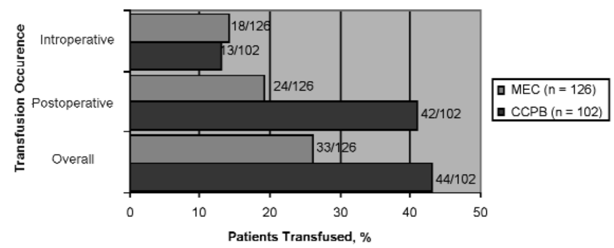

Figure 5. Transfusion rates for patients with hematocrits >35%. MEC indicates miniaturized extracorporeal circuit; CCPB, conventional cardiopulmonary bypass.

the MEC group (296 units total) received transfusions at a rate of 3.2 units per transfused patient (Table 6).

Examination of the complication rates for the 2 groups (Table 7) reveals that the kinds and frequencies of complications were similar with no statistically significant differences. There were 2 deaths each among the 200 patients in the CCPB group and the 250 patients in the MEC group. One stroke occurred in the CCPB group, and there were no strokes in the MEC group. The elevations in creatinine concentration in the 2 groups were similar, and, more importantly, no patient in either group required dialysis (Table 7).

DISCUSSION

Hemodilution is a well-documented consequence of CPB. The Medtronic Resting Heart System seeks to reduce the effects of hemodilution by miniaturizing the extracorporeal circuit. The reduced hemodilution associated with the miniaturized system produces a reduced requirement for blood transfusions. This reduction is seen in our comparison of the 2 groups of patients in this study. The reduction in the transfusion rate in the MEC group can be attributed to the miniaturization of the extracorporeal circuit.

Notably, intraoperative transfusion rates were not different for patients who were not anemic. This observation is easily understood by the fact that these patients had hematocrits sufficiently high that the usual hemodilution produced by the circuits was not large enough to prompt initiating a transfusion.

Not only did fewer patients in the MEC group receive transfusions, but the MEC patients who did receive transfusions also were administered fewer units of blood per transfusion than transfused patients in the CCPB group. The number of units administered per patient decreased dramatically in the MEC group compared with the CCPB group. Only 3.2 units were used per patient in the MEC group, compared with 5.1 units per patient in the CCPB group. Overall, 3.2 units of blood were needed per patient in the CCPB group, whereas only 1.2 units of blood per patient were needed in the MEC group.

Abdel-Rahman et al [2005] reported that they experienced no clinical benefit with a MEC; however, their report did verify the safety of the device. We believe these investigators failed to achieve statistical significance because of their relatively small sample size (only 40 patients). Our experience included a learning curve with surgeries on 20 patients, in which all of the perfusionists participated. This experience allowed an open discussion of the technical aspects of the device's function, which we believe shortened our learning curve. In fact, if we eliminate the first 70 patients by treating them as cases in a larger learning curve and then divide the last 200 patients into 2 groups of 100, we achieve a greater reduction in transfusion requirements. We believe this reduction to be related to our increased exposure to the device. There are diminishing returns in this approach; hence, there is a point below which no further reduction in transfusion rate can be achieved. We believe, however, that our experience with a learning curve of 20 patients, allowed us to attain significant increases in clinical benefits.

In a study of blood loss and transfusion requirements, Nollert et al [2005] reported that their use of a MEC did not lead to clinically relevant changes. Their study was

Table 5. Transfusion Rates for Patients with Hematocrits >35%*

	CCPB (n = 102), % (n)	MEC (n = 126), % (n)	P
Intraoperative	13 (13)	14 (18)	NS
Postoperative	41 (42)	19 (24)	<.001
Overall	43 (44)	26 (33)	<.001

*CCPB indicates conventional cardiopulmonary bypass; MEC, miniaturized extracorporeal circuit; NS, not statistically significant.

Table 6. Total Transfusion Requirements*

	CCPB	MEC
Intraoperative, units	184	116
Postoperative, units	458	184
Total, units	642	300
Units/patient	3.2	1.2
Units/transfused patient	5.1	3.2

*CCPB indicates conventional cardiopulmonary bypass; MEC, miniaturized extracorporeal circuit.

Table 7. Postoperative Complications*

	CCPB (n = 200), %	MEC (n = 250), %
Death	1	0.8
Stroke	0.5	0
Renal failure	1.5	2
Require dialysis	0	0
Atrial fibrillation	18	12
Sternal infections	0	0
Reoperation for bleeding	1	1.2

*CCPB indicates conventional cardiopulmonary bypass; MEC, miniaturized extracorporeal circuit.

terminated after 2 incidents of air entry into the closed circuit. Our system included an active air-removal device. Air entrained through the venous line originates from suture holes at the venous cannulation site or the retrograde coronary sinus cannula (if used) and is certainly dependent on the negative pressure of the kinetic venous drainage. The placement of partial-thickness pursestring sutures at the cannulation sites was part of the learning curve for the surgeons. Avoiding full-thickness sutures is sometimes not possible because of the thinness of the atrial wall. In these cases, we discovered that felt pledgeted pursestrings or a free silk ligature around the cannulation site was an effective, expeditious, and simple resolution of this issue. The perfusion staff must balance the negative pressure of the kinetic venous drainage against the volume status of the patient. Once this balance has been established, the pressure will be dependent on the changes in heart position during various exposures. The safety feature of the in-line venous air-removal device is the third line of defense against the aspiration of any venous air.

Beghi et al [2006] reported that their experiences with a MEC gave good results, including good hemodynamic support, safety, and low morbidity [Ferraris 2004]; however, their study did not demonstrate the miniaturized system to be superior to the CCPB system. These investigators also discussed that the size of their study population (30 patients in the test group and 30 patients in the control group) limited their ability to solidly confirm their results. We support these investigators' conclusions of the good clinical benefits of a MEC. Our results with a larger number of patients confirm the superiority of the miniaturized system to the conventional system with respect to the criteria of blood transfusion requirements.

Folliguet et al [2003] described a series of 279 consecutive patients who underwent coronary artery bypass surgery. These investigators selected 40 MEC patients and compared them with 40 matched control patients who underwent operations that used an open conventional system. They found no statistically significant difference in transfusion rate. Thirty-four percent of the MEC patients received transfusions, and 29.7% of the control patients received transfusions. This result was obtained despite a significantly higher ($P < .001$) perioperative hemoglobin concentration in the MEC group. The investigators appropriately noted the roles of the anesthesiologists and pump technicians.

We continue to use the MEC for all of our surgeries. As we have gained further experience, we have expanded the role of this device to include all mitral surgeries and thoracic aorta surgeries, including those requiring circulatory arrest; however, for mitral valve and thoracic aorta surgeries, we have adapted a coated reservoir for use.

This series is the largest known data set to date that has compared transfusion data for a MEC (Medtronic's Resting Heart System) and a CCPB circuit. In conclusion, our data support the use of a miniaturized circuit for reducing hemodilution and blood transfusion requirements in open heart surgery.

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