Improved Quality Control Utilizing Continuous Blood Gas Monitoring and Computerized Perfusion Systems

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ABSTRACT

The effect continuous blood gas monitors and computerized perfusion documentation systems have on the performance and reproduction of clinical events during cardiopulmonary bypass was studied. Patients undergoing elective coronary artery bypass procedures were randomly placed into three classifications. Group one received no continuous monitors and manual documentation. Group two had continuous monitoring and manual documentation. Group three has continuous monitoring and computerized case documentation. The implementation of computerized monitoring and documentation systems reduces the number of events outside of desired physiological limits and improves the ability to re-create clinical events.

INTRODUCTION

Standards of care were introduced to the medical community in 1917 with the adoption of surgical standards by the American College of Surgeons[1] establishing minimum standards for medical records and a process of internal review. In 1953, the formation of the Joint Commission on Accreditation of Hospitals (JCAH) was formed through the cooperative efforts of the American College of Surgeons, American College of Physicians, American Hospital Association, American Medical Association and the Canadian Medical Association. The goal of the commission was to seek voluntary compliance with established minimum standards. The implementation of the Medicare and Medicaid system in the 1960's promoted the development of random review of medical records to determine the necessity of hospital admissions and treatment. This form of Utilization Review (UR) was the major method of quality assurance in most hospitals until the 1980's. In an effort to eliminate the subjectivity associated with the UR method, the JCAH established in 1984 standards of medical care review which deviated from the normal numerical standards to those of qualitative comprehensive review processes. The guidelines of the JCAH were designed to monitor the quality and appropriateness of care by each clinician, as well as ongoing clinical education for each department in the hospital.

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Standards for perfusion care, until recently, have been carried under the auspices of cardiac surgeons who supervise cardiopulmonary bypass procedures. Although the quality of perfusion care is vital to the outcome of cardiac surgical patients, a time has come to establish a separate standard and quality measure for perfusion departments to follow. In 1987, the American Academy of Cardiovascular Perfusion published minimum standards for perfusion practice.[2] Establishing minimum considerations for the perfusionist in the areas of record management and documentation, equipment selection, personnel requirements, and management of perfusion.

The increasing use of Continuous In-Line Monitors (CILM) has been dramatic since their introduction. The accuracy, efficacy, and cost effectiveness in perfusion management has been reported.[3,4] Many general statements have been made with regards to suspected patient benefits from the use of CILM's, but little qualitative documentation on their alteration of perfusion management techniques is available.[5] One study reports an increased compliance to pre-defined physiological parameters and concludes that the use of CILM increases the safety margins during cardiopulmonary bypass. [6]

The introduction of micro-computer technology to the operating room has found a natural home in the perfusion market. The large amount of data lends naturally to the use of computerized perfusion management. Early programs were developed to organize manual data entries by the perfusionist into a data base. From this point multiple statistical analysis and graphic presentations can be ordered. Most of these early systems were customized data base managers which require constant input from the user. Computerized record management has several advantages for the perfusion manager and quality assurance officer. Computerized perfusion records allow consistent data acquisition and recording techniques when dealing with a variety of perfusion staff, creating uniform perfusion records and data bases for each CPB patient. In addition, it allows rapid graphic presentation of physiological trends and procedure summaries.

The development of a clinical quality assurance program will fulfill four primary purposes.[1,7] First, quality assurance review will allow a continual assessment of appropriateness of clinical procedures and patient management. Second, data obtained from clinical assessment can form a basis

for continuing education and department risk management priorities.[1,8] Third, a sufficient data base established may serve as a basis for credentials and staff privileges. Last, hospital quality assurance and risk management programs are deemed valuable assets in mitigating liability against the institution and practitioners.[1,9]

The purpose of this clinical investigation is to evaluate the effects of the introduction of CILM and computerized records on the management of cardiopulmonary bypass in our institution. This retrospective analysis was accomplished by thorough establishment of clinical standards and markers of perfusion care, and then comparing the effect of CILM and computerized perfusion records on these indicators. The CILM used in this evaluation was the CDI 300[a] along with the Shiley Computer Aided Perfusion System (CAPS).[b]

The Shiley CAPS system is a computerized data management system capable of interfacing multiple perfusion monitoring devices and formatting a computer generated perfusion record. The heart of the CAPS system is a heart lung machine (HLM) interface which gathers signals from the heart lung machines integral safety and perfusion monitoring devices as well as up to 14 outside analog signal inputs. The HLM interface then transmits these signals via a standard RS232 series data transmission line to a stand alone MSDOS[c] compatible computer. The CAPS program interprets the data signals from the HLM interface and creates a patient specific database. Information from the database is used to construct a real time display of equipment function and perfusion parameters. All items interfacing with the HLM interface board may be displayed in the computer generated window. Unlike other systems reported to date, CAPS automatically writes all data from the HLM interface into the database every minute. In addition, the perfusionist may enter events and comments from a customized menu selection. At the end of the procedure, an institutionally formatted perfusion record can be generated.

MATERIALS AND METHODS

To determine the effect of introducing CILM and computerized perfusion record management systems on the performance of cardiopulmonary bypass, a retrospective analysis of adult patients undergoing elective CABGX3 was done. All patients received the same perfusion management scheme and extracorporeal circuit (ECC) equipment. The ECC consisted of a hollow fiber membrane oxygenator (HFMO),[d] roller pump,[e] PVC tubing,[f] and 25 micron arterial line filter. The ECC was primed with 2200ml of a balanced electrolyte solution, 12.5g of 25% human albumin, 25g Mannitol, and 5,000 units of beef lung heparin. The patients were anticoagulated with 300u/kg of beef lung heparin. After assurance of adequate anticoagulation, CPB was initiated to a cardiac index of 2.4 L/min/M^2.

The patient was cooled to a bladder temperature of 30 - 32°C. Alpha Stat ventilation management techniques were employed to maintain pH and blood gas parameter within the desired limits listed in Table 1. Base deficits were corrected with sodium bicarbonate only after rewarming to normothermia to maintain a base excess within normal limits. Volume requirements were treated with a balanced electrolyte solution and no patients required the administration of blood components during CPB. No changes in perfusion personnel or surgical and perfusion techniques occurred during this period.

Group 1 (n=50) received no CILM or computerized perfusion record. All perfusion documentation was manually completed by a perfusion assistant or secondary perfusionist using the hospital perfusion record. Each record was reviewed for conformity to the desired limits of charting and laboratory analysis frequency. Laboratory results were screened for variances outside of the pre-defined desired limits for ECC as outlined in **Table 1**. Results of the record review were entered into a databases for analysis. Data placed in the database included total CPB time, aortic cross clamp time, total number of perfusion record entries made during the CPB run, total number of entries made during the cross clamp only, the mean time between laboratory analysis, and the total number of labs drawn during the procedure. Mean data entry intervals for the total CPB run and during the cross clamp period were calculated by dividing the respective time period by the number entries specific for that time period. Each physiological variance was listed as being either above or below the defined range and the number of variances in each category was listed in the database. Significance between each category was calculated using the student's paired t-test.

Group 2 (n=50) received the same ECC as described for Group 1 with the addition of the CDI 300 sensor placed distal to the HFMO and proximal to the arterial line filter. Calibration of the CDI sensor and monitor was done per manufacturer's instructions. The CDI 300 sensor was not introduced into the CDI cell until recirculation of the ECC priming solution was done for five minutes with a gas to blood flow ratio of 1:1 at an FiO_2 setting of 21%. This technique is employed to displace any existing dissolved CO_2 in the priming solution. CPB was initiated and maintained in the fashion described. Each record was reviewed for mean entry and sample times as outlined for Group 1 along with variances in the desired physiological values.

Group 3 (n=20) was a continuation of Group 2 patients and incorporated a computerized perfusion record generated by the CAPS system. The effect on consistency of the data entry interval was evaluated. Statistical analysis was done utilizing the student's paired t-test.

RESULTS

Figure 1 lists the desired ranges for the physiological parameters monitored in the record analysis as well as the documentation standards. Table 1 lists the cumulative data collection from Group 1 and 2. Mean CPB and XC times are listed as well as mean sample times and total number of

a. Cardiovascular Devices, Inc., Irvine, CA
b. Shiley Inc., Irvine, CA
c. Microsoft Corporation, Redmond, WA
d. Medtronic Blood Systems, Inc., Minneapolis, MN
e. Shiley Inc., Irvine, CA
f. Baxter/Bentley Laboratories, Inc., Irvine, CA
g. Lotus Development Corp., Cambridge, MA

laboratory samples drawn in each phase. Statistical significance is identified for each comparative group showing significance at the 99.9% confidence limit.

Figure 2 graphically illustrates the effect of introducing the CILM to the ECC on the number of variances for each physiological variable with the exception of pHa High which was statistically unchanged by the addition of a CILM device to the ECC.

Figure 3 depicts the relationship of documentation characteristics between the total CPB and XC phase of CPB. No statistically significant changes were noted between the CPB and XC periods for each group, however, significant increases in data entry intervals occurred between Group 1 and Group 2 when the CILM was introduced. Significant changes in data entry interval occurred again with the introduction of the CAPS system when compared to Group 1 and Group 2 ($p<0.001$).

DISCUSSION

Statistical analysis of mean CPB and XC times in **Table 1** shows no statistically significant differences in CPB time nor XC time despite the varying combinations of surgical/perfusion teams. It may be assumed that both groups are statistically well matched. Evaluation of data entry interval during the entire CPB run and during application of aortic cross clamp in Group 1 revealed that no significant data entry time variances occurred. The actual data entry time interval was consistent throughout the entire cardiopulmonary bypass procedure.

The introduction of the CILM into the arterial line caused a significant increase in time between data entry intervals during CPB. This is the result of a decrease in the number of laboratory samples drawn and the resulting increase in mean time between each laboratory analysis. Group 1 patients received an average of 3.98 laboratory analysis during CPB. After the introduction of the CILM in Group 2, the average sample rate decreased to 2.86 per CPB procedure. This represents a 29% reduction in the number of laboratory determinations. Laboratory analysis determinations decreased as the perfusion manager's confidence in the predictability of CILM information increased. One possible clinical consequence in this decrease in laboratory samples may be longer time periods between ACT determinations while on CPB. This may have a significant effect on the heparin management and anticoagulation control, particularly during the rewarm cycle.

Figure 1 illustrates the effects of introducing the CILM on the pre-defined physiological quality assurance markers. In group 1, we see significant variances in the pHa High, $PaCO_2$ Low, and PaO_2 High categories. This can be explained by hyperventilation of the HFMO by the perfusionist to maintain a respiratory alkalotic state desired for alpha stat perfusion management. Since continuous pH and blood gas data were not available in group 1 patients, the perfusionist selected high gas to blood flow ratios and Fraction of Inspired Oxygen (FiO_2) in fear of not meeting the oxygen consumption and carbon dioxide production needs of the patient. Incorporation of the CILM into Group 2 reduces the over compensation of the perfusionist when continuous arterial pH and blood gas data is available to aid in setting HFMO ventilation settings.

Incorporation of CILM devices to the ECC also fulfills the function of a safety.[5] Continuous data allows the perfusionist to operate in a more narrow physiological window, reducing the number of potentially pathological situations for the patient. Group 1 patients elicited a 10% variance in the low pO_2 indicators. Ten percent of the patients where CILM was not available elicited a pO_2 less than 150mm Hg. This situation could have occurred for 21 minutes plus the time for analysis (approximately 10 minutes) before the perfusionist was alerted to the situation. The converse situation of undesirable high PaO_2's occurred in 37% of the arterial blood gas determinations in Group 1. This subjects the patient to potentially higher incidences of microembolism and myocardial reperfusion oxygen injury as a result of free radicals with little benefit in increased oxygen delivery to the systemic tissue.[10,11]

Documentation standards for perfusion record entries was set at five minute increments. At this level of data recording, a large enough patient specific database can be established to accurately recreate events during CPB. Retrospective analysis of data entry times during manual perfusion documentation in Group 1 and 2 patients shows a significant variance between actual data (Group 1=8.5 min., Group 2=9.95 min.) and the quality assurance standard (five minutes). An insignificant increase in data entry times occurred when the CILM was introduced. This directly correlates to the increase in the mean sample times and the resulting decrease in documentation of fewer laboratory samples. Introduction of the CAPS system promptly returns the data entry interval to the quality assurance standard. The user may select how often data is displayed on the final hard copy, thus matching the perfusion record to the institution's documentation standard. The ability of the CAPS system to automatically sample equipment and patient information from the HLM interface without a manual user prompt allows continuous building of the database even during critical and intensive points in the CPB procedure such as initiation, termination, and aortic cross clamping. This assures a predictable patient database for every personnel combination, eliminating individual operator induced variances to the perfusion record. All desired information is complete and recorded on a pre-defined time table.

The incorporation of CILM and computerized record management system will have a direct and indirect effect on the quality assurance program management for the perfusion department. An immediate and direct effect of introducing CILM to the ECC can be seen in the reduction of CPB pH and blood gas values outside pre-defined limits. Narrowing of physiological parameter windows ensures more consistency in perfusion management from case to case and staff to staff. The use of computerized record generation that interfaces with the variety of equipment used during CPB will allow a more consistent database to be created for each CPB procedure.[12] Recreation of events will be more accurate and eliminate much of the work in determining what happened between perfusion record entries. Computerized record management also allows the perfusionist to dedicate more time to the monitoring of the ECC by the perfusionist, eliminating the distractions of manual charting. Indirect quality assurance effects of CILM and a computerized

record management systems includes the creation of a standardized database for each procedure and each staff member. This can be an valuable tool in designing continuing education tools for the staff perfusionist. The incorporation of CILM devices and computerized record system will make the perfusion manager more efficient at applying CPB therapies and present a new margin in patient safety.

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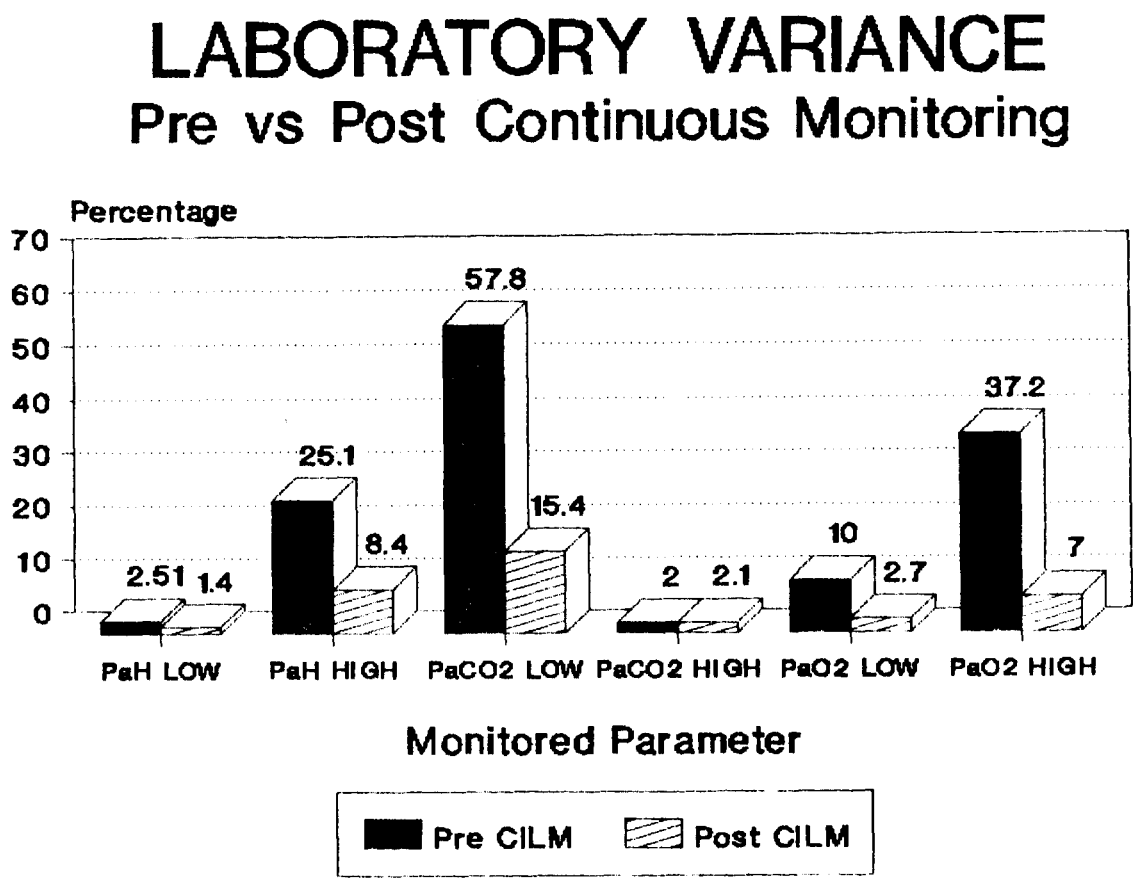
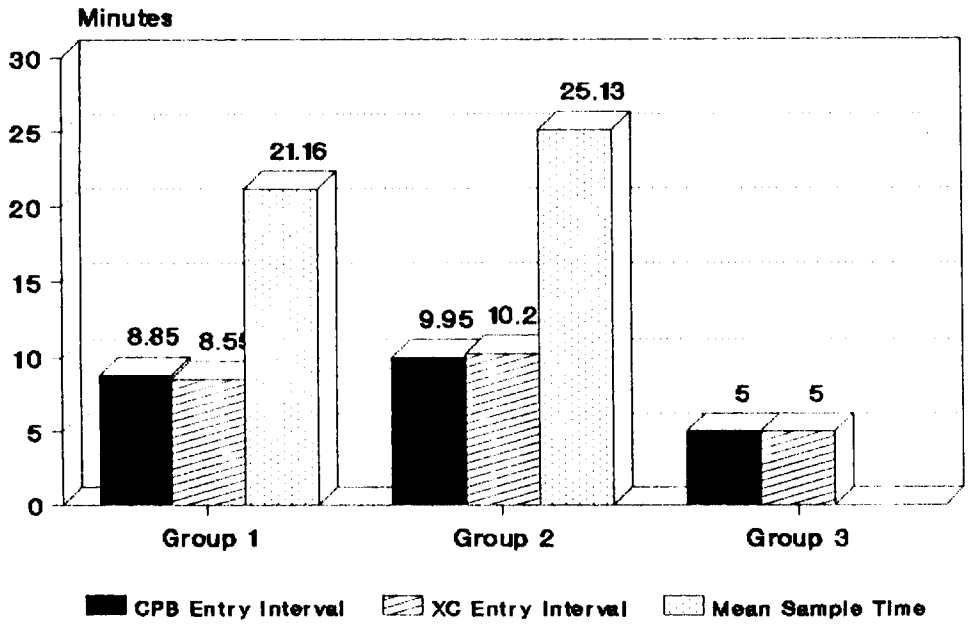
LEGENDS

Figure One: Figure one lists the physiological parameters evaluated during cardiopulmonary bypass record evaluation.
Figure Two: Figure two grafts the variance in physiological parameters from before and after CILM introduction.
Figure Three: Figure three illustrates the variance perfusion data entry intervals with each phase of computerized record management interval.



Perfusion Record Data Entry Intervals



Desired Entry Interval q5min.

Physiological Parameter Limits

PARAMETER	VALUE
PaH LOW	>7.35
PaH HIGH	<7.45
PaCO2 LOW	>35 mmHg
PaCO2 HIGH	<42 mmHg
PaO2 LOW	>150 mmHg
PaO2 HIGH	<250 mmHg

Desired operating range for CPB