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A Clinical Comparison of Two Commercially Available Pediatric Hemoconcentrators

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Abstract: Hemoconcentration is a technique that involves selective removal of plasma water and some dissolved solutes by way of an ultrafiltration membrane. Hemoconcentrators (HC) are routinely used during pediatric cardiopulmonary bypass (CPB) to remove free plasma water and various inflammatory mediators. This paper examines two different commercial HCs, the Dideco DHF0.2 and the Minntech Hemocor HPH® 400. Both products were evaluated when used for prebypass ultrafiltration (Pre-BUF), and postbypass modified ultrafiltration (MUF). Five HCs were evaluated for each product, and the two groups were compared during the two different phases of the cardiac procedure. During the pre-BUF period, both groups of HCs were tested at a transmembrane pressure (TMP) gradient of 500 millimeters of mercury (mmHg). The mean amount of ultrafiltrate (UF) removed by the Dideco DHF0.2 was 81.4 milliliters per minute (mL/min), and the mean amount of UF removed by the Minntech Hemocor HPH 400 was 90.8 mL/min during the pre-BUF period. During the peribypass period flow parameters were much harder to define. As a result, these data are not reported. During the MUF procedure, the mean amount of UF removed by the Dideco DHF0.2 was 74.2 mL/min at an average MUF flow rate of 130 mL/min. The mean amount of UF removed by the Minntech Hemocor HPH 400 was 81.4 mL/min at an average MUF flow rate of 127 mL/min. Both products performed adequately under the clinical circumstances described above. The Minntech HPH 400 produced a hemofiltrate that was consistently tinged with a slight red color. The Dideco DHF0.2 consistently produced a hemofiltrate that was noticeably clearer than that of the Minntech device. **Keywords:** hemoconcentrator, hemofiltration, pediatric, cardiopulmonary bypass. *JECT. 2004; 36:66–68*

Ultrafiltration is a convective process wherein blood is pumped through a microporous membrane. Particles in the blood with a molecular mass less than the pore size are filtered at a rate proportional to a transmembrane pressure (TMP) gradient. Ultrafiltration membranes that are used in hemofilters allow the passage of molecules with a molecular weight of less than ~50,000–65,000 Daltons. Thus, ions and small chemicals present in plasma are filtered freely. Molecules that are bound to plasma proteins would not be filtered effectively by an ultrafiltration membrane. In 1928, Brull (1) first introduced the concept of removing excess fluid from the intravascular space in patients with renal failure by the filtration of blood through an ultraporous membrane. In 1976, Romagnoli et al. first reported the use of hemoconcentrators (HC) in open-heart surgery (2). A 1996 report stated that over 90% of United States and Canada pediatric centers incorporated HCs into their cardiopulmonary bypass (CPB) circuits (3). Currently, HCs are used in pediatric CPB circuitry to reduce inflammatory mediators, plasma water, and to concentrate plasma proteins (4–7). Commercially available products are currently offered in a wide variety of sizes and materials. Two HCs used primarily for pediatric CPB, the Dideco DHF0.2 (Dideco/Cobe Cardiovascular, Inc., Arvada, CO) and the Minntech Hemocor HPH 400 (Minntech Corporation, Minneapolis, MN), were evaluated at this institution. Both brands of HCs are dry prime units and do not require rinsing before use. Both HCs were evaluated before and after CPB. Table 1 compares the product specifications of both products.

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MATERIALS AND METHODS

Ten patients were randomly assigned to two different groups of five each and the two groups were compared during two different phases of the cardiac procedure. Group 1 was identified as the DHF0.2 group and Group 2 was deemed the HPH 400 group. Both groups of HCs were crystalloid primed before use. Patients eligible for this evaluation were limited to those under 8 kg in weight who would need CPB for correction of their cardiac anomalies. Individual patient parameters are shown in Table 2 for each of the two groups. A Jostra HL-20 heart–

Table 1. Product specifications.

	Dideco DHF0.2	Minntech HPH 400®
Prime volume	30 mL	27 mL
Surface area	0.25 m^2	0.30 m^2
Material	Polyethersulfone	Polysulfone
Pressure drop	50 mm Hg	61 mm Hg
Maximum TMP*	500 mm Hg	500 mm Hg

*TMP = transmembrane pressure.

lung machine (Jostra AG, Lund, Switzerland) was used for all 10 of the patients studied. The CPB circuitry was identical for both groups except for the HC used. The circuits used consisted of a Dideco Lilliput one (D901) hard-shell oxygenator with a ¼-inch pump boot, a 3/16-inch arterial line with a Dideco Infant (D736) arterial line filter (ALF), and a ¼-inch venous line. Blood was shunted off the ALF purge line into the HC and then back into the venous reservoir. A negative vacuum pressure of –200 mm Hg was applied to the effluent side of the HC. The CPB circuit was primed in the normal fashion, and 100 mL of packed red blood cells were added to the circuit.

During the pre-BUF phase, the blood prime was recirculated through the HC at a flow rate yielding an HC inlet line pressure of 300 mm Hg. As hemofiltrate was removed from the CPB circuit, aliquots of a pre-BUF solution (1000 mL Normosol R with 25 mEq of $NaHCO_3$ and 500 IU of heparin) were infused into the circuit to replace the effluent. When the pre-BUF solution had been rinsed through the circuit, the HC effluent line was clamped, and the pre-BUF phase was considered terminated. The time it took to complete the pre-BUF phase, and the amount of UF removed was noted. The ultrafiltration rate of the device was determined by dividing the amount of UF removed by the time it took to complete the pre-BUF phase.

Table 3. Patient data.

	Group 1 (n = 5)	Group 2 (n = 5)	P-Value
Age (months)	3.8 ± 4.9	1.4 ± 1.8	0.35
Weight (kg)	4.5 ± 1.7	4.5 ± 1.5	0.97
Height (cm)	55.6 ± 8.1	55.4 ± 6.4	0.97
Male (%)	60	80	
CPB time (min)	126 ± 35.2	109.6 ± 48.3	0.56
Cross clamp time (min)	47.3 ± 26.7	59.7 ± 9.7	0.44
DHCA (min)	6.5 ± 3.5	4.0	

At the end of CPB and when the MUF circuit was established, MUF was instituted. Arteriovenous MUF was used via the cardioplegia circuit; the perfusionist determined the cut-off point for MUF termination by assessing when the pump circuit had been adequately rinsed, clearing it of residual blood. The MUF time, MUF flow rate, and amount of UF removed were noted and used to calculate the ultrafiltration rate of the devices during MUF. The color and appearance of the UF removed were noted during both the pre-BUF and MUF phases. Care was taken not to exceed a TMP of 500 mm Hg for either device during any of the surgical phases.

The data were expressed as means ± standard deviation. Comparison between the two groups was done utilizing the Student's t-test. A p-value of less that .05 was considered significant.

RESULTS

The two different groups' patient demographics are compared in Table 3. There were no significant differences between the groups with respect to the patient's physical characteristics or CPB parameters. The results of UF rate for both groups are presented in Table 4. There

Table 2. Demographic data.

Group 1: Dideco DHF0.2							
Age (m)	Sex	Wt. (kg)	Ht. (cm)	CPB	XCl	DHCA	Repair
0.13	f	3.8	51	144	47	4	Interrupted Ao. Arch
0.17	m	3.2	51	176	62	9	Stage 1 Norwood
12	f	7.3	70	86	10		Bidirect. Glenn
4	m	5	54	120			Bilat. Bidirect. Glenn
2.5	m	3.3	52	104	70		VSD
Group 2: Minntech HPH 400							
Age (m)	Sex	Wt. (kg)	Ht. (cm)	CPB	XCl	DHCA	Repair
2	m	5.6	59	100	49		Repair of TOF
0.37	f	3.5	51	135	62		Stage 1 Norwood
0.1	m	4.2	55	51			RVOT patch, B-T shunt
4.38	m	6.4	64	85			Bidirect. Glenn
0.27	m	2.7	48	177	68	4	Stage 1 Norwood

Times for CPB, cross clamp (XCl), and deep hypothermic circulatory arrest (DHCA) are reported in minutes.

Table 4. Ultrafiltration data.

	Group 1 (n = 5)	Group 2 (n = 5)	p-Value
PreBUF UF rate (mL/min)	81.4 ± 29.3	90.8 ± 20.4	0.57
MUF UF rate (mL/min)	74.2 ± 17.4	81.4 ± 16.0	0.51

was no significant difference in UF rate in either the preBUF or MUF phases of the observation. The Minntech HPH 400 removed a slightly larger amount of UF than the Dideco DHF0.2 in both phases, but this amount was neither clinically nor statistically significant. The observation of a reddish tinge in the UF of the Minntech HPH 400 is interesting, but this finding needs further investigation as to its significance. Table 5 shows patient outcome data. There were no significant differences in outcomes for the two groups; however, with such a small *N* the study lacks power to judge these outcome data adequately.

DISCUSSION

The inflammatory effects of CPB can be profound, especially in neonates and infants (8). A variety of therapies have been developed to ameliorate the systemic inflammatory response to CPB (9–11). Ultrafiltration is among the therapies credited with reducing inflammatory reactions in children (12, 13). Children are greatly affected by hemodilution and the large amount of pediatric CPB circuit surface area (14). Current pediatric CPB circuit volume can be two to three times the size of a small neonate's circulating blood volume, making the hemoconcentrator a very important component of the pediatric CPB circuit. The Dideco DHF0.2 pediatric hemoconcentrator is new to the CPB marketplace; therefore, the authors compared it to a more familiar device, the Minntech HPH 400. At the time of the study, the Dideco device was not yet released for general distribution.

Both HC performed as expected, with the Minntech device having a slightly better UF rate. The Minntech device has a larger pressure drop, which would produce a higher UF rate, but this may have also been the reason that the device consistently produced an ultrafiltrate that was slightly red in color. The color of the ultrafiltrate is suspicious and may indicate trauma to red blood cells, but further testing needs to be performed to confirm this theory.

Table 5. Postoperative data.

	Group 1	Group 2	*P*-Value
Time on inotropes	4.2 ± 2.5	5.9 ± 4.8	0.50
Time intubated	6.7 ± 9.8	7.7 ± 6.4	0.86
Unit time	13.2 ± 12.7	9.7 ± 7.8	0.61
Hosp. LOS	19.3 ± 15.2	14.9 ± 10.0	0.60
Pt. charges	$134,819.24	$138,132.96	0.96

Time on Inotropes, time intubated, time in the pediatric intensive care unit, and hospital length of stay (Hosp. LOS) are reported in days.

In conclusion, the Dideco DHF0.2 hemoconcentrator performed adequately under clinical conditions. The Dideco device compared favorably to the Minntech HPH 400, a more familiar device at this institution. The observation that the Dideco DHF0.2 produced a consistently clearer ultrafiltrate than the Minntech HPH 400 may be attributable to a lower pressure drop across the device.

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REFERENCES

1. Brull L. Realization de l' ultrafiltration in vivo. C R Soc Biol. 1928; 99:1605–08.
2. Romagnoli AHJ, Keats A, Milam J. External hemoconcentration after deliberate hemodilution. Abstracts of Scientific Papers. American Society of Anesthesiologists Annual Meeting. 1976;269–70.
3. Groom RCAB, Albus R, Lefrak EA. Pediatric cardiopulmonary bypass: A review of current practice. Interna Anesth Clin. 1996;34: 141–63.
4. Kern F, Schulman S, Lawson D, Darling E. Pediatric cardiac anesthesia. In: Extracorporeal Circulation and Circulatory Assist Devices in the Pediatric Patient. Lake C, ed.. Stamford, CT:Appleton & Lange. 1998:219–58.
5. Bouman C, van Olden RW, Stoutenbeek CP. Cytokine filtration and adsorption during pre- and postdilution hemofiltration in four different membranes. Blood Purif. 1998;16:261–68.
6. Darling E, Shearer I, Nanry K, et al. Modified ultrafiltration in pediatric cardiopulmonary bypass. J ExtraCorp Technol. 1994;26:205–09.
7. Darling E, Nanry K, Shearer I, Kaemmer D, Lawson S. Techniques of paediatric modified ultrafiltration: 1996 survey results. Perfusion. 1998;13:93–103.
8. Wan S, LeClerc JL, Vincent JL. Inflammatory response to cardiopulmonary bypass: Mechanisms involved and possible therapeutic strategies. Chest. 1997;112:676–92.
9. Lodge AJ, Chai PJ, Daggett CW, Ungerleider RM, Jaggers J. Methylprednisolone reduces the inflammatory response to cardiopulmonary bypass in neonatal piglets: Timing of dose is important. J Thorac Cardiovasc Surg. 1999;117:515–22.
10. Molicki JS, Draaisma AM, Verbeet N, et al. Prime solutions for cardiopulmonary bypass in neonates: Antioxidant capacity of prime based on albumin or fresh frozen plasma. J Thorac Cardiovasc Surg. 2001;122:449–56.
11. Lau CL, Posther KE, Stephenson GR, et al. Minicircuit cardiopulmonary bypass with vacuum assisted venous drainage: Feasibility of an asanguineous prime in the neonate. Perfusion. 1999;14: 389–96.
12. Gaynor JW. Use of ultrafiltration during and after cardiopulmonary bypass in children. J Thorc Cardiovasc Surg. 2001;122:209–11.
13. Shimpo H, Shimamoto A, Sawamura Y, et al. Ultrafiltration of the priming blood before cardiopulmonary bypass attenuates inflammatory response and improves postoperative clinical course in pediatric patients. Shock. 2001;16:51–4.
14. Skaryak LA, Lodge AJ, Kirshbom PM, et al. Low-flow cardiopulmonary bypass produces greater pulmonary dysfunction than circulatory arrest. Ann Thorac Surg. 1996;62:1284–8.