SURGERY FOR CONGENITAL HEART DISEASE

PULMONARY FUNCTION AFTER MODIFIED VENOVENOUS ULTRAFILTRATION IN INFANTS: A PROSPECTIVE, RANDOMIZED TRIAL

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Objective: **We sought to examine the effects of modified venovenous ultrafiltration after cardiopulmonary bypass on pulmonary compliance in infants.** ***Methods:*** **We prospectively enrolled 38 infants undergoing their first operation for congenital heart disease. Infants were randomized to receive 20 minutes of modified ultrafiltration after bypass or control. Static and dynamic compliance was measured after induction of anesthesia, before and immediately after filtration in the operating theater, 1 hour after return to the pediatric intensive care unit, and 24 hours after the operation. Length of time on the ventilator, inotropic requirements, and length of stay in the intensive care unit were recorded.** ***Results:*** **Modified ultrafiltration produced a significant immediate improvement in dynamic (pre-ultrafiltration 2.5 ± 1.9 mL/cm H_2O to post-ultrafiltration 2.9 ± 2.7 mL/cm H_2O, *P* = .03) and static (pre-ultrafiltration 2.1 ± 0.9 mL/cm H_2O to post-ultrafiltration 2.9 ± 2.1 mL/cm H_2O, *P* = .04) compliance. However, there was no significant difference in the change in dynamic (*P* = .3) or static (*P* = .7) compliance in the ultrafiltration and control groups when compared before the operation, after the operation, and at 24 hours. There was no significant difference in the time to extubation between patients and control subjects (140 ± 91 hours vs 90 ± 58 hours) or the length of intensive care unit stay (10.0 ± 9.1 days vs 7.4 ± 5.7 days).** ***Conclusions:*** **Modified ultrafiltration produces an improvement in pulmonary compliance after bypass in infants. However, these improvements are not sustained past the immediate post-ultrafiltration period and do not lead to a decreased length of intubation or intensive care unit stay. (J Thorac Cardiovasc Surg 2000; 119:501-7)**

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Cardiopulmonary bypass (CPB) is associated with an inflammatory response that results in tissue edema and organ dysfunction primarily involving the heart, lungs, kidneys, and brain.[1] Chemical mediators, including cytokines, have been implicated in this proinflammatory state. Recently, modified ultrafiltration (MUF) has been used as a method to reduce circulating cytokines after CPB and decrease their undesirable side effects.[2]

MUF is a process that removes water and low-molecular-weight substances under a hydrostatic pressure gradient.[3] It is carried out after weaning from CPB but before administration of protamine.[4] MUF has been shown to induce hemoconcentration, reduce bleeding, and decrease total body water in the pediatric patient.[5] The CPB-induced inflammatory state is thought to be

Table I. *Diagnoses of children in MUF and control groups*

	MUF (n = 19)	*Control (n = 19)*
Ventricular septal defect	2	5
Transposition of the great vessels	4	3
Atrial ventricular canal	1	1
Truncus arteriosus (type I)	1	0
Tetralogy of Fallot	1	2
Total anomalous pulmonary venous return	1	0
Hypoplastic left heart syndrome	2	3
Tetralogy of Fallot with pulmonary atresia	1	0
Coarctation of the aorta and ventricular septal defect	2	0
Ventricular septal defect with pulmonic stenosis	1	1
Double-outlet right ventricle and coarctation of the aorta	1	0
Atrial septal defect and ventricular septal defect	1	0
Transposition of the great vessels and truncus arteriosus	0	1
Mitral valve repair	0	1
Double-outlet right ventricle, coarctation of the aorta, transposition of the great vessels, and ventricular septal defect	0	1
Cor triatriatum	0	1
Aortic and subaortic stenosis	1	0

greater in pediatric patients.[6] Infants are at special risk of an accentuated inflammatory response because of their size, hemodilution, prolonged bypass times, and complex operations requiring extreme degrees of hypothermia.[7]

Clinically, pulmonary dysfunction may be the most common manifestation of the post-CPB inflammatory response.[8] This may adversely affect cardiopulmonary interactions after surgery, delaying extubation and discharge from the intensive care unit. Several investigators have shown that ultrafiltration produces immediate improvement in pulmonary function in children[9] and may lead to a shorter ventilatory course and possibly a shorter pediatric intensive care unit (PICU) stay.[5,10] However, these studies have primarily concentrated on short-term outcomes or have included a broad range of patient ages and weights. This has made it difficult to assess the clinical effect of ultrafiltration on the high-risk infant population.

The purpose of this prospective, randomized controlled study was to compare postoperative pulmonary compliance in infants undergoing MUF after CPB to control post-CPB infants who did not undergo MUF. Patients were followed up to determine whether any improvement in pulmonary compliance persisted beyond the immediate postoperative period and whether this resulted in earlier extubation or discharge from the PICU.

Methods

This study was approved by the Institutional Review Board of Children's Hospital and Medical Center (Seattle, Wash). A power analysis indicated that 15 patients would be needed in each group to show a 20% difference in pulmonary compliance by using a 2-sided significance level of 5% ($\alpha = .05$) with power set at 80% ($\beta = .8$). Patients less than 1 year of age who required CPB for a primary operation for congenital heart disease were eligible for the study. Infants with a pre-existing coagulation disorder, evidence of sepsis, or pre-existing pulmonary disease were excluded from the study. There were 157 patients less than 1 year of age who had open cardiac operations during the study period. Of this group, 43 families had consent requested, and 3 families refused consent. There were 31 patients ineligible for the study because of previous cardiac surgery; 23 patients were not eligible because of sepsis, coagulation disorders, or pre-existing lung disease. Seven patients did not have consent requested because the surgical case was very small (atrial septectomy). The remaining 53 patients were operated on as emergencies, second cases, or on the weekend; thus the laboratory was unable to accommodate cytokine specimens for the other arm of the study (not reported here). After written parental consent was obtained, infants were randomly assigned at the time of surgery to the MUF or control group. Randomization was performed by sealed envelopes prepared from a table of random numbers. Patients assigned to the MUF group underwent 20 minutes of filtration after separation from CPB. Venovenous ultrafiltration was performed as previously reported.[11] Briefly, blood was drawn from the venous cannula in the inferior vena cava and returned after filtering into the superior vena cava. The ultrafilter used (Minntech HPH 400; Minntech Corporation, Minneapolis, Minn) filters particles of 65,000 d and less. Inotropic support, if any was provided, was adjusted before institution of the filtration. No adjustments of inotropic agents occurred while filtering. If transfusion was required during MUF, blood was transfused through the aortic cannula still in place. Then protamine was given to reverse heparin anticoagulation. Patients in the control group were separated from CPB, but heparin was not reversed for 20 minutes. Caregivers in the PICU were blinded to the patient's filtration status.

All children were intubated with a cuffed endotracheal tube by the anesthesiologist, unless the child had an uncuffed endotracheal tube in place with no air leak around it. After induction of anesthesia but before surgical incision, baseline static and dynamic pulmonary compliance measurements were obtained for each child (baseline measurement). Repeat measures of compliance were obtained within the first hour after admission to the PICU (admission measurement) and then again at 24 hours after admission to the PICU (24-hour measurement). Children who underwent MUF had additional

Table II. *Selected characteristics of children in the MUF and control groups*

	MUF (n = 19)	*Control (n = 19)*	P *value*
Age (wk)	9.6 ± 14.4	11.9 ± 15.0	.6
Weight (kg)	3.9 ± 1.7	4.3 ± 1.3	.4
CPB time (min)	122 ± 38	104 ± 45	.2
Aortic crossclamp time (min)	54 ± 26	44 ± 22	.2
Deep hypothermic circulatory arrest (min)	45 ± 21 (n = 10)	55 ± 23 (n = 6)	.2
Baseline dynamic compliance (mL/cm H_2O)	2.3 ± 1.5 (n = 17)	3.0 ± 2.3 (n = 17)	.3
Baseline static compliance (mL/cm H_2O)	2.7 ± 1.3 (n = 17)	3.1 ± 2.3 (n = 17)	.5

Values are expressed as means ± SD.

Table III. *Mean dynamic and static compliance in MUF and control groups at 3 intervals*

	Dynamic compliance (mL/cm H_2O)		*Static compliance (mL/cm H_2O)*	
	MUF group	*Control group*	*MUF group*	*Control group*
Baseline	2.3 ± 1.5	3.0 ± 2.0	2.7 ± 1.3	3.1 ± 2.3
Admission	2.4 ± 1.8	2.9 ± 1.8	2.5 ± 2.2	2.5 ± 1.4
24 h	1.9 ± 0.8	2.6 ± 1.4	1.8 ± 0.8	2.4 ± 1.2
P value*	.3		.7	

**P* value from a repeated-measures analysis of variance comparing change in compliance between the MUF and control groups across the 3 time periods.

measurements of both static and dynamic compliance performed in the operating room after CPB immediately before and at completion of MUF.

Static and dynamic pulmonary compliance was measured by using a Ventrak model 1550 pediatric/neonatal pulmonary function machine (Novametrix Medical Systems, Inc, Wallingford, Conn) with the neonatal adapter. Measurements were performed during hand ventilation, with care taken to deliver the same tidal volume for each breath. Static compliance was calculated from the averaged measured plateau pressures and volumes of 3 breaths with good plateau wave forms. Dynamic compliance calculations were taken from the Ventrak machine during hand ventilation.

Additionally, demographic data, length of CPB, use of deep hypothermic circulatory arrest, complications, use of inotropic drugs, use of peritoneal dialysis catheters for alleviation of abdominal compression caused by edema (placed at the surgeon's discretion), baseline and highest subsequent creatinine levels, change in weight at 24 hours, duration of intubation, and days in the PICU were recorded.

Statistical analysis was performed with the SPSS statistical package (SPSS Inc, Chicago, Ill). Comparisons between groups were made by using the Student *t* test. The Levene test for equality of variance was used to ensure equal variances between groups. Groups with unequal variances were compared by using the *t* test for groups with unequal variance. Comparisons within groups were made by using the *t* test for paired data and the repeated measures analysis of variance for comparisons of more than 2 groups. Nonparametric data were compared by using the Mann-Whitney test.

Results

Thirty-eight patients were enrolled in the study. In 4 patients (2 undergoing MUF and 2 control subjects) pulmonary compliance measurements were not obtained. Preoperative diagnoses are presented in Table I. The 2 groups were not appreciably different in age, weight, preoperative hematocrit levels, CPB time, duration of deep hypothermic circulatory arrest, or preoperative static or dynamic compliance (Table II). The MUF group showed a significant increase from post-CPB/pre-MUF to post-MUF hematocrit levels (21.7% ± 3.4% vs 31.6% ± 4.8%, $P = .006$). The mean amount of fluid filtered was 497 mL ± 155 mL (143 mL/kg ± 64 mL/kg). The control group also showed a small but significant rise in hematocrit value from post-CPB levels after transfusion from the CPB circuit (23.6% ± 4.2% vs 25.7% ± 5.0%, $P = .01$).

Static (2.1 ± 0.9 to 2.9 ± 2.1, $P = .04$) and dynamic (2.5 ± 1.9 to 2.9 ± 2.7, $P = .03$) compliance both improved significantly immediately after ultrafiltration (before MUF to after MUF). However, there was no appreciable difference in the change in compliance between the MUF and control groups when dynamic and static compliance were compared across 3 time periods: baseline measurement, PICU admission measurement, and 24-hour postoperative measurement (Table III).

Clinical outcomes were similar for the 2 groups. Sixteen (84%) of the 19 children survived in both

Table IV. *Selected outcomes of children in the MUF and control groups*

	MUF group	*Control group*	P *value*
Hours intubated (mean ± SD)	140 ± 91	90 ± 58	.08
Median (range)	138 (16.5–330)	91 (10.4–210)	
Days in PICU	10.0 ± 9.1	6.3 ± 5.7	.1
Median (range)	7.5 (1–40)	6.5 (1–13)	
Percentage change in preoperative to postoperative day 1 weight	0.2 ± 0.2	0.2 ± 0.1	.7
Change in creatinine (mg/dL)	0.4 ± 0.3	0.1 ± 0.2	.02
Inotrope use in first 24 h			
Epinephrine	10 (53%)	9 (47%)	.7
Dobutamine	3 (18%)	2 (13%)	.7
Amrinone	8 (47%)	4 (27%)	.2
Peritoneal dialysis catheter use	11 (58%)	10 (53%)	.7
Survived (yes)	16 (84%)	16 (84%)	1.0

groups. Six children in the MUF group had their sternums left open, and 4 children in the control group had open sternums (2 reopened shortly after the operation). There was no appreciable difference in the length of PICU stay in the MUF (10.0 ± 9.1 days) versus control (7.4 ± 5.7 days) groups ($P = .3$) or the number of hours intubated after the operation (MUF group 140 ± 91 hours vs control group 90 ± 58 hours, $P = .8$). The use of inotropic drugs in the first 24 hours after the operation in the MUF versus control groups, including epinephrine (53% vs 47%, $P = .7$), dobutamine (18% vs 13%, $P = .7$), and amrinone (47% vs 27%, $P = .2$), was similar. The use of a peritoneal dialysis catheter to reduce abdominal edema in the MUF versus control groups (58% vs 53%, $P = .7$) did not differ significantly. There was an increase ($P = .02$) in change from baseline to highest postoperative creatinine levels in the children who received MUF (0.4 ± 0.3 mg/dL) as opposed to those who did not (0.1 ± 0.2 mg/dL). The difference in the percentage change of preoperative weight to weight on postoperative day 1 (0.2 ± 0.1 vs 0.2 ± 0.2, $P = .4$) was not significantly different between the MUF and control groups, respectively.

There were no complications attributable to the MUF technique. The overall percentage of complications was similar between the MUF and control groups. One (5.3%) child in the MUF group and 4 (21%) children in the non-MUF group required reoperation for excessive bleeding. One child in the MUF group required postoperative extracorporeal membrane oxygenation and subsequently died.

Discussion

The principal finding of this study is that MUF after CPB in infants did result in immediate improvements in both static and dynamic pulmonary compliance, but the effect was not sustained after admission to the PICU or 24 hours after the operation. Our findings concur with those reported by Meliones and colleagues,[9] who reported on a series of 11 patients in whom MUF after bypass contributed to an immediate improvement in dynamic pulmonary compliance compared with that found in control subjects. However, the study by Meliones and colleagues did not monitor patients beyond the immediate postoperative period, and thus it was not possible to know whether the improvement was sustained. MUF has been reported to contribute to a shorter duration of mechanical ventilation in children, suggesting a more sustained improvement. Naik and colleagues[5] found a respiratory benefit to MUF for a subgroup of patients, those who underwent low-flow, low-temperature CPB. This subgroup had a shorter ventilator course if they received MUF (mean, 2 days; range, 1-8 days) versus that of control patients (mean, 7 days; range, 4-14 days, $P < .01$). Unfortunately, in spite of randomization, the control patients were significantly smaller than the patients in the MUF group (4.2 vs 6.7 kg, $P = .02$) and overall had more complex operations, making it hard to separate these factors from the effects of MUF.

In our study no sustained pulmonary benefits of MUF could be demonstrated after the first hour or at 24 hours after the operation in the PICU. Also, both groups of children had similar needs for inotropic support and no significant difference in weight change between the preoperative period and postoperative day 1, suggesting ongoing capillary leak. These results are similar to those of Naik and colleagues,[5] who found improved hemodynamics immediately after MUF but did not find differences in 24-hour inotropic requirements or urine output.

Why are these improvements not sustained? A possi-

ble reason is that pulmonary compliance is affected both by excess fluid from the hemodilutional effect of bypass, as well as by the systemic inflammatory response. Ultrafiltration after bypass decreases total body water and removes inflammatory cytokines. However, the initiation of the systemic inflammatory response most likely occurs during rewarming.[12] Therefore MUF starts after the inflammatory cascade has been activated. Thus it may be that the salutary effects of hemoconcentration and removal of water after bypass by MUF are unable to overcome the ongoing effects of capillary leak possibly caused by an activated ongoing inflammatory response.

It is also possible that no long-term positive effect of MUF was seen because of the technique of venovenous MUF, as opposed to arteriovenous MUF. The volume of ultrafiltrate removed in this study is similar to that reported in studies of arteriovenous MUF, as is the rise in hematocrit level,[13] and venovenous MUF has been shown to remove cytokines. However, because there have not been any direct studies done that compare the 2 techniques, one cannot rule out that these results are not obtained on the basis of type of ultrafiltration. Another limit of this study is that our intermediate outcome (pre-MUF to post-MUF compliance) was not adequately controlled. However, another study, which did examine both MUF and control groups immediately after CPB, found that MUF did improve compliance, whereas no favorable changes were observed in compliance in the control group.[9]

The 2 clinical, randomized controlled trials in which there was significant pulmonary improvement after MUF did not use MUF alone. Journois and colleagues[14] compared an intervention group who underwent high-volume, zero-balance hemofiltration during rewarming plus post-CPB MUF to a control group who received post-CPB MUF alone. In this study the intervention group had a significantly shorter time to meet extubation criteria (11 vs 28 hours, $P = .02$). Bando and colleagues[15] studied 100 patients, including neonates and children. They compared dilutional ultrafiltration during CPB followed by MUF after CPB to a control group who underwent only conventional ultrafiltration during CPB. They found a significant decrease in duration of ventilatory support in the intervention group. When the subgroup of neonates was examined, the difference in need for ventilatory support was accentuated, with the intervention group requiring a markedly shorter duration of support (59.3 vs 242.1 hours, $P < .001$). Because neither of these 2 studies examined MUF alone but rather studied a combination of filtration during CPB and MUF, it is hard to attribute the ventilatory outcomes to MUF. Possibly the technique of dilutional filtration followed by MUF will prove to be the most optimal technique for shortening the need for ventilatory support in infants after CPB.

In conclusion, MUF has been shown to be a useful technique for the removal of excess fluids in infants after CPB. However, in this study MUF led only to short-term improvements in pulmonary compliance, which were not sustained and did not permit earlier extubation or discharge from the PICU.

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Commentary

It is generally acknowledged that ultrafiltering the cardiopulmonary bypass (CPB) perfusate is beneficial. Routine ultrafiltration during CPB, especially during rewarming before separation from CPB, has been widely practiced for decades. In the past several years, "modified ultrafiltration" has been recommended by some groups as a technique that has benefits beyond those of conventional ultrafiltration. The filtration process is the same in both conventional and modified ultrafiltration, the difference being that conventional ultrafiltration is performed during CPB and modified ultrafiltration is performed after separation from CPB.

Like most nonessential practices, modified ultrafiltration has its enthusiasts and its skeptics. It seems clear, nevertheless, that modified ultrafiltration does have certain benefits. This is hardly a profound conclusion, given the observation that filtration (of some variety) of the CPB perfusate has been widely used for many years. On the other hand, the modified ultrafiltration process can be cumbersome, or worse. More quantitative information than that which currently exists will be necessary before we can determine whether the benefits outweigh the risks.

The current dilemma can be characterized in the following way. Conventional ultrafiltration filters the CPB perfusate while the patient is still being supported by CPB. No additional extracorporeal circulation is necessary, and when the patient is separated from CPB, no additional maneuvers are required. Conventional ultrafiltration, therefore, is "invisible" to the surgeon. The distraction factor and the annoyance factor are both zero. Risk is essentially absent, and the surgeon can give full attention to addressing issues that are occasionally of critical importance in the immediate postbypass period, such as physiologic stabilization of a patient whose condition is marginal or control of serious hemorrhage. Modified ultrafiltration filters the CPB perfusate in exactly the same way as conventional ultrafiltration, except the filtration process is performed after separation from CPB. The modified ultrafiltration process is a form of extracorporeal circulation, and there must be risks related to this second bypass run. Moreover, the surgeon must pay careful attention to the modified ultrafiltration process at a time when many other issues require attention.

It is not clear how much weight the surgeon should assign to each of these various competing factors when deciding whether or not to use conventional or modified ultrafiltration. Furthermore, it is not really a question of either/or. Probably the most important questions are how much incremental physiologic benefit does a period of additional modified ultrafiltration provide to a given patient beyond that achieved with aggressive conventional ultrafiltration, and is that incremental benefit worth the added risk, distraction, annoyance, and delay that to some degree attend the modified ultrafiltration exercise. After all, if the same or nearly the same benefit can be obtained with the conventional technique, why bother? Each surgeon must come to his or her own decision. At the current time, the quantitative information necessary to make an informed decision in this regard is lacking. The necessary information can only be obtained through carefully designed clinical studies.

The study by Keenan and associates was designed to add to our understanding of modified ultrafiltration. It examines the effect of modified ultrafiltration on pulmonary function in a series of infants requiring cardiac surgery, an issue of some significance. Unfortunately, the study provides us with little data in support of modified ultrafiltration. The study shows that there were no differences in the change of either static or dynamic pulmonary compliance in both the control and the modified ultrafiltration groups, when examined before the operation, immediately after the operation, and 24 hours after the operation. Additionally, there were no differences between control and modified ultrafiltration groups when clinical outcome variables, such as time to extubation and length of intensive care unit stay, were examined.

One part of the analysis did demonstrate significant findings. Static and dynamic pulmonary compliance were both shown to improve when values taken immediately before the modified ultrafiltration period were compared with values taken immediately after the modified ultrafiltration period. The authors conclude that the modified ultrafiltration itself was the cause of this improvement. Unfortunately, these data are open to numerous interpretations. The values taken before modified ultrafiltration were measured immediately after separation from CPB. The values taken immediately after modified ultrafiltration were taken presumably about 30 minutes later, after a 20-minute period of modified ultrafiltration. Similar static and dynamic pulmonary compliance values were not taken at similar time points in the control group, leaving open to question whether the improvement in the modified ultrafiltration group was due to the filtration itself or to any one of a number of other rapidly changing variables that exist in the first hour after separation from CPB. During CPB, total lung collapse is present for up to several hours. Microatelectasis and macroatelectasis may gradually resolve in the early post-CPB period,

causing significant changes in serial measurements of static and dynamic pulmonary compliance during this period. Resolution of airway secretions, improvement in airway reactivity, partial removal of interstitial edema with positive airway pressure, and fluctuating amounts of intrapleural fluid collections could equally well explain serial changes in pulmonary compliance in the first hour after CPB.

Additionally, as in many of the other studies examining the potential benefits of modified ultrafiltration, the control group consists of patients undergoing no ultrafiltration whatsoever. Given the widespread use of conventional ultrafiltration, it would seem that the most pertinent comparisons would be obtained if conventional ultrafiltration were used in the control group.

In the final analysis, the study by Keenan and colleagues does not provide a better understanding of the effects of modified ultrafiltration on pulmonary function in infants, and in the bigger picture we are no further along in our knowledge with respect to whether modified ultrafiltration is really worth the effort, especially when conventional ultrafiltration is aggressively performed as the alternative strategy.

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