One of the most demanding challenges facing clinicians on a daily basis is the desire to appropriately translate science into routine clinical practice; so broad is the recognition of this difficulty that the discipline of “translational research” has been developed. Translational research involves taking the basic scientific knowledge and discoveries and integrating them into the clinical care of our patients and although this appears to be a simple task, it is one that is often difficult to realize. How has cardiac surgery performed in this respect? Specifically have we taken what we have reported with respect to cerebrovascular injury and implemented the appropriate changes?

CEREBROVASCULAR INJURY AND CARDIAC SURGERY

Cerebrovascular injury is a devastating event to an individual and is a significant consumer of health budgets globally. Patients presenting for cardiac surgery have a well-documented risk of compromised neurologic outcome, which increases with age resulting in an increasing proportion of perioperative deaths, and is also an important cause of perioperative morbidity. The incidence of gross neurologic deficit increases exponentially with age. As the number of elderly patients presenting for cardiac surgery increases, the total cohort of patients with this compromised neurologic outcome increases proportionately. While Type 1 (gross) neurologic deficits such as stroke affect a small but significant proportion of cardiac surgical patients, Type 2 (cognitive) deficits have been reported to be present in up to 79% of patients after cardiopulmonary bypass (CPB). These altered neurologic outcomes often have a more significant impact in the older patient where an increase above a higher baseline deficit results in an inability to cope at the same functional capacity post-operatively (1).

ETIOLOGY OF CEREBROVASCULAR INJURY AND CARDIAC SURGERY

Cerebral Microembolism

Altered neurological outcome has been studied extensively with a number of factors identified as causal in
producing subtle psychological, cognitive, and behavioral changes in patients following cardiac surgery. Cerebral microembolism has been attributed as one of the primary causes of neurologic injury in patients. Hammon et al. (2) reported a significant reduction in cognitive deficits long-term in patients with a decrease in emboli. Stygall et al. (3) also showed that an increase in intraoperative microembolic events was significantly associated with a greater decline in neuropsychological functioning 5 years after coronary artery bypass graft surgery. There are a number of mechanisms relating to the CPB circuit and surgical technique that have been found to cause the introduction of emboli during CPB. Rodriguez et al. (4) found that the amount of emboli detected through the middle cerebral artery (represented as high-intensity transient signals using transcranial Doppler ultrasound) can be related to the initiation of CPB, particularly due to the volume of air introduced into the venous cannula at the time of connecting the right atrium cannula to the venous return line of the circuit. An increase in the volume of air retained in the venous cannula resulted in the increase in incidence of cerebral microemboli (5). It was also shown that de-airing the venous cannula reduced the number of microemboli detected.

Surgical interventions, such as aortic manipulation through aortic clamping events, were found by Hammon et al. (2) to result in emboli production. Single aortic clamping was found to produce fewer emboli than multiple aortic clamping. Taylor et al. (6) demonstrated that during surgical interventions such as the initiation of CPB and during the start of cardiac ejection after cross-clamp removal, were periods, which produced significantly higher embolic rates than during events such as aortic cannulation and decannulation, and cross-clamp application and removal. However, they found that the largest proportion of microemboli observed during coronary artery bypass graft using closed system CPB occurred during perfusionist interventions, with drug administrations into the venous reservoir resulting in significantly higher embolic rates than blood sampling. The fluid level in the venous reservoir of the hard-shell oxygenator has also been attributed to emboli production, such as in a study by Mitchell et al. (7), where in vitro trials and clinical observations showed that the lowering of the venous/cardiotomy reservoir volume caused an increase in the index of microembolic activity.

**Cerebral Oxygen Saturation**

Cerebral hypoperfusion, in particular, the imbalance between cerebral oxygen supply and demand, is also thought to have important implications for the development of brain injury in patients resulting from the use of CPB during cardiac surgery. A report by Croughwell et al. (8) demonstrated that increasing arterial-venous oxygen difference and decreasing jugular bulb saturation were both associated with postoperative neuropsychological impairment. Murkin et al. (9) evaluated the effect of intraoperative monitoring of cerebral oxygenation using near infrared spectroscopy (NIRS) with tailored interventions aimed to improve clinical outcomes in 200 patients. The study demonstrated that the interventions decreased periods of prolonged desaturation and were associated with a shorter intensive care unit length of stay. More recently, Slater et al. (10) demonstrated an improvement in neurocognitive outcome in patients in whom cerebral oxygen saturation was maintained and a reduction in hospital length of stay.

**Physiologic Parameters**

The maintenance of physiologic parameters and cerebral autoregulation has also been shown to influence clinical outcomes (11,12). The adverse effects of variations in acid-base management of patients undergoing CPB can include hypoxia, hyperoxia, acidosis, and alkalemia, and their consequences (13). Maintenance of physiological parameters such as blood gas, pH, activated clotting time, and blood temperature is paramount to be able to avoid neurologic injury in patients (14). In particular, monitoring, maintaining, and regulating the many variables within the blood gas results by the perfusionist ensure that homeostasis is maintained.

**MONITORING VARIATION DURING CARDIOPULMONARY BYPASS**

**Transcranial Doppler Ultrasound**

The PMD100 transcranial Doppler (TCD) ultrasound (Spencer, Seattle, WA) is a device used for emboli detection in the middle cerebral arteries, represented as high-intensity transient signals, using 2 mHz pulsed-wave Doppler transducers. Detection of cerebral embolic events utilizing TCD during cardiac surgical procedures has been widely reported in a variety of different clinical situations (15). Barbut et al. (16) demonstrated the value of embolic monitoring using TCD in 20 patients undergoing CPB. They identified embolic signals in all patients studied, with the majority of signals detected during the application of the aortic cross-clamp or partial occlusion clamp. In a recent review, Murkin (5) highlighted the value of TCD in detecting microemboli of previously unrecognized origin, such as from air entrained by surgical purse string sutures or during perfusionist interventions.

**Embolus Detection and Classification System**

The Embolus Detection and Classification (EDAC) Quantifier (Luna Innovations, Roanoke, VA) provides continuous, real-time feedback on the quantity and volume of gaseous microemboli at multiple points in the extracorporeal circuit during CPB. The technology utilized in this device is significantly different from the other
microemboli counting devices through the use of 5 MHz “active sonar” transducers. The EDAC has been validated in previous studies (17,18). Most recently, Hammon et al. (2) reported that EDAC was found to have a better ability in discriminating between true emboli and noise (e.g., motion artifacts, radio frequency interference, and other causes of false alarms).

**Cerebral Oximetry**

A measure of cerebral oxygenation can be provided by devices which utilize NIRS. One such device is the INVOS Cerebral Oximeter (Somanetics, Troy, MI), which allows the utilization of a technique to assess regional saturation of brain tissue, in a continuous, non-invasive manner. Cerebral oximetry using NIRS is an optical technology that relies on the relative transparencies of biological tissue to near infrared light. Two sensors placed on the forehead are able to measure \( rSO_2 \) in the territory supplied by the middle and anterior cerebral arteries. The validity of this technology has been supported in several studies (19).

**Blood Gas Monitoring**

The CDI 500 (Terumo Corporation, Japan) is an in-line blood gas monitor, which provides real time continuous monitoring of the patients physiological responses to CPB and provides monitoring of \( pO_2, pCO_2, pH, HCO_3^- \), and \( K^+ \). The CDI 500 is accurate in the measurement of blood gas parameters when compared with laboratory results and has also been shown to facilitate the management of perfusion, allowing better maintenance of blood gas parameters within physiological limits. Trowbridge et al. (20) demonstrated that the continuous information from the CDI 500 allowed the perfusionist to more accurately control blood gas parameters while on CPB which resulted in improvement in a number of postoperative outcome variables.

**INTEGRATED MONITORING SYSTEMS**

Groom and colleagues (21) reported a system to obtain a thorough understanding and redesign of the process of care associated with cardiac surgery. They have developed a system, which simultaneously measures some embolic activity, cerebral oxygen saturation, and physiologic parameters, as well as uses a video recording device during cardiac surgery. To date, the evaluation of this methodology in a rigorous, prospective manner has not been reported.

**CONTINUOUS QUALITY IMPROVEMENT**

The importance and benefits of quality assurance and quality control in health care delivery are well recognized. Riley (22), in an editorial in The Journal of Extracorporeal Technology, promoted the role of the perfusion profession in recognizing the importance of quality improvement and reporting in the performance of CPB. The events surrounding the Bristol enquiry in the United Kingdom in 1997 have led to a heightened recognition of the need for structured data management, data collection, and quality control initiatives in cardiac surgery. The Australasian Society of Cardiac and Thoracic Surgeons national database project is evidence that this process is taking place in Australia. However, reports of the application of formalized continuous quality improvement processes in cardiac surgery are limited (23).

The implementation of the quality control process requires the identification of quality indicator variables that could be utilized to define specified quality outcomes. The routine analysis of these quality indicator variables allows the achievement of a continuous quality improvement (CQI) process. The model described by Rath and Strong (24) is an approach that standardizes the CQI process. This model is structured as a 5-step cyclic process abbreviated to “DMAIC” (Figure 1):

1. Define—Define the problem.
2. Measure—Gather baseline data on the problem.
3. Analyze—Identify root causes of the problem from the data.

![Figure 1. The DMAIC methodology.](image-url)
4. Improve—Implement solutions that address the root cause(s) of the problem and evaluate (measure and analyze).
5. Control—Maintain the improvements by standardizing the process.

The DMAIC process under CQI has been successfully introduced into the perfusion practice at Flinders Medical Center (25).

BIOFEEDBACK

Biofeedback may be defined in the surgical context as a process that provides “real time information from psychophysiological recordings about the levels at which physiological systems are functioning” (26). Biofeedback techniques have been previously applied in a number of surgical specialties, including colorectal and urology (27). Biofeedback during CPB could be used in combination with the detection of embolic activity such as with the TCD and EDAC, changes in cerebral oxygen saturation (INVOS), or variations in physiologic parameters (CDI 500). Feedback, by way of auditory stimuli, from these monitoring devices inform the cardiac surgical team of the effect of their clinical practice on the patient during surgery.

INTRODUCING CHANGE

Combining our understanding of etiology, our ability to measure and monitor practice, and the use of structured CQI processes may provide the opportunity to both monitor and assist with the introduction of change into clinical practice. The following methodology provides an example of the application of biofeedback techniques structured according to the DMAIC process:

1. Define and Measure
To audit current practice, routine surgical management with additional monitoring is performed, with all team members blinded to the readings of the following monitoring devices:
- Transcranial Doppler Ultrasound—monitored bilaterally on the middle cerebral artery. All data recorded is stored electronically and assessed using the standard observer criteria for embolus detection (28).
- Embolus Detection and Classification System—to monitor embolic activity in the CPB circuit, one positioned on the outlet side of the arterial pump prior to the oxygenator, a second detector positioned on the outlet of the oxygenator prior to the arterial filter, and a third positioned distal to the arterial filter in the arterial line. All data is stored electronically.
- INVOS Cerebral Oximeter—cerebral oxygen saturation recorded during CPB, with data stored electronically.
- CDI 500 Blood Gas Monitoring—physiologic parameters monitored and data stored electronically using a CPB data management system.
- A video recording device used intraoperatively.

Data recorded from the initiation of manipulation of the aorta, to decannulation from bypass. Continuous feedback from the monitoring devices to the cardiac surgical team occurs in real-time via auditory stimulus (i.e., device alarm).

2. Analyze
All data recorded using the TCD and EDAC ultrasound devices, INVOS cerebral oximeter, CDI 500 in-line blood gas monitor, and video recordings are evaluated to determine temporal relationship between adverse events (i.e., embolic activity, decrease in cerebral oxygen saturation, or outside of pre-defined range physiologic parameters) or anesthetic, perfusion and surgical events, for example:
- Increased embolic activity
- Decreased cerebral oxygenation $rSO_2 < 40\%$ or $rSO_2 > 20\%$ below baseline
- Retained air in the venous cannula
- Blood sampling or drug administration

3. Improve and Control
Results of analysis and interpretation of “define and measure” are presented and discussed with all members of the surgical team. Based on the analysis of the data, techniques are developed and introduced to decrease adverse events during cardiac surgery. To reduce the production of emboli, techniques are introduced based on published strategies such as:
- De-airing of the venous line by the surgeon to prevent air being retained in the venous cannula
- Site selection by the surgeon for clamp application or proximal graft technique to minimize intervention due to aortic manipulation (such as application and removal of the aortic cross-clamps)
- Avoiding the introduction of air into the CPB circuit during blood sampling or drug administration by the Perfusionist

To maintain cerebral oxygenation, an intervention strategy is introduced (Yao’s) (29,30):
- Increase $FiO_2$ if $< 100\%$
- Increase $CO_2$ if $< 35 \text{ mmHg}$
- Increase blood pressure
- Increase cardiac output
- Decrease cerebral oxygen consumption by deepening anesthesia
- Vasodilate cerebral vessels with a nitroglycerin drip
- Transfuse blood products (if hematocrit $< 20\%$)
The improvement of the intervention strategy for the maintenance of physiologic parameters is based upon current standard perfusion protocols and management. Blood gas level is maintained to avoid falling outside pre-defined parameter ranges, such as pH <7.35 and >7.45, pCO$_2$ <35 and >45, pO$_2$ <100, and HCO$_3$ <20. Subsequent data analysis that demonstrates improvement will allow standardization of practices to maintain process control.

SUMMARY

Evidence for improved clinical outcomes and reduced neurologic injury by reducing adverse events causal in production of microemboli are well documented. Performance of CPB may also be improved by monitoring cerebral oxygenation and physiological parameters, through the reduction in variation of the process of care. Despite the evidence, the introduction of new techniques into clinical practice can be as challenging as the research and development that has gone into developing them. The clinical practice of cardiac surgery involves a large multi-disciplinary team requiring a coordinated approach from the surgical, anesthetic, perfusion, and nursing disciplines. Each team member has a defined role, with the overall process of care being comprised of a large number of individually performed tasks. Although systems have been proposed by groups such as Groom and colleagues (21) to obtain a thorough understanding of the process of care associated with cardiac surgery, no prospective trials have been reported to initiate change in cardiac surgery clinical practice. Barriers to the introduction of changes in clinician practice exist and we propose a method by which change may be introduced more readily. By achieving the outcomes of this strategy we are able to provide a framework for change.

REFERENCES