Abstracts for Oral and Poster Presentations

for the

American Society of Extra-Corporeal Technology

40th International Conference

March 21–24, 2002

Hilton New Orleans Riverside

New Orleans, Louisiana
THE EFFECTS OF ALBUMIN SUPPLEMENTATION DURING CARDIOPLEGIA ADMINISTRATION: AN IN VITRO ANALYSIS

Increasing the colloid osmotic pressure (COP) of blood cardioplegia (BCP) reduces myocardial edema and may preserve cardiac function following CPB. The purpose of this study was to investigate the effects of albumin (ALB) supplementation on cardioplegia COP.

A self-contained cardioplegia delivery system administered supplemental ALB to four BCP ratios (1:1, 4:1, 8:1, and 20:1). Three methods of supplementation were utilized: 1. 25% ALB combined with BCP at four rates (0, 13, 25, and 50 mL/L), 2. 25% ALB added to crystalloid to create carrier solutions with final ALB concentrations of 1.19, 2.27, and 4.17%, 3. ALB delivery rate of 50 mL/L combined with 1.19, 2.27, and 4.17% carrier solutions. Endpoints included initial and post-supplementation hematocrit (HCT), total serum protein (TSP), and COP.

Without supplemental ALB, TSP was less affected with increasing blood to crystalloid ratios (1:1 −1.7 ± 6.2 %, 4:1 −40.6 ± 5.1 %, 8:1 −20.6 ± 4.1 %, 20:1 − 6.0± 5.7%). Measured COP fell most substantially with lower blood to crystalloid ratios (1:1 −64.3 ± 5.0 %, 4:1 −39.5 ± 10.5 %), but was nearer baseline in 8:1 −14.6 ± 4.2% and 20:1 −6.0 ± 1.9%. TSP of 1:1 and 4:1 BCP increased (p < 0.0003 and p < 0.02) across all methods. TSP of 8:1 BCP was augmented (p < 0.008) with all methods except 1.19 and 2.27% carrier solutions. COP of 1:1 BCP increased (p < 0.0003 and p < 0.02) across all methods. TSP and COP of 20:1 BCP was augmented (p < 0.007 and p < 0.006) across all methods with the exception of carrier solutions.

In conclusion, TSP and COP of blood cardioplegic solutions are increased with supplemental albumin administration, with quantitative enhancement dependent upon the dilutional effects of the blood to crystalloid ratio.

Rebecca L. Ahlgren, Alfred H. Stammers, Tunisia A. Ellis, Chen Gao, Hunter B. Holcomb, Bernadette T. Nutter, Ryan G. Schmer, Lynette M. Hock
Division of Clinical Perfusion Education, University of Nebraska Medical Center, Omaha, NE
A NATIONAL STUDY OF JOB SATISFACTION AND BURNOUT AMONG PERFUSIONISTS

A national qualitative survey of perfusionists to assess their level of job stress, career satisfaction, and burnout in various organizational settings was performed. The hypothesis for this study is incorporated into the following research questions: 1) Is there an association between job satisfaction and burnout among perfusionists? 2) Is there an association between level of burnout and intention to leave their job or profession among perfusionists? 3) Is there a difference in job satisfaction and burnout across different organizational affiliations of perfusionists?

Invitations to participate in the survey were sent by electronic mail to the 1,478 AmSECT members with an email address. To categorize perfusionists, the Phase Model of the Maslach Burnout Inventory was used. It is based on the Maslach Model, but extends it by suggesting the order of severity in which persons experience burnout.

Two hundred eighty-three responses to the survey were received. The results were: 1) As burnout increases, job satisfaction decreases; 2) As burnout phase increased from low to high, this was associated with a greater intention of the perfusionists to leave their job for a lateral move or demotion within 6 months; and 3) there was insufficient evidence to show a difference between employee satisfaction and burnout based on organizational affiliation. The perfusionists who answered the inquiry appeared to be clear about their role at work, have adequate resources, and feel they are treated fairly by supervisors. Organizational climate, communication, training, participation, trust, and culture were evaluated positively. Although the respondents considered interdepartmental communication adequate, higher management or corporate communication was portrayed as needing improvement.

Perfusionists are for the most part satisfied with their job performance. In general, they are not as burned out (emotionally exhausted, reduced sense of personal accomplishment, and depersonalized) as other professions, but those who are burned out have lower job satisfaction. It will be important to use this information as a benchmark and follow the profession as it changes over the next few years.

Mary Murphey Ames, Anne Osborne Kilpatrick, James Zoller, Joseph J. Sistino, Mindy Blackwell, Jeffrey Acsell
Medical University of South Carolina, Charleston, SC
TRANSFERRING AIR FORCE FLIGHT SIMULATION TRAINING EFFECTIVENESS TO UNIVERSITY-BASED CARDIOPULMONARY BYPASS SIMULATION TRAINING: “A MODEL FOR SUCCESS”

Real-time, interactive simulators are used extensively for teaching pilots to employ the operational characteristics of their aircraft. Pilots can “fly” a multimillion-dollar aircraft without risk to the aircraft, other people, or themselves. They can encounter realistic scenarios to prepare them for actual flight situations. They can experience rarely occurring phenomena without risk, and prepare to react to problems before they occur.

Medical errors are an increasing phenomenon in military and civilian healthcare systems. Medical simulations have gained widespread acceptance in the military, particularly in combat medical triage. But many medical professionals must react in emergency situations without the benefit of practice training. Rather, they must learn from real life patient situations. The sophisticated medical procedure of operating the heart-lung machine during open-heart surgery operations is an example. Similar to pilots, perfusionists (the professionals who operate the heart-lung machine) must react to multiple variables, in hurried timed sequences and in extremely stressful situations. Mismanagement of cardiopulmonary bypass can lead to death or increased morbidity of the patient. The goal of this research is to apply simulation technologies learned in the Air Force to medical arenas that will decrease the incidence of medical errors.

The effectiveness of scenario-based research involves real-time simulator training for enhancing the skills of cardiovascular perfusionists who will be assessed for three training applications: 1) initial skill acquisition and consolidation for students, 2) capstone training for recent graduates entering the profession, and 3) continuation training for experienced practitioners. A high fidelity simulator has been constructed at Midwestern University, College of Health Science, Cardiovascular Science Program, Glendale, Arizona where mentor-based training is ongoing.

Midwestern University, College of Health Science,
Fresenius Medical Care, Air Force Research Laboratory-Mesa, Glendale, AZ
Platelet inhibitors, especially the platelet GP IIb/IIIa receptor antagonists, have demonstrated their effectiveness in reducing the acute ischemic complications of percutaneous coronary intervention (PCI) and in improving clinical outcomes in patients with acute coronary crisis. Three common platelet inhibitors used in PCI and consequently seen in emergent cardiopulmonary bypass for failed PCI are: abciximab, eptifibatide, and tirofiban.

Platelet inhibitors were studied in this model to determine if platelet aggregation inhibition would be demonstrated by a decrease in the maximum amplitude of the Thrombelastograph® monitor in samples containing platelet inhibitors when compared to a control sample with no platelet inhibitors. Twenty milliliters of fresh whole blood samples were drawn by venipuncture into citrated collection tubes. The samples were divided into four groups. Following reconstitution with calcium, platelet inhibitor concentrations were calculated to reach 80% platelet inhibition, and this was confirmed by platelet aggregation. Ten volunteers were utilized, and each test was performed in duplicate.

Parameters measured were R time, K time, alpha angle, maximum amplitude (MA), and % platelet inhibition.

Point of care testing to analyze platelet function during emergency cardiopulmonary bypass is important for patient management of the coagulopathy associated with administration of platelet inhibitors.

Lori A. Bailey, Joseph J. Sistino, Walt Uber
Medical University of South Carolina, Charleston, SC
Increasing numbers of obese patients are presenting for cardiac surgery employing cardiopulmonary bypass (CPB). The conventional heparin dose is a pre-CPB bolus of 300 iu/kg of total body weight (TBW). During CPB the ACT is maintained at >480 s. At the end of the procedure, protamine is administered to neutralize heparin and achieve hemostasis. Calculation of lean body mass (LBM) may be a more accurate method of determining drug doses as opposed to TBW and may avoid giving obese patients a relative overdose of heparin, which must subsequently be neutralized with protamine. Both of these drugs can have serious side effects. Heparin can induce thrombocytopenia, and protamine has been known to cause reactions in patients allergic to fish, vasectomised men, and some insulin dependent diabetics. LBM can be determined by different methods. This study employed bioelectrical impedance analysis (BIA) as a simple, quick, and accurate method of calculating LBM.

A comparison was made between two groups of patients whose body mass index was > 27 kg/m²: Group 1, n = 13, mean BMI = 32, mean body fat = 36% received the conventional dose of 300 iu/kg Heparin for their TBW. Group 2, n = 14, mean BMI = 31, mean body fat = 35% received a dose of 300 iu/kg heparin for their calculated LBM. ACT’s were measured before and after heparin administration and during bypass. Additional heparin was administered as required to maintain ACT >480 s. Mean ACT results and total heparin doses were analyzed using unpaired two tailed t-tests.

Our results indicate that, with care, a reduction of up to 25% in the doses of heparin (p = 0.0032) and protamine (p = 0.0026) can be achieved for a substantial number of patients classified as ‘overweight’ or obese.

Mya S. Baker, Julian R. Skoyles, Matt Shajar, Henry Skinner, David Rrichens, Ian Mitchell
Nottingham City Hospital, UK
THE TAS™ YIELDS SIGNIFICANTLY DIFFERENT ACTIVATED CLOTTING TIME VALUES DURING CARDIOPULMONARY BYPASS COMPARED TO THE HEMOTEC™ ANALYZER

Side-by-side activated clotting time (ACT) analyses were performed with the TAS™ (Bayer) and HemoTec™ (Medtronic) analyzers in two cardiac surgical centers by the same team of four perfusionists. Manufacturers’ instructions for use were followed. The HemoTec™ devices were considered the historic control and had passed Proficiency Testing. Blood samples from 31 cardiopulmonary bypass (CPB) patients were analyzed. The results of the correlation testing are presented in the table.

<table>
<thead>
<tr>
<th>Peri-operative CPB Event</th>
<th>n Pairs (# Missing)</th>
<th>TAS™ sec Mean (SD)</th>
<th>HemTec™ sec Mean (SD)</th>
<th>Regression $r^2$ Value (p)</th>
<th>Mean Difference TAS™-HemoTec™ sec (SD)</th>
<th>Paired t-test p (Power)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All CPB Events</td>
<td>256 (13)</td>
<td>506 (226)</td>
<td>585 (302)</td>
<td>0.771 (&lt;0.001)</td>
<td>−79 (150)</td>
<td>&lt;0.001 (0.97)</td>
</tr>
<tr>
<td>Group 1 baseline, pre-CPB</td>
<td>27 (3)</td>
<td>199 (150)</td>
<td>173 (95)</td>
<td>0.776 (&lt;0.011)</td>
<td>26 (82)</td>
<td>0.105 (0.14)</td>
</tr>
<tr>
<td>Group 2 postheparin, pre-CPB</td>
<td>59 (8)</td>
<td>167 (121)</td>
<td>148 (84)</td>
<td>0.779 (&lt;0.001)</td>
<td>18 (60)</td>
<td>0.020 (0.44)</td>
</tr>
<tr>
<td>Group 3 on-CPB</td>
<td>168 (4)</td>
<td>618 (120)</td>
<td>726 (194)</td>
<td>0.334 (&lt;0.001)</td>
<td>−108 (158)</td>
<td>&lt;0.001 (0.94)</td>
</tr>
<tr>
<td>Group 3 on-CPB w/Aprotinin</td>
<td>62 (3)</td>
<td>637 (128)</td>
<td>740 (176)</td>
<td>0.453 (&lt;0.001)</td>
<td>−102 (131)</td>
<td>&lt;0.001 (0.84)</td>
</tr>
<tr>
<td>Group 4 post-CPB, post-protamine</td>
<td>35 (3)</td>
<td>139 (83)</td>
<td>127 (67)</td>
<td>0.871 (&lt;0.001)</td>
<td>12 (32)</td>
<td>0.036 (0.72)</td>
</tr>
</tbody>
</table>

n = sample size, (SD) = one standard deviation, $r^2$ = regression coefficient, $p = \alpha$, $\beta$ = estimated power to find a difference = 10% at $\alpha = 0.05$.

In Group 3, analysis of variance supported a significantly higher difference between the two devices when Aprotinin was administered versus not administered ($\alpha = 0.003, \beta = 0.70$). The HemoTec™ averaged about 170 sec higher than the TAS™ in the presence of Aprotinin and about 70 sec higher without Aprotinin on CPB. Multiple linear regressions revealed that the difference between the TAS™ and HemoTec™ ACTs correlated with both temperature ($p < 0.001$) and the presence of Aprotinin ($p = 0.002$). The statistical power of this correlation study was adequate for the larger sample pairings.

The TAS™ and HemoTec™ devices yield substantially different ACT values during most perioperative phases of CPB.

CHARITY WORK—IS IT BENEFICIAL TO THOSE INVOLVED?

Many of us give up some of our time with varying degrees of frequency and amount, during our careers to go, work, and share our expertise in other countries, for whatever reasons.

Working outside the highly developed, high technology and affluent areas of the United States and the European Economic Community health care systems on a full time basis, brings a whole new perspective to the problems we encounter daily. Especially when compared to those we have to deal with on a normal day-to-day basis when inside these systems.

We hope to show what it is possible to achieve in comparing two different countries, Peru in South America, and the former Yugoslavian Republic of Croatia. Both of which were very different in terms of expertise, finance, and local attitude to having a national pediatric cardiac surgery service, rather than an ad-hoc visiting team system. Prior to the provision of a long, term multiple visits per year, commitment from the International Children’s Heart Foundation. With a commitment to develop and hopefully achieve, more sustainable long-term goals, in terms of training, education, organizational and practical hands on experience. This is not only in terms of a financial but also the practical and day-to-day organizational perspective, but also in terms of physical surgical results.

Finally, what we as professional team members have gained personally from this long-term interaction with these countries will be assessed.

Matthew Davis
International Children’s Heart Foundation, Memphis, TN

TREATING PULMONARY HYPERTENSION IN SURGICAL VENTRICULAR SEPTAL DEFECT—A NOVEL ANSWER

Pulmonary hypertension in association with Ventricular Septal defects, as the primary defect, or in association with others, is no longer the major life-threatening problem it once was within highly developed western healthcare systems. In the developing world, with only very limited access to Nitric Oxide therapy and extracorporeal membrane oxygenation (ECMO) postoperatively; it is still a major complication.

The incidence of pulmonary hypertensive patients with Ventricular Septal defects encountered in the less developed areas of the world is still an issue. The International Children’s Heart Foundation quickly realized that an answer needed to be found to improve the outcome of this large group of patients with untreated pulmonary hypertension post operatively.

The solution was the development of a double flap valve closure patch. It provides both a simple and comparatively cheap answer. This acts as a safety blow-off; permitting limited right to left blood shunting to occur at ventricular level thus maintaining systemic circulation, in the presence of pulmonary hypertensive crises, with self-closure in the presence of normal ventricular pressures.

We will show how this flap valve patch has been used in a mixed group of patients in terms of age and diagnosis, with what we feel are excellent results in many different countries.

The criteria for the application of this technique will be shown in comparison to a formal VSD patch repair. Our postoperative management and our long-term follow up data will be discussed.

Matthew Davis, William Novick, Visjna Ivancan
International Children’s Heart Foundation, Memphis, TN
Approximately 8% of African Americans are heterozygous (recessive) Ss for hemoglobin S, and have the sickle cell trait, while 0.15% are homozygous (dominant) SS for sickle cell disease. In sickle cell disease, there is a HbS of 90–95% and significant sickling at pO₂ of 40 mmHg. Hemoglobin S transports O₂ normally. However, when it releases O₂ into the body tissues, HbS crystallizes and causes red cells to take on the classic sickle shape. Sickle cell disease patients present with a clinical sequelae of chronic anemia, recurrent sickle crises, multi-organ system damage and ultimately, premature death. All organ systems are affected by the vascular occlusions caused by aggregates of sickled red cells. Acidosis, hypoxemia, hypothermia, and low peripheral blood flow leading to stasis, are the precipitating events leading to infarctive crises. The use of extracorporeal circulation in patients undergoing open-heart procedures may cause various physiological changes. Sickle cell patients are at an increased risk of bleeding especially from the risks associated with exchange transfusions and hemorrhage.

Inflammatory inhibition is thought to occur through the reduction of both humoral and cellular mechanisms. It is unknown whether the utilization of either aprotinin or methylprednisolone would reduce the inflammatory and cellular changes associated with CPB when treating patients who suffer from sickle-cell disease. Therefore, an *in vitro* analysis will be conducted using fresh whole blood from sickle cell disease patients to determine if either aprotinin or methylprednisolone will reduce the sickling of blood when exposed to the stresses of cardiopulmonary bypass.

Tunisia A. Ellis, Alfred H. Stammers, Rebecca L. Ahlgren, Chen Gao, Hunter B. Holcomb, Bernadette T. Nutter, Ryan G. Schmer, Lynette M. Hock
Division of Clinical Perfusion Education, University of Nebraska Medical Center, Omaha, NE
A RETROSPECTIVE STUDY OF POSTOPERATIVE HYPERTHERMIA IN PATIENTS UNDERGOING CARDIOPULMONARY BYPASS

New strategies in perfusion management during cardiopulmonary bypass (CPB) are sought out in an effort to reduce or eliminate negative sequelae of CPB. One negative sequelae of CPB is the systemic inflammatory response syndrome (SIRS). According to the 1991 Consensus Conference of the Society of Critical Care Medicine and the American College of Chest Physicians, one of the indicators of SIRS is postoperative hyperthermia (temperature greater than 38°C). The purpose of this study was to first perform a retrospective multivariate analysis of intraoperative perfusion management strategies and correlate them to postoperative incidence of hyperthermia.

After initial analysis, clinical outcomes, such as ventilation time, length of stay, and incidence of stroke, were compared between the hyperthermic and normothermic groups. The outcomes were collected from the Society of Thoracic Surgeons Database. After Institutional Review Board approval, medical records of 186 patients were reviewed. These patients underwent coronary artery bypass surgery or valvular repair or replacement surgery at Rush Presbyterian St. Luke’s Medical Center between September 2000 and September 2001. Of these, 57 patients experienced postoperative hyperthermia, a 31% incidence. The mean mechanical ventilation hours for hyperthermic group was 22.79 ± 6.41 and the normothermic group was 13 ± 1.63 (p = 0.043). The mean length of stay for the hyperthermic group was 5.43 ± 0.72 and 6.23 ± 0.56 for the normothermic group. The incidence of stroke was 1% in both groups.

Based on these findings, postoperative hyperthermia may not be an independent predictor of negative sequelae related to CPB. However, postoperative hyperthermia in conjunction with other clinical findings may be an indicator of the systemic inflammatory response in the cardiac surgery patient.

Matt Forthofer, Lauara Budzien, Robin Sutton, Gary Tsarovsky, Mike Djuric
Rush University, Chicago, IL
THE EFFECT OF PRE-PRIMED OXYGENATORS ON GAS TRANSFER EFFICIENCY

Cancellation of on-pump CABG after the circuit is primed may result in the discard of unused circuits. In some off-pump cases, a surgeon may request that the circuit be primed, but complete the surgical procedure without utilizing the circuit. The major concerns about the unused circuit are its sterility and the performance of the oxygenator after it has been primed for a long period of time. The goal of this study is to determine whether pre-priming of the circuit with and without albumin has an effect on the gas transfer efficiency of oxygenators during simulated cardiopulmonary bypass.

Monolyth integrated membrane lungs (Sorin Biomedical, Arvada, CO) were used to deoxygenate and oxygenate fresh bovine blood. Oxygenators were pre-primed for 72 (n = 6) and 24 (n = 6) hours prior to testing. In control group (n = 6), oxygenators were tested immediately (0 hr) after they were primed. Three different priming solutions were utilized: physiological saline solution (Group A), 1.25% of human albumin (Group B), and 5% human albumin (Group C). Test blood was modified to the American Association of Medical Instrumentation Standards prior to testing. The blood flow through the oxygenators was set at 2 LPM and 4 LPM with gas (FiO2 at 1.0) to blood flow ratio at 1:1. Cultures were also obtained from pre-primed oxygenators to test the circuit’s sterility.

Oxygen transfer in oxygenators primed for 0 hr at blood flow of 4 LPM were 203 ± 9.7 (Group A), 263.1 ± 52.9 (Group B), and 270.5 ± 13.1 mL/min (Group C, p < 0.01 vs Group A). In oxygenators pre-primed for 72 hrs, the CO2 transfer were 135.0 ± 21.8 (Group A), 104.9 ± 2.4 (Group B), and 148.9 ± 26.6 mL/min (Group C, p < 0.006 vs Group B). In addition, the pressure drop at 4 LPM was 56.5 ± 5.5 (Group A), 82.6 ± 13.4 (Group B), and 67.6 ± 15.3 mmHg (Group C, P < 0.05 vs Group B). In Group A, O2 transfer was 203.5 ± 9.7 (0 hr), 272.4 ± 66.6 (24 hr), and 260.8 ± 31.1 mL/min (72 hr, p < 0.01 Vs 0 hr). In Group B, O2 transfer was 263.1 ± 52.0 (0 hr), 302.7 ± 77.4 (24 hr), and 235.2 ± 16.5 mL/min (72 hr, P < 0.02 vs 24 hr). Cultures obtained from 12 pre-primed oxygenators across all time periods demonstrated no organism growth for up to 5 days.

In conclusion, oxygen transfer increases in oxygenators pre-primed with albumin immediately after they were primed. However, gas transfer decreased after they were primed with albumin for 72 hrs. Oxygenators pre-primed for 24 hrs and 72 hrs with 0.9% saline had better O2 transfer than those primed for 0 hr.

Chen Gao, Alfred Stammers, Rebecca Ahlgren, Tunisia Ellis, Hunter Holcomb, Bernadette Nutter, Ryan Schmer
Division of Clinical Perfusion Education, University of Nebraska Medical Center, Omaha, NE
THE EFFECT OF SURFACE MODIFICATION AND APROTININ ON CELLULAR INJURY DURING SIMULATED CARDIOPULMONARY BYPASS

Cardiopulmonary bypass (CPB) elicits derangements to the formed elements of blood due to the physical stresses of extracorporeal flow. Methods of reducing the impact of CPB include circuit surface modification and pharmacological supplementation. The purpose of this study was to examine the effects of aprotinin in combination with surface modification during simulated CPB.

Fresh whole bovine blood was used to prime standard CPB circuits divided into four groups (n = 3): control (CTR), aprotinin 300 KIU/mL (APR), Poly (2-methoxyethylacrylate) coating (PMEA), and APR with PMEA (APR-PMEA). Physical stresses included venous reservoir negative pressure (~85 mmHg), arterial line pressure of 150 mmHg at 5 LPM, and air-blood interface, applied over a 90-minute period. Samples were drawn at the following times: 0, 10, 45, and 90 minutes. Endpoints included platelet count, plasma free hemoglobin (PFHb), and thromboelastography (TEG).

Platelet count did not change (138.9 ± 15.0 vs. 102.9 ± 21.0, p = ns) throughout the 90-minute experimental periods in any group. PFHb increased significantly (mean of 19 fold) throughout the experiment, but was not affected by any treatment. The TEG index declined in the CTR (3.6 ± 0.4 vs. −16.2 ± 2.9, p < .0003), PMEA (5.9 ± 0.8 vs. −2.7 ± 3.8, p < .02) and APR-PMEA (4.6 ± 1.0 vs. −2.8 ± 0.3 p <.0003) groups, but not in the APR group (3.6 ± 2.2 vs. −1.3 ± 3.3 p = .10).

In conclusion, neither APR nor PMEA had an effect on either red cell hemolysis or platelet count, but APR treatment alone significantly attenuated the derangements in coagulation induced in this extracorporeal model.

Benjamin L. Greenfield, Kelly R. Brinkman, Kelly L. Koziol, Martin W. McCann, Kellie A. Merrigan, Lee P. Steffen, Kylie A. Woods, Alfred H. Stammers
Division of Clinical Perfusion Education, University of Nebraska Medical Center, Omaha, NE
PERFUSION TREATMENT ALGORITHM: METHODS OF IMPROVING THE QUALITY OF PERFUSION

The pathophysiological consequences associated with cardiopulmonary bypass (CPB) has generated a movement away from this technology in the treatment of heart disease. The negative outcomes are multifactorial in origin and may be associated both with the conduct of CPB and the instrumentation of extracorporeal flow. The purpose of this study was two-fold: 1) To develop a bedside patient risk assessment to aid in the development of a perfusion care plan, and 2) To identify the controllable variables utilized during CPB that contribute to overall morbidity.

Controllable perfusion related variables that were positively linked to improved patient outcomes were identified from randomized, peer-reviewed human studies. Such variables as hematocrit, mean arterial pressure, thermic perfusion, blood lactate, colloid osmotic pressure, pulsatile perfusion, acid base homeostasis, oxygenation, and coated circuitry were included. Patient risk assessment was developed using the Society of Thoracic Surgeon database, where 61 variables affecting postoperative morbidity were identified. These variables were utilized to develop a bedside tool (Mortality Assessment Perfusion Score (MAPS)) to guide the perfusion patient care plan. The MAPS generates a specific value that may predict patient morbidity and mortality.

In conclusion, the improvement in patient outcome may be associated with both the change in conduct of CPB and the quantitative assessment of patient risk stratification and a patient treatment algorithm.

Hunter B. Holcomb, Alfred H. Stammers, Chen Gao, Bernadette T. Nutter, Tunisia A. Ellis, Rebecca L. Ahlgren, Ryan G. Schmer, Lynette Hock
Division of Clinical Perfusion Science, University of Nebraska Medical Center

CORRELATION OF ECARIN CLOTTING TEST AS MEASURED WITH THE HEMOTEC DEVICE, HEMOCHRON DEVICE, AND THE THROMBOLYTIC ASSESSMENT SYSTEM

Continuous monitoring at the point of care when using hirudin is required in cardiopulmonary bypass to allow minute-by-minute modulation of the hirudin dose to maximize patient safety. To correlate hirudin concentrations levels between laboratory measurement and point of care coagulation devices, HemoTec, Hemochron, and Thrombolytic Assessment System.

Blood from five healthy volunteers were withdrawn. Hirudin levels were varied from (0, 1, 2, 3, 4, 5 ug/mL). A calibration curve was constructed and the linearity of the calibration curve was analyzed. Blank cartridges for the devices were filled with ecarin reagent, standard human plasma, and citrated whole blood with hirudin added and placed into the various device chambers. Samples of citrated whole blood with hirudin were also assayed by the university’s laboratory.

There is no standardized reference method available to evaluate the performance characteristics of the varying ecarin clotting time (ECT) methods being used. The lack of standardization results in method-to-method variation that may be significant in some cases. Our results that included only healthy volunteers do not ideally represent patient samples we are likely to encounter when patients with heparin-induced thrombocytopenia (HIT) undergo cardiopulmonary bypass.

The clinical application of hirudin or other direct thrombin inhibitors in CPB on a routine basis will require additional studies, both in vitro and in vivo, confirming that ECT point of care tests meets the same standards as the techniques associated with clinical laboratory tests and patient’s response.

Bonnie Jo Houchen, Joseph Sistino, Jeffrey Acsell
Medical University of South Carolina, Charleston, SC
THE EFFECTS OF APROTININ ON TWELVE DIFFERENT ACT TESTS

It is generally accepted that some activated clotting time (ACT) test results are altered by the presence of aprotinin in blood. Since aprotinin is frequently used during cardiopulmonary bypass (CPB), we have investigated its effect on several ACT tests using whole blood from CPB patients. With IRB approval, blood samples were collected from CPB patients before and after full heparinization (300 u/kg). Each blood sample was divided into two aliquots and aprotinin was added to one. Both aliquots were used simultaneously to perform 12 ACT tests. The following table illustrates, for each test and time point, the ACT in seconds using both aprotinized (A) and non-aprotinized (N) blood.

<table>
<thead>
<tr>
<th>Test</th>
<th>Activators</th>
<th>Machine</th>
<th>Unheparinized (sec)</th>
<th>Heparinized (sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n</td>
<td>N</td>
<td>A</td>
</tr>
<tr>
<td>Max-ACT</td>
<td>Glass, Celite, Kaolin</td>
<td>ACTAlyke</td>
<td>14 126 ± 13 129 ± 13</td>
<td>15 592 ± 252 603 ± 227</td>
</tr>
<tr>
<td>G-ACT</td>
<td>Glass</td>
<td>ACTAlyke</td>
<td>10 177 ± 21 229 ± 39*</td>
<td>N/A</td>
</tr>
<tr>
<td>C-ACT</td>
<td>Celite</td>
<td>ACTAlyke</td>
<td>10 131 ± 15 161 ± 22*</td>
<td>10 513 ± 117 791 ± 156*</td>
</tr>
<tr>
<td>K-ACT</td>
<td>Kaolin</td>
<td>ACTAlyke</td>
<td>10 135 ± 11 138 ± 14</td>
<td>10 492 ± 53 588 ± 111*</td>
</tr>
<tr>
<td>FT/CA510</td>
<td>Celite</td>
<td>Response</td>
<td>13 144 ± 18 163 ± 17*</td>
<td>14 544 ± 133 903 ± 108*</td>
</tr>
<tr>
<td>P214</td>
<td>Glass</td>
<td>Response</td>
<td>7 132 ± 26 184 ± 15*</td>
<td>N/A</td>
</tr>
<tr>
<td>FTK-ACT</td>
<td>Kaolin</td>
<td>Response</td>
<td>9 132 ± 19 139 ± 14</td>
<td>10 588 ± 80 569 ± 89</td>
</tr>
<tr>
<td>ACT</td>
<td>Kaolin</td>
<td>Gem</td>
<td>13 120 ± 21 121 ± 20</td>
<td>11 462 ± 55 481 ± 60*</td>
</tr>
<tr>
<td>ACT+</td>
<td>Kaolin</td>
<td>Jr. Signature</td>
<td>14 132 ± 12 135 ± 11</td>
<td>13 496 ± 112 512 ± 53</td>
</tr>
<tr>
<td>HMT</td>
<td>Celite</td>
<td>Rapidpoint</td>
<td>14 161 ± 57 205 ± 52*</td>
<td>15 448 ± 73 618 ± 109*</td>
</tr>
<tr>
<td>SonACT</td>
<td>Celite</td>
<td>Sonoclot</td>
<td>13 140 ± 39 147 ± 28</td>
<td>12 420 ± 63 852 ± 207*</td>
</tr>
<tr>
<td>HR-ACT</td>
<td>Kaolin</td>
<td>HMS</td>
<td>13 145 ± 17 143 ± 13</td>
<td>15 571 ± 182 630 ± 201*</td>
</tr>
</tbody>
</table>

Data is expressed as Mean ± SD.
*Denotes significant difference (p < 0.05) between N and A group (Paired t-test).

Nine of the 12 tests were significantly affected by aprotinin with either heparinized or unheparinized blood samples. Each test responded uniquely to the presence of aprotinin in the sample producing results ranging from 12–51% above nonaprotinized values. Also, several tests that were affected by aprotinin in heparinized blood samples were unaffected with unheparinized blood samples. This data may be in conflict with aprotinin’s well documented anticoagulatory affect, and demonstrates that none of the tests, regardless of the activator, will respond to aprotinin identically.

K. Jones, F. Nasrallah, S. Graham, E. Darling, N. Clay, M. Hauser, B. Searles
SUNY Health Science Center, Syracuse, NY
**HOW COMPUTER TECHNOLOGIES MIGHT BE UTILIZED TO FOSTER PROFESSIONAL DEVELOPMENT: A CASE REPORT OF www.perfusionkoea.org**

Advances in the Internet and communication technologies have enabled many perfusion-related websites to provide detailed and reliable information to perfusionists. However, these websites are also faced with various members’ needs that require updating or changing these websites for flexible and fast responses. Despite the rapid increase in number of these websites, little is known about the structures, performance, and effective utilizational methods of such websites.

This case report examines the www.perfusionkorea.org, a virtual organization that works across space and time with links strengthened by webs of communication technologies. It also describes the main task of www.perfusionkorea.org and its effects on the Korean Perfusion Society. In addition, website maintenance and resource management task, which are important factors for long-term survival are discussed using statistical data analysis based on IP tracing programs. Finally, the possibility of www.perfusionkorea.org, as a prototype of virtual organization activities we can expect to see commonly in the near future is discussed.

Although we utilized a tremendous amount of multimedia technique to attract members, we found that the significance of the perfusionists’ website would come from active participation of members rather than a new, complicated technology or eye-catching graphics.

This case report proves the synergistic effects of the combination of the field of perfusion and the Internet technologies. It also suggests that new methodological strategies and approaches can be developed and tested in order to provide perfusionists with the future directions in the health care system of tomorrow.

Kuna Kim
Ajou University Medical Center, Korea

**CLINICAL OUTCOMES OF COMPLETE X-COATING CIRCUIT IN MAST CONDENSED BYPASS SETTING**

To present clinical outcome and blood utilization data of a preliminary clinical trial using a complete X-coating circuit in a condensed setting.

Twenty (n = 20) consecutive coronary surgery patients were studied prospectively. Range, mean, and percentage were calculated for age, BSA, respiratory support times, ICU length of stay (LOS), hospital LOS and intra-operative transfusion requirements. Two patients in extremis, operated on emergently were excluded from statistical analysis. MAST system utilized X-coating tubing, cannulae and Capiox SX18 oxygenator.

Average age was 65 years (52–78 yrs), average BSA 1.85 (1.60–2.45) with 65% being males. Average CPB time was 103 minutes (60–180 minutes) with clamp time 67 minutes (40–129 minutes) and average 3.9 grafts. Average intraoperative packed cell transfusion was 0.5 units (0–3 units) with 61% not requiring any transfusion. Average intra operative platelet count was 152,000 (120–205K). Average immediate postoperative count was 150,000 (106–204K). Percentage change in platelets ranged from −22% to +44%. There was no mortality. Average respiratory support time was 9.6 hours (4–26 hours) with 44% extubated within 6 hours and 78% within 12 hours. Average ICU LOS was 1.3 days (1–4 days) with 78% having less than 24 hours stay and 94% less than 48 hours stay. Average hospital LOS was 6.4 days (4–11 days) with 89% discharged by 7days.

Complete X-coating circuit is safe and improved outcome parameters in our institution.

K. McCusker, V. Vijay, B. Helm, D. Sisto
Portsmouth Regional Hospital and Albert Einstein College of Medicine
TRILLIUM HEALTH CENTRE'S EXPERIENCE WITH THE JOSTRA ROTAFLOW CENTRIFUGAL PUMP SYSTEM

The Jostra Rotaflow, new to North America, is an innovative centrifugal pump used for extracorporeal support. At the Trillium Health Centre it is the centrifugal pump of choice for routine cardiopulmonary bypass, kinetic assisted venous drainage, and other forms of extracorporeal support. Its unique shaftless flow channel design provides a low prime, high flow efficiency and low hemolytic index. It has the benefits that are associated with centrifugal pumps as well as the built-in safety features of a bubble and level sensor which until now were only associated with roller pumps. It is modular in nature making it easily transportable from one Jostra HL-20 heart lung machine to another and can be operated as a stand-alone unit if the need arises. When integrated with the HL-20, the heart lung machine will supervise and regulate the functions of the Rotaflow unit, stopping the pump in an alarm situation. One of the advantages of integration is the capability for pulsatile flow with the ability to generate a pulse pressure equivalent to roller pumps. The purpose of this presentation is to familiarize the perfusion community with the unique design and features of the Rotaflow centrifugal pump system along with its clinical applications. The small prime, versatility, and safety features of the Jostra Rotaflow make it a very attractive centrifugal pump system that provides for the needs of both the patient and the perfusionist.

Arthur Melo, Onkar Singh, Cyril Serrick
Trillium Health Centre

PULSATILE MECHANICAL CARDIAC ASSISTANCE IN PEDIATRIC PATIENTS

Mechanical cardiac assistance for neonates, infants, children, and adolescents may be accomplished with ventricular assist devices (VAD). The Berlin Heart VAD consists of extracorporeal, pneumatically driven blood pumps for pulsatile, uni- or biventricular assistance for patients of all age groups. The blood pumps and cannulae are heparin-coated. The IKUS 2000 drive unit has the required compressor performance for pediatric pump sizes.

The Berlin Heart VAD was used in a total number of 424 patients from 1987 up to date at our institution. In 45 pediatric patients, aged 2 days–17 years, the Berlin Heart VAD was applied for long term support (1–111 days, mean 20 days). There were three patient groups: Group I: “Bridge to transplantation” with various forms of cardiomyopathy (n = 21) or chronic stages of congenital heart disease (n = 9). Group II: “Rescue” in intractable heart failure after corrective surgery for congenital disease (n = 7) or in early graft failure after heart transplantation (n = 1). Group III: “Acute myocarditis” (n = 7) for either bridge to transplantation or bridge to recovery.

Seventeen patients were transplanted after support periods of between 4 and 111 days with 12 long-term survivors, living now up to 10 years. 5 patients (Groups I and III) were weaned from the system with 4 long-term survivors. In Group II only one patient survived after successful transplantation.

Prolonged circulatory support with the Berlin Heart VAD is an effective method for bridging until cardiac recovery or transplantation in the pediatric age group. Extubation, mobilisation and enteral nutrition are possible. For long term use, the Berlin Heart VAD offers advantages over centrifugal pumps and ECMO in respect to patient mobility and safety.

F. Merkle, W. Boettcher, B. Stiller, R. Hetzer
Deutsches Herzzentrum, Berlin
EVALUATION OF PHOSPHORYLCHOLINE (MIMESYS) COATED OXYGENATORS DURING CARDIOPULMONARY BYPASS IN ADULTS

A new generation of coating extracorporeal circuitry has entered the North American market place. This new biocompatible coating process uses a substance called phosphorylcholine, which is covalently bonded to the surface of the Sorin Monolyth oxygenator. It has been available in Europe since 1998, and was released in Canada in November of 2000.

In two Canadian centers, 160 Mimesys coated oxygenators were randomly evaluated against their uncoated control group for resistance and pressure differentials. In 98 cases, patient outcomes were evaluated for transfusion, length of stay, stroke, and mortality. Platelet count drops were compared with previously published literature on other coating processes available to perfusionists. There was no difference found in pressure differentials or resistance with the control group. Platelet count drops were comparable to previously published results with Carmeda and Trillium coated oxygenators. In the group of 98 patients studied for outcomes, preoperative stroke rate was 8% due to preexisting factors. This placed the group in a high risk category for postoperative strokes, predicted at about 10.0%. The measured stroke rate in the Mimesys coated group was only 1.0%.

QEII Health Sciences Center, Halifax, Nova Scotia, University Hospital, Edmonton, Alberta
Cobe-Sorin Cardiovascular, Boulder, CO

A MULTICENTER INVESTIGATION INTO THE OCCURRENCE OF HIGH PRESSURE EXCURSIONS

The occurrence of sudden increases in premembrane pressures and pre/post membrane differentials has drawn considerable attention and debate in the perfusion community over the past few years. Several terms have been applied to this phenomenon but the term that best describes this event is High Pressure Excursions, due to their sudden and often transient nature.

The causes of High Pressure Excursions are to some degree uncertain, but the increase in their appearance seems to be closely related to the removal/absence of Serum Albumin from priming solutions.

To investigate the reasons why HPE occurs in some cardiopulmonary bypass cases, we present our findings in a multicenter, retrospective analysis of 2,713 CPB cases. Of the 31 known cases of HPE, 81 preoperative and perioperative data points were gathered in the three different centers. Our findings indicate that HPE had an occurrence of 1.14 %, with 97% of them occurring in CÃ½BG patients. The mean time for this phenomenon to occur, was 7.9 ± 7.2 minutes, and the average time until resolution was 27.5 ± 14.0 minutes.

Gerard J. Myers, Joseph J. Karov, Patrick R. Weighell, Brian J. McCloskey, Alison M. Holt, Scott McTeer, Sandy L. Maxwell
QEII Health Sciences Center, Halifax, Nova Scotia, Health Canada, Ottawa, Ontario, Foothills Hospital, Calgary, Alberta, University Hospital, Edmonton, Alberta
ASSESSING THE EFFICACY OF TWO THERAPIES AIMED AT REDUCING POST-CARDIOPULMONARY BYPASS BLOOD LOSS

Postoperative bleeding remains a significant complication of cardiopulmonary bypass (CPB). New pharmaceutical and circuit coating innovations have been developed to ameliorate post-CPB blood loss. The goal of this study was to examine the relative merit of two such treatments: Aprotinin (Trasylol®) and Trillium™ coated oxygenators.

Sixty-seven patients undergoing primary cardiac surgery with CPB were randomly assigned into 4 groups: Group I (n = 20) received aprotinin/Trillium, Group II (n = 20) aprotinin/non-Trillium, Group III (n = 14) no aprotinin/Trillium, and Group IV (n = 13) no aprotinin/non-Trillium (control group). Demographic data was similar between all groups (p > 0.1). Chest/mediastinal tube drainage was recorded to assess bleeding at 4 time points: 1, 3, 6, and 24 hours postop. In addition, blood products administered post-CPB (up to 24 hours postop) were recorded.

Significant blood loss was noted between groups at 3, 6, and 24 hours postop (p = 0.011, p = 0.006, p = 0.047, respectively). At all time points, Group IV had the greatest mean blood loss, followed in decreasing order by Group III, Group II, and Group I. There was also a significant difference in the incidence of blood product administration between the 4 groups, specifically packed red blood cells (p = 0.006) and platelets (p = 0.032). Group IV received the most blood products, whereas Group I received the least.

The combination of Aprotinin use with a Trillium coated oxygenator provided the best protection against blood loss and subsequent blood product administration.

Jennifer Navratil, Shannon Herzog, Scott D. Niles, James M. Ploessl, Jeffrey E. Everett
University of Iowa Health Care, Iowa City, IA

EVALUATION OF THE RAPID POINT COAG, BAYER DIAGNOSTICS

The Rapid Point™ Coag is an automated laboratory analyzer for determining the hemostatic properties of whole blood. The instrument performs a variety of coagulation tests including prothrombin time (PT), activated partial thromboplastin time (APTT), protamine response test (PRT), heparin management test (HMT), heparin titration test (HTT), and ecarin clotting time (ECT). The current evaluation is for the HMT and HTT. The Accent® Heparin Management System stores case data and performs the necessary calculations to determine heparin dosing requirements, heparin and protamine response curves giving the user all the necessary information to determine the anticoagulation status of the patient.

When administering high doses of heparin, as in cardiopulmonary bypass (CPB), the ACT is commonly used to assess the anticoagulation status of the patient. The HMT correlates very well with the activated clotting time (ACT). The ACT is inherently affected to varying degrees by the hemodilution and hypothermia that is generally involved when undergoing CPB. The HMT appears to overcome these factors. The correlation between anti-Xa activity (the result of heparin administration) for the HMT appears to be significantly more linear when used for monitoring patients undergoing CPB as opposed to the ACT. The HMT and HTT, together, performs a heparin dose response (HDR) that correlates well with the HDR on the Hepcon® HMS.

Eight patients were monitored utilizing two systems in a side-by-side perspective evaluation. The Hepcon® HMS for the ACT Medtronic Inc. and the Rapid Point™ Coag from Bayer Diagnostics were employed. The instruments were observed to determine the preferential method for monitoring anticoagulation during CPB.

Jason Newsome
Charleston Area Medical Center, Charleston, WV
Cardiopulmonary bypass (CPB) exposes blood to artificial surfaces, resulting in mechanical damage to the formed elements of the blood, and activation of several biological cascades. Since artificial CPB circuits are negatively charged, the utilization of both albumin and hetastarch in prime solutions can have an affect on protein adsorption, which in turn, may lead to a cascade of destructive coagulation and inflammatory effects. The following study examined the biocompatibility of Poly(2-methoxyethylacrylate) coating, or PMEA, a surface coating marketed under the trade name of X-Coating.

An in vitro analysis was conducted utilizing fresh whole human blood and an extracorporeal circuit (n = 18 - venous reservoir, oxygenator with an integrated heat exchanger, arterial filter). Group I consisted of nine nontreated circuits, and Group II consisted of nine tip-to-tip X-Coated circuits. Each group was divided evenly into three subgroups, which included hetastarch, crystalloid and albumin. Two units of one-day old citrated human blood were utilized per circuit. Constant conditions maintained included hematocrit 30% ± 2, temperature 37°C ± 1, and a flow of 4L/min. Samples were collected at 0, 60, 120, and 240 minute intervals. Endpoint measurements included thromboelastography (TEG), activated clotting time (ACT), total protein, platelet count, hematocrit (Hct), thrombin anti-thrombin ELISA assay, beta-thromboglobulin, IL-8, C3a, and Scanning Electron Microscopy (SEM).

TEG results showed that there was a reduced trend in platelet function for non-coated groups in comparison to X-Coated circuits. The coagulation index was significantly higher in X-Coated circuits for both the crystalloid (+) and albumin (+) groups. However, it was found that hetastarch was significantly more degenerative on platelet function (+), despite the use of coated or non-coated circuits. Other results showed that for non-coated circuits, platelet count was not significantly affected by the use of various priming components, crystalloid (+ 1,000/mm³), albumin (+ 1,000/mm³), and hetastarch (+ 1,000/mm³). However, for X-Coated circuits, platelet counts were maintained for crystalloid groups (+ 1,000/mm³) and higher in albumin groups (+ 1,000/mm³), but again significantly degenerative for hetastarch groups (+ 1,000/mm³). Also, SEM demonstrated that fibrin deposition was present on non-treated circuitry and absent with the use of X-Coating.

In summary, this study found that priming components do have a significant effect on coagulation with albumin being most beneficial and hetastarch most harmful. X-Coating will maintain platelet function and number along with preventing fibrin deposition. In conclusion, X-Coating will improve the biocompatibility of circuits and when used in conjunction with albumin will result in decreased cellular activation and enhance biocompatibility.

Bernadette T. Nutter, Alfred Stammers, Ryan G. Schmer, Rebecca L. Ahlgren, Tunisia A. Ellis, Chen Gao, Hunter B. Holcomb, Lynette Hock
Division of Clinical Perfusion Education, University of Nebraska Medical Center, Omaha, NE
CORONARY ARTERY BYPASS GRAFTING: AN OFF-PUMP VERSUS ON-PUMP REVIEW

There has recently been an exponential increase in the number of coronary artery bypass grafts (CABG) being done without the use of cardiopulmonary bypass (CPB). However, the benefits of off pump coronary artery grafting (OPCAB) are still being determined. Our study reviewed the patient data on risk factors, intraoperative parameters and postoperative outcomes at two city hospitals for the period of August 2000 to September 2001.

Out of the total of 883 patients, 46.2% were OPCAB cases. The slightly higher predicted mortality of 3.5% for CPB cases than 3% for OPCAB was not statistically significant. There were no differences seen between the two groups in terms of age, gender, BSA, left main disease, and number of previous heart operations. Intraoperatively, OPCAB patients had fewer distal graft anastomoses (2.4 ± 1.0 vs 3.2 ± 1.0, \( P < 0.001 \)). Postoperatively, patients in the OPCAB group had less chest drainage twelve hours postsurgery (604 ± 337 mls vs 686 ± 582 mls, \( P < 0.05 \)), sustained fewer strokes (0.2% vs 2.1%, \( P < 0.05 \)), were significantly less transfused (15.4% vs 32.5%, \( P < 0.001 \)), and were discharged earlier (7.3 ± 5.6 days vs 8.5 ± 9.1 days, \( P < 0.05 \)). Other outcomes showed no significant difference in intubation times, ICU stay, evidence of myocardial infarction, reoperation rate for grafting, TIA’s, and infection. There was a mortality rate of 2% in the OPCAB group as compared with 4.2% for patients undergoing CPB (\( P = 0.057 \)).

Postoperative morbidity may be lower in OPCAB patients, but there are unresolved issues of adequate revascularisation of all diseased coronary arteries and satisfactory long-term graft patency.

Kieron C. Potger
Royal North Shore Hospital, Sydney, Australia
REDUCING MEDICAL ERRORS: PATIENT EVENT REPORTING FOR EXTRA-CORPOREAL THERAPIES

In late 1999, the Washington DC Institute of Medicine’s (IOM) Committee on Quality of Health Care in America released its first report entitled “To Err is Human.” (Modern Healthcare March 5, 2001, www.modernhealthcare.com) The Committee reported more than 100,000 patient deaths annually related to medical errors. A system for extra-corporeal therapy (ECT) patient-related event reporting has been designed and employed since 1997. Reportable patient events are defined to fall into seven main categories. The category description and average reported frequency for the last 12 months are:

<table>
<thead>
<tr>
<th>Patient ECT Event Category</th>
<th>Description of Event</th>
<th>Reported Frequency Per Million Opportunities $[# \text{ of sigma (} \sigma \text{)}]$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Death</td>
<td>Patient expired during surgery; Death may or may not be related to ECT</td>
<td>2,428 $[4 \sigma]$</td>
</tr>
<tr>
<td>Neurological Sequelae</td>
<td>Patient suffered a neurological insult during or following a clinical procedure</td>
<td>106 $[5 \sigma]$</td>
</tr>
<tr>
<td>Coagulation Issues</td>
<td>Adverse patient outcome or death during or following a case where coagulation complications were identified</td>
<td>159 $[5 \sigma]$</td>
</tr>
<tr>
<td>Treatment Interruption</td>
<td>Adverse patient outcome or death during or following a procedure where treatment interruption occurred</td>
<td>312 $[4 \sigma]$</td>
</tr>
<tr>
<td>Medication or Blood Errors</td>
<td>Medication or blood administration errors and/or adverse patient reactions</td>
<td>60 $[5 \sigma]$</td>
</tr>
<tr>
<td>Aberrant Practice</td>
<td>Clinician deviation from protocol or procedure resulting in adverse reaction</td>
<td>587 $[4 \sigma]$</td>
</tr>
<tr>
<td>Patient Injury</td>
<td>Patient injury due to events unrelated to the specific ECT procedure</td>
<td>62 $[5 \sigma]$</td>
</tr>
</tbody>
</table>

In addition to the patient-related events, equipment, and disposable item related events or failures are reported to a central database. The frequency of reported events is monitored and reported as the number of events per million opportunities (PMO) to fail. Patient-related event reports run at about 5,527 PMO and disposable-related reports run at about 398 PMO. Six Sigma quality improvement methods have been applied to the event reporting system.

Each institution in our network employs event reporting for continuous quality improvement. Individual hospital teams and subsets of institutions participate in national benchmarking of the frequency of these events and improvement in processes to decrease patient-related event during CPB.

J. Riley, G. Justison, M. Pearson, A. Steg, P.A. Zabetakis
Fresenius Medical Care—Extracorporeal Alliance, Lexington, MA
CONTINUOUS QUALITY IMPROVEMENT TO EVOLVE FROM A PERFUSION SERVICE TO AN EXTRA-CORPOREAL THERAPY SERVICE TO MEET CUSTOMER EXPECTATIONS. PART I: PROFESSIONAL AND REGULATORY LITERATURE REVIEW TO AUTHOR FIVE NEW CLINICAL POLICIES

In March 2001 the Washington DC Institute of Medicine (IOM) released its second report entitled “Crossing the Quality Chasm” and states that the US Healthcare System is “plagued by a serious quality gap” and “we need to reinvent the system.” (Modern Healthcare March 5, 2001.) Reorganization in clinical operations to combine the management of acute dialysis, apheresis, perfusion, and autotransfusion services, and the desire to reduce medical errors even further, provided the opportunity to redesign our quality systems. The foundation for the new quality system is five clinical policies.

<table>
<thead>
<tr>
<th>Policy Name</th>
<th>Description</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Safety</td>
<td>Provides standards for a safe and effective environment for patients and workers</td>
<td>1.1 Patient Safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.2 Workplace Safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.3 Extra-Corporeal Circuit Safety Device Usage</td>
</tr>
<tr>
<td>2. Quality Systems</td>
<td>Provides standards for quality improvement monitoring activities</td>
<td>2.1 Continuous Quality Improvement Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.2 Event Reporting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.3 Regulatory Agencies</td>
</tr>
<tr>
<td>3. Professional Development</td>
<td>Provides opportunities for personal and professional growth</td>
<td>2.4 Laboratory Management</td>
</tr>
<tr>
<td>4. Clinical Practice</td>
<td>Intended to improve the safety of specific practices common to all extra-corporeal therapies</td>
<td>3.1 Professional Organization Participation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.2 Continuing Education and Development</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.3 Annual Performance Review</td>
</tr>
<tr>
<td>5. Customer Satisfaction</td>
<td>Provides standards for clinician relationships with their customers</td>
<td>4.1 Blood Component Administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2 Medication Preparation and Administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.3 Physician Orders</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.1 Understand Customer Needs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.2 Meet Customer Requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.3 Customer Feedback</td>
</tr>
</tbody>
</table>

The policy standards are based on recognized professional organization, federal and state government agency, and accreditation group published essentials and standards. The policies list the essential behaviors that clinicians should exhibit during the provision of extra-corporeal therapy procedures. Part II will present the 12-month results of the audit for the clinical adoption of the five clinical policies within a large extra-corporeal therapy service group.

Fresenius Medical Care–Extracorporeal Alliance, Lexington, MA
HIGH-VOLUME, ZERO BALANCE ULTRAFILTRATION IMPROVES PULMONARY FUNCTION IN A MODEL OF POST-PUMP SYNDROME

It has been suggested that Zero Balance Ultrafiltration (Z-BUF) attenuates the inflammatory response associated with cardiopulmonary bypass (CPB). We propose to examine the effectiveness of Z-BUF using an established porcine CPB model that enduces post-pump syndrome. This model has demonstrated that while CPB or low dose endotoxin alone will not cause pulmonary injury, when they are combined sequentially acute lung injury will develop.

Following committee approval, a control and treatment group consisting of Yorkshire pigs (30–40 kg) were anesthetized, ventilated, and then cannulated at the right femoral and vein and artery and exposed to CPB for 60 min. Following CPB, a low-dose endotoxin (1g/kg) was administered and the animals were monitored for 3.5 hrs. The treatment group (n = 5) received high-volume Z-BUF (122 ± 41 ml/kg) and the control group (n = 5) did not. Hemodynamics, blood gases, and pulmonary functions were measured before, during, and after CPB.

During the experimental time course there were no differences in C.O., MAP, Na+, K+, Ca++, and IL-8 concentrations between groups. The following table compares pulmonary parameters of the 2 groups from baseline to 3.5 hours post-CPB.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Control Baseline vs. 3.5 CPB</th>
<th>Z-BUF Baseline vs. 3.5 CPB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial PO2 (mmHg)</td>
<td>238 ± 60 vs 78 ± 40*</td>
<td>279 ± 32 vs 195 ± 95</td>
</tr>
<tr>
<td>Pulmonary Compliance (ml/cm H2O)</td>
<td>32.2 ± 5.9 vs 8.4 ± 4.2*</td>
<td>35.2 ± 7.0 vs. 27.68.1</td>
</tr>
<tr>
<td>Lung dry/wet ratio</td>
<td>8.44 ± 0.81</td>
<td>6.05 ± 0.65</td>
</tr>
</tbody>
</table>

Data is expressed as mean ± standard deviation. *Denotes significant difference (p < 0.5) from baseline.

This result suggests that Z-BUF improves the pulmonary function in this model of lung injury and may be an effective tool in attenuating the CPB derived inflammatory process.

M. Robins, J. Vossler, X. You, F Nasrallah, G. Nieman, B. Searles, E. Darling
SUNY Health Science Center, Syracuse, NY
TEMPERATURE INACCURACIES DURING CARDIOPULMONARY BYPASS

Cerebral hyperthermia due to perfusate temperature above 37°C during the rewarming phase of CPB has been suggested as a contributor to postoperative neurological deficit. The purpose of this study was to determine accuracy of the Spiral Gold membrane oxygenator arterial temperature coupling system (oxygenator temperature) and the CDI 500 arterial blood gas shunt sensor (CDI temperature).

Seventeen patients undergoing CPB were studied. Oxygenator temperature and CDI temperature were compared to an indwelling temperature probe in direct contact with the arterial perfusate. The temperature of the indwelling probe was validated to be the actual temperature of the blood. Blood, bladder, room and water temperatures, as well as arterial line pressure, blood flow and hemoglobin were recorded every 10 minutes during hypothermic CPB and every minute after the start of rewarming. The data was analyzed using Student’s paired \( t \)-test, Student’s \( t \)-test with equal variance and Pearson correlation. The actual blood temperature was significantly higher than the oxygenator temperature for two of the four temperature probes (mean = 1.61°C and 0.91°C, \( p < 0.0001 \)). A significant positive correlation between the actual temperature and the oxygenator temperature error was observed for the same two probes (\( r = 0.44, p < 0.0001 \)), which suggests an increase in temperature error as the patient gets warmer. The actual temperature was significantly higher than the CDI temperature in all patients (mean = 1.2°C, \( p < 0.0001 \)). However, the CDI temperature error did not correlate with any of the other measured parameters. In conclusion, the coupling port on the Spiral Gold oxygenator generates inaccurate and misleading temperatures.

The perfusionist should consider these inaccuracies when using coupled temperature measurements and may consider the use of a direct temperature measurement system. Based on CDI data, perfusate temperature should be managed as not to exceed 35.8°C in order to maintain a patient delivery temperature of 37°C, minimizing cerebral hyperthermia.

M. Salah, R. Sutton, G. Tsarovsky, B. Sanders, M. Djuric
Department of Perfusion Technology, Rush University, Chicago IL
THE EFFECTS OF APROTININ ON PLATELET FUNCTION IN BLOOD EXPOSED TO EPTIFIBATIDE: AN IN-VITRO ANALYSIS

The preoperative use of platelet inhibitors has increased the risk of bleeding during cardiac surgery. Aprotinin has been shown to preserve hemostatic function in patients undergoing CPB. The purpose of this study is to investigate the effect of aprotinin on coagulation in blood exposed to eptifibatide.

Freshly collected bovine blood was utilized in an in-vitro model of extracorporeal circulation. Blood was separated into two groups: activated (60 minutes exposure to bubble oxygenation) and nonactivated. Within each group there were two subgroups: control (n = 3), eptifibatide (2.8 µg/mL, n = 3), aprotinin (250 KIU/mL, n = 3), and eptifibatide with aprotinin (2.8 µg/mL, 250 KIU/mL, n = 3). Twenty-four modified extracorporeal circuits utilizing a hardshell venous reservoir and cardioplegia heat exchanger were used. Blood flow was maintained at a rate of 1.25 L/min for a total of 170 minutes, at 37°. Samples were collected at 0, 20, 50, and 110 min intervals with the following variables measured: thromboelastography (TEG), activated clotting time (ACT), and hematocrit (Hct).

Results demonstrated that at 110 Minutes, the TEG Index (TI) was decreased by two-fold in the activated group compared to the nonactivated group (−6.13 ± 3.49 vs. 5.18 ± 0.08, p = .0003). The administration of aprotinin resulted in preservation of the TI (5.73 ± 2.91) vs. eptifibatide treated blood (−9.18 ± 2.47), p = 0.0001. Aprotinin combined with eptifibatide reduced coagulation derangements when compared to eptifibatide alone (−1.52 ± 0.626 vs. −9.18 ± 2.47, p = .0069).

In conclusion, aprotinin attenuated the negative effect of eptifibatide on platelet function, resulting in improved coagulation.

Ryan G. Schmer, Alfred Stammers, Rebecca L. Ahlgren, Tunisia A. Ellis, Chen Gao, Hunter B. Holcomb, Bernadette T. Nutter, Lynette Hock
Division of Clinical Perfusion Education, University of Nebraska Medical Center, Omaha, NE
QUALITY OF RED BLOOD CELLS USING AUTOTRANSFUSION DEVICES: A COMPARATIVE ANALYSIS.

Cell salvage devices are routinely used to process and wash red blood cells (RBCs) shed during surgical interventions. Even though the principle theory of cell saving is the same, the actual process to achieve this is very different from one device to another. The purpose of this study was to compare the quality of washed, concentrated RBC produced by five very different cell saving devices specifically the Cobe BRAT 2, Medtronic Sequestra1000, Haemonetics Cell Saver 5, Medtronic Autolog, and the Fresenius CATS. Reservoir and washed red blood cells were analyzed for hematocrit (Hct), platelets (PLT), leukocytes (WBC), potassium (K+), heparin, plasma free hemoglobin (PFH), and RBC recovery rate.

<table>
<thead>
<tr>
<th></th>
<th>Post Hct (%)</th>
<th>% RBC Recovery</th>
<th>Recovery Rate (ml/min)</th>
<th>% Removal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>WBC</td>
</tr>
<tr>
<td>Sequestra</td>
<td>57 ± 6</td>
<td>76 ± 16</td>
<td>10 ± 2</td>
<td>66 ± 14</td>
</tr>
<tr>
<td>BRAT 2</td>
<td>54 ± 8</td>
<td>94 ± 18</td>
<td>14 ± 5</td>
<td>30 ± 26</td>
</tr>
<tr>
<td>CATS</td>
<td>66 ± 7</td>
<td>87 ± 23</td>
<td>14 ± 5</td>
<td>45 ± 32</td>
</tr>
<tr>
<td>Cell Saver 5</td>
<td>45 ± 6</td>
<td>94 ± 16</td>
<td>22 ± 7</td>
<td>35 ± 17</td>
</tr>
<tr>
<td>Autolog</td>
<td>62 ± 2</td>
<td>79 ± 24</td>
<td>18 ± 5</td>
<td>78 ± 11</td>
</tr>
</tbody>
</table>

The Haemonetics and BRAT 2 had the highest RBC recovery. All devices adequately removed heparin and potassium. The Medtronic Autolog had the highest removal of platelets & PFH while the BRAT had the lowest. While the Autolog had the highest leukocyte removal, leucocytes were not adequately washed out by any of the autotransfusion devices.

In conclusion while all cell saving devices use the same theory of centrifugation, the actual washed RBC product is very different from one device to another.

Cyril J. Serrick, Mary Scholz, Arthur Melo, Onkar Singh, Dionne Noel
Trillium Health Centre
USE OF APROTININ DURING CARDIOPULMONARY BYPASS IN A PATIENT WITH PROTEIN C DEFICIENCY: A CASE REPORT

This case study reviews cardiopulmonary bypass (CPB) management in a Protein C deficient patient undergoing tricuspid valve replacement with the use of Aprotinin. The presence of Proteins C inhibits factors Va and VIIa in the extrinsic coagulation pathway and inactivates tissue plasminogen activator, thus maintaining hemostasis. Protein C deficiency can cause hypercoaguability, and may result in thrombolic episodes, especially in areas of low blood flow or during activation of the extrinsic pathway.

A 17-year-old male presented with severe tricuspid regurgitation, dilated right atrium, and impaired conduction pathway. The patient had a history of three prior tricuspid valve replacements. Protein C deficiency was first diagnosed after thrombosis of the second valve prosthesis. Other case studies in protein C deficient patients suggested the use of fresh frozen plasma (FFP) in pump prime to restore Protein C levels, ATIII replacement prior to heparin administration, and avoidance of Aprotinin due to its known competitive inhibition of activated Protein C. Two units of FFP were given by anesthesia prior to the administration of Aprotinin and two units of FFP were added to the pump prime. The full Hammersmith loading dose of Aprotinin was administered to the patient just prior to initiation of CPB. The same dose of Aprotinin was added to the pump prime just prior to the initiation of CPB. Additional heparin (100 units/kg) was administered every hour during bypass. ACTs were performed every 15 minutes and thromboelastographs were performed every hour. The patient recovered from surgery without major complications. There were no perioperative or postoperative thrombolic events. The patient was discharged on day 41 and is doing well. Postoperative arrhythmias were a contributing factor to his delayed discharge.

The use of Aprotinin in a Protein C deficient patient undergoing open-heart surgery may be safe if Protein C levels are restored prior to administration of Aprotinin and anticoagulation is carefully monitored.

Alicia Sievert, Mary McCall, Mindy Blackwell
Medical University of South Carolina, Charleston, SC
EXAMINING THE EFFECTIVENESS OF LEUKOCYTE DEPLETION DURING ORTHOTOPIC LIVER TRANSPLANTATION AT DECREASING COAGULOPATHIES AND ACUTE GRAFT REJECTION

The objective of this study was to determine if there was a clinically significant decrease in acute graft rejection and coagulopathies using leukocyte depletion (LD) during human orthotopic liver transplantation (OLT). Clinical evidence suggests that reperfusion of a graft organ is a primary source of pro-inflammatory stimuli, particularly activated leukocytes and platelets, which may lead to hepatic inflammation and decreased liver function postoperatively. These major morphological changes on the subcellular level occur as adhesion molecules are expressed on endothelial cells and neutrophils begin to adhere to these cells. Leukocyte activation during reperfusion has also been associated with an increased incidence of blood loss during reperfusion due to depletion of hemostasis components by the enhanced activity of enzymes such as plasmin, trypsin, and leukocyte proteases. Previous studies suggest that leukodepleted reperfusion prevents ultrastructural damage and interstitial edema.

A randomized prospective study was performed on OLT patients undergoing veno-venous (V-V) bypass. Group 1 patients received LD of all banked blood and cell-salvaged blood. Additionally, a LD filter was placed in the V-V bypass line that was used during the first 10 minutes of reperfusion. Group 2 received no LD. Acute graft rejection was measured by evaluating standard liver function tests, length of hospital stay, and length of time on ventilator compared to baseline after treatment. Coagulation status was monitored by intraoperative thromboelastograms and the total amount of blood products used during surgery. Data were compared by standard T-tests.

This study will determine whether LD may be beneficial at reducing acute graft rejection and coagulopathies associated with reperfusion injury during OLT.

Alicia Sievert, Todd Smyre
Medical University of South Carolina, Charleston, SC
BIOREACTORS FOR TISSUE ENGINEERING, A NEW ROLE FOR PERFUSIONISTS?

Tissue engineering is an exciting new area of medicine with rapid growth and expansion over the last decade. It has the potential to profoundly impact the practice of medicine and influence the economic development in the industry of biotechnology. In almost every specialty of medicine, the ability to generate replacement cells and develop tissues will change the focus from artificial organs and transplantation to growing replacement organs from the patient’s own stem cells.

Once these organs are at a size that requires perfusion to maintain oxygen and nutrient delivery, then automated perfusion systems termed “bioreactors” will be necessary to sustain the organ until harvesting. The design of these “bioreactors” will have a crucial role in the maintenance of cellular function throughout the growth period. The perfusion schemes necessary to determine the optimal conditions have not been well elucidated and will undergo extensive research over the next decade. The key to progress in this endeavor will be development of long term perfusion techniques and identifying the ideal pressures, flow rates, type of flow (pulsatile/non-pulsatile), and perfusate solution.

Perfusionists are considered experts in the field of whole body perfusion, and it is possible that they can participate in the development and operation of these “bioreactors”. Additional education of perfusionists in the area of tissue engineering is necessary in order for them to be an integral part of these exciting new areas of medicine.

Joseph J. Sistino
Medical University of South Carolina
TEMPERATURE DEPENDANT EFFECTS OF CARBON DIOXIDE ON CEREBRAL OXYGEN SATURATION DURING PEDIATRIC CARDIOPULMONARY BYPASS

Neurological injury during cardiopulmonary bypass has become an area of major concern in recent years. The Somanetics INVOS Cerebral Oximeter can be used to assess cerebral oxygen delivery. This noninvasive device measures mixed oxygen saturation in the brain by transmitting infrared light through a pair of "somasensors' placed on the patient’s forehead.

The purpose of this experiment is to determine a relationship between the arterial carbon dioxide tension and the cerebral oxygen saturation as measured by the INVOS device. The null hypothesis is that there is no relationship between these two parameters at any of the following temperatures: 37, 32, 25, or 18°C prior to circulatory arrest.

Data collection includes arterial blood temperature, esophageal temperature, perfusion flow rate, average cerebral oxygen saturation, mean arterial temperature and carbon dioxide tension. The oxygen saturation was corrected to baseline values to account for individual variation.

Preliminary results in the first 10 patients did not show a significant correlation during cooling at 32°, 25°, or 18°C between the percent baseline change in average cerebral oxygen saturation and the carbon dioxide tension. However, during rewarming the correlation coefficient between these two variables increased as the temperature increased from 25 to 37°C. The relationship between the percent baseline change in average cerebral oxygen saturation and the carbon dioxide tension approached significance (p = .06) at 37°C.

This study shows the importance of maintaining normal pCO2 levels during the rewarming phase of cardiopulmonary bypass in order to maximize cerebral oxygen delivery.

Amanda E. Watson, Mary M. McCall, Joseph J. Sistino, Scott M. Bradley
Medical University of South Carolina, Charleston, SC
THE HEATER-COOLER-UNIT–A CONCEIVABLE SOURCE OF INFECTION

Even drinking water is contaminated with pathogenic microorganisms. This does not necessarily pose a risk for healthy individuals but may result in serious consequences in people with impaired immune system.

This is particularly valid if drinking water is used for medical purposes. The Heater-Cooler-Unit (HCU) connected with heat-exchangers or blankets by tubing and connection is a closed water circuit that contains microorganisms and algae. While connecting the tubing with the heat-exchanger spilling of water cannot be avoided. Microbiological examinations show that units are polluted by germs and particles and expose the patient and OR-equipment to potential and increased risk of infection should this HCU water contact the patients vasculature thus as skin and airway. As a result of the high incidence of particle and algae in the HCU malfunction occurs. Sampling show >1000/ml CFU (Colony Forming Unit) at 36°C and 55/ml CFU at 20°C on average. The specific findings include Pseudomonas and Legionella.

To disinfect HCU seems to be very difficult. Often HCU do not provide any technology to reduce bacterial or other contamination. The instruction for use of oxygenators often exclude the use of disinfectants. Maintenance instructions for the HCU advocate the use of disinfectant, which bear the risk of oxygenator damage and of heat-exchanger leakage. The effect of chemical disinfectants and heat-exchanger-membranes have not been examined, they may impair heat-exchanger permeability and function. As an alternative to chemical and thermal disinfection, we used the alternative method of filtration. Using a membrane filter element, we noticed a decreasing number of CFU from 55 CFU to sterile conditions at 20°C and from >1000 CFU to 100 CFU at 36°C. In addition we noticed a removal of other particles and algae.

In conclusion the decreasing number of CFU may lower the risk of infection and the removal of particles and algae maintain a proper function of the HCU.

Heinz Weitkemper, Andreas Spilker
Heart Center North Rhine, NorthRhine Westalia, Germany

OXYGENATOR PERFORMANCE IN AORTIC SURGERY WITH HYPOTHERMIC CIRCULATORY ARREST

Sixty patients undergoing repair of thoracic aortic aneurysm with hypothermic circulatory arrest were examined. Thirty-two patients were perfused with a capillary membrane oxygenator with protein coating and polyethylene heat exchanger (A), and the remaining 28 cases employed a capillary membrane oxygenator with a steel heat exchanger and heparin coating (B). Heat exchanger performance was 0.83 (A) versus 0.55 (B). Myocardial protection was performed with crystalloid cardioplegia in all cases. Perfusion time (149, A vs. 161 min, B), ischemic time (70, A vs. 73 min, B), cooling phase (65, A versus 77 minutes, B), and reperfusion time (57, A vs. 64 min,B) were lower in group A.

The amount of packed red cells transfused was significantly lower in Group A (1.16 A vs. 2.51 units, B). Lactate was lower in group A on CPB before and after hypothermic arrest with normal systemic flow and adequate perfusion. Platelet count shows a significant drop in Group B (267–116) vs. Group A (234–150). (The Mann Whitney U-Test was employed to compare differences between groups).

We therefore conclude that perfusion time is lower, when protein coated oxygenators with high efficiency heat exchanger are used.

Heinz Weitkemper
Heart Center North Rhine, NorthRhine Westalia, Germany
THE PROTECTION OF WARM INDUCTION AND REPERFUSION ON OPEN HEART SURGERY IN CAD PATIENTS

To study the protection of warm induction and reperfusion on CAD patients myocardium.

Methods: Twenty-four CAD patients were randomly divided into two groups: a group of warm blood (warm induction and reperfusion blood cardioplegia, n = 12) and a group of cold crystalloid (n = 12). The aortic crossclamp time and CPB time in the two groups was the same. Venous blood sample was taken from coronary sinus in pre-bypass and post-bypass time to measure creatine kinase (CK-MBmass), troponin I(TnI).

CK-Mbmass and cTnI release in the group of cold blood were higher than those in the warm blood group (P < 0.05), myocardial ultrastructre was more excellent in group of warm blood than group of cool blood.

The technique of warm induction and reperfusion has a good protection on open-heart surgery in CABG.

Bing Yang-ji, Jin Ping-Liu, Zheng Yi-Feng, Long Cun
Department of Cardiopulmonary Bypass, Cardiovascular Institute & Fuwai Hospital, Beijing, China
APPLICATION OF A MINIATURE EXTRACORPOREAL CIRCUIT WITH ASANGUINEOUS PRIME IN A RAT MODEL OF CARDIOPULMONARY BYPASS

A clinically relevant model of rat CPB would be a valuable tool for studies on bypass pathophysiology and therapeutic strategies. Previously published rat models had a number of limitations including a large circuit surface area, a requirement of donor blood for prime, and difficulties achieving full CPB. The purpose of this study is to establish a rat model that will overcome these limitations. A miniature circuit was designed that included a filtered reservoir, heat exchanger, membrane oxygenator, and arterial inline blood gas monitoring. The circuit performance was evaluated including prime volume, compliance, dynamics, gas, and heat exchange in accordance with the modified AAMI standards. Circuit was primed with a crystalloid solution (9.5 ± 0.5 ml) and CPB was established (male sprague-dawley, 430–475 g, n = 5) by cannulating left common carotid artery for the arterial line and the external jugular vein advancing down to the right ventricle for venous drainage. The animals were placed on full flow normothermic CPB (110 ml/kg/min) for 1 hour and allowed to recover for 2 hours. Hemodynamics, hemoglobin (Hb) and blood gases were analyzed before, during and after CPB. Data was expressed as mean ± sd and t-test was used for the comparison between pre- and post- CPB. Sham operation group (n = 4) was included for the same procedure and analysis except CPB. The results of hemodynamics, Hb and blood gases of perioperation in the rats with CPB were listed in the table. Hemoglobin at 60 minutes post-CBP was lower compared to pre-CBP. However, no statistically significant differences between pre- and post-CBP on hemodynamics and blood gases were found in comparison to sham group.

We established a miniature circuit with asanguineous prime for rat CPB model with clinically acceptable results of hemodynamics, blood gases and hemodilution, which could be used for further clinically relevant studies.

X.M. You, F. Nasrallah, E. Darling, M. Robins, N. Clay, G. Nieman, B. Searles
SUNY Health Science Center, Syracuse, NY

<table>
<thead>
<tr>
<th></th>
<th>CPB (n = 5)</th>
<th>Sham (n = 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-CBP</td>
<td>30 min</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>101 ± 5</td>
<td>N/A</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>68 ± 5</td>
<td>N/A</td>
</tr>
<tr>
<td>MBP (mmHg)</td>
<td>79 ± 5</td>
<td>47 ± 4*</td>
</tr>
<tr>
<td>PaO2 (mmHg)</td>
<td>109 ± 15</td>
<td>209 ± 86</td>
</tr>
<tr>
<td>PaCO2 (mmHg)</td>
<td>42 ± 5</td>
<td>25 ± 2*</td>
</tr>
<tr>
<td>Hb (g/dl)</td>
<td>15.7 ± 1.1</td>
<td>9.4 ± 0.5*</td>
</tr>
</tbody>
</table>

*p < 0.05, in comparison with Pre-CBP, N/A/ = not available.
HAVE PREDICTORS FOR LEFT VENTRICULAR DYSFUNCTION FOLLOWING AORTIC VALVE REPLACEMENT CHANGED DUE TO IMPROVEMENTS IN MYOCARDIAL PROTECTION

The purpose of this study is to identify whether preoperative ejection fraction and aortic valve pressure gradients are predictive of left ventricular dysfunction after aortic valve replacement. This will be assessed by a retrospective review of echocardiograms prior to surgery and up to 6 months following after aortic valve replacement.

The experiment will be modeled after a previous experiment completed by Hammermeister et al. for the Veterans Administration Cooperative Study on Valvular Heart Disease in 1989. This study concluded that: “the strongest predictor of postoperative dysfunction was preoperative dysfunction”. The major risk factors for postoperative left ventricular dysfunction were found to be: low ejection fraction, history of a preoperative myocardial infarction, large aortic valve pressure gradient.

Since this publication more than 12 years ago there have been significant changes in myocardial preservation techniques. Myocardial protection techniques now include blood cardioplegia, retrograde cardioplegia delivery, and substrate enhancement of the blood cardioplegia prior to reperfusion.

The null hypothesis is that there is no difference in the predictors for postoperative dysfunction when compared to the original study. The study will utilize multiple logistic regression analysis to determine whether the outcome, postoperative left ventricular dysfunction, is still affected by the same preoperative variables.

Chanda G. Cummings, Joseph J. Sistino, J. Todd Smyre, Adell E. Bell
Medical University of South Carolina, Charleston, SC
MATRIX METALLOPROTEINASE ACTIVATION IN AN EXTRACORPOREAL CIRCULATION CIRCUIT

Matrix metalloproteinases (MMPs) are a family of degradative enzymes that have roles in both normal physiology and pathology. As the levels of activated MMPs rise, the balance between normal tissue reconstruction and pathologic degradation is disrupted and vascular integrity may be compromised. Increased MMP levels have been associated with the inflammatory response and cardiopulmonary bypass (CPB). Prior research by this institution found that specific MMP species function during and after CPB. Whether and to what degree the extracorporeal circuit (ECC) induces the release of MMPs from endogenous circulating cells in the blood has yet to be determined.

Purpose: initiate MMP activity in blood via exposure to an ECC and reduce activated MMPs using leukocyte-depleting filter.

Autologous whole bank blood was exposed in vitro to an ECC for 90 minutes per trial (n=3). The ECC design consisted of a pediatric membrane oxygenator, an arterial line filter for the control circuit, and ¼” heparin coated tubing. A positive displacement pump was used. Normothermic temperature was maintained and sample analyses were corrected for dilutional hematocrit. Samples were centrifuged for collection of plasma and then stored at −20°C until analysis of MMP release using ELISA.

The MMP-9 plasma levels increased by three fold at 90 minutes on pump in the control trials with the average baseline MMP-9 level of 47.63 ng/mL and the average MMP-9 level at 90 minutes equal to 147.60 ng/mL.

Exposure of whole blood to a standard ECC is associated with an increase in MMP-9 plasma levels. Components of the ECC itself may be responsible for the MMP activation, although the mechanism is unknown at this time. Future studies will focus on interruption of this process as well as examination of other MMP species involved in the response. Three trials will be performed using an experimental loop circuit incorporating a leukocyte depletion filter.

Susan Heaton, Francis Spinale, Himali Gunasinghe, Joseph Sistino, Mindy Blackwell
Medical University of South Carolina, Charleston, SC
MID AND LONG TERM USE OF AN ONLINE BLOOD GAS MONITORING DEVICE (CDI 500®) IN PATIENTS UNDERGOING EXTRACORPOREAL MEMBRANE OXYGENATION

Online blood gas monitoring improves the safety of patients during extracorporeal circulation. Also for mid and long-term extracorporeal support an online device might be superior because of the unlimited availability of patient data and the potential reduction of the number of blood samples. However, no device is available until yet. In a prospective study the CDI 500® (Terumo) heparin coated system for online blood gas analysis was tested in patients on extracorporeal membrane oxygenation (ECMO) comparing the results with them of intermittent “bloody” measurement using ABL 715 (Radiometer).

The completely heparin coated ECMO setup consisted of a tube system with centrifugal pump (Biomedicus®, Medtronic), an oxygenator (QuadroxD, Jostra), and cannula (Jostra) using femoro-femoral insertion. The CDI 500® arterial shunt sensor was integrated via bypass using a stopcock manifold and purge lines between outlet side luer connector of oxygenator and the venous inlet of pump. Priming and de-airing of the system was without any evident problems.

The online device was used in 10 patients with a mean application time of 48 ± 54 hours (range 4–89). The differences between online and sample measurements were 7.5 ± 3 % for pO₂, 6.5 ± 2.5 % for pCO₂, 2 ± 0.5 % for pH and 11 ± 10.5 % for potassium, respectively while be deviation of the parameters pO₂, pCO₂ and pH ranged within acceptable values as know from blood gas analyzers. The potassium measurements showed no uniform characteristic. After more than 14 hours all sensors (n = 7) developed fibrin clots inside the sensor without any impaired of measurements.

The CDI 500® arterial shunt sensor with heparin coating is a safe device for mid and long term use in patients on ECMO. Especially excellent and simple pO₂ and pCO₂ measurements will allow a safe control of the oxygenator function in this application.

M. Kaluza, U.F.W. Franke, Th. Wahlers
Department of Cardiothoracic and Vascular Surgery, Friedrich-Schiller-University Jena, Germany
MIDTERM USE OF A BIOLINE® COATED OXYGENATOR WITH A CLOSED HOLLOW FIBER IN EXTRACORPOREAL MEMBRANE OXYGENATION FOR POSTCARDIOTOMY HEART FAILURE

One of the most important problems of midterm use of hollow fiber membrane oxygenator (MO) in extracorporeal membrane oxygenation (ECMO) is reflected by oxygenator failure due to plasma leakage or gas transfer failure. The open pores of the hollow fibers are the major cause for condensation problems. MO with silicon membrane might reduce the failure rate due to this reason, however an inadequate debubbling and the large nonvascular surface area are disadvantages.

The oxygenator QuadroxD (Jostra) is a MO with a closed membrane and a bioline® coating for midterm use, it has a surface area of 1.8 m² and needs a priming volume of 250 ml. This oxygenator was used in 9 patients in the context of femoro-femoral ECMO for low cardiac output support from 01/2001–09/2001. The setup included a completely heparin coated ECMO setup consisting of a tube system with a centrifugal pump (Biomedicus®, Medtronic) and cannula sets 17/21 Fr. or 21/21 Fr. (Jostra) using femoro-femoral percutaneous insertion.

We observed a mean running time of this setup including the QuadroxD of 33 ± 34 hours (4–89). Flows approx. 3.5 to 4.6 L/min was reached depending on cannula size. The observed pressure drop across the oxygenator using a flow of 4.0 L/min was 32 ± 2 mmHg. No oxygenator failure necessity for change out was notified in these 9 patients. There was an excellent gas transfer over the complete running time monitored by CDI 500® (Terumo) arterial shunt sensor.

We therefore conclude that an ECMO setup applying the oxygenator QuadroxD leads to excellent results in patients following postcardiotomy heart failure up to 4 days.

M. Kaluza, U.F.W. Franke, A. Bergmann, Th. Wahlers
Department of Cardiothoracic and Vascular Surgery, Friedrich-Schiller-University Jena, Germany
PERFUSION, THE INTERNET, AND A WEBPAGE: 101

Since the commencement of the Internet, the growth of web pages onto the global super highway has been phenomenal. The ever-growing mass of web pages range from the unsophisticated single pages to the multiple-paged online retailers and news broadcasts. Almost everyone today is rushing to announce his or her online existence.

A web page is a billboard open to the world, for a global audience. Like an open forum, web pages are able to publish information to a very wide audience. Through the use of text and graphics, an institution or company’s products, achievements, activities, announcements etc. can effortlessly and instantaneously be displayed on everyone’s desk. Used together with e-mail, a web page gives people an alternative method of contact and communication.

With regular updates, information displayed on a web page could always be up-to-date and current. This helps keep the cost of publishing down for a company as it does away with expensive printing of hundreds of brochures or publications due to revisions. On top of that, unlike paper-based publications, web pages can never be “thrown away”. Your page, once launched would always be there, ready to be viewed again and again.

Web pages are still generally a very new concept in perfusion services and we will describe how achievable this process can be to the novice. Having a web page can serve to declare your technical competence and level of sophistication to potential clients. A well-designed page can even help sway prospective clients in your favor. Like a badge of pride, they can be “worn” on the Internet for the world to see.

Mark M. Nuszkowski, Scott D. Niles
University of Iowa Health Care, Iowa City, IA

IN VIVO EVALUATION OF THE QUADROX MEMBRANE OXYGENATOR

The use of membrane oxygenators has become a standard in surgeries requiring cardiopulmonary bypass (CPB). Although safe and efficient, these oxygenators cannot provide the superior capabilities and environment of the native lungs. Therefore, ongoing research by manufacturers of membrane oxygenators is critical for continuing improvement in the performance of membrane oxygenators, as they strive to resemble the characteristics of the native lungs.

In this study, performance of the Quadrox membrane oxygenator with the Bioline coating was evaluated on 25 consecutive patients requiring CPB during open-heart surgery. The following parameters were recorded during the evaluation: blood flow (L/min), pressure drop across the membrane (mmHg), oxygen transfer (VO₂), bladder temperature (°C), sweep gas (L/min), Fi₀₂ (%), arterial temperature (°C), venous temperature (°C), and heater-cooler temperature (°C). Also, blood gases were recorded every 30–45 minutes. The mean patient BSA was 1.99 ± 0.19 m², mean CPB time was 142.4 ± 35.7 minutes, mean pressure drop was 43.9 ± 15 mmHg, mean blood flow was 4.26 ± 0.8 L/min, mean Fi₀₂ were 0.56 ± 0.09 %, and the mean coefficient for heat exchange was 1.43 ± 2.5.

Quadrox demonstrated excellent gas exchange and heat exchange capabilities and a low-pressure drop across its membrane. We conclude that the Quadrox is a safe, effective, and simple to use oxygenator for routine CPB.

Jason Sarnecki, Joel Pellot, David Durdov, Robin Sutton, Gary Tsarovsky, Mike Djuric
Rush University, Chicago, IL
ANTECOAGULATION MANAGEMENT IN A PEDIATRIC PATIENT
DEMONSTRATING A HEMOSTATIC ABNORMALITY

A six-year-old patient in preparation for an elective surgical repair of a complex
multi-level left ventricular outflow tract obstruction demonstrated heparin resistance,
delaying cardiopulmonary bypass (CPB). The patient successfully underwent surgeries
at another institution at 2 months of age (repair of a double outlet right ventricle
complex) and 11 months of age (revision of the left ventricular outflow tract),
respectively. However, detailed records were unavailable. A baseline activated clotting
time (ACT) of 133 seconds was obtained. Beef lung sodium heparin was administered
at 300 u/kg and the ACT value decreased to 86 seconds. A repeat dose of 300 u/kg of
heparin was administered from a different lot of heparin via central venous line. The
ACT value was inadequate at 280 seconds. The procedure was abandoned and the
patient was monitored and tested for coagulation defects postoperatively. Testing did
not detect heparin induced platelet antibody (HIPA) or heparin-induced
thrombocytopenia (HIT), and there were no findings indicative of thrombosis.
Prothrombin time (PT) and activated partial thromboplastin times (APTT) were elevated
possibly as a result of heparin/antithrombin inhibition of factors IXa and Xa. The
finding of decreased AT III levels related to the transient effects of heparin
administration and pre-operative diagnosis was noted. The patient returned to the
operating room 2 days later. Transfusion of exogenous AT III (fresh frozen plasma FFP)
was administered preoperatively and intra-operatively by anesthesia with subsequent
correction of the coagulation profile. The CPB circuit was primed with 1 unit of FFP. A
bolus of 300 u/kg of heparin established adequate anticoagulation (ACT = 452 sec.).
Cardiopulmonary bypass and surgical repair of the defect was completed without
complications. Cardiopulmonary bypass was conducted for 100 minutes requiring 3000
additional units of heparin. Activated clotting times ranged from 414–524 sec. The
patient was successfully weaned from CPB. Antithrombin III deficiency in pediatric
patients is a presumptive diagnosis based on heparin resistance (failure to obtain ACT’s
> 480 seconds after initial bolus of 600 u/kg of heparin). Congential Antithrombin
deficiency or heparin antibodies were implicated as factors for this heparin resistance.
Further diagnostic testing is in progress. Impending risk of hemostatic abnormalities
should be anticipated in the re-operative pediatric cardiac patient.

Juan L. Tucker, Michael L. Schmitz, Charles E. Johnson, Sherry C. Faulkner,
Jonathan J. Drummond-Webb
Arkansas Children’s Hospital, University of Arkansas for Medical Sciences Campus,
and Central Arkansas Veterans Hospital, Little Rock, AR