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Improving Cardiopulmonary Bypass: Does Continuous Blood Gas Monitoring Have a Role to Play?

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Abstract: The CDI™500 (Terumo Cardiovascular Systems, Ann Arbor, MI) is an in-line blood gas monitoring device that has been used in clinical practice for over a decade. Few randomized studies have evaluated the value of this device with respect to improved perfusion management. We routinely use automated continuous quality indicator programs to assess perfusion management. The aim of this study is to investigate in a prospective randomized trial the role of in-line blood gas monitoring in the improvement of blood gas management during cardiopulmonary bypass (CPB) utilizing continuous quality indicators. Patients were randomized into two groups (Control, CDI). Patients in the Control group received our standard CPB blood gas management, with intermittent blood gas results. Continuous blood gas measurements from the CDI™500 were recorded at 20-second intervals, with the perfusionist blinded to these measurements. Patients in the CDI group received standard CPB blood gas management, in addition to continuous blood gas measurements visible on the CDI™500, the alarm system activated, and the data recorded. Perfusion management for all cases was guided by institutional protocols. One hundred patients (50 in each group) were included in the study. No significant difference existed between the groups on demographic, surgical, or clinical outcomes. Blood gas levels of patients in the CDI group were able to be maintained in accordance to protocol a greater percentage of the time, e.g., pCO_2 management was 2% versus 20% (p = .008); this was most notable for differences between the Control and the CDI group for pCO_2 > 45 mmHg (p = .003). Practice variation determined via statistical control charts improved for both pH and pCO_2, represented by a decrease in the variation associated with practice. Continuous blood gas monitoring with the CDI™500 results in significantly improved blood gas management as determined by adherence to institutional protocols. **Keywords:** cardiopulmonary bypass, perfusion, physiology. *JECT. 2010;42:191–198*

The practice of cardiopulmonary bypass (CPB) has changed and evolved over the past 50 years. The continual development of technology of the components of the heart lung machine has endeavored to produce a physiological environment that reduces the impact of CPB on patients. Monitoring of CPB has advanced over the last 20 years, with the successful integration and development of devices measuring both mechanical and physiological parameters. While monitoring introduces a safety aspect to clinical practice with integrated alarms and pump shut downs, more importantly, it can also provide information on the patient's physiological state during CPB enabling patient care to be managed in real-time.

One established example of the integration of real-time monitoring into current clinical practice is the use of "in-line" venous saturation and hematocrit monitors. The increase in use of these devices is documented in numerous monitoring and device surveys published since 2000 (1–4).

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Their successful integration into clinical practice may be due to the relative low cost of the disposable cells, the integration of monitoring ports into oxygenators, and the manufacturer rebates for the use of these products. The real-time information from these devices can reduce the potential for delay in the diagnosis of reduced tissue perfusion and irreversible damage to the patient (4–6). Nevertheless, monitoring controversies still exist within the profession of perfusion, with no clearly defined standards of monitoring mandated. Professional bodies have published recommendations for standards of monitoring (7), but there are no recommendations or guidelines based on peer-reviewed evidence.

At our institutions we have previously demonstrated the advantages of automated electronic data collection (8) and have implemented a Continuous Quality Improvement (CQI) program based upon this. The development of an automated generation and feedback process utilizing QI of CPB allows us to audit intraoperative clinical information and evaluate the adherence to our institutional protocols (9,10). One area that our QI process tracks is blood gas management during CPB, which we have identified as an area for improvement within our group. With the implementation of our CQI program in 2005, we demonstrated significant variation in the management of pCO_2 during CPB within our group practice.

Cardiopulmonary bypass patients are subject to physiological variations in their blood gas levels due to oxygenation, electrolyte changes, and fluid shifts that occur during CPB. Potential adverse patient outcomes due to these variations may include hypoxia and hyperoxia, hypocapnea and hypercapnia, and acid base alterations (11). Currently the accepted blood gas management practice of the American Society of Extracorporeal Technology during CPB involves intermittent sampling of blood, utilizing laboratory blood gas analyzers, usually every 20–30 minutes or whenever deemed appropriate by protocol or clinical practice (12). These devices use electro-chemical technology to analyze both blood gases and electrolytes. The accessibility of these devices may be varied within different institutions, with analyzers situated locally within operating theatres, in intensive care units, or even in a centralized hospital laboratory, potentially resulting in delays in the analysis and reporting of results (2). Alternatively, in-line blood gas monitoring allows for real-time monitoring of the "adequacy of perfusion", and one device currently available for use in CPB is the CDI™500 (Terumo Cardiovascular Systems, Ann Arbor, MI). The CDI™500 provides continuous real time blood gas and electrolyte measurements for pO_2, pCO_2, pH, bicarbonate (HCO_3^-) and potassium (K^+).

The concept and use of continuous in-line blood gas monitoring itself is not without controversy. In the early 1990s numerous articles were published (13–15) questioning this technology as a "standard of care" and the possible legal implications arising from not using such a device (14). The disposables cost and the lack of published clinical evidence are seminal to the debate and extent of the CDI™500's use in clinical practice. Similarly, its level of adoption has been varied. Surveys of adult perfusion practices have shown varying levels of adoption. Stammers et al. (1) reported 37% of U.S. respondents were using continuous in-line blood gas monitoring in 1998; in the Australian and New Zealand survey (3) regular use of only 5.2% was reported in 2003, whilst most recently Charriere et al. (2) reported a usage of 28% in France in 2007. The use of this technology appears more wide spread for pediatric surgery with the 2005 North American Pediatric survey reporting an increased use of arterial in-line gas monitoring (76.9% compared with 66.9% in 1989) (4).

The CDI™500 has been clinically evaluated to provide precise and accurate data when compared to laboratory blood gas analyzers (16,17). A number of publications (18–20) have highlighted the use of continuous in-line blood gas monitoring as a safety device, assuming detection of device failure would occur earlier if this technology were in place. In 2000, Trowbridge et al. (21) demonstrated, in the only published prospective, randomized, albeit underpowered, clinical trial on a small group ($n = 59$) of patients, relating in-line blood gas monitoring to patient outcomes, limited clinical benefit associated with the use of the CDI™500.

We present in this paper the outcome of a prospective, randomized trial that we conducted to investigate the role of continuous in-line blood gas monitoring in the improvement of blood gas management during CPB by determining whether our clinical protocols for blood gas management were better adhered to and the variation in clinical practice reduced.

METHODS

The study was reviewed and approved by the Bellberry Human Research Ethics Committee and was undertaken at Ashford Hospital during the period of February to June 2007. Informed consent was obtained from all patients undergoing cardiac surgery utilizing CPB, except for those patients requiring emergency surgery, off-pump procedures, or those whose first language is not English. Following informed consent, patients were randomly assigned into one of two groups: the Control or the CDI group by a computerized random number generator (Excel, Microsoft®, Redmond, WA) prior to entering the operating theatre. The surgical, intensive care, and postoperative management teams were blinded to the randomization. In the Control

group, blood gas management during CPB was guided using current institutional protocol, which involved intermittent blood gas sampling at the following time points: after cross clamp application and stabilization of bypass, after cross clamp removal, and when clinical practice dictates. The samples were analyzed using the ABL700 blood gas analyzer (Radiometer, Copenhagen, Denmark), which is situated in the intensive care unit, a 5-minute walking distance from the operating theatre. The perfusionist made clinical decisions based on results of the blood gas analysis of the samples. Patients in the Control group were also monitored using the CDI™500 in-line blood gas monitor, although the perfusionist was blinded to the monitor after initial calibration. In the CDI group, blood gas management was guided by the CDI™500, where the perfusionist made clinical decisions based upon the results of the blood gas analysis of the samples and the real-time blood gas results. Alpha-stat pH blood gas management was used for all patients in this study, with target ranges defined as: $pCO_2 > 35$ and < 45 mmHg, $pO_2 > 100$ mmHg, and $pH > 7.35$ and < 7.45.

A CDI™500 sensor cell was placed into the CPB circuit at initial set-up. The cell was calibrated prior to each procedure according to the manufacturer's instructions (CDI™ Blood Parameter Monitoring System 500 Operator's Manual, Terumo Cardiovascular Systems, Ann Arbor, MI). Flushing the circuit with CO_2 prior to priming often results in excess residual CO_2 in the prime. The prime CO_2 concentration was normalized by FiO_2 manipulation to produce a $pH > 7.0$ and pCO_2 within range, as the manufacturer's instructions advise that exposure of the cell to acetate containing prime solutions with a $pH < 7.0$ for longer than a few minutes can cause significant pCO_2 inaccuracy.

Surgical and Perfusion Management

One of three surgeons, one of two perfusionists, and one of three anesthetists performed all procedures. All patients received a standard moderate fentanyl-based anesthetic technique. Cardiopulmonary bypass surgery was performed using an arterial roller pump of an S3 heart lung machine (Stockert, Munich, Germany) and patient temperature was controlled with a Hemotherm heater cooler unit (Cincinnati Sub Zero, Cincinnati, OH). Cardiopulmonary bypass was initiated after cannulation of the aorta with a 22 Fr ascending aortic cannula (DLP, Medtronic, Minneapolis, MN or Argyle, St. Louis, MO), and either a single 36/51 Fr two-staged atrial cannula (Sarns™, Terumo Corporation, Tokyo, Japan), or a 32–36 Fr bicaval cannulation (Sarns™, Terumo Corporation, Tokyo, Japan). The circuit consisted of a hard-shell membrane oxygenator (Capiox® SX25RX, Terumo Corporation, Ann Arbor, MI) and biopassive SMARxT® (Sorin Group, Arvarda, CO) tubing and a 40 μm arterial filter (Dideco D743, Sorin Group, Mirandola, Italy). The circuit was primed with 1610 mL crystalloid prime consisting of 1000 mL Plasmalyte 148, 500 mL Albumin (4%), 50 mL sodium bicarbonate (8.4%), 50 mL Hartmanns solution, and 10,000 IU heparin sodium. Activated clotting time was maintained above 400 seconds and was measured using the Hemochron 801 (International Technidyne Corporation, Edison, NJ).

Cardioplegic arrest was induced with 25–30 mmol/L of blood cardioplegia (32–34°C) at induction and 16–25 mmol/L of intermittent bolus when required. The CPB protocol included arterial flow of 1.8–2.4 L/min/m^2, gravity venous drainage, and tepid systemic temperature management (32–35°C). All routine interventions such as rewarming, transfusion, and administration of pharmacological agents were performed according to standard institutional protocol by the perfusionist conducting the case. Cardiotomy suction was not used in any of the coronary artery revascularization group.

Electronic Data Management

The process used for data management within our institutions has previously been reported (9,10). The Cardiac Surgery Research Database is based in our hospital server, and is accessible using the Microsoft Access (Microsoft Corporation, Redmond, WA) interface. Intra-operative data collected (electronically or manually entered) via the S3 Data Management System (Stockert, Munich, Germany) is processed and integrated into the database. Quality control (QC) reports are generated when values outside of the defined CPB quality indicator (QI) parameter (e.g., pCO_2, pO_2, pH) values have been detected. Electronic data integrated into the Data Management System was collected every 20 seconds from the following peripheral devices: CDI™500 in-line blood gas monitor, AS3 anesthetic machine (Datex–Ohmeda, Helsinki, Finland) and Cobe® SAT/CRIT monitor (Sorin Group, Arvarda, CO).

Statistical Analysis

All data were analyzed using the SPSS® 15.0 (SPSS Inc., Chicago, IL) statistical software package. Comparisons were made between the Control and the CDI group based on patient demographic, outcome, and postoperative parameters. Continuous data were analyzed using *t*-test or Mann-Whitney *U* test, depending on normality. Categorical data were analyzed using χ^2 statistic using continuity correction and Fisher's exact test where appropriate. Statistical process control charts for trend and spread analysis were created using SPCXL software (SigmaZone Software, Winderemere, FL).

RESULTS

There were 146 cardiac surgery patients operated on at Ashford Hospital during the period of February to June 2007. Of these, 110 patients were eligible for recruitment and were recruited for the study. Ten patients were

later excluded, as their surgery was performed off-pump. A total of 100 patients were enrolled into the trial, 50 in the Control group and 50 in the CDI group. Patient demographic and pre-operative clinical data are presented in Table 1. Intra-operative and patient outcomes data are shown in Tables 2 and 3, respectively. There was no significant difference between the Control and CDI group in any of the demographic, pre-operative, or intra-operative parameters. There was also no difference between groups in the incidence of major morbidity or mortality.

The percentage of cases where QC reports have been generated due to the detection of blood gas levels outside of target ranges for the Control and CDI group are shown in Table 4. There was a significant difference ($p = .008$) in the number of QC deviations from practice protocol produced for pCO_2 management (<35 or >45 mmHg), with the 20% deviation in the Control group reduced significantly to only 2% in the CDI group.

The percentage of CPB time where blood gas levels are outside of target ranges based on the values recorded

Table 1. Demographic and pre-operative parameters.

Parameter		Control Group ($n = 50$)	CDI Group ($n = 50$)	p-value
Age (years)		73 (22–85)	72 (43–87)	.735
Sex	Male	74 (37)	66 (33)	.513
	Female	26 (13)	34 (17)	
Weight (kg)		77.5 (47.0–102.0)	80.0 (54.0–124.0)	.299
Body surface area (m^2)		1.9 (1.6–2.2)	1.9 (1.5–2.5)	.359
Smoking history		52 (26)	54 (27)	1.000
Hypertension		70 (35)	58 (29)	.298
Hypercholesterolemia		44 (22)	44 (22)	1.000
Diabetes		25 (12)	20 (10)	.726
Respiratory disease		14.0 (7)	16.0 (8)	1.000
Peripheral vascular disease		10 (5)	4 (2)	.269
Cerebrovascular disease		8 (4)	10 (5)	1.000
Recent myocardial infarct <90 days		10 (5)	14 (6)	.758
Angina Class	I–II	60 (17)	60 (12)	1.000
	III–IV	39 (11)	40 (8)	
Ejection fraction (%)		50 (24–65)	60 (30–65)	.110
Creatinine (μmol/L)		79 (40–190)	89 (40–150)	.191
Hemoglobin (g/dL)		14.2 (10.2–16.3)	13.8 (10.0–16.6)	.340
Euroscore		3.0 (.9–26.9)	3.7 (.9–9.8)	.874
Admission: Urgent		17 (7)	4 (2)	.080

Categorical data presented as percentage (n). Continuous data presented as median (range).

Table 2. Intra-operative parameters.

Parameter		Control Group ($n = 50$)	CDI Group ($n = 50$)	p-value
Procedure type	CABG	70 (35)	48 (24)	.054
	Valve	14 (7)	28 (14)	
	CABG/Valve	8 (4)	20 (10)	
	Others	8 (4)	4 (2)	
Re-operation		10 (5)	8 (4)	1.000
Procedure time (min)		134.5 (73–245)	122.5 (56–241)	.164
CPB time (min)		58.0 (15–140)	55.0 (27–125)	.361
Cross-clamp time (min)		35 (10–109)	35 (15–101)	.718
Pacing		8 (4)	4 (2)	.678
RBC/patient (units)		0 (0–2)	0 (0–2)	.568
FFP/patient (units)		0 (0–2)	0 (0–2)	1.000
Platelets/patient (50 mL/unit)		0 (0–5)	0 (0–8)	.252
Minimum hemoglobin (g/dL)		8.1 (6.5–11.2)	8.3 (6.5–30.0)	.983
Average MAP (mmHg)		56.1 (41.1–68.5)	54.1 (37.3–74.4)	.048
Average flow (L/min/m^2)		3.8 (2.5–4.5)	3.8 (2.8–5.2)	.547
Minimum temperature (°C)		34.5 (26.8–35.4)	34.4 (31.8–36.1)	.684
Maximum temperature (°C)		37.1 (36.3–37.5)	37.1 (35.9–37.5)	.252

Categorical data presented as percentage (n). Continuous data presented as median (range).
CABG, Coronary artery bypass grafting; RBC, Red blood cell; FFP, Fresh frozen plasma; MAP, Mean arterial pressure.

Table 3. Patient outcomes parameters.

Parameter	Control Group (n = 50)	CDI Group (n = 50)	p-value
RBC/patient (units)	1 (0–7)	1 (0–4)	.354
FFP/patient (units)	0 (0–8)	0 (0–2)	.672
Platelets/patient (50 mL/unit)	0 (0–10)	0 (0–10)	.570
Post-operative blood loss 4 hours (mL)	285 (50–2680)	290 (40–1260)	.970
Ventilation time (hrs)	19.0 (6.8–103.6)	17.4 (5.9–77.8)	.357
Maximum post-operative creatinine (mmol/L)	98 (44–261)	87 (39–183)	.872
New renal failure	2 (1)	.0 (0)	.495
Stroke	6 (3)	2 (1)	.356
New coma	2 (1)	2 (1)	1.000
Encephalopathy	0 (0)	2 (1)	1.000
Return to theatre	6 (3)	2 (1)	.617
Length of stay in ICU (min)	27.4 (14.0–1176.0)	24.3 (15.5–122.0)	.649
Length of stay (days)	10 (3–79)	11 (6–34)	.825
Length of post-operative stay (days)	8 (2–77)	8 (5–31)	.994
Mortality	6 (3)	2 (1)	.617

Categorical data presented as percentage (n). Continuous data presented as median (range).
RBC, Red blood cell; FFP, Fresh frozen plasma; New renal failure: Increased creatinine >200 µmol/L and a new requirement for dialysis; Encephalopathy, Incidence of delirium, confusion, coma or seizures; ICU, Intensive Care Unit.

Table 4. Blood gas levels quality control reports.

Blood Gas Parameter	Control Group QC Reports (n = 50)	CDI Group QC Reports (n = 50)	p-value
pCO_2 < 35 or > 45 mmHg	20.0 (10)	2.0 (1)	.008
pO_2 < 100 mmHg	.0 (0)	.0 (0)	–
pH < 7.35 or > 7.45	26.0 (13)	18.0 (9)	.469

Data presented as percentages (n) of cases where QC reports have been generated due to a violation of the pre-defined target blood gas ranges.
QC, Quality control.

Table 5. CDI™500 blood gas levels.

Blood Gas Parameter	Control Group % CPB Time (n = 50)	CDI Group % CPB Time (n = 50)	p-value
pCO_2 < 35 mmHg	.9 (.0–77.6)	1.2 (.0–31.6)	.771
pCO_2 > 45 mmHg	2.5 (.0–79.8)	1.1 (.0–40.0)	.003
pCO_2 < 35 or > 45 mmHg	7.2 (.0–85.0)	3.3 (.0–41.7)	.002
pO_2 < 100 mmHg	.0 (.0–1.1)	.0 (.0–2.9)	.544
pH < 7.35	1.0 (.0–27.4)	.1 (.0–18.0)	.033
pH > 7.45	2.5 (.0–94.2)	3.6 (.0–81.8)	.496
pH < 7.35 or > 7.45	6.1 (.0–94.2)	4.6 (.0–83.3)	.309

Data presented as median (range) for the percentage of CPB time blood gas values are outside the target ranges.

using the CDI™500 in-line monitor values for patients in the Control and the CDI group are presented in Table 5. Although there was no significant difference in the percentage of CPB time that the pCO_2 was <35 mmHg between the Control and the CDI group, a significant difference (p = .003) was observed for pCO_2 > 45 mmHg. The statistical control charts for pCO_2 > 45 mmHg are illustrated in Figure 1. In the Control group (Chart A), the central line of tendency (CEN) for CPB time for pCO_2 > 45 mmHg was

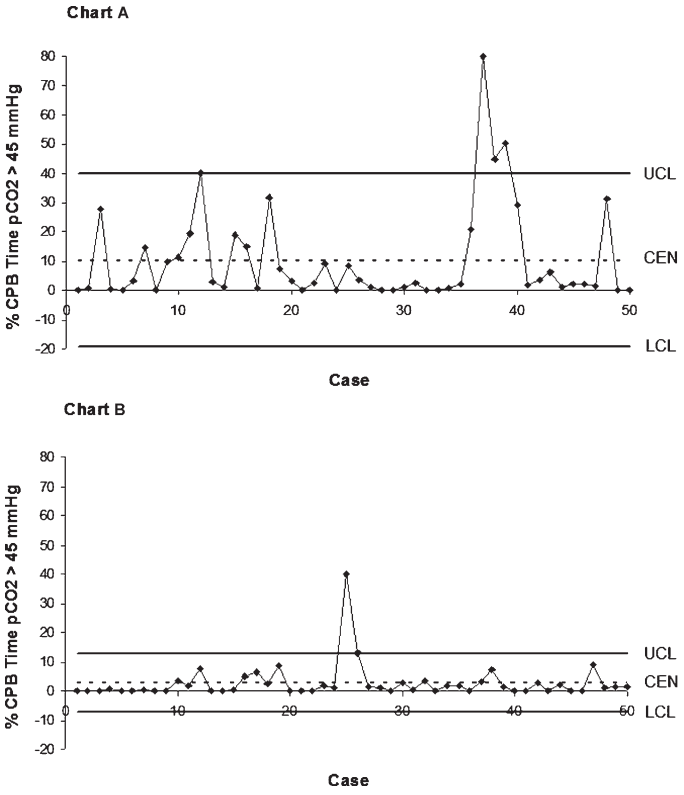

Figure 1. Percentage of CPB time pCO_2 is >45 mmHg for each case in the Control (Chart A; n = 50) and CDI group (Chart B; n = 50). The pCO_2 values were based on the CDI™500 in-line blood gas monitor. The upper (UCL) and the lower (LCL) control limit, and the central line of tendency (CEN) are also shown for each group.

10.4%, with an upper control limit (UCL) of 39.9% and a lower control limit (LCL) of –19.2%. Whilst in the CDI group (Chart B), the CEN was 2.7% (UCL = 12.8%, LCL = –7.3%). In comparison to the Control group, a considerable

decrease in variation in the management of pCO_2 is evident in the CDI group with the use of the CDI™500 in-line blood gas monitor. This can also be observed in the management of pH between the Control and the CDI group; in particular in the percentage of CPB time that pH was <7.35, as presented in the statistical control charts in Figure 2. There was also a decrease in variation in the management of pH in the CDI group (Chart B) where the CEN was 1.0% (UCL = 5.3%, LCL = –3.2%). This is in comparison to the Control group (Chart A), where the CEN was 2.9% (UCL = 14.5%, LCL = –8.6).

In addition, there were a number of cases in the Control group where the management of pCO_2 was >45 mmHg out-of-range for over 40% of CPB time. An example of one of these cases is shown in Figure 3. The first intermittent sampling analysis showed the pCO_2 level to be 46 mmHg and the second intermittent sampling, which was taken after the cross clamp was removed during re-warming, showed the pCO_2 level to be 44 mmHg. However, over 80% of pCO_2 levels were outside the target range (>45 mmHg).

Variation between the practices of individual perfusionists was evident in the control group, where the median percentage of time where the pCO_2 was out of range varied significantly between perfusionists (10.2% CPB time (0–85) compared with 3.1% (0–30.2), p = .033). Such variation was not evident in the CDI group (3.8% CPB time (0–41.7) compared with 2.3% (0–14.3), p = .08). No effect over time (learning curve) was evident in the incidence of practice variation over the study period.

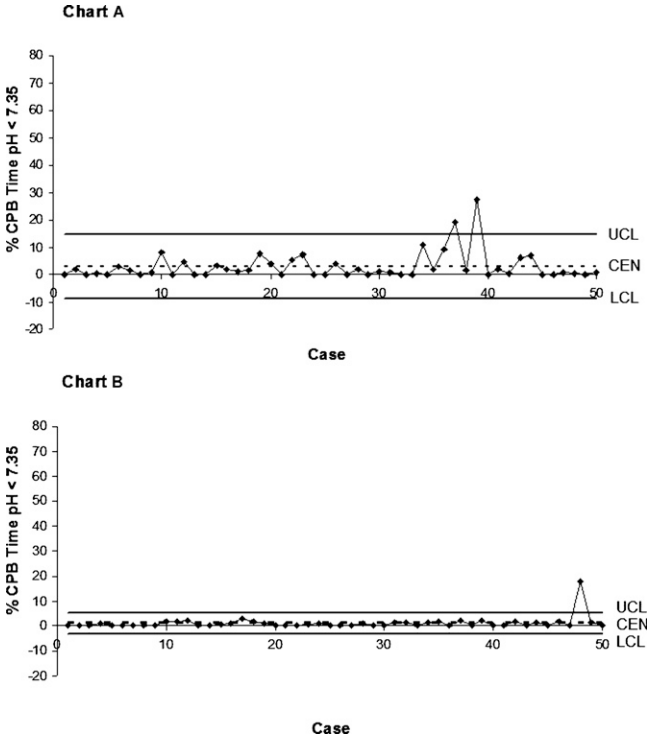

Figure 2. Percentage of CPB time pH is <7.35 for each case in the Control (Chart A; n = 50) and CDI group (Chart B; n = 50). The pH values were based on the CDI™500 in-line blood gas monitor. The upper (UCL) and the lower (LCL) control limit, and the central line of tendency (CEN) are also shown for each group.

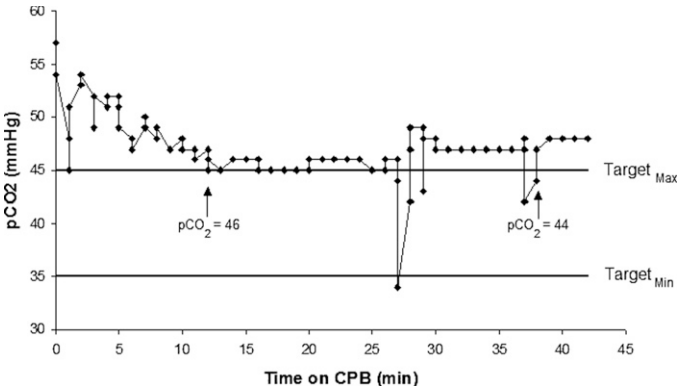

Figure 3. Management of pCO_2 during cardiopulmonary bypass for a single case in the Control group. The percentage of CPB time $pCO_2 > 45$ mmHg is about 80%. The target range for blood gas management of pCO_2 is between 35 mmHg ($Target_{Min}$) and 45 mmHg ($Target_{Max}$). The time the two intermittent blood gas samples were taken are shown as black arrows, with the corresponding pCO_2 results.

DISCUSSION

Continuous blood gas monitoring with the CDI™500 reduced the variation in practice seen in blood gas management in our practice. This was most evident in the pCO_2 management where $pCO_2 > 45$ mmHg was reduced from occurring in 20% of cases to 2%. Monitoring of patients' physiological state is an integral component of CPB and the accuracy of information used for blood gas management is pertinent to improving patients' clinical outcomes. Whilst institutional protocols provide us with guidelines in which to direct our clinical practice, auditing clinical performance is imperative to evaluate adherence to and the adequacy of protocols. Through the CQI program implemented at our hospital, which included regular auditing and feedback of data collected during procedures, we highlighted blood gas management, a component of CPB where we were unable to achieve our desired performance targets (i.e., practice within protocol range). This had been identified, even after team meetings were conducted to try to improve blood gas management performance with increased diligence within our perfusion group. Blood gas management, in particular pCO_2 control, as an indicator for perfusion performance in our practice, is based on pCO_2 being required for maintenance of acid-base balance and autoregulation of the vascular beds of the brain, heart, and lungs. It is also dependent on the patient's metabolic rate and substrate utilization, which can be influenced by the perfusionist during CPB.

The use of the CDI™500 allowed us to improve our blood gas management, minimizing the variation seen with

intermittent sampling, and producing a "tighter control" within the parameters of pCO_2, pO_2, and pH. With intermittent sampling, perfusionists do not have access to real-time information and may be unaware of periods where blood gas levels are outside the appropriate ranges and changes made to gas management may not correct the situation. In this study, we have improved pCO_2 management in our practice in the CDI™500 group as evidenced firstly by the reduction in bypass time in which the blood gases were outside of protocol range; secondly the absolute number of deviations from our ideal practice; thirdly the reduction in practice variation as demonstrated by the process control charts; and finally by the reduction in variation of practice between perfusionists. The availability of real-time blood gas results will vary between institutions, and may be dependent on the use of central laboratories or local automated blood gas analyzers. In our institution, the location of the blood gas analyzer, situated in the intensive care unit some distance from the operating theatre, is a major factor causing a delay of at least 5 minutes in the analysis and reporting of samples. Additionally there is a cost component associated with the use of theatre (perfusion) staff involved in handling and measuring these samples. Therefore, due to this time delay with intermittent sampling, the results do not reflect the current metabolic state of the patient at the time the results are available and able to be interpreted by the perfusionist. The "real-time" information provided by CDI™500 allows clinical decisions to be made and implemented immediately.

In the study reported by Trowbridge et al. (17), a learning curve associated with the use of the CDI™500 in-line blood gas monitor and a variation in the ability of individual perfusionists to manage blood gases using this technology, which improved over the trial period, was reported. Similarly, we found a variability between perfusionists in the Control group ($p = .033$), however this was reduced in the CDI group reflecting an improvement in management ($p = .080$). Unlike Trowbridge, no effect over time (learning curve) was demonstrated; this observation may have been due to the training in use of the device prior to the commencement of the trial.

Three previously published monitoring surveys (1–3) highlighted the low incidence of in-line blood gas monitors used in clinical practice, ranging from less than 20% in Australia and New Zealand to 30% in the United States, with intermittent sampling still the most common form of procedure used to manage blood gas levels during CPB. Why this technology of in-line blood gas monitoring has not been embraced in perfusion practice may have a multifactorial answer? The major barriers to the widespread adoption of this technology appear to be cost and lack of clinical outcomes evidence. The disposable optical cells, calibration gases, and monitors add considerable expense to each procedure. The cost benefit for utilizing this technology, in savings due to "reduced blood gas analysis expenditure" depends upon not only a reduction in performance of laboratory based tests but also upon the reimbursement schedules for such tests. Additionally, use of the CDI™500 requires in vivo calibration for the potassium sensor, and does not report factors of interest to the perfusionist such as glucose and lactate levels, thus it does not eliminate the requirement for intermittent sampling during bypass using a laboratory blood gas analyzer.

The clinical outcomes demonstrated by Trowbridge et al. (21) are not demonstrated in this report; however this study was not designed to provide adequate statistical power to demonstrate an improvement in patient clinical outcomes. This study included a small cohort of 100 patients, of which, the routine predicted mortality was 2–3%. Demonstration of beneficial patient outcome data utilizing the CDI™500 may be possible in the future, with the development of perfusion based data registries such as International Consortium Evidenced Based Practice registry (22) and the Perfusion Downunder Collaboration database (23). Large prospective randomized trials are ultimately required to produce meaningful outcomes data; however appropriate metrics of success will need to be determined. An additional limitation was the lack of evaluation of hyperoxia, this resulted from our lack of inclusion of a hyperoxic level in our institutional quality indicators.

CONCLUSION

Our aim was to investigate whether the use of the CDI™500 resulted in an improvement in perfusion performance as determined by our blood gas management. We have clearly demonstrated that continuous blood gas monitoring results in significantly improved blood gas management as determined by adherence to institutional protocols. It is therefore difficult to build an argument for not using such technology in the routine management of the patients to whom we are charged with their care.

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