Abstracts

DATABASE REVIEW: CLINICAL OUTCOMES OF NON-COATED AND MULTI-COATED CARDIOPULMONARY BYPASS CIRCUITS IN INFANTS

PURPOSE: To assess the clinical effects of non-coated and multi-coated circuits used in pediatric cardiac surgery.

MATERIALS: Coated circuits were constructed with three different coatings materials. The Arterial-Venous loop was composed of Medtronic Trillium coating, the oxygenator with the Lilliput I PhISIO coating, and remaining conduits with Cobe SmartX. The non-coated group contained medical grade Poly Vinyl Chloride (PVC) tubing.

METHODS: A retrospective review of a patient database using non-coated and multi-coated cardiopulmonary bypass (CPB) circuits in infants (IRB # 03 06-067X).

<table>
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<th>Non-Coated (n=87)</th>
<th>Multi-Coated (n=29)</th>
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<td>NS</td>
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<td>Blood Added on CPB (%)</td>
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<td>HCT increase following MUF (%)</td>
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<td>Anion Gap increase (mEq)</td>
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<td>Length of Stay [LOS] (days)</td>
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<td>9.4 7.7</td>
<td>NS</td>
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<tr>
<td>Mortality (%)</td>
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<td>NS</td>
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<td>Time on Ventilator (hrs)</td>
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<td>Chest Tube Drainage (cc/kg/24hr)</td>
<td>27.4 30.4</td>
<td>27.4 30.4</td>
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</table>

PARTICIPANTS: The patient populations were of risk categories two and three as described by Jenkins 2002, kilogram body weights ≤ 6.0, no aprotinin administration, and the use of MUF (Modified Ultrafiltration) following bypass.

RESULTS: The use of multi-coated circuits in this population trended toward improved post MUF hematocrits despite less blood administration on bypass, decreased LOS, time on ventilator, and mortality. However, the use of multi-coated circuits also resulted in an increased anion gap post-surgery, additional chest tube drainage, and higher defibrillation rates post cross-clamp removal.

CONCLUSION: Multi-coated CPB circuits trended towards benefiting moderate risk group infants.

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UTILIZATION OF THE CDI 500® FOR CONTINUOUS BLOOD GAS MEASUREMENT DURING EXTRACORPOREAL MEMBRANE OXYGENATION SIMULATION

The Oximetrix® III Opticath (Abbott Critical Care Systems) is frequently cited for continuous measurement of venous saturation in a variety of applications, including extracorporeal membrane oxygenation (ECMO). Additional information would be useful for patient management during critical periods of ECMO such as initiation and termination. The CDI 500® (Terumo Inc.) is an inline blood gas monitoring tool commonly used during cardiopulmonary bypass (CPB) procedures to continuously assess blood gases, hematocrit, potassium, and bicarbonate. The purpose of this experiment was to evaluate the efficacy of the CDI 500® in trending venous blood gases during ECMO. An ECMO simulation circuit consisting of a silicone rubber membrane oxygenator (Medtronic Inc.) and a stainless steel heat exchanger (Medtronic Inc.) was constructed, and a standard venous reservoir bag (Medtronic Inc.) was used to represent the patient. The CDI and the Opticath were incorporated into a stopcock manifold that originated just prior to the oxygenator and returned flow to the venous line. The circuit was primed with fresh porcine blood and conditioned with the addition of CO₂ to simulate typical venous blood under ECMO conditions. After an initial calibration procedure, samples were drawn and analyzed by an AVL Opti CCA (Roche) every four to eight hours for a period of seven days, with calibration of each device at sample intervals. The data was plotted and a least squares regression line was calculated. The average drifts for venous saturation of the CDI and Opticath after three days were 5.7% and 8.8% respectively. At day seven, drift for the CDI was 8.2% and the Opticath was 12.4%. Based on these findings, the CDI 500® is a safe and effective tool for utilization during ECMO.

Aaron Schreur, Scott Niles, James Ploessl
University of Iowa Hospitals and Clinics
A NOVEL APPROACH IN SEQUESTERING LEUKOCYTES IN BLOOD CIRCUITS; REDUCTION IN PROTEASE LEVELS

BACKGROUND: Matrix metalloproteinases (MMPs) are a family of zinc dependent proteases, which play a role in tissue remodeling. Cardiopulmonary bypass (CPB) is associated with a systemic inflammatory response, which induces MMP expression. While leukocyte-reducing filters (LRF) have been demonstrated to attenuate this inflammatory response, but the effects on MMP expression are poorly understood.

METHODS: The following experiment employed 3 different circuits in which porcine blood (n=2) was continuously flowing through each circuit for up to 1.5 hours. First, a continuous circuit without an LRF was used as a reference control. Second, a single leukocyte reducing circuit (S_LRF) allowed blood to continuously flow through the filter for up to 1.5 hours. Finally, a multi-leukocyte reducing filter circuit (M_LRF) had blood circulate through each individual LRF for 30 minutes at a time. Blood samples were taken pre and post filter for every 30 minutes for. Plasma MMP-9 relative abundance was examined by gelatin zymography.

RESULTS: In the S_LRF group, MMP-9 abundance steadily increased over time, (277±64% at 1.5 hours before the filter vs. baseline set at 100%). However, in the M_LRF group, MMP-9 abundance did not change from baseline values, (87±8% at 1.5 hours before the filter vs. baseline set at 100%).

CONCLUSION: The unique findings were two-fold. First, the neutrophil degranulation product, MMP-9, increased over time in the S_LRF circuit. This likely reflects neutrophil sequestration and degranulation within the filter. Second, circulating the blood through multiple filters for 30 minutes at a time decreased MMP-9 abundance, which in turn likely reflects an abrogation of neutrophil degranulation. Therefore, the utilization of multiple LRFs during CPB may attenuate tissue damage caused by the inflammatory response, which occurs post CPB.

Theresa A. Brinsa, Robert E. Stroud, Jonathon T. Smyre, Francis G. Spinale
Medical University of South Carolina
TRANSFUSION-FREE CARDIOPULMONARY BYPASS IN JEHOVAH’S WITNESS PATIENTS WITH A BODY WEIGHT LOWER THAN 5 KG

Cardiac surgery in pediatric Jehovah’s Witness patients is a great challenge for the cardiothoracic surgery team, especially for the perfusionist. Jehovah’s Witness patients and their families do not accept donor blood transfusions. Autologous blood transfusions are also rejected if there is no continuous contact between the circulation and the sequestered autologous blood.

We report the conduct of cardiopulmonary bypass (CPB) during open-heart surgery in three infants with a body weight of 3.1 kg, 3.5 kg and 4.5 kg, respectively, without transfusion of blood components.

A small volume CPB circuit with a priming volume of 200 ml including the arterial line filter was designed to decrease the degree of hemodilution. A dedicated pediatric heart lung machine console with remote pump heads as well as intensive blood conservation efforts allowed the operation without the use of donor blood. The CPB circuits were primed with crystalloid solution only. The procedures were performed in normothermia or in moderate hypothermia. Pre-CPB hemoglobin levels were 8.5 g/dl, 10.6 g/dl and 10.8 g/dl. The measured hemoglobin concentrations on CPB ranged from 5.5 to 5.9 g/dl, 6.4 to 6.8 g/dl and 5.9 to 6.5 g/dl, respectively. The patients did not receive any blood or blood products during their entire hospital stay.

Wolfgang Boettcher, Frank Merkle, Michael Huebler, Andreas Koster, Fritz Schulz, Michael Kopitz, Hermann Kuppe, Peter Lange, Roland Hetzer
German Heart Institute
CORONARY BARORECEPTORS IN HUMANS

Previous studies have identified the presence of coronary baroreceptors in animal models. We set up a study to explore the presence of coronary baroreceptors in humans. This was done with isolated, graded aortic root perfusion in patients during cardiopulmonary bypass.

With ethical approval 12 patients with normal coronary arteries, aged 58–75 (mean 69) years, undergoing mitral valve surgery were recruited to the study with informed consent. Those with aortic valve incompetence, coronary or peripheral artery disease and diabetes mellitus were excluded.

They were randomised to have their coronary perfusion pressure set low at 50mmHg for 90seconds, then adjusted high to 80mmHg for 90seconds (L-H) or the reverse sequence (H-L). Average arterial pressure and approximately constant systemic flow over 30 second periods were used to calculate vascular resistance (SVR). The first six experiments followed initiation of cardio-pulmonary bypass and aortic clamping but prior to delivery of cold blood cardioplegia, blood temperature was 32°C. The remaining six were conducted prior to removal of the aortic cross clamp at 37°C. Coronary sinus blood samples were analysed to exclude myocardial ischaemia.

Coronary sinus blood samples showed insignificant variation in oxygen saturation, lactate and troponin T. Three patients were excluded because of unstable blood pressure. In the (L-H) group SVR reduced in 4 of 4 remaining patients (mean −9.4%, range −3.9 to −19.6%). In the (H-L) group SVR increased in three patients (mean +2.0%, range 1.1 to −3.7) but decreased in two (−8.9% and −15.8%).

These preliminary results although not statistically different suggest the presence of coronary baroreceptors in humans. The reflex vascular responses are similar to those previously reported in animal models.

*Yorkshire Heart Centre, Leeds General Infirmary, Institute for Cardiovascular Research
EVALUATION OF A MINIATURE ECMO CIRCUIT

Background: The standard neonatal ECMO circuit (bladder, roller-pump, silicon membrane oxygenator, heat exchanger) has remained fundamentally unchanged since the 1980's. Extracorporeal technology, however, has witnessed many significant advancements in the past two decades. Modern oxygenators, consoles, pumps, and biocompatible surface treatments are now standard in many neonatal perfusion applications. These new materials have characteristics, which may reduce blood use, blood trauma and inflammation, and thereby improve outcomes when applied in the ECMO arena. Unfortunately, there have been few investigations establishing the performance and applicability of these devices for long-term support. Therefore, the purpose of this project is to evaluate the performance of a miniature ECMO circuit consisting of current generation technologies in an animal model.

Methods: A miniature ECMO circuit was designed. All circuit components have the benefit of a modified surface (X-Coating, Terumo Corp, Ann Arbor MI). The oxygenator uses hollow fiber technology with integrated heat exchanger (Baby Rx 05, Terumo Corp, Ann Arbor MI). Blood flow is generated via a PC-coated centrifugal pump (Revolution, Cobe/Stockert, Arvada, CO). The compact pump base, with its remote pump arm, (SIII 3, Cobe/Stockert, Arvada, CO), permits the minimization of tubing lengths and the positioning of the entire circuit within inches of the bed and patient. Continuous arterial and venous blood gas monitoring is provided by the CDI 500 (Terumo, Corp, Ann Arbor, MI). The Committee for the Humane Use of Animals approved this study. Three sheep (mean weight 13 kg) were placed on either VV or VA ECMO using standard neck cannulation techniques. The physiologic condition of the animals were monitored in the usual fashion including regular measurements of heart rate, temperature, blood pressure, arterial blood gases, pump, flow rate, electrolytes and volume balance. Blood trauma was monitored via measurement of plasma free hemoglobin, platelet count and HCT. The coagulation system was monitored via measurement of activated clotting time (ACT) with a target time of 180 sec. Oxygenator function was evaluated through calculation of oxygen transfer and pressure drop across the membrane. The gas effluent port of the oxygenator was monitored for signs of plasma leakage across the membrane fiber. After each trial, the entire circuit is gently flushed and visually inspected for macro clot formation.

Results: The designed circuit had a priming volume of 145 milliliters. The average ECMO duration was 42 hours (20–58 hours). Oxygen transfer at discontinuation of ECMO was not significantly different from initiation. There was no evidence of plasma leakage from the gas outlet port of the Terumo SX-05 oxygenator. There were no significant changes in plasma free hemoglobin from initiation to termination. Platelet counts trended lower at termination. Post-ECMO circuit analysis showed no or minimal visible signs of fibrin or clot deposition in the tubing, connectors or pump.

Conclusion: This pilot study uses an ECMO circuit design that departs dramatically from the typical North American systems. The careful selection of a console with a small “footprint” and remote centrifugal pump arm allowed for tighter circuit dimensions, facilitating a 70% reduction in priming volume over a traditional neonatal ECMO circuit. While not FDA approved for long-term use in the United States the application of hollow fiber oxygenators for neonatal cardiac ECMO is gaining momentum. These preliminary data suggest that the use of the Terumo SX-05 for long-term support is feasible. The combination of prime reduction and biocompatible surface treatment could reduce the known complications of ECMO.

Bryan Terry, Gordon Gunst, Richard Melchoir, Edward Darling, Bruce Searles
State University of New York Upstate Medical University
CLINICAL PERFORMANCE AND BIOCOMPATIBILITY OF NOVEL HYALURONAN BASED HEPARIN BONDED EXTRACORPOREAL CIRCUITS

Purpose: Documented in vitro and ex vivo advantages of novel hyaluronan based heparin bonded extracorporeal circuits were tested under challenging clinical setting.

Methods: 20 patients undergoing reoperation for CABG were allocated into two groups (N=10): Group 1: Hyaluronan based heparin bonded circuits (GISH Biomedical Inc., USA) and Group 2: Uncoated control circuits. Complete blood count, fibrinogen, albumin, C3a, IL-2 levels and thromboelastography data were documented. Hollow fibers were collected for consecutive biomaterial studies by optical and electron microscopy (SEM). Desorbed protein amount, phagocytic capacity (PC) and index (PI) were compared on fibers.

Results: Platelet counts demonstrated significant differences at T3, T4 and T5 in coated group (p<0.05). Leukocyte counts were lower in T3-T6 in Group 1 (p<0.05). Albumin and fibrinogen levels were better preserved in Group 1 at T4-T6 (p<0.01). C3a and IL-2 levels were lower at T3-T6 in study group (p<0.05). Postoperative hemorrhage was 412±50 ml in Group 1 and 684±50 ml Group 2 (p<0.05). Intubation period and need for transfusion were lower in Group 1 vs. control (p<0.05). Platelet adhesion was significantly lower in study group. Amount of desorbed protein was 1.44±0.01 mg/dl in Group 1 and 1.94±0.01 mg/dl in control (p<0.05). PC and PI were significantly lower in Groups 1. SEM demonstrated better surface preservation in coated group.

Conclusion: Novel hyaluronan based heparin bonded circuits reduce platelet adhesion-aggregation and protein adsorption and provide better perioperative clinical status through platelet, albumin and fibrinogen sparing effects.

Serdar Gunaydin, Kevin McCusker*, Venkatamarana Vijay**
Numune Training & Research Hospital, Ankara-Turkey, *Portsmouth Regional Hospital
IMMEDIATE POST LVAD IMPLANT SUPPORT; TWO APPROACHES

Increased use of left ventricular devices (LVAD) as bridges to transplant has revealed the need for short-term right heart support for de-airing and right ventricular recovery. Two approaches are now implemented as the patient is weaned from regular cardiopulmonary bypass.

Dependant upon patient needs, the surgeon may select a high flow or low flow approach to what is essentially right heart bypass. Both utilize the existing venous drainage from the right side of the heart. The higher flow returns blood through a 1/4-inch tube connected to a modified LV cannula to the pulmonary artery. This will provide flows as high as 3.5 Liters. The low flow method uses the cardioplegia line, which goes unused during LVAD insertion, attached to the same modified LV cannula with flows between 400 and 600 ml/min. Each method has its advantages, disadvantages and quirks.

The results are functionally successful in allowing support of the right heart and de-airing of the ventricular device.

P. L. Syracuse, Carolyn Yager, M. Smedira
The Cleveland Clinic Foundation
SMALLEST CHILD IN NORTH AMERICA BRIDGED TO TRANSPLANT WITH BERLIN HEART VENTRICULAR ASSIST DEVICE

The EXCOR Berlin Heart was successfully used as a pediatric left ventricular assist device (LVAD) as a bridge to transplant. The pneumatically driven paracorporeal device successfully supported a 7 kg patient for 53 days until a suitable heart was obtained for transplantation.

Gan Dunnington, Justin Sleasman, Ed Park, A. Alkhaldi, M. Pelletier, B. Reitz, R. Robbins
Midwestern University
THE FUTURE OF THE PERFUSION RECORD—AUTOMATED DATA COLLECTION VS MANUAL RECORDING

The perfusion record is a legal representation of the procedure. The hand written perfusion record has been the most common method of recording events during cardiopulmonary bypass. This consists of recording various parameters (eg. blood flow, Arterial pressure) at variable intervals (eg. every 5 or 10 minutes or when an event occurs). It provides a snapshot of the case, however it is open to individual bias, data omission (due to more pressing events), and is highly variable between different perfusionists. This is in significant contrast to the automated record generated by integrated data management systems that provide continuous collection of data and allow event recording by means of simple key strokes. In addition they incorporate data from other monitoring devices (eg. physiological monitoring, blood gas analyser). This allows more time for the perfusionist to concentrate on the patient and not the perfusion record whilst simultaneously producing a more accurate record of the perfusion.

The aim of this study was to compare and contrast the quality and accuracy of manual versus electronic perfusion records. We prospectively analyzed 17 cases, in which the perfusionist in charge of the case maintained a manual record, whilst a second perfusionist entered relevant events on the electronic record generated by the Stockert S3 Data Management System /Data Bahn (Munich, Germany). The data records were then compared.

Analysis of the perfusion records demonstrated significant variations in the recorded information. We identified the following areas to demonstrate the most inconsistency. Measurement of the arterial perfusion pressures (eg manual record mean maximum 69.1 mmHg vs electronic 74.2*, range of variation −4 to 25 mmHg), temperature recording (eg arterial outlet temperature manual record minimum °C 33.3 vs electronic 31.2*, range of variation −0.7 to 6.9 °C) and cardioplegia volume (eg manual record 839.2 ml vs electronic 834.8, range of variation −80 to 175 ml) (*p<0.05). In addition the limitations of the electronic systems were also highlighted. Our system did not incorporate electronic gas flow data and the manual record provided more detail than the electronic record.

This study demonstrates the variability in the two methods of reporting, and highlights the wide variation that can occur. The use of an automated system provides the opportunity to minimize transcription error and remove observer bias. In addition we have integrated the automated perfusion record into our cardiac data base, which allows the data to be utilized for multiple purposes, including quality control, research and data sharing.

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*Ashford Hospital, Flinders Medical Centre

JECT. 2005;37:81–120
DATABASE REVIEW EVALUATING CLINICAL OUTCOMES OF PEDIATRIC CARDIAC SURGERY WITH AND WITHOUT APROTININ

OBJECTIVE: To determine the effectiveness of aprotinin in pediatric cardiac surgery.

METHODS: A database review was used to evaluate outcomes of patients undergoing cardiopulmonary bypass (CPB) who were given aprotinin (n=62) versus patients who were not given aprotinin (n=63). In the aprotinin group, a test dose of 1 ml was given prior to an anesthesia loading dose of 30,000 Kallikrein Inactivator Units (KIU) per kilogram (kg) and a pump prime dose of 30,000 KIU/kg. Following surgery, patients received an aprotinin infusion for 6-24 hours in the ICU at a rate of 7,100 KIU/kg/hr or no more than 50,000 KIU/hr. All patients were of risk categories two and three (Jenkins, 2002), experienced a period of Modified Ultrafiltration (MUF) following CPB, and all circuits were coated.

RESULTS: The use of aprotinin was associated with higher defibrillation rates after aortic cross-clamp removal, more blood added during CPB, a longer length of stay, and no difference in the amount of packed red blood cells (PRBC) given post-operatively or in the ventilator time. However, the AG increase was less in patients receiving aprotinin and there was a marginally shorter median ventilator time.

CONCLUSION: While the data does not clearly indicate better outcomes with aprotinin, it may, at this dose, decrease the median time spent on mechanical ventilation.

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REDUCING LUNG INJURY AFTER CPB BY MAINTAINING LUNG PERFUSION AND MECHANICAL VENTILATION DURING CPB

Postoperative lung injury is one of the most frequent complications of cardiac surgery believed to be resulting from routine cardiopulmonary bypass (CPB). However, other factors can contribute to the outcome such as ischemic reperfusion injury manifested as abnormal gas exchange, poor lung mechanics, substances released from injured lung tissue and reduction of products normally released by the lung.

Strategies for reducing lung injuries are maintaining lung perfusion during CPB by providing adequate flow to the bronchial arteries to provide the 5% of the whole body oxygen uptake necessary even under hypothermic conditions. Maintaining adequate pulmonary artery (PA) perfusion during CPB can attenuate ischemia reperfusion injuries. Maintaining mechanical ventilation during CPB will attenuate lung injuries. Appropriate mechanical ventilations during CPB can limit microadelaclasis, hydrostatic pulmonary edema, poor compliance and a higherincidence of infection, all associated with hypoventilation.

Advance strategies developed base in current research focus on maintaining lung ventilation and PA perfusion during CPB to potentially minimize postoperative lung injury will be addressed.

L. Ottinot, R. Chan
CW Post School of Cardiovascular Perfusion
COLDAGGLUTININS AND THEIR EFFECTS ON CARDIOPULMONARY BYPASS

Cold agglutinins (CA) are autoantibodies that bind to RBC’s only at low temperatures. This reaction increases blood viscosity and can induce sludging and hypoperfusion to the microcirculatory beds. Organ perfusion and flow can be impaired resulting in organ dysfunction and damage. These complications only take place if internal temperatures fall below the thermal amplitude for agglutination. CA’s are located in the sera (serum) of patients; screening for these should be done prior to cardiac surgery where hypothermia and cold cardioplegia will be used. Temperature level and severity of this phenomenon is patient dependant and is predictable with laboratory screening. Plasmapheresis can be instituted pre-op if profound hypothermia and circulatory arrest is required for surgery. Complications due to CA’s include: hemolysis, microvascular occlusion, complement fixation, renal and hepatic insufficiency, and myocardial infarction. A review of numerous patient cases and journal articles will further specify the effects cold agglutinins while on cardiopulmonary bypass and alternate strategies that can be used to minimize their effects in the future.

M. Brewer, R. Chan
CW Post School of Cardiovascular Perfusion
A 64 year-old male with ischemic cardiomyopathy presented for evaluation by the Mechanical Support Team. The patient had a longstanding history of coronary artery disease (status-post angioplasties × 3). He had a myocardial spect perfusion scan which demonstrated a large infarcted area with no reversible ischemia. Despite maximized medical therapy he remained a NYHA functional class IV with an ejection fraction of less than 25% and a cardiopulmonary exercise test with a peak VO$_2$ of 9.3 (ml/K/m)(RER = 1.05). It was determined based on his continued reduction in cardiac function and medical history, which included diabetes, neuropathy, congestive heart failure (three recent admissions for flash pulmonary edema), and renal insufficiency (Cr. Clearance 44.5 ml/min) he met the inclusion criteria for Destination Therapy.

He was implanted with the HeartMate XVE left ventricular assist device and after an uncomplicated post-operative course, was discharged home on the sixteenth post-op day.

He remains at home, with no readmissions, now a NYHA functional class I, enjoying a more active lifestyle.

The latest statistics show the number of patients with congestive heart failure increasing by some 180,000 per year (AHA). Mechanical assist devices remain a viable option for patients who do not qualify for cardiac transplantation. Compared to OMM therapy for end-stage congestive heart failure, the HeartMate XVE improves long-term survival and the quality of their lives.

Dennis M. Long, Michael A. Sobieski, Mark S. Slaughter
Midwestern University Perfusion Program, Division of Cardiovascular Surgery
Advocate Christ Medical Center
SENSITIVITY OF A MODIFIED ACT TEST AT HIGH LEVELS OF BIVALIRUDIN

Background: Accurate assessment of anticoagulation status during cardiac surgery can be valuable for novel therapeutics, including direct thrombin inhibitors. The Ecarin Clotting Time (ECT) has been reported to be sensitive and accurate for use in cardiac surgery, but is not commercially available. The ACT, the standard for heparin monitoring, has been reported to display a lack of sensitivity to higher levels of hirudin as used for example, in on-pump cardiac surgery. Both the ACT and ECT have been successfully used for monitoring bivalirudin (BVR) at levels studied in off-pump cardiac surgery. A new ACT assay, the ACTT, was developed to increase the linearity of the test response to BVR at higher concentrations.

Objective: Following Ethics Committee approval, a pilot study was performed to evaluate dosing of BVR for on-pump surgery and to correlate the response seen with various ACT assays, the Pharmanetics ECT and the assayed BVR concentration in the patients’ blood.

Methods: Following informed consent, 10 sequential patients presenting for elective cardiac surgery requiring cardiopulmonary bypass received BVR anticoagulation in lieu of heparin. Dosing was fixed and not titrated on the basis of monitoring results. At baseline and 15-minute intervals, blood samples were collected for ACT (ACTT, Celite, kaolin, ACT+), ECT and BVR level measurements.

Results: Over the entire range of BVR levels, the ACTT and the ECT were twice as sensitive to BVR (slope ∼28.5 sec/μg/ml BVR) than any ACT (slope ∼14 sec/μg/ml). This difference in sensitivity is also evident at lower concentrations of BVR (BVR <10 μg/ml), with the ECT and ACTT showing slopes near 40 and the ACT slopes varying from 18 – 27.

Conclusion: The ACTT assay is equally sensitive to the level of BVR as the ECT and may offer a simpler method for monitoring BVR during cardiac surgery. The ACTT is sensitive to BVR level and at the dose evaluated, yields similar values to those targeted for heparin anticoagulation.

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*International Technidyne Corporation, **Institute Fur Anasthesie, Deutsches Herzzentrum Berlin, ***The Medicines Company
2004 SURVEY OF ECMO IN THE NEONATE FOLLOWING OPEN-HEART SURGERY: CIRCUITRY AND TEAM ROLES

INTRODUCTION: The incidence of post-cardiotomy ECMO support following congenital heart surgery has increased over the last several years. This potentially requires that patient be transitioned from an cardiopulmonary bypass circuit with the newest extracorporeal technology to an ECMO circuit containing components originally developed three decades ago. Recognizing this some institutions have begun introducing modern extracorporeal components into their ECMO circuit design. The prevalence, success and failures of these pioneering efforts is not widely appreciated in recent ELSO center based surveys. Therefore the purpose of this study is to identify the current state-of-the-art for cardiac ECMO technology used by perfusionists in the United States.

METHODS: Every pediatric open heart surgery team listed in the AmSECT Pediatric Registry was included in the study. Perfusionists from each center were contacted by telephone and asked a series of standardized questions regarding (1) program demographics, (2) ECMO circuitry designs, and (3) the algorithm for clinical staffing of these challenging clinical cases. Data from all participating centers was pooled and is presented as a percentage of total respondents.

RESULTS: Of the estimated 140 centers in the United States performing neonatal CPB, responses from 70 (50%) were collected. Forty four percent of the responding centers were primarily pediatric only programs, while the remaining 56% were adult/pediatric mixed centers. ECMO was used as mechanical assist at 94% of the centers. A hollow fiber oxygenator is used routinely for neonatal post-CPB ECMO by 19% of the responders and used at least once by 40% of the centers. Roller pumps are used by 65% of the centers while 12% used centrifugal pumps routinely for neonatal post-CPB ECMO. For neonatal post-CPB ECMO, perfusionists are responsible for set-up and initiation in 79% of the centers. Perfusionists sit shifts for this ECMO patient population at 46% of the centers.

DISCUSSION: This survey shows that in the subset of neonatal ECMO patients, there is a much greater use of hollow fiber oxygenators and centrifugal pumps when compared to more general ECMO surveys. Perfusion involvement is also higher in this group of ECMO patients.

Gordy Gunst, Bryan Terry, Richard Melchoir, Bruce Searles, Edward Darling
SUNY-Upstate Medical University
OPTIONS FOR POST CARDIOTOMY SUPPORT: HEPARIN COATED ECMO VS. VENTRICULAR ASSIST DEVICES—A DECISION ANALYSIS MODELING APPROACH

Post cardiotomy failure requiring ventricular assist occurs in about 1% of adult patients undergoing cardiac surgical procedures. The decision regarding the modality of support involves many factors including coagulation status, pulmonary vascular resistance, and the presence of biventricular failure.

One method of support is short-term ventricular assistance. This incurs the cost of the device, which is substantial, and allows for reduced anticoagulation in the first 24 hours. Another option is a heparin coated ECMO circuit. This allows for reduced anticoagulation, can support the lungs if necessary, and can be used as a bridge to ventricular assist devices after the patient is further evaluated and expected to recover. The use of a heparin coated ECMO circuit requires 24 hour monitoring, but the cost of disposables is considerably less than the cost of ventricular assist devices.

This decision analysis will evaluate the relative outcomes and costs associated with selection between these modalities of support. Clinical evidence from the past five years of patients who received post cardiotomy support with either ECMO or ventricular assist devices or a combination of both will be used to validate the current model.

Jason R. Nance, Joseph J. Sistino
Medical University of South Carolina
REJECTING THE EFFECTS OF THE SYSTEMIC INFLAMMATORY RESPONSE TO CARDIOPULMONARY BYPASS: CAN SINGLE DOSE STEROIDS BLUNT SIRS?

**Purpose:** The use of cardiopulmonary bypass (CPB) for heart surgery is associated with the development of a significant systemic inflammatory response syndrome (SIRS), which can affect patient outcome. Many pathways are involved in initiating and maintaining SIRS. We studied whether a single dose of steroids after the induction of anesthesia could blunt the SIRS from CPB.

**Methods:** Prospective, randomized, double blinded placebo control trial (Dexamethasone 100 mg vs. saline). Patients undergoing elective CAB, less than 80 yrs with normal ejection fraction and no acute MI were randomized. C3a, IL-6 and norepinephrine levels were measured; pre-bypass, 30 minutes after initiation of bypass and 24 and 72 hours after termination of CPB.

**Results:** Twenty-eight patients were randomized: 13 study vs. 15 controls. There were no differences between the groups (age, sex, diabetes, smoking, hypertension, number grafts, CPB or cross clamp times). The study group demonstrated a significantly lower levels of IL-6 (p=0.0005) at 24 hrs and norepinephrine (p=0.05) at 72 hrs. There were no differences in C3a between the groups. No infections occurred in either group. There was no difference in: length of stay, ICU time, time to extubation, A-a gradient or chest drainage between groups.

**Conclusion:** A single dose of dexamethasone reduces IL-6 and norepinephrine associated with CPB. Additional agents blocking other pathways to further reduce the SIRS of CPB may be needed to demonstrate a clinical effect on patient outcome.

Mark S. Slaughter, Michael A. Sobieski, II, Wailam A. Kwok, Antone J. Tatooles and Pat S. Pappas
Division of Cardiovascular Surgery, Advocate Christ Medical Center
INVESTIGATION OF FOUR DIFFERENT TUBING COATINGS FOR SPALLATION DURING ROLLER-PUMP USE FOR CARDIOPULMONARY BYPASS SURGERY

Background: Patients undergoing heart surgery are at risk of having biological as well as inorganic micro-emboli introduced into their blood circulation via the heart and lung bypass machine. Macroscopic and microscopic biologic aggregates and inorganic debris that arise from heart surgery can contribute to post-operative co-morbidities such as multiple organ dysfunction as well as neurological complications. Inorganic micro-emboli can be generated from ruptured tubing caused by continuous physical contact of the roller pump. Manufacturers of CPB circuits now offer various types of heparin coatings and surface modifications to polyvinyl chloride (PVC) tubing to be more biocompatible with the blood components of the human body. Although there is clinical evidence of their bio-compatibility, there is little research on their durability.

Aim of the study: To investigate the durability of four different manufactures’ coated tubing for detection of spallation by scanning electron microscopy (SEM).

Method: Five mock circuits containing a removable 12 micron filter were constructed containing four different coated tubing, X-Coating (Terumo CSC MI), SMARxT (Cobe CO), GBS (Gish CA), Carmeda (Medtronic CA) and one uncoated tubing serving as the control. Six trials were run on each type of tubing in which the filter was removed from the circuit and analyzed for spallation by SEM analysis. SEM analysis will provide information on the size and number particles per filter.

Results: Results of the SEM will be statistically analyzed by a one-way ANOVA followed by post hoc multiple pair-wise comparisons to determine a difference in number of particles per tubing. All results will be considered significant at the 0.05 level.

Joseph Lewis, Jonathan T. Smyre
Medical University of South Carolina
THE DISTRIBUTED PERFUSION EDUCATIONAL MODEL:
A SHIFT IN PERFUSION ECONOMIC REALITIES

In recent years a steady decline in the number of perfusion education programs in the United States has been noted. At the same time, there has been a parallel decline in the number of students graduated from perfusion educational programs in the United States. Also, as noted by several authors, there has been an increase in demand for perfusion graduates. The decline in programs and graduates has also been noted in anesthesia and surgical residency programs. The shift is due to a combination of economic and clinical factors. First, decreased reimbursement has lead to reallocation of hospital resources. Second, the original enthusiasm for beating heart coronary artery bypass surgery was grossly overestimated and has lead to further reallocation of hospital resources and denigration of cardiopulmonary bypass. This paper describes two models of perfusion education programs: Serial Perfusion Education Model (SPEM) and the Distributive Perfusion Education Model (DPEM). Arguments are presented that the SPEM has some serious limitations and challenges for long-term economic survival. The authors feel the DPEM along with dependence on tuition funding can survive the current clinical and economic conditions and allow the profession to adapt to changes in scope of practice.

Jon W. Austin, Edward L. Evans, Harry R. Hoerr, Jr
Midwestern University
DETERMINING THE EFFECTS OF PERFUSION COMPONENTS ON PULSATILE FLOW AS MEASURED IN TERMS OF AN ENERGY EQUIVALENT PRESSURE

Background: In patients undergoing cardiopulmonary bypass, pulsatile perfusion has been shown to decrease pulmonary vascular resistance, cerebral vascular resistance, improve renal function, and prevent ischemic changes, especially during longer periods of perfusion. It has also been associated with a reduced number of major complications post-operatively, such as death and myocardial infarctions as compared to nonpulsatile perfusion. There is much debate over the definition of optimal pulsatility during pulsatile perfusion. Pulse pressure (PP) and energy equivalent pressure (EEP) have been used to determine the magnitude of wave forms generated during pulsatile perfusion, but few studies have determined what values of these measurements are the most beneficial to patients. To ensure optimized pulsatility to the patient during CPB, the dampening effects of the circuit components need to be minimized.

Aim of the Study: The aim of this study to determine which combination of four commercial membrane oxygenators and 3 different cannula types provided the most optimal pulsatile waveform as measure by the EEP.

Methods: In a porcine model, the combination of four different membrane oxygenators (Capiox SX 25 Terumo MI, Vision Gish CA, Avant Cobe CO and Affinity Medtronic CA) and 3 types of aortic cannulas (Plastic tip 24 fr. DLP, metal tip 24 fr. Baxter, 24 fr. Soft Flow Terumo) were randomized using a circuit containing a roller pump with pulsatile capability. The pressure and flow wave forms were recorded (BioBench National Instruments Corp.) for each combination of cannula and oxygenator. This data was used to calculate the EEP for multiple wave forms of each individual combination. One-way ANOVA was used to analyze the data with post hoc pair wise combination to find individual differences.

Results: Stratification by cannulas revealed the plastic tip 24 fr. DLP cannula had the highest average EEP (mean = 56 mmHg std 2.3 mmHg, p value < 0.01). Stratification by oxygenators among cannulas showed the Affinity to have the highest average EEP (mean = 55 mmHg std 3.1, p value < 0.01). Analysis of the individual combination of cannulas and oxygenators found the Plastic tip DLP cannula and the Affinity oxygenator produced the highest mean EEP (mean = 66 mmHg std 3.4 mmHg, p value < 0.001).

Conclusion: The variation among the averages of calculated EEP measurements for different combinations of perfusion components, oxygenators and cannulas, show that the optimal pulsatility is dependant on these variables. The first step for any center deciding to try or implement pulsatile perfusion is to change to perfusion components with minimal pressure drops across them.

Hayden Miller, Jonathan T. Smyre
Medical University of South Carolina
SUCCESSFUL USE OF A COMPETENCY STEP-EXAM IN A PERFUSION EDUCATION PROGRAM

The use of a competency exam in clinical science and medical education programs is controversial and technically challenging. The perfusion education program at The Ohio State University (Circulation Technology) separates the didactic and laboratory phase of the program from the clinical phase by a competency exam. Each student must pass the competency step-exam to gain entry to their clinical rotations. The purpose of this communication is report the development, use and results of the step-exam.

The step-exam is a 200 question exam employing multiple choice items. The exam is modeled after several health-related national certification exam processes. The exam has content validity based on the published, written objectives for the education program. Each item on the exam has a history of use and meets criteria for difficulty, discrimination and distraction.

The exam ranks students and identifies incompetent students in regard to the program learning objectives. The following table lists student success. The step-exam determines student progress from the didactic to the clinical phase.

<table>
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<th>Year Accepted</th>
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*Does not include returning/remediating students; TBD = to be determined; **graduates passing exam.

The competency step-exam is a reliable and important tool to help assure successful quality outcomes for the program.

Circulation Technology Division, The Ohio State University, Columbus, OH
ISOLATED LIMB INFUSION: AN ALTERNATIVE TO ISOLATED LIMB PERFUSION

Isolated limb perfusion (ILP) with the administration of cytotoxic drugs has been successfully used to treat melanomas of the extremity since it was first introduced in 1958. The use of hyperthermia (40 °C) combined with chemotherapy agents, primarily Melphalan, has resulted in a higher tumor cell kill rate than previously reported without the use of hyperthermia. This has lead to the standard technique of hyperthermic isolated limb perfusion (HILP) for treating melanomas of the extremity. While still considered a palliative treatment as the cancer is generally advanced, the technique of HILP has improved quality of life for patients by reducing the need for disfiguring and debilitating amputations.

HILP involves open surgical dissection and cannulation of the peripheral vessels and is associated with a high morbidity rate. Blood transfusions, systemic drug leak, infection, damage to the vessels and nerves are all potential hazards associated with this technique. Variances including circuit design, temperature control, prime constituents, pump flow and drug delivery may impact the effectiveness of the procedure. An alternative technique termed Isolated Limb Infusion (ILI) was introduced in 1992 at the Sydney Melanoma Unit in Australia, which significantly reduces the morbidity associated with HILP without compromising results.

ILI is a less invasive and simpler procedure involving the use of angiographic catheters percutaneously inserted via the femoral vessels (in Vascular Radiology) and does not require a heart-lung machine and related circuitry. Instead, the delivery of Melphalan is delivered via a 20 ml syringe attached to high flow stopcock and luered tubing set with a cardioplegia heat exchanger. A pneumatic tourniquet is placed at the upper end of the extremity, the extremity is wrapped in a warming blanket and blood is recirculated via a 20 ml syringe. Limb temperature is monitored by myocardial temp probes placed in the lower and upper extremity. After the limb is sufficiently warmed, a dose of Melphalan is delivered and recirculated for 30 minutes. The drug is then washed out prior to releasing the tourniquet. Preliminary data suggests the resultant local hypoxia and acidosis induced by this procedure potentiates the cytotoxic effects of Melphalan.

As ILI is less invasive than HILP, repeat exposure to chemotherapy in a short time is possible and may result in a more effective response to eliminating tumors. Tumor cells weakened by the first treatment may be more susceptible to the cytotoxic drugs on the 2nd or 3rd exposure. Compared to systemic chemotherapy only, the isolated limb technique has resulted in improved results in patients with advanced melanomas of the extremity. Complete remission is obtained in 50% of patients treated with HILP with Melphalan, and partial response in another 35–40% of patients. Due to the invasiveness of HILP and the related morbidity and expense, the technique of ILI may be a more desirable option as morbidity is greatly reduced and results appear similar. There is a vital role for the perfusionist with the application of this technique in this potentially expanding area of cancer therapy.

Patricia McDermott, Richard Walczak, Jr., Douglas Tyler, Ian R. Shearer
Duke University Hospital
STABILITY OF HUMAN THROMBIN PRODUCED FROM 11 ML OF PLASMA USING THE THROMBIN PROCESSING DEVICE, TPD™ SYSTEM

**Introduction:** Autologous human thrombin can be produced by activating the patient's own plasma. By adding calcium chloride (CaCl₂) to the anticoagulated plasma, the coagulation cascade will be initiated and active thrombin produced. However, thrombin obtained by this method looses its activity very quickly and is not practical for use during surgery. The aim of this study was to investigate the stability of the thrombin produced using the Thrombin Processing Device (TPD™ System, ThermoGenesis Corp.) when produced and stored at different temperatures.

**Materials and Methods:** The TPD consists of a tubular chamber containing activating beads. Plasma (11 ml) and reagent (CaCl₂ and ethanol, 3.75 ml) was added to the TPD. After 20 min incubation, active thrombin was harvested. As the temperature in the operating room can vary, the production of thrombin was done at 18°C (64F), 24°C (75F) and 27°C (81F), n=4/group. The produced thrombin was then stored at the production temperature as well as at 4°C (39F) and 35°C (95F). The functional activity of thrombin was assessed by time to clot formation, using a fibrinogen concentrate as substrate, after 2, 4 and 6 hours of storage. A clot time of <5 seconds was considered acceptable.

**Result:** Thrombin produced at 18°C had clot times of <5 sec for 6 hours when stored at 4°C, for 4 hours when stored at 35°C, but lost its activity in 2/4 units after 2 hours when stored at 18°C. When the thrombin was produced at 24°C the clot times were acceptable for 6 hours at both 4°C and 35°C, and for 2 hours at 24°C. Acceptable clot times were obtained after 6 hours in thrombin produced at 27°C, at all temperatures (4, 27 and 35°C).

**Conclusion:** The stability of thrombin produced by the TPD is dependent of both the production temperature and the storage temperature. Human thrombin with a stability of up to 6 hours can be obtained using the TPD when the active thrombin is produced at 24 and 27°C and stored at 4 or 35°C.

Trista Madsen, Haihong Zhu, Vijay Kumar, Elisabeth Semple
Thermogenesis Corporation
**SURVIVAL AFTER HYPERKALEMIC CARDIAC ARREST AND IMMEDIATE RESCUE WITH EXTRACORPOREAL LIFE SUPPORT**

**Introduction:** Extracorporeal Life Support (ECLS) is well described for treatment of liver failure, sepsis, respiratory failure, and cardiac failure. Hyperkalemic cardiac arrest is a rare condition that is amenable to rescue with ECLS.

**Case Report:** A three month-old, 3.0 kg infant with an endocardial cushion defect, severe aortic valve regurgitation, and a hypoplastic right ventricle was transferred to Arkansas Children’s Hospital where she was stabilized and listed for cardiac transplantation. Five days after admission, the infant had bradycardia twice within 5 minutes with heart rates as low as 40 bpm with systolic pressures of 50 torr followed by complete cardiopulmonary arrest 3–5 min later. Cardiopulmonary resuscitation (CPR) was begun. Arterial blood gas analysis after 3 minutes of CPR showed pH = 6.80, PCO₂ = 108 torr, pO₂ = 31 torr, base excess = 17.3, and ionized potassium = 9.93 mEq/dL. On review of the patient’s chart, we found a miscalculation for a potassium dosage that led to the hyperkalemic arrest. Extracorporeal Life Support (ECLS) was emergently employed. During CPR, the right common carotid artery (10 Fr arterial Biomedicus®) and right internal jugular vein (12 Fr venous Biomedicus®) were cannulated. ECLS was initiated at 500 ml/min (108ml/kg or 1.9 L/min/m²) The patient spontaneously developed a rhythm but remained pulseless. Resuscitation drugs included 8.0 ml 50% dextrose with 1 unit human insulin, 100 mg calcium chloride, 3 mg lidocaine, 2 gm mannitol, and multiple doses of sodium bicarbonate. Initiation of ECLS caused the potassium level to decrease from 10.3 mEq/dL to 9.31mEq/dL. Systolic blood pressure ranged from 70–80 torr. After 7 hr of ECLS, flow was reduced to 400 ml/min (86 ml/kg or 1.5 L/min/m²) and 2 hr subsequently, flow was reduced to 370 ml/min (80 ml/kg or 1.4 L/min/m²), and bumetanide was started. Over the next 24 hours the urine output totaled 805 mls (11.2 ml/kg/hr). Serum potassium reduced to 3.95 mEq/dL. After 45 hours of ECLS, support was weaned and discontinued. After decannulation, a magnetic resonance imagine revealed no structural brain defects. No neurological abnormalities were found with standard neurological testing of the infant. The infant later had a palliative cardiac surgical procedure and was removed from the transplant list. She recovered and was discharged home.

**Conclusion:** Despite one reported failure of ECLS with hyperkalemic cardiac arrest, ECLS is a potentially life-saving therapy for such cases. There has been a report of a successful rescue from hyperkalemic arrest with cardiopulmonary bypass, but this is the first description of a successful rescue with ECLS for hyperkalemia using ECLS.

Juan L. Tucker, Charles E. Johnson, Lorrie L. Baker, Michael L. Schmitz, Jonathan J. Drummond-Webb
Arkansas Children’s Hospital
THE BASIC AND CLINICAL RESEARCH ON CEREBRAL PROTECTION DURING GREAT VESSEL SURGERIES

Objective: To assess different techniques for cerebral protection during great vessel surgeries involving aortic arch through basic and clinical research.

Methods: Deep hypothermic circulatory arrest (DHCA, as control group) and retrograde cerebral perfusion (RCP) were compared in this study. In animal experiments, after DHCA and RCP were established, cerebral blood perfusion was observed by fundus fluorescein angiography (FFA), color Doppler sonography and isotope scanning. The concentration of Na\(^+\) - K\(^+\) ATPase, superoxide dismutase (SOD), glutathione peroxidase (GSH – PX), malondialdehyde (MDA) were measured. The level of nitric oxide (NO) was detected by nuclear magnetic resonance (NMR) and calcium fluorescent intensity of vital brain slice by Laser Confocal Scanning Microscope (LCSM). Some preliminary clinical observations were made with ophthalmoscope. In clinical observation, the clinical parameters and outcomes of DHCA (n = 17) and RCP (n = 66) were recorded and compared.

Results: FFA, color Doppler sonography and isotope scanning (99m Tc-ECD) all demonstrated that cerebral perfusion existed during RCP. Compared with DHCA, RCP could attenuate cerebral injury through maintaining higher concentration of Na\(^+\) - K\(^+\) ATPase, SOD, GSH - PX and decreasing production of MDA, NO and calcium overload. Comparison also showed that RCP could reduce operative mortality due to neurological injury and neurological complications (p < 0.05).

Conclusion: In animal experiment cerebral injury can be assessed by measurement of calcium fluorescent intensity of vital brain slice, production of NO and some biochemical markers. FFA, color Doppler sonography and isotope scanning are practicable and sensitive methods to monitor cerebral perfusion in clinics. RCP is one practical technique for cerebral protection during great vessel surgeries involving aortic arch.

Dong Pei-Qing, Guan Yu-Long, Yang Jing
Department of Extracorporeal Circulation, Beijing An-Zhen Hospital
Capital University of Medical Sciences, Beijing Heart, Lung and Blood Vessel Medical Institute Beijing
A RETROSPECTIVE ANALYSIS OF PLATELET GEL IN CARDIAC CASES. ITS EFFECTS ON LENGTH OF STAY AND BLOOD PRODUCT USAGE

OBJECTIVE: Evaluate the effects of Autologous Platelet Rich Plasma or Platelet Gel on a patient's length of stay and blood product usage in coronary artery bypass surgery. This is a pilot study used to determine if these variables are valid. Control charts were used to analyze the data and measure the variability of other non-cardiac complications.

METHODS: 110 patient records were retrospectively analyzed with regard to overall hospital length of stay, ICU stay and blood product usage. 62 patients were in the treatment group, and 48 patients made up the control group. Each group was treated with either a standard CABG procedure or standard off pump procedures.

RESULTS: The experimental group N=62, 42 males (67%) and 20 females (33%) who underwent standard CABG were treated with APRP or Platelet Gel on the vein harvest and sternal closure locations. The average age of the treatment group was 64.1 yrs. (40–92 yrs.) 16 patients (25%) were diabetic and 46 (75%) were not diabetic. The control group N=48, 29 males (60%), 19 females (40%) who underwent CABG with both on and off pump procedures. 11 (23%) patients were diabetic and 37 (77%) were not diabetic. The overall length of hospital stay showed no significant difference between the control and treatment groups. However, by focusing on the patient within one SD of the mean there is a difference in the ICU length of stay of the two groups. The control group mean was 3.1 days and the treatment group mean was 2.2 days. Overall blood product usage was decreased by 10% in all areas including PRBC, FFP, Platelets. PRBC’s 122 units in control group and 110 units in treatment group. FFP usage was 76 units in control group and 69 units in treatment group. Platelets 447 units in the control group and 406 units used in the treatment group.

DISCUSSION: The initial analysis of the data showed little difference in any of the measures, length of stay, ICU stay, and blood product usage. With further analysis using control charts however, it became clear that there was a measurable difference in ICU length of stay. The difference is meaningful because ICU time is expensive and very labor intensive. Overall, the use of platelet gel showed a decrease in the quantity of blood products used by 10%. This small analysis is a window into a much larger study of 500 additional patients completed in 2004. Much of the reported data in platelet gel research is based on soft perceptive data rather than hard measurable data. This research attempted to establish the credibility to continue to evaluate these same measures in a larger and more complex statistical analysis.

Mark D. Gilpin
Coastal Extracorporeal Technology
GASEOUS MICROEMBOLI AND THE INFLUENCE OF MICROPOROUS MEMBRANE OXYGENATORS

Gaseous microemboli (GME) are still an unsolved problem of extracorporeal circuits they are associated with organ injury during cardiopulmonary bypass. Microbubbles of different sizes and number are generated in the blood due to different components of the extracorporeal circuit as well as surgical maneuver.

The aim our study was to observe the behavior of microporous membrane oxygenator at GME in the daily use and in an in-vitro model.

For the detection of microbubbles we used a two-channel ultrasonic bubble counter (UBC) based on 2 MHz Doppler-System with special ultrasound probes. The amount and sizes of GME was monitored in front and behind the oxygenator. In 30 scheduled cases with 3 different oxygenators and different surgical procedures we observed the bubble activity in extracorporeal circuit. In addition we used an in-vitro model to study the ability of 6 different oxygenators by removing air in different tests.

The tested oxygenators were manufactured with different membrane technologies. The result of our investigations showed that different membrane design lead to a partly removal of GME as well as a change in size and numbers of microbubbles.

Heinz-Hermann Weitkemper, Bernd Oppermann, Andreas Spilker, Hermann-J. Knobl, Reiner Korfer
Heart-Center of North-Rhine Westphalia
A NOVEL TRANSFUSION ALGORITHM FOR MICROVASCULAR BLEEDING IN CARDIAC SURGERY

Hospitals have identified bloodless medicine programs (BMPs) as a convenient mechanism to reduce complications, reduce overall expenditures, and offer innovative marketing schemes. One component of our BMP is a novel transfusion algorithm for blood component therapy utilizing the Thromboelastograph, developed using an evidence-based approach.

After IRB approval, a pilot transfusion algorithm in cardiac surgery was evaluated for a five month period. Compliance and efficacy of the algorithm was assessed by the frequency of inappropriate transfusions, preventable hemorrhagic events, and acute thrombotic events. The influence of clinician discretion, operative procedure, and preoperative coagulation status were evaluated by intergroup comparison.

Compared to the historical control set, there was a 27% reduction in transfusion of non-erythrocyte components. Although the transfusions were generally supported by the algorithm (transfused group R=8.8+3.4, MA=50.5+17.4 vs non-transfused group R=5.4+2.6, MA=67.6+5.1, p<0.05), compliance with the algorithm was only marginal (rFVIIA=100%, Plt=71%, FFP=17%, CRYO=10%). No preventable hemorrhagic or thrombotic events occurred.

The implementation of a carefully designed transfusion algorithm may safely reduce transfusion requirements, but measures should be taken to promote compliance.

Geisinger Medical Center
COMPARISON OF THE HEMOCHRON® RXDX ANTICOAGULATION MANAGEMENT SYSTEM WITH EMPIRICAL PRACTICE; A PROSPECTIVE, RANDOMISED CONTROLLED TRIAL

**Aim:** The aim of the study was to determine if using the Hemochron ® RxDx Anticoagulation Management System (AMS) during routine cardiac surgery could significantly reduce protamine requirements, post-operative bleeding and transfusion requirements. This system was designed to provide patient-specific dosing using individualised dose-response curves.

**Methods:** A total of 108 patients undergoing elective CABG or single valve procedures were enrolled into a powered (80%) prospective study to evaluate the Hemochron® RxDx AMS. Patients were randomised to either the RxDx group (n = 54) or control group (n = 54). The primary outcome measure was protamine dose with secondary evaluation of 24-hour post-operative chest drainage and transfusion requirements.

**Results:** RxDx treated patients received significantly lower doses of both heparin (P = 0.001) and protamine (P < 0.001). There were no significant differences between the two groups regarding post-operative blood loss (P = 0.98) and transfusion requirements (P > 0.10).

**Conclusions:** Implementation on the Hemochron® AMS provides patient-specific heparin and protamine dose determination consequently proving it an efficient tool for significantly reducing the doses received by this group of patients. In this instance, however, no significant benefits were observed in terms of post-operative bleeding and blood product usage. We conclude that residual circulating heparin or protamine is not a significant contributory factor for post-operative bleeding in routine cardiac surgery.

Tracey Dennis
Nottingham City Hospital
A 12 year old hemophiliac boy with FVIII antibodies presented with refractory bleeding. Recombinant FVIIa was administered at a 90μg • kg⁻¹ at Q6 intervals without improvement. In order to determine if larger doses of rFVIIa would effectively establish hemostasis, a titration test was performed using thromboelastography.

A circulating concentration of a 90μg • kg⁻¹ rFVIIa dose was calculated using the volume of distribution data from the product insert. (1.28μg • cc⁻¹). Six rFVIIa titrations were evaluated with the TEG, including (S1) 0.00μg • cc⁻¹, (S2) 1.28μg • cc⁻¹, (S3) 2.56μg • cc⁻¹, (S4) 5.12μg • cc⁻¹, (S5) 10.24μg • cc⁻¹, and (S6) 20.48μg • cc⁻¹.

The rFVIIa had no effect on the maximum amplitude, but improved the R-time, K, and alpha angle, resulting in a dose dependent improvement in the coagulation index (before Q6 dosing = no end point, after Q6 dosing (S1)=−22.2, S2=−4.7, S3=−1.6, S4=−1.4, S5=−1.5, S6=−1.6). The results indicated the optimal concentration for this patient was 2.56μg • cc⁻¹ (approximate dose 180 μg • kg⁻¹). The rFVIIa therapy was adjusted, resulting in satisfactory hemostasis and discharge without further complication.

Thromboelastography was successfully used to titrate an individual rFVIIa dose to achieve the desired result.

Cody Trowbridge, Alfred Stammers, Bianca Yen, Myra Klayman, James Pezzuto Geisinger Medical Center
SUCCESSFUL UTILIZATION OF EMERGENT EXTRACORPOREAL LIFE SUPPORT IN A PEDIATRIC PATIENT WITH AN AVULESED RIGHT MAIN STEM BRONCHOUS: A CASE REPORT

Utilization of extracorporeal life support (ECLS) in trauma has been reported with mixed success. The following case report describes the utilization of ECLS in a pediatric patient who presented in extremis in acute pulmonary collapse.

A 17-month child was playing at home and received a crushing injury when a large timber fell on her back. Following emergency transport to our facility the patient was triaged and stabilized for an initial 48 hours. Despite maximum respiratory support the patient developed subcutaneous emphysema and which necessitated the emergent implementation of veno-venous ECLS. While on support a bronchoscopy revealed a totally avulsed right main stem bronchus. The patient underwent surgical repair while on ECLS and in the intensive care unit. Immediately following the operative procedure ECLS was terminated and the patient was discharged on postoperative day 12.

We report the successful utilization of extracorporeal life support for a pediatric trauma patient at a non-ECLS center.

Alfred H. Stammers, Cody C. Trowbridge, Myra H. Klayman, Bianca R. Yen, James Murdock, Christopher Gilbert
Geisinger Medical Center
HEPARINASE INDUCES AN IN VITRO STATE OF HYPERFIBRINOLYTIC ACTIVITY IN THE THROMBOELASTOGRAPH™

The thromboelastograph™ (TEG) is a point-of-care coagulation monitor that has been in clinical use for over 25 years. Its applicability in identifying hemostatic derangements has been well established. It is possible to determine the effect of residual heparin in sample of blood with the use of a heparinase cartridge. The purpose of this study was to evaluate the effect of heparinase on thromboelastographic determination of coagulation.

TEG coagulation profiles from cardiac patients were examined over a consecutive 12-month period. There were 559 patients with a total of 1288 profiles examined. TEG profiles included both kaolin (K) and kaolin heparinase (KH) samples. 37.2% of KH samples demonstrated hyperfibrinolytic (greater than 5%) activity when comparing the maximum amplitude at 30 minutes post maximum amplitude, while K samples exhibited less than 1% hyperfibrinolysis. There was no observed clinical sequela associated with the hyperfibrinolysis.

The utilization of heparinase in a postoperative TEG sample exhibits an in vitro hyperfibrinolytic condition that was not present in kaolin treated profiles. This ex vivo effect demonstrates an confounding effect of heparinase in an isolated blood sample.

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THERMODILUTION CARDIAC OUTPUT SIMULATOR FOR TRAINING AND TROUBLESHOOTING

The thermodilution cardiac output is a standard of care in many critical care units. Commonly these devices are operated by physicians, nurses, respiratory therapists and clinical perfusionists. Formal training is infrequent as the techniques tend to be mastered on the job. A device that is capable of accurately simulating the thermodilution cardiac output waveform would provide formal training. Additionally, a device that could accurately simulate known errors would provide further study in troubleshooting.

The thermodilution cardiac output simulator circuit consists of an ABIOMED BVS 5000 disposable in series with a heat exchanger and flow probe. These components are connected to the Medtronic Preload-Afterload cart recirculates tap water for priming and maintaining flow in the circuit. The 110cm thermodilution cardiac output catheter is advanced from just before the inlet of the BVS5000 through the upper and lower chambers to just beyond the distal valve.

The flow registered with the flow probe, and confirmed by graduate cylinder, was matched by thermodilution cardiac output measurement to confirm appropriateness of the simulator circuit. Parameters including injectate temperature, injectate volume, speed of injection, calibration factor and distal tip placement were evaluated. The appropriate falsely high or falsely low cardiac output value resulted for the changed parameter. The waveform was unique for the changed parameter also.

This simulator is a useful tool in the training of circulation technology and respiratory therapy students at The Ohio State University. The circuit is unique in the representation of the cardiac anatomy, but will benefit from the addition of a shunt model. The true benefit will be in the evaluation of troubleshooting skills to improve patient care.

Richard Phipps, Jillian Garmon, Jeffrey B. Riley, Allison J. Spiwak
The Ohio State University
In the present setting of fiscal and other constraints placed upon the business world during economically challenging times, there exists both intentional and unintentional opportunities for unfair and illegal treatment of employees. Hospitals and other health care facilities or organizations are not immune. In fact, given the demographics of our field and the general ‘graying’ of our colleagues, a disproportionally higher number of perfusionists reside within the age-protected guidelines established by both federal and state law.

Not coincidentally, the pressures on hospitals to stay solvent in the presence of decreasing reimbursement and declining revenues may well create a prescription for unfair treatment of employees.

This presentation will explain the basic concepts of the protections afforded employees by law with regard to freedom from harassment and discrimination in the workplace. Matters related to: the hostile workplace environment; age, sex, and race discrimination; and adverse employment actions will be explained and illustrated by applicable case law. In this regard, it is intended that the presentation will enhance the opportunity for perfusionists to be cognizant of both the express and implied behaviors (both verbal and non-verbal) that may be detrimental to an employment situation, as well as to be cognizant of some of the remedies at law available regarding adverse employment circumstances.

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AN UPDATE ON PEDIATRIC PERFUSION PRACTICE IN NORTH AMERICA: 2004 SURVEY RESULTS

The devices and techniques used for pediatric cardiopulmonary bypass undergo continuous change. New techniques and clinical comparisons of devices are frequently reported in the literature, however information about the extent to which these techniques and devices are adopted into clinical practice at centers are not well described.

We conducted a mail survey of North American pediatric open-heart centers to gain perspective on current clinical practice. The survey questions requested program demographic data, information about device use, and the extent to which various techniques are used at centers. In December of 2004 surveys were mailed to North American pediatric open-heart centers. This survey was a follow-up of three earlier surveys completed at the end of 1989, 1994, and 1999. This survey was similar in format and content to the earlier surveys. Questions were added to address new techniques and devices that have emerged over the years. The current survey provides a cross sectional perspective of clinical practice in 2004. The series of surveys document the historical progression of clinical practice over the past 16 years. Survey data is useful for identifying variation and trends in practice. Practice surveys may also be useful for identifying areas where there are gaps between evidence based knowledge and clinical practice. Variation often occurs when there is uncertainty or during periods when new techniques emerge.

Robert Groom, Shane Froebe, Janine Martin, Mike Manfra, Catherine Morse, Andreas Taenzer, Reed Quinn.
Maine Medical Center
A CLINICAL OBSERVATION ON MYOCARDIAL PROTECTION WITH DIFFERENT CARDIAC PLEGIA INFUSION PRESSURE ON INFANTS UNDERGOING OPEN HEART SURGERY

The cardioplegia infusion pressure is one of the important parameters, which may have a direct effect on the adequacy of myocardial protection in both adult and infant CPB patients. At present there is no firm evidence as to what the optimal cardioplegia delivery pressure is. The purpose of this study was to observe the myocardial protective effects of three cardioplegia infusion pressure regimes on infants undergoing open-heart surgery.

A consecutive series of 45 infants undergoing repair of ventricle septal defects (VSD) with CPB were randomly assigned into three groups according to cardioplegia infusion pressure: G1, P=60 mm Hg; G2, P=45 mm Hg; G3, P=30 mm Hg. The pressures were measured via a needle inserted into the aortic root. Serum enzyme concentration and cardiac troponin I (cTnl) were measured before the operation, and at 0.5, 6, 24 hours after unclamping. The electric arrest induction and return time, mechanical ventilating time, duration of ICU and hospitalization were also recorded.

The cardioplegia infusion pressure was related to the electric arrest induction time (r=−0.181 p=0.223) and return time (r=−0.296 p=0.048). The electric arrest induction time and the return time in G3 were longer than in G1 (23.7±5.5s vs. 18.7±5.5s, p<0.05; 43.7±22.1s vs 25.1±16.0s, p<0.05). The spontaneous sinus rhythm returning rate was 14/15 in G2, 13/15 in G1 and G3. The CK-MB, LDH and CTnI level were higher in all groups at time points after cross-clamping release (CCR) than the basic levels(p<0.01). LDH at 6h after CCR is higher in G1 than in G3 (587.8±125.5u/L vs 522.7±142.5u/L, p<0.05). The mechanical ventilating time, ICU duration, post-operation duration and use of dopamine, dobutamine were similar between three groups. 1 case in G1 and 1 in G3 needed adrenaline support while none in G2.

Overall, cardioplegia infusion pressure ranging from 30 mm Hg to 60 mm Hg appears to offer safe and effective myocardial protection in infants undergoing open-heart surgery. Among the three groups, the 45 mm Hg pressure seemed to be the most effective.

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PRINCIPLES OF SIMULATION APPLIED TO PERFUSION TECHNOLOGY:
2005 UPDATE

Despite the use of simulators in perfusion education over the last thirty years, perfusion educators are far behind other disciplines and technologies in the effective application of high fidelity simulation outside of the operating room. The purpose of this communication is to report the continued development and use of simulation models in two US perfusion education programs drawing on modern principles of simulation.

Historically, US perfusionists and others have reported the use of mechanical reservoir-based simulators, computer software to simulate certain aspects of perfusion and rudimentary electro-mechanical interfaces between computers and heart lung machine equipment. One Australian company has developed a computerized mechanical simulator. Educational and private groups around the world including Asia are actively working on computer-based high fidelity simulators for perfusion. In respect to worldwide effort, the USA is barely keeping pace in the progress of developing perfusion simulators. Perfusion simulator design and education/testing protocols are based on job analysis, DACUM analysis of competencies, and evaluation of critical or crisis patient events for perfusionists. There are no recent studies of perfusion critical events or “near misses”, and very little reporting of perfusion accidents regardless of the national consensus for the need to reduce medical errors. A process to identify and develop routine and crisis event simulations (FMEA) is presented with an evaluation process (AMOD scale) to quantitate and rank examinee competency performance for both the simulator and patient practice. The concept of Perfusion Crisis Resource Management (PCRM) is introduced.

As heart-lung machines become more computerized and menu-driven, surgical procedures grow in complexity, and accreditation, licensure, certification and government impose competency standards, the use of high-fidelity simulation will become essential to perfusion practice. As pilots and other health care professionals have already learned, high fidelity simulation contributes significantly to the preparation and competency testing of perfusion students and certified perfusionists.

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EXTRACORPORIAL CIRCUIT FLUID DYNAMICS AND FLUID COMPOSITION: THE EFFECTS ON THROMBUS FORMATION

**Background:** Extracorporeal devices used for short term cardiac support and destination therapy are still hindered by the risk of thromboembolic events. Emboli form on the blood contact surface of the device in the presence of appropriate anticoagulation and are shed to the patient circulation. Certain devices are more prone to emboli formation and it is possible that fluid dynamics including flow and velocity aid in this phenomenon. This research examined two blood flow rates on fibrin formation in the model circuit.

**Methods:** The model consisted of a Medtronic ECMO assist reservoir in series with a standard roller pump and heat exchanger. The circuit was primed with heparinized bovine blood and maintained at normothermia. Ten ECMO assist reservoirs were divided into two sub groups based on flow. Each group was exposed to one blood flow for 12 hours. At termination the assist reservoir was rinsed with normal saline and examined for fibrin formation.

**Results.** The surface area of each ECMO bladder was evaluated for fibrin formation by mapping the surface area affected. The evaluation revealed that the lower flow rates produced the most fibrin formation based on total area involved.

**Conclusions:** This limited study demonstrated that the model is capable of showing a difference between high and low flow rates on fibrin formation. We observed that there is an incidence of fibrin formation in areas of changing velocity regardless of flow. Ventricular assist devices designed with areas of large velocity change may be more prone to surface thrombus formation. This model may well be refined to demonstrate problem areas on the bench top during device development.

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EVALUATION OF THE BAYER RAPIDPOINT® 405 POINT OF CARE TESTING SYSTEM DURING ADULT CARDIOPULMONARY BYPASS

The use of point of care testing (POCT) in the cardiac operating room can provide nearly immediate return of critical diagnostic indicators thereby eliminating delays in the correction of pathological physiology. Central laboratories have a well-defined methodology in operation, calibration, quality control and validation of clinical instrumentation, however, since perfusionists use POCT analyzers in alternate environments and with a restricted patient population, evaluation and validation should be carried out under the projected conditions of use. The purpose of the present work was to compare the results of aliquots of blood analyzed in the OR by a Bayer Rapidpoint® 405 with those returned by the lab. A syringe was used to remove blood from the arterial sampling stopcock of the oxygenator and directly placed onto the sample port of the Rapidpoint® 405. Following automated aspiration, the syringe with the remainder of the sample was immediately sent to the lab and analyzed in the usual fashion (Bayer Rapidlab® 865). Analytes compared were those routinely charted on the perfusion record: pH, pCO₂, pO₂, base excess, hematocrit, potassium, and glucose. Single classification ANOVA with two groups with equal sample sizes, correlation, Pasing-Bablok regression, and Bland-Altman analyses were performed. Results for the POCT analyzer were well correlated with the lab for all analytes. Rapidpoint® pH (n=113), pO₂ (n=113), base excess (n=112), hematocrit (n=111) and potassium (n=112) were similar to lab values, while pCO₂ (n=113; p=0.004) and glucose (n=110; p=0.001) were significantly different. Bland-Altman bias for the latter two analytes were −1.60 mmHg and −15.2 mg/dl. The former bias was considered not clinically significant while it is concluded that the Rapidpoint® 405 glucose results should be interpreted appropriately.

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