



Selected Abstracts
for the
Australasian Society of Cardio-Vascular
Perfusionists Inc.

21st Annual Scientific Meeting
November 5–6, 2004

Canberra
Australian Capital Territory
Australia

REDESIGNING CARDIOPULMONARY BYPASS—A FOCUS ON MODIFIABLE PRECURSORS TO NEUROLOGIC INJURY

While there have been significant advances in CPB over the past 50 years, there remain significant opportunities for improvement. A portion of patients undergoing cardiac surgery may develop focal and/or subtle brain injuries secondary to cardiac surgery. Embolism and hypoperfusion are the dominant mechanisms for focal neurologic injuries among coronary artery bypass graft (CABG) surgery patients. There is evidence that in some cases these injuries may be related to cardiopulmonary bypass (CPB). Furthermore, recent studies suggest that these mechanisms may also produce the more prevalent cognitive deficits experienced by many patients. "The aim of our current work is to obtain a thorough understanding of the processes of care associated with the production of embolic activity, cerebral hypoperfusion, and hemodynamic aberrations that often occur during CPB.

We have developed a system for the simultaneous recording of physiologic parameters, Transcranial Doppler, CPB circuit Doppler (in flow and out flow), and measurement of near infrared regional cerebral oxyhemoglobin saturation with the NIRS INVOS Cerebral Oximeter (Somanetics, Troy MI) during CPB. The system captures physiologic data from the patient monitor and the heart lung machine at 20 second intervals. Emboli counted in the CPB circuit and right and left cerebral arteries were continuously measured using the PMD 100 Digital Power M-Mode Transcranial Doppler (Spencer Technologies, Seattle WA). The M-Mode Doppler from the CPB circuit, M-Mode Doppler TCD, and the digital camera recording were displayed onto a single screen using a video splitting device (Keywest Technology, Kenexa, KA). Physiologic data was electronically acquired from the patient monitor and CPB machine using the Databahn Stöckert System (Stöckert Instrumente GmbH, München, Germany). All data and signals were electronically synchronized. Continuous variables were studied using control charts to aid in identifying instability in processes and special cause variation.

We have observed wide variation in embolic counts detected in the cerebral arteries and CPB circuit, NIRS, and physiologic parameters. We have also noted increased emboli counts in the CPB circuit and in the cerebral arteries related to the method of venous drainage, the entrainment of air into the venous line, the return of ultra filtration effluent blood into the cardiotomy reservoir, blood sampling techniques, and medication administration. We have observed variation in cerebral NIRS values related to retraction and positioning of the heart during construction of the distal coronary anastomoses on the posterior coronary arteries. We have further demonstrated that in many cases, when the embolic activity is recognized it can be attenuated or eliminated in real time through communication between the perfusionist and cardiac surgeon. We have developed a patient level report that may be reviewed by the surgical team following each procedure to provide an understanding of when embolic activity and unwanted variation in physiologic parameters occur during the procedure.

Use of this model provides the surgical team with detailed information regarding the contribution of CPB to the creation of precursors of neurological injury. This system provides meaningful data to guide the surgical team in the redesign of the CPB system and associated techniques.

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NEW CLINICAL PRACTICE: DOES IT ALTER NEUROLOGICAL AND NEUROPSYCHOLOGICAL OUTCOME?

Evidence-based advances in cardiac surgery can be difficult to determine when the outcome variable events rate being examined is very low. Such is the case when we attempt to measure changes in clinical practice designed to result in improved neurological outcomes, as the event rate for stroke as an outcome variable is extremely low. Over the last 20 years the importance of neuropsychological outcomes following cardiopulmonary bypass (CPB) have been identified as a major cause of morbidity as well as surrogate markers of more overt neurological outcomes. One nidus for this has been the Key West "outcomes" meeting, which has specifically focused on this area.

Perfusion practice has evolved largely empirically over the last 50 years. Advances have been driven by a combination of factors including research, the influence of the medical industry, and individual and collegial experience. These developments, in concert with advances in surgery, anaesthesia and postoperative intensive care have combined to improve the final outcome for the patient. What specific changes in the practice of perfusion have resulted in improved clinical outcomes? Recently a group of clinicians, consisting of perfusionists, surgeons, and anaesthesiologists, came together to critically review relevant literature and promote guidelines for evidence-based practice standards in perfusion. As part of their initial review they focused on practices that have demonstrated improvements in neurological or neuropsychological outcomes and the evidence which supported their adoption into clinical practice. Six areas were identified including pH and temperature management, glucose management, handling of shed blood, manipulation of the aorta and arterial line filtration.

The ability of the perfusion profession to recognize the importance of research and put it into practice is extraordinarily important as is working with industry to introduce beneficial technology into clinical practice. This is recently evidenced with the emerging interest in multimodality brain monitoring including EEG/BIS monitoring, cerebral oximetry, and transcranial Doppler. The emphasis is not on monitoring for monitoring's sake, but on reacting to and actively responding to changes in these monitored parameters during surgery and as a result of post hoc analysis. The objective is to demonstrate improved patient outcomes.

More recent observations and research findings suggesting changes in clinical practice that result in improved outcomes include the routine use of intraoperative echocardiography, the recognition of the role of perfusion interventions in emboli generation, and the role of aprotinin in neurological protection. As we better understand the varied aetiology of cognitive deficit following CPB such as cerebral microemboli, global cerebral hypothermia, temperature management hyperthermia and rewarming, inflammation, cerebral edema, pharmacological and genetics influences, we are more likely to be able to explore pathways to clinical improvement.

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IMPROVED OUTCOMES VIA A COMBINATION OF THE THROMBOELASTOGRAPH™ AND A TRANSFUSION ALGORITHM

The goal of transfusion medicine is to assure the maintenance of adequate concentrations of the circulating elements of blood, to provide physiological well-being. During cardiac surgery all surgical and medical interventions need to be critically evaluated to meet this transfusion goal. Methods that counter conservatory efforts must be modified or replaced with alternatives that promote blood conservation. The establishment of such a program must be multifactorial and include the following facets:

- Directed volume replacement utilizing a mixture of crystalloid and colloidal solutions
- Autologous blood conservation techniques
- Prudent and quantitative assessment of coagulation status

Each of these interventions must be regulated through the application of rigid guidelines, created in algorithmic style, that utilize quantitative assessment of specific variables. Furthermore, although numerous modalities for intervention exist, only those that have been scientifically scrutinized for their efficacy applied. The establishment of an effective blood conservation program is stratified along levels that are related to the acuity of the patient. The highest levels incorporate mandatory elements that are universal, while the lower tiers utilize techniques that are situation-dependent.

In 2002, we evaluated the utility of the Thromboelastograph™ (TEG™, Haemoscope Corporation, Chicago, Illinois, USA, distributed by Medtel Corporation, New South Wales, Australia) in a clinical trial involving several hundred cardiac and non-cardiac patient, and coordinated by the following departments: pathology, perfusion, laboratory medicine, and cardiac surgery. From this evaluation we determined that the TEG resulted in a change in means by which point-of-care coagulation monitoring at our institution would be performed. The decision was made to purchase eight of these devices, which are placed throughout the hospital system. To date prospective institution review board approved research has been conducted on patients in surgery, trauma, and cardiology. Additional research involving case studies for recombinant factor VII, bovine thrombin antibodies, factor V Leiden, and platelet gel have been completed. Several transfusion algorithms utilizing the TEG have been devised and are in clinical use.

In summary, the use of the TEG has resulted in the establishment of a quantification process for assessing coagulation status of patients presenting with a multitude of ailments. The TEG is used to determine interventions for both hypercoagulable and hypocoagulable states as well as determine the presence of surgical bleeding. The development of a transfusion algorithm for cardiovascular surgery is presented.

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PRACTICAL HEMOSTASIS, POINT-OF-CARE COAGULATION MONITORING, CLINICAL EXPERIENCE

It has long been recognized that bleeding and the need for repeat surgery is associated with significant increases in patient morbidity and mortality. The problems with coagulation management in the operating room are twofold. First, the waiting time for laboratory results delays treatment and often leads to the inappropriate (over/under) use of blood and/or blood products in the cardiac surgical patient. Second, the rapidly changing state of a patient's coagulation profile, immediately post cardiopulmonary bypass, leads to further problems with management.

Over the past five years our unit has established a coagulation laboratory with the introduction of point-of-care coagulation monitoring above the standard use of the Activated Clotting Timer device. The coagulation lab has the ability to perform a full range of whole blood coagulation tests within the operating rooms enabling quick diagnoses of impending coagulopathies and providing assistance in distinguishing the source of bleeding that may occur.

The coagulation profiles created using point-of-care monitoring currently consists of the following: Heparin dose, Ca⁺, ACT/Heparinase, Prothrombin Time / INR, Activated Partial Thrombin Time, Platelet count / Function and measurement of Clot integrity. Along with the use of point-of-care monitoring an extensive quality assurance program is also required as part of the service. Results given by point-of-care coagulation monitors are used in conjunction with transfusion algorithms to give a direction for transfusion management.

The literature continually refers to "Empiric" transfusion practices particularly in the area of cardiac surgery and operating rooms. These transfusion practices are based on observation and guess work rather than measurement. In the hands of trained personnel point-of-care coagulation analyzers can provide a clear indication for transfusion in the operating room, resulting in appropriate transfusion practice and the use of blood and/or blood products.

Coagulation point-of-care coagulation monitoring is now considered standard practice within our operating room services and is used routinely in majority of major surgical and trauma cases as an adjunct with red cell salvage. In our cardiac practice Coagulation point-of-care coagulation monitoring, Platelet sequestration, Platelet gel, Anti-fibrinolytic therapy, and Heparin coated circuits combined with Low heparin management are part of our armamentarium to reduce the requirement for massive homologous transfusion in complex cardiac surgery. Appropriate use of our homologous blood supply has the potential to reduce demands on the blood transfusion service and reduce the patient exposure to transfusion-associated problems.

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RELIABILITY OF POINT-OF-CARE BLOOD GAS, ELECTROLYTE, LACTATE AND GLUCOSE MEASUREMENT DURING CARDIOPULMONARY BYPASS

The key objective of point-of-care testing (POCT) otherwise referred to as near patient, or bedside testing, is to generate a result quickly so that appropriate treatment can be implemented, leading to an improved clinical or economic outcome. Especially during cardiopulmonary bypass for cardiac surgery, where dynamic changes in blood gas, electrolytes, lactate, and glucose values need to be closely monitored, POCT is an essential component of the total care of the cardiac surgical patient. Recently, the GEM Premier analyzer was upgraded to the GEM Premier 3000. In addition to pH, pCO₂, pO₂, Na⁺, K⁺, Ca²⁺, and hematocrit measurement, glucose and lactate can also be measured on the GEM Premier 3000. In this prospective randomized clinical study, the analytical performance of the GEM Premier 3000 was compared with the Ciba Corning 860 analyzer for blood gas / electrolytes / metabolites, and for hematocrit with the Sysmex 2100 instrument.

During a six-month period, 127 blood samples were analyzed on both the GEM Premier 3000 analyzer and our laboratory analyzers (Ciba Corning 860 / Sysmex 2100 instrument), and compared using the agreement analysis for quantitative data by Bland and Altman.

With exception of K⁺, the other parameters (pCO₂, pO₂, Na⁺, Ca²⁺, hematocrit, glucose, and lactate) can be described in terms of the mean and standard deviation of the differences. For K⁺-measurement on the GEM Premier 3000 a clear linear trend ($r=0.79$, $P<0.001$) was noticed, i.e., in the lower or upper K⁺ reference range the GEM Premier 3000 measured systematically to low or to high, respectively. Furthermore, in comparison with the other parameters, a therapeutically unacceptable systematic difference (mean of difference: -2.2 , $P=0.05$) in hematocrit measurement on the GEM Premier 3000 was observed. The variance of the readings for the GEM Premier 3000 measurements was at clinical acceptable levels.

The simplicity and the convenience of only one consumable make the GEM Premier 3000 analyzer very suitable for POCT during cardiopulmonary bypass for cardiac surgery; however interpretation for clinical therapy needs to be done with caution, since some GEM Premier 3000 parameters are unreliable.

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NON-HEART-BEATING DONOR (NHBD) IN LUNG TRANSPLANTATION: A FEASABILITY STUDY

Despite incorporating a number of strategies to increase donor numbers, including the use of 'extended or marginal' donors and living donors, donor shortage remains the limiting factor in solid organ transplantation. Low organ donation rates have led to an increase in transplant waiting lists and mortality. Several International Renal and Hepatic transplantation centres have successfully utilized Non-Heart-Beating Donors (NHBD) as a source of organs for transplantation. Following on this success, lung transplant centres are now considering the NHBD as an adjunct to the classical Heart-Beating Donor program. Based on the current body of evidence supporting the use of organs from NHBD the Alfred Hospital Lung Transplant Service proposes to establish a clinical program for NHBD Lung donation. We have obtained funding to also investigate the possibility of a 'Multi-Organ' NHBD model. This paper will give an overview of the results of our laboratory work undertaken to evaluate the safety and efficacy of this source of organs and of the international experience so far.

Using a large animal model, we explored 6 variations of warm ischemia (50–240 min), topical cooling (60–120 min), flush perfusion, and cold storage (30–120 min) to mimic different human NHBD lung retrieval scenarios. Functional status of ventilated NHBD lungs post retrieval was assessed initially via 300 ml blood flush (pre-post flush PaO₂) then on an ex-vivo ECMO rig utilizing Steen solution and N₂ / CO₂ infusions, for 2 hr. All lungs achieved excellent PaO₂/FIO₂ (550–600 mmHg) and PVR (200–400 d/s/cm–5) with no net weight gain during a 2 h evaluation period. PA pressures (5–15 mmHg) also remained stable. Initial post-blood flush PaO₂ correlated well with measured PaO₂ at 30 min on the rig ($r^2=0.78$).

Our NHBD team also met with ethics, legal, trauma/emergency, intensive care and operating theatre teams, and the state organ donor service (ODS) to recommend utilization of NHBD lungs and to develop appropriate guidelines for clinical protocols.

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CHANGES IN BLOOD CELLULAR COMPONENT CONCENTRATION WITH MODIFIED ULTRA-FILTRATION (MUF)—INSIGHTS INTO THE BENEFICIAL EFFECT OF MUF

Modified ultra-filtration (MUF) is widely used as a technique to haemo-concentrate following cardiopulmonary bypass (CPB) in children. In addition to removing a volume of plasma filtrate, MUF removes proinflammatory cytokines from the circulation. This may reduce activation and sequestration of neutrophils in the lung with positive effects on gas exchange, pulmonary vascular resistance and lung compliance. We assessed whether the proposed reduction of pulmonary sequestration with MUF were mirrored by an elevation of blood cellular elements in the circulation after correction for changes in circulating volume.

Thirty paediatric cardiac surgery patients were recruited from our elective bypass cases between June and September 2003. Median age was 1.2 years. Median CPB time was 95 minutes. MUF was performed after separation from CPB. Total white blood cells, neutrophils, and other parameters were measured pre-bypass, before and after MUF. Values shown are mean $\pm$ SEM.

Average duration of MUF procedure was 6.5 $\pm$ 4 minutes. Average of 46 $\pm$ 6 ml/Kg of fluid was removed from the circulation. Hematocrit was used to calculate a concentration correction factor of 35%. Our findings showed that neutrophils increased by 173% during MUF (range -26% ~ 1850%) and 138% increase after subtracting 35% haemo-concentrate factor. The Neutrophil count more than doubled in 14 out of 28 cases. Mean preoperative neutrophils were 4.4 $\pm$ 6 (10^9 /L) and pre-MUF were 4.8 $\pm$ 9 (10^9 /L), there is no significant difference between preoperation and pre-MUF neutrophil count, $P>0.05$. Mean neutrophils from pre-MUF sample were 4.8 $\pm$ 9 (10^9 /L) compare post-MUF 8 $\pm$ 1 (10^9 /L). There is highly significant different neutrophil count between pre- and post- MUF procedure, $P<0.01$, even after subtracting the 35% concentration index.

Modified ultrafiltration results in a significant increase in neutrophils in bloodstream. This increase is perhaps from neutrophils that had returned to the circulation after being activated and sequestered in various organs, especially lungs due to the systemic inflammatory response to CPB. Inflammatory mediators are responsible for promoting firm adhesion of neutrophils and trans-endothelial migration (neutrophil sequestration into the tissues) particularly in the lungs post ischemia (reperfusion injury). Previous studies have demonstrated reduction in inflammatory mediator during the MUF procedure. Furthermore, warm blood with a high COP and high Hct returned directly to the lungs may also contribute to neutrophils returning into the bloodstream. Although no mechanistic inference can be drawn on the basis of this study, the observed increase in neutrophil count and possible decrease in pulmonary neutrophil sequestration may ameliorate postoperative pulmonary dysfunction.

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EVOLUTION OF ECMO AT THE ALFRED HOSPITAL

The first successful case report on Venous Arterial (VA) ECMO was published in 1972, since then ECMO has been widely used with varied success. The study by Zapol et al. in 1979 somewhat curbed enthusiasm for using ECMO for Adult Respiratory Distress Syndrome (ARDS), but work by Bartlett established ECMO as viable therapy for neonates. In 1986, Gattinoni published results using Venous Venous (VV) ECMO for ARDS. It was after the success that we began using VV ECMO for ARDS in 1990.

Our early experience was with VV ECMO in ARDS patients, with disappointing results, and many technical problems affecting outcomes. Our initial circuit comprised the Bio Pump (Medtronic, Minneapolis, USA) and the ECMO silicon membrane (Medtronic, Minneapolis USA), a device that required high doses of heparinization. Anticoagulation was and continues to be the main problem for ECMO. Too little anticoagulation leads to thrombotic complications and too much anticoagulation leads to haemorrhagic complications. The first break through in improving our results came in the form of Carmeda Coated circuits (Medtronic Minneapolis USA). This allowed us to use lesser doses of heparin and use the Maxima oxygenator, a small efficient microporous Hollow Fibre Membrane Oxygenator (Medtronic). Although we reduced our haemorrhagic complications, we ran into problems with oxygenators developing plasma leak. In one patient, device failure due to plasma leak required the changing out of 10 devices over a 240-hour period. Despite these problems we continued to use the HFMO and the results we obtained were comparable with the literature. Our greatest success came from short-term VA supports for patients who had overdosed. In 2002 we began using the Jostra Quadrox-D oxygenator, (Jostra, Hirrlingen Germany), a P-methylpentene HFMO, heparin coated, solid membrane and the Rota Flow centrifugal pump (Jostra), a device with excellent flow characteristics and no low-flow zones to allow heat to build up or thrombus to form within the pump head. Despite these advances in technology, we found that survival for 2002 was one patient of ten. However, none of the deaths in this group was attributable to morbidity arising out of device failure. An internal review of these cases concluded that an ECMO training program needed to be established to train all staff, Medical and Nursing the basics of ECMO. Since establishing the program, we have seen both a marked increase in the utilization and success of ECMO. Our unit now utilizes ECMO for respiratory failure, primary pulmonary graft failure, primary cardiac graft failure, post cardiectomy support, bridge to VAD, and septic shock. Our results are summarized in the table below.

Table 1. Incidence of use and outcome of ECMO at Alfred Hospital 1990–2004

	1990–2002	2003–2004
Patients	40 patients (41 instances)*	30 patients (32 instances)**
Survivors	14 (34%)	19 (59%)
Duration of support	1–26 days	1–27 days
Total support	230 days (6% of total time)	258 (35% of total time)
Average support	5.6 days	8.1 days

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IS ECMO A TREATMENT OPTION FOR SEVERE MENINGOCOCCAL DISEASE?

Meningococcal Septicaemia is a rare and potentially fatal disease with the occurrence in the Australian population at 1–2 per 100,000. Of these cases, the disease proves to be fatal in about 10% of patients. At the Royal Children's Hospital Melbourne, nine patients who presented with severe meningococcal disease and were failing conventional medical therapy have been treated with ECMO since 1991.

This group had a median age of 9 months, BSA of 0.46 m², support duration of 43 hours and resulted in four survivors and five deaths.

In the patients that died, the full calculated ECMO flow (150ml/kg for patients less than 10kg, and 2.4 L/min/m² for patients over 10kg) was unable to be achieved in three patients and difficult to maintain in the other two patients during the support period. Two of the four survivors were aged over 12 years and had a sternotomy performed allowing direct cardiac cannulation. This enabled flows greater than 2.4 L/min/m² to be achieved consistently, which may be an important factor in outcomes for this patients group. All patients older than 4 years of age survived.

In this small group of patients, ECMO successfully supported the circulation in 4 out of 9 patients. Two of four survivors also utilized a sternotomy to gain direct cardiac cannulation enabling greater than calculated flows to be achieved. This is an important observation for this patient group and should be considered in all patients presenting with severe meningococcal disease regardless of age.

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PERFUSION PRACTICE IN AUSTRALIA AND NEW ZEALAND

Current clinical practice in perfusion and best perfusion practice are not necessarily intimately linked, however, to give a clear understanding of what is current practice in Australia and New Zealand we undertook a detailed survey to determine current practice of all known centers performing cardio-pulmonary bypass (CPB).

Sixty-one centers were identified as performing procedures utilizing CPB. The perfusionist responsible for CPB in each institution was sent a detailed electronic survey comprising 233 single answer questions and 12 questions allowing commentary. Questions covered both pediatric and adult CPB. The specific aim of this survey was to interrogate the performers of procedures utilizing cardiopulmonary bypass about the equipment and strategies that they used in the 2003 calendar year that represented the predominant practice of perfusion in their institutions.

Eighty seven percent of centers identified as performing bypass surgery responded within 19 days of the survey being circulated; this represented a caseload of approximately 20,688 adult and 1,282 pediatric cases. We initially report data relating to adult CPB. These data allowed us to profile a standard adult bypass setup that would consist of a membrane oxygenator (100% of respondents), hard-shell venous reservoir (HSVR, 80%), roller pump (63% exclusively as the main arterial pump) with a mixture of biocompatible, and non-biocompatible circuit components (77%), including pre-bypass (96%) and arterial line (94%) filters. Monitoring most typically would consist of HSVR low levels (100%, with servo regulation of the arterial pump 85%), microbubble alarm (93%, servo regulated 80%), arterial line pressures (100%, servo regulated 77%), inline venous O₂ saturation (100%) and inline hematocrit (58%). Standard management for CPB consisted of an ACT >200 prior to cannulation (82%), >400 prior to initiation of bypass (93%) with a patient temperature target of 28–34 (median 32°C), measured at least by a nasopharyngeal temperature probe. Alpha stat acid base management (83%), PaO₂ target of 150–250 mm Hg, and blood cardioplegia (always 77%, nearly always 20%). Flow indices would be typically between 1.8 and 2.4 l/min/m². An increased flow index would be employed in certain patient cohorts (e.g., elderly, neurologically high risk). Cardiectomy blood would nearly always be returned to the circuit (86%) with a varying practice to sometimes process or discard. Pediatric perfusion practice is somewhat more polarized than for adults. While most of the equipment and monitoring devices are similar the clinical practice appears to still show wide variance.

We have been able to quantify current practice in Australia and New Zealand. Clearly defined practices are evident, for example the universal use of membrane oxygenators, prebypass and arterial line filtration. However, other practices vary from common practice in the northern hemisphere such as the choice of arterial pump type, use of online blood gas and hematocrit monitoring, and the use of a total biocompatible coated circuits. There have been significant changes in antipodean perfusion practice over that last decade. Whether the driving force in change has been evidence based is not clear, however future change and development will be heavily focused on improving the outcomes for patients undergoing cardiac surgery with CPB.

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HEAT EXCHANGER EFFICIENCY REDUCED BY FIBRIN DEPOSITION: IS IT PATIENT OR DEVICE RELATED?

Several documented cases of reduced heat exchanger efficiency when using the Terumo Capiox SX18 oxygenator at the John Hunter Hospital prompted an investigation into its cause.

An affected device was rinsed and small particles of material around the top of the membrane compartment were observed. It was postulated that these particles lodge within the stainless steel tubes of the heat exchanger and reduce its efficiency. Further examination of rinsed devices demonstrated varying amounts of the material, identified as fibrin, blocking the inlets of the heat exchanger tubes and additional small particles, which had passed through the tubes, at the top of the membrane compartment.

Terumo SX25 oxygenators, which share the same heat exchanger module, manufactured over nine months previously, also demonstrated fibrin deposition indicating that this was not a new problem. The more precise water temperature measurement available with the Jostra HCU20 water heater cooler allowed previously unrecognised subtle decreases in heat exchanger performance to be noted.

A review of the perfusion and medical records of those patients with subnormal heat exchanger performance revealed that heparin resistance, at least one Activated Clotting Time (ACT) less than 500 seconds, and body weight greater than 90Kg were contributing factors. Transient transmembrane pressure excursions had not occurred in any of these cases. A revised heparinization and anticoagulation monitoring protocol eliminated the occurrence of decreased heat exchanger efficiency, however, deposits of fibrin were still observed. Terumo engineers postulated that inadequate deairing of the heat exchanger caused higher blood flow through the remaining tubes with increased turbulence; however, an improved deairing protocol did not eliminate fibrin deposition. In all cases the distribution of fibrin followed the blood flow path on the inlet of the heat exchanger and the quantity deposited varied but the individual deposits were around the same size indicating a correlation with blood flow path and rate of fibrin deposition.

The Terumo Capiox SX18RX with "X" coating became available and was introduced. Initially some cases of fibrin deposition were noted, however, no cases have been encountered in the last six months. In conclusion, fibrin deposition in the Terumo Capiox SX18 was unrelated to transient transmembrane pressure excursions and occurred regardless of the adequacy of heparinization. It appeared to be related to disturbed blood flow patterns within the heat exchanger inlet. Large patients who had been on heparin therapy were at a higher risk of this event occurring.

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SIZE MAKES A DIFFERENCE: MINIMIZATION OF THE CPB CIRCUIT

The Northern New England Cardiovascular Disease Study Group, founded in 1987, is a voluntary regional consortium that exists to develop and exchange information related to improving quality, safety, effectiveness, and costs of medical interventions in cardiovascular disease. We study the process of care using data registries in an effort to discover variations in the processes of care and to identify best practices.

Variation in CPB (cardiopulmonary bypass) lowest HCT (hematocrit) and transfusion practices between surgeons and between centers prompted the consortium to begin examining the nadir HCT on CPB as a variable in our perfusion data registry. We have observed a strong inverse relationship between nadir CPB HCT and postoperative low output failure as evident by the need to return to CPB after separation, the need for intra-aortic balloon pump support, and in-hospital death. Patients that experience a single HCT of less than or equal to 19% during CPB had more than twice the mortality of patients with a HCT of 25% (n=6,980 CABG patients, p of trend <0.001). This relationship persists despite risk adjustment using logistic regression. Female patients and men with small body habitus were more likely to have a low HCT during CPB. Subsequent to these findings the team at Maine Medical Center developed a strategy to reduce the incident of Low HCT during CPB. The use of a HCT prediction formula, small CPB circuits with reduced prime volume for small patients, and an autologous blood priming technique ("autopriming or RAP") resulted in a significant reduction in the number of patients exposed to low HCT. In a recent analysis of perfusion registry data that included transfusion rates (n=10,730), we observed a dose-dependent increase in risk of infections, low output failure, and an increase in hospital mortality related to RBC transfusions (unpublished data).

Low HCT is associated with low output failure, the need for cardiac support, and in hospital mortality. Homologous red blood cell transfusions are associated with increased risk of pneumonia and in hospital mortality. It is critical that the surgical team has an awareness that the size of the patient makes a difference with regards to the risk for low HCT, transfusion, and in-hospital morbidity and mortality. Furthermore, opportunities to reduce blood loss and excessive dilution of patients should be addressed prior to surgery by cardiologists, particularly for small patients. A number of opportunities are available to modify the precursors to anemia in the operating room. CPB circuits should be matched to the patient's size. A multidisciplinary approach, which includes the use of low prime CPB circuits, is needed to reduce both anemia and transfusions. Size does makes a difference and efforts to minimize the CPB circuit by matching the circuit to the patient's size should be undertaken to provide the best possible care for every patient.

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IMPROVED OUTCOMES DURING CARDIAC SURGERY—A MULTIFACTORIAL ENHANCEMENT OF TECHNIQUES OF CARDIOPULMONARY BYPASS

Patients presenting for cardiac surgery with cardiopulmonary bypass (CPB) are more likely to have pre-existing comorbidities, which has resulted in a steady increase in the risk associated with CPB. The resulting challenge has mandated the optimization of perfusion care. The purpose of this study was to retrospectively evaluate the impact of a number of aggregate, evidence based perfusion care changes on patient outcome.

After Institutional Review Board approval, two groups of patients were compared. The control group (n=420) included all patients undergoing CPB in a 18-month period preceding a multifaceted change in perfusion techniques. The treatment group (n=272) included all patients undergoing CPB after the following changes:

Multifactorial enhancement of perfusion techniques.

- Phosphorylcholine coated circuitry (COBE Cardiovascular, Colorado, USA)
- Continuous arterial and venous in-line blood gas monitoring (Terumo Card., Michigan USA)
- Dedicated myocardial protection system (Quest Medical, Texas, USA)
- Centrifugal Pump (COBE Cardiovascular, Colorado, USA)
- Thromboelastograph whole blood coagulation monitoring (Haemoscope CO. Illinois, USA)
- Continuous Autotransfusion System (Terumo Card., Michigan USA)
- Prime solution with albumin replacing high molecular weight starch
- Perfusion clinician quality improvement plan

After matching the groups by procedure, multiple variables were analyzed, including demographic, preoperative, operative, and postoperative parameters. Both univariate and multivariate methods of analysis were included, which utilized propensity analysis and balancing score technologies.

The treatment group had a lower mortality rate than the control group (2.9% vs 9.3%, $p=0.001$) despite being similar in predicted mortality ($10.1\pm7.6\%$ vs $9.7\pm8.1\%$, $p=NS$) and other preoperative and operative parameters. The lower mortality rate was concurrent with a lower incidence of reoperation for bleeding (8.8% vs 4.4%, $p=0.018$), sternal infection (2.6% vs 0.7%, $p=0.062$), permanent stroke (3.3% vs 1.1%, $p=0.050$), and cardiac arrest (3.8% vs 1.1%, $p=0.025$), and a trend of decreasing rates for other complications.

In conclusion, the patients treated after evidence based changes in CPB care were implemented had a decreased complication and mortality rate. Changes in perfusion practice can be implemented to improve the overall outcome of patients undergoing cardiac surgery.

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PRE-CLINICAL ANIMAL TRIAL AND CLINICAL PILOT TRIAL EXPERIENCE WITH THE VENTRASSIST LVAS.

Limitations of the current generation of mechanical cardiac assist-devices are their inherent size, valve-dependency and bearings, which are subject to wear. Throughout the history of the clinical application of LVADs, the clinical trilogy of infection, mechanical failure, and thromboembolism have bedevilled the long term application of artificial heart technology. The Ventrassist™ LVAS is a novel, implantable, mixed flow, electromechanical left ventricular assist device developed by Ventracor Pty Ltd specifically for long term support of the failing heart. The 298 g titanium alloy pump contains a four lobed impeller hydrodynamically suspended in the blood path. At 2300 rpm the device pumps 5.4 L/min at 4.8 watts power utility.

To refine the design the LVAS was implanted into 40 sheep for periods of 48 hours to 1 month for a cumulative support duration of 4.8 years. LVAS connections were from the left ventricular apex to descending thoracic aorta. All implants were performed as 'off-pump' procedures. All animals were euthanased and organs subject to pathological examination. Once the LVAS design was 'fixed', the pre-clinical trial was initiated in 11 non-anticoagulated sheep for a support duration of at least 3 months. Subsequently, the clinical pilot trial began in June 2003. To date, 8 patients have received the Ventrassist™ LVAS as either destination therapy or as a bridge to transplant. The aim of the pilot trial at The Alfred was to evaluate the safety of the VentrAssist™ in patients who were gravely ill from congestive heart failure, were no longer responding to optimal medical therapy and had no other options available to them.

Of the 11 sheep in the preclinical trial, 2 died in the perioperative period due to complications of anaesthesia and monitoring. The remaining sheep were euthanased at 1 month (n=1), 3 months (n=6), and 6 months (n=2). Total support duration was 2.8 years. The pump performed free of malfunction with flows of up 4.5 litres/min. There was no device thrombosis or haemolysis. The Ventrassist clinical trial has enrolled 8 patients (7M, 1F), age range 53–75yrs. Indications for support were Ischaemic Cardiomyopathy (n=4) and Ischaemic heart disease (n=4). Four patients received a Ventrassist™ LVAS as destination therapy, 3 as bridge to transplant and 1 as a bridge to the future. Post implant ICU stay ranged from 10–70 days and Length of Hospital stay ranged from 30–76 days. Patients are discharged to home and managed as hospital outpatients. The cumulative duration of support is presently 3.3 years. As of September 2004, there have been 4 deaths in this group with a 30-day mortality of 25%.

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UNIVERSAL PERFUSION SYSTEM WITH PINE-TREE SHAPED AORTIC CIRCUIT FOR THORACIC AORTA SURGERY

Thoracic aorta surgery usually requires cardiopulmonary bypass with two or more pumps for systemic and cerebral perfusion. It is not easy for even an experienced perfusionist to choose the appropriate cerebral perfusion system. (i.e., retrograde vs. antegrade) and set it up in a short period of time.

We developed a universal aortic circuit and extra-corporeal circulation circuit for thoracic aorta surgery. The aortic circuit has 5 branches and a pre-connected extra-corporeal circulation system. We named this the "pine-tree shaped aortic circuit" (PTAC). The PTAC requires only a single pump system and no extra filters. It can be adapted to any kind of cerebral perfusion by the closing of selected branches. We designed the caliber and length of each branches for ideal perfusion flow by calculation and experiments. We performed thoracic aorta surgery using either a general perfusion system (one that uses 3 pumps for main and cerebral perfusion) or the PTAC system, and we compared their priming volume, set-up time, and cost.

Fourteen subjects undergoing urgent thoracic aorta surgery were randomly assigned to two groups of 7. The PTAC system was used for Group A and the general perfusion system for Group B. Data are expressed as means $\pm$ SD. The Student *t*-test was used to analyze differences between groups. There was a significant difference in priming volume (Group A: 1110 $\pm$ 0 ml; Group B: 2400 $\pm$ 0 ml; $P < 0.05$), set-up time (Group A: 5.37 $\pm$ 0.53 min; Group B: 35 $\pm$ 4.20 min; $P < 0.05$), and cost (Group A: 671,870 yen; Group B: 699,450 yen; $P < 0.05$). No cerebral infarction occurred in either group and all patients recovered well.

The PTAC system saved priming volume, perfusion circuit set-up time, and cost. We believe that the PTAC system can take the place of conventional multi-perfusion systems.

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NEUROLOGICAL MONITORING THROUGH THE INVOS® CEREBRAL OXIMETER

INVOS® cerebral oximetry non-invasively measures and monitors change in the Hb oxygen saturation in the microvasculature of the frontal lobes of the cerebrum. It does not differentiate between arterial and venous blood and therefore does not require a pulse. This enables the system to operate satisfactorily during CPB, and even during circulatory arrest. Since blood in the cerebrum is made up of approximately 75% venous blood, 20% arterial blood, and 5% capillary blood, the readings of the oximeter are clinically consistent with venous sampling.

By indirectly monitoring cerebral venous oxygen saturation, we can, albeit indirectly, monitor the balance/imbalance of oxygen supply and demand within the cerebrum. It is sensitive to both inadequate oxygenation as well as compromised cerebral blood flow. This monitoring can potentially reduce or even prevent in certain circumstances neurological damage related to or occurring during cardiac surgery and or CPB. An adhesive sensor is attached to the forehead that emits near infrared (NIR) light. NIR light easily penetrates skin, tissues and bone. Two photodiodes detect light reflecting back from the head and using regression analysis the light absorption occurring in the skin, subcutaneous tissue and bone can be removed from the signal to leave a depth resolved signal. This signal is then representative of the deeper brain tissue regional oxygen saturation, rSO_2 .

Early reports in the literature regarding the efficacy of cerebral oximetry were mixed with some reports (Litscher G, Schwarz G) suggesting that the actual number generated was of less importance than the trend. Further, Goldman and Iglesias in separate studies presented at Outcomes 2004, showed further support that maintaining rSO_2 at equal to pre-operative levels and at $\geq$ 75% of preoperative levels respectively, could reduce hospital length of stay. Our experience, while limited mostly to difficult, long cases, e.g., DHCA for aortic dissection, has given us some interesting feedback. The monitor has almost universally trended with expectation. For example, with increases in pCO_2 , MAP, pump flow, Hct, or FiO_2 , the cerebral oxygen saturation rises. Conversely with decreases in any of these parameters the rSO_2 falls.

With this confidence in the trending of the cerebral oximeter, when the device trends in a direction other than expectation it is reasonable to go looking for a cause. This may well lead to the early detection of a problem, possibly before it may have become apparent through other means.

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