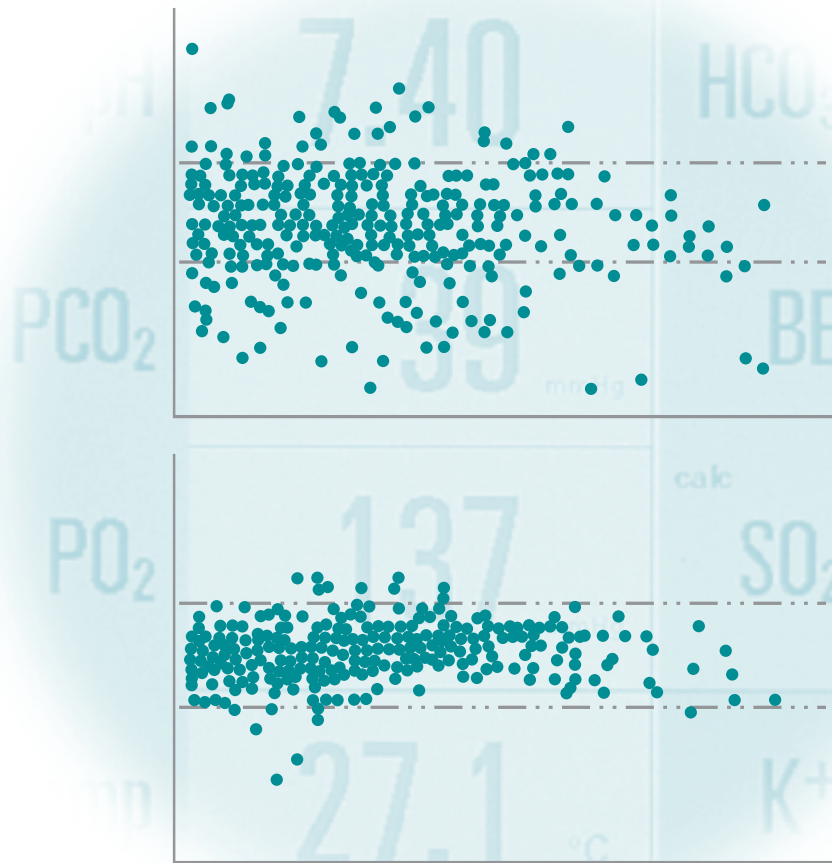



*STUDY SYNOPSIS*

*The Effects of Continuous Blood Gas Monitoring During Cardiopulmonary Bypass:*

*A Prospective, Randomized Study, Parts I & II*



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### Target, Methods and Investigation

This two-part prospective, randomized clinical study investigated:

- The benefit of continuous in-line blood gas monitoring and its effect on the quality of patient care
- The accuracy of the CDI™ 500 Blood Parameter Monitoring System compared to laboratory analyzers

59 patients undergoing cardiopulmonary bypass during cardiac surgery were randomized into two groups:

- Control group – blood gas monitoring managed with intermittent blood sampling, every 20-30 minutes
- Treatment group – blood gas monitoring managed with continuous in-line monitoring, using data from CDI 500 System

The CDI 500 System was used to record continuous blood gas parameters in all cases. However, for patients in the Control group, the system's display was not available to the perfusionist during the case.

Surgical protocol for patients in both groups included:

- Coronary artery bypass grafting (CABG), valvular surgery, or both
- Identical anesthetic and postoperative care
- Standardized flow rates 2.0 – 2.4 l/min/m<sup>2</sup>
- Mild hypothermia (32° C)
- Alpha-stat management

### Demographic Parameters

Compared to the control group, the treatment group contained significantly more diabetic, renal failure, and chronic obstructive pulmonary disease patients. No other differences existed in demographic, pharmacological, surgical, or anesthetic parameters. (Table 1)

Parameter	Treatment Group	Control Group	P Value
Number	30	29	NS
Age (years)	64.6 ± 12.2	61.1 ± 12.2	NS
Gender (male/female)	22/7	20/10	NS
Weight (kg)	88.1 ± 23.0	85.7 ± 19.6	NS
Height (cm)	169.3 ± 16.5	173.6 ± 11.0	NS
BSA (m <sup>2</sup> )	2.01 ± 0.30	2.01 ± 0.25	NS
Re-operation (%)	13%	17%	NS
Diabetic (%)	47%	7%	0.0001
Hypertension (5)	60%	48%	NS
Renal failure (%)	13%	3%	0.01
COPD (%)	20%	7%	0.01
MI (%)	27%	17%	NS
CHF (%)	13%	14%	NS
Preop ejection fraction (%)	53.2 ± 9.2	48.2 ± 14.3	NS
LM (%)	13%	7%	NS

TABLE 1

### Data Comparison

All patients were classified according to risk:

- High-risk (Cleveland Clinic Clinical Severity Score > 3)
- Low-risk (Cleveland Clinic Clinical Severity Score 0 - 3)

Blood gas events were recorded in all patients, based on measurements obtained from the CDI 500 System every 7.5 minutes.

- The number of events that fell outside the following acceptable ranges were calculated as a percent of the total events per patient.

pH	7.35 – 7.45
pCO <sub>2</sub>	35 – 45 mmHg
pO <sub>2</sub>	150 – 250 mmHg

After risk stratification, the patients were classified according to the quality of blood gas management.

- Classification accomplished by calculating the number of blood gas values which fell outside of normal range as a percent of total events.
- The mean and standard deviation for all patients was calculated.
- Five groups were established based on ascending levels of deviation.

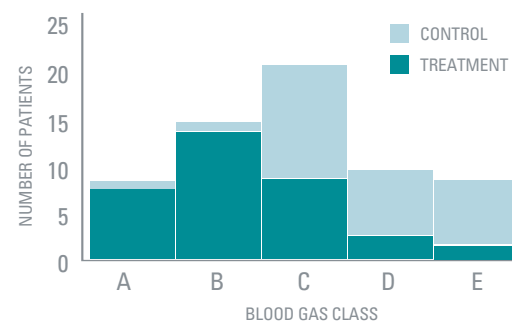


FIGURE 1

- Group A: best blood gas management – least number of events outside of acceptable range
- Group E: worst blood gas management – most number of events outside of acceptable range

Not surprisingly, the higher quality blood gas management groups A and B were dominated by patients in the Treatment group, and the lower quality groups D and E were dominated by patients in the Control group. (Figure 1)

### Accuracy and Precision of the CDI 500 System

The measurements of the CDI 500 System were compared with those of a laboratory analyzer:

- Accuracy of the CDI 500 System was defined as the bias or mean difference between the two sets of measurements.
- Precision of the CDI 500 System was defined as within  $\pm 2$  SD of the difference between the two sets of measurements.

Sample one was taken before an *in vivo* calibration was performed on the CDI 500 System, and samples two and three were subsequent to the *in vivo* calibration. (Table 2)

	pH (units)	pCO <sub>2</sub> (mmHg)	pO <sub>2</sub> (mmHg)	K <sup>+</sup> (mEq/mL)	n
Sample 1	0.01 ± 0.06	0.9 ± 7.0	-3.3 ± 14.9	N/A	62
Sample 2	0.00 ± 0.04	-1.6 ± 5.9	3.6 ± 26.0	-0.3 ± 0.8	61
Sample 3	0.00 ± 0.06	-3.3 ± 7.0	2.5 ± 28.2	0.2 ± 0.5	37
CLIA '88 Target	± 0.04	± 5.0	± 3 SD	± 0.5	N/A

TABLE 2

### Outcomes by Blood Gas Management Quality

The Control group consisted of 12 high-risk and 17 low-risk patients. The Treatment group consisted of 12 high-risk and 19 low-risk patients. The total patients' blood gas parameters fell outside of range  $10.8 \pm 8.7\%$  of the time.

Patients in the A and B categories – those with fewer events out of acceptable range, or tighter blood gas control – spent significantly less time on mechanical ventilation, in the ICU and in the hospital. (Figures 2-6)

Complications included:

- Cardioversion
- Pacing
- Pharmacological support
- Documented arrhythmias
- Inotropic support
- Mechanical assistance
- Morbidities



FIGURE 2



FIGURE 3

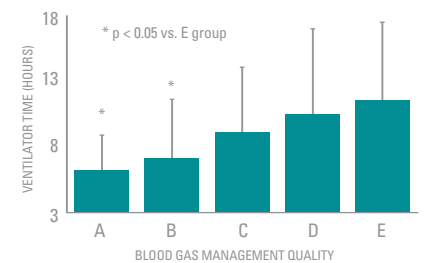


FIGURE 4

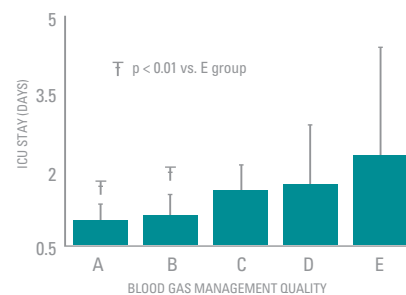


FIGURE 5

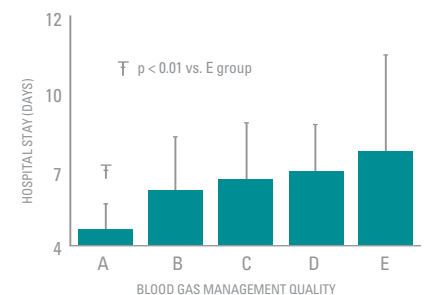


FIGURE 6

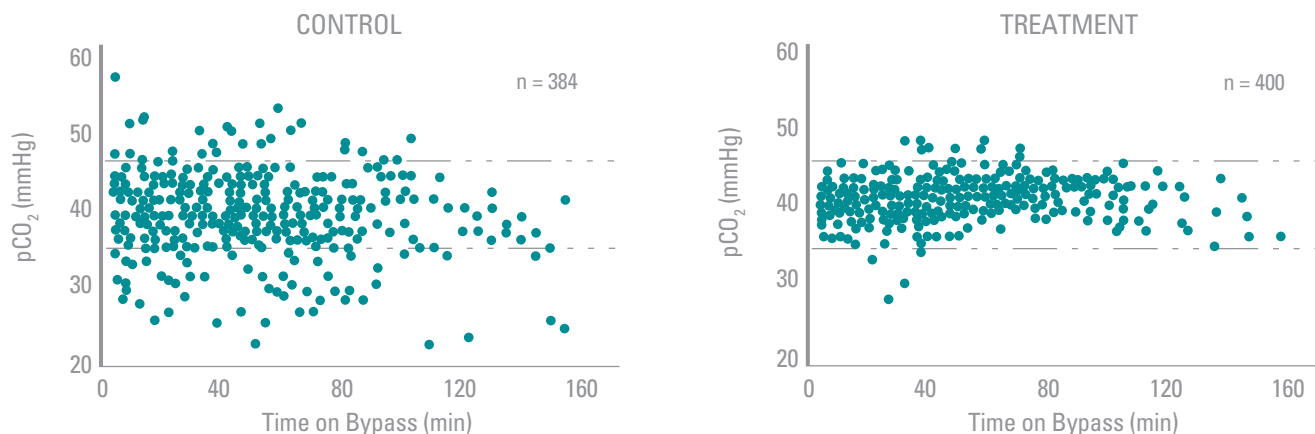
### Selected Outcome Parameters and Pharmacological Support

A number of outcome parameters were compared between the Control and Treatment groups. (Table 3)

Agent/Parameter	Treatment Group	Control Group	P Value
Operative inotropes	10%	17%	NS
Intraoperative complication: cardioversion	3%	14%	NS
Intraoperative complication: pacing	10%	17%	NS
Operative antiarrhythmic support	0%	10%	0.05
Postoperative antiarrhythmics	10%	18%	NS
Postoperative cardiac glycoside	0%	11%	0.05
Hospital stay (days)	5.8 ± 1.9	6.5 ± 2.6	NS
ICU stay (days)	1.3 ± 0.5	1.8 ± 1.4	NS
Ventilator time (hours)	8.6 ± 4.8	9.8 ± 5.8	NS
Pulmonary morbidity	0%	3%	NS
Renal morbidity	0%	3%	NS

TABLE 3

## Examples of Utility of Continuous In-line Monitoring



### *pCO<sub>2</sub> Management*

- The Control group fell outside of range more than 5 times as often as the Treatment group.
- The greatest difference in blood gas control between experimental groups occurred with pCO<sub>2</sub>.

### *pCO<sub>2</sub> – Clinical Implications*

- pCO<sub>2</sub> management is important for auto regulation of vascular beds in the brain, heart and lungs.
- Changes in the cerebral blood flow during cardiopulmonary bypass is intimately related to pCO<sub>2</sub> maintained during hypothermia.

### *pO<sub>2</sub> – Clinical Implications*

- Significant metabolic disruption is associated with pO<sub>2</sub> values lower than 30 mmHg and death typically results from tension lower than 20 mmHg.
- Hyperoxemic conditions are associated with significant physiological impairment (maldistributed capillary flow and decreased oxygenation), increased damage to red cell rheology, and decreased postoperative organ performance.

### *pH – Clinical Implications*

- The effects of acidemia upon the cardiovascular system are particularly pernicious and can include decreased cardiac output, decreased arterial blood pressure, decreased hepatic and renal blood flow, and centralization of blood volume.
- Alkalemia can compromise cerebral and myocardial perfusion by causing arteriolar constriction. Neurological abnormalities may ensue, including headache, tetany, seizures, lethargy, delirium, and stupor.

### *Conclusions*

- In-line monitoring with the CDI 500 System provides a level of accuracy comparable to laboratory analysis such that clinical decisions can be based on its output.
- The use of in-line monitoring results in improved blood gas management.
- Improved blood gas management results in improved patient outcomes.

For a reprint of the complete study, please go to:  
[www.terumo-cvs.com/trowbridge](http://www.terumo-cvs.com/trowbridge)



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