Original Article

Point of Care Testing after Congenital Heart Surgery

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Key words:
lactate, congenital heart

Objective: Goal directed therapy (GDT) has been proven to reduce morbidity and mortality in critical illness. Point of care testing (POCT) allows rapid turn around time (TAT) of critical data, yet data suggesting improved outcomes is very limited.
Design: Beginning July 2001, POCT in the form of the i-STAT handheld analyzer was integrated in the management of patients after congenital heart surgery at Miami Children's Hospital. Blood lactate measurements were performed serially for 24 hours after surgery. Based on a lactate value, medical therapy was escalated, diminished or left unchanged after surgery. Outcome data was collected prospectively for later review. Mortality at 30 days after surgery was compared for patients undergoing a GDT protocol to a group of historical cohorts. The operative risk for all operations was determined using the Risk Adjustment for Congenital Heart Surgery-1 (RACHS) scoring system.
Setting: A 16 bed cardiac intensive care unit located in a 268 bed free standing pediatric hospital.
Patients: Outcomes of all patients undergoing congenital heart surgery from July 2001 through September 2008 (Group B) were compared to historical controls in our institution from June 1995 through June 2001 (Group A). There were 1,656 patients in Group A and 1,919 patients in Group B. Patients in Group B were smaller and younger than those in Group A (median weight 6.2 vs. 8 kg., $p<0.001$; median age 161 vs. 327 days, $p<0.001$).
Measurements and results: The 30 day mortality was lower for Group B as compared to Group A (2.2 % vs. 6.2%, $p<0.001$). Significant reduction in mortality between Group B and Group A was noted in neonates (4.3% vs. 12%, $p=0.001$) and infants (1.3% vs. 2.6%, $p=0.01$). Patients undergoing the highest risk operations (RACHS-1 groups 5+6) had a 70% reduction in mortality when comparing Group B to Group A, (9% vs. 30%, $p=0.001$), with a smaller but statistically significant difference in mortality for those patients undergoing lower risk operations (RACHS-1 groups 1 and 2, Group B 0.5% vs. Group A 1.5%, $p<0.01$).
Conclusions: The combination of GDT and POCT significantly reduced mortality in patients undergoing congenital heart surgery. This improvement is greatest in the youngest patients and those undergoing higher risk surgeries.

Introduction

Point of care testing (POCT) refers to any laboratory test performed outside the central laboratory by non-laboratory personnel.[1] Traditionally, POCT is performed at the bedside or in close proximity to the patient. Obvious differences exist in the care delivered to a patient in a general ward or out patient setting as opposed to a critical care unit.[2] Decision making for patients in a hospital ward or outpatient setting is usually non-urgent in nature. Treatments can be delayed for hours or even days without untoward effects from the delay in management. In the critical care unit, life-threatening processes often require decision making in minutes, not hours. The critical care unit provides a unique environment that should take full advantage of the potential of POCT, yet despite the availability of numerous POCT devices, little data supports the almost intuitive perception that POCT would improve outcomes in the critically ill.

Received August 3, 2009
Accepted September 28, 2009

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The development of critical care areas in hospitals began in the 1950's. The term intensive care unit was coined by Peter Safar at Baltimore City Hospital in 1958.[3] From 1960 onward, the number of critical care units internationally exploded. Critically ill patients were noted to have unique demands, and as the understanding of critical care physiology grew, so did the demand on traditional laboratory services. Unique to the critically ill patient is a pathophysiological state that is rapidly changing or evolving. Also, medical management of these patients may have rapid untoward consequences if inappropriately administered or monitored. Clinicians must therefore respond to these changes quickly and appropriately.[4]

To meet the demands imposed by newly developed critical care units, hospital laboratories developed batched tests that could be performed in central laboratories with a more rapid turn around time (TAT) than traditional laboratory tests. These so call "STAT" tests became invaluable to clinicians. As the need to perform these tests continued to increase, STAT laboratories were developed. These STAT labs offered a limited number of tests and were usually closely located to high demand areas such as critical care units, operating rooms or emergency departments.

Advances in microprocessor technology have allowed small devices (even handheld) to perform many of the critical laboratory tests performed in STAT labs. Arterial blood gas analysis, electrolytes, glucose and a myriad of other tests can be performed at the patient's bedside with a TAT that could not be matched even by STAT laboratories.

In July 2001, we decided to incorporate one such device into our clinical practice in a pediatric cardiac intensive care unit (CICU). The device, the i-STAT™ blood gas analyzer, was chosen for a number of reasons. First, it was extremely portable and could easily be transferred from room to room in the CICU. Second, it was the only point-of-care device offering whole blood lactate measurements in the United States at that time. We believed the combination of a rapid TAT and serial blood lactate measurements would allow us to devise a clinical strategy for managing children after heart surgery that would result in improved outcomes.

Patients and Methods

1. Patients

Patients included all patients undergoing congenital heart surgery in a 268 bed free standing children's hospital from June 1995 through September 2008. Patients were recovered in a 16 bed CICU. Care was rendered by a multidisciplinary cardiovascular team consisting of attending board certified pediatric cardiologists, pediatric intensivists, neonatologists, physician assistants and nurses.

2. Study Design

Near patient testing in the form of a POCT device, the i-STAT™ analyzer (Abbott™) was introduced to the CICU in July of 2001. The i-STAT™ analyzer is a handheld device which uses different cartridges to perform various lab tests. Each cartridge can run a number of tests and takes 120 seconds to report the results. The lactate cartridge (CG4) also measures pO_2, pCO_2 and pH. The patients ID and the nurse's ID are directly scanned (using an integrated bar code scanner) into the i-STAT™ analyzer, 0.2 cc's of blood are instilled into the cartridge and then the cartridge is inserted into the analyzer. After the result is displayed on the analyzer's screen, printed out, and reviewed by the CICU team members. The analyzer is then placed in a docking station where the results are transferred by wireless infra-red communication to the hospital laboratory's information system. The data is then made available, world-wide and in real-time via the internet on the programs electronic critical care health record (-Rounds, Teges™). The POCT laboratory data can be reviewed on any computer with internet access, or even with a smart phone.

The i-STAT™ analyzer self calibrates every eight hours. In addition, the device is calibrated with the insertion of each individual cartridge. The accuracy of the i-STAT™ lactate analysis was determined at the onset of the study with the simultaneous measurement of lactate via the POCT device and the central laboratory's lactate analyzer (Beckman LX 20, Diamond Diagnostics, Holliston, MA, USA) for 40 consecutive samples.

From July 2001 through September 2008, serial arterial blood lactate levels were measured in all postoperative patients. Blood lactate levels were routinely checked more frequently in neonates during the early postoperative period because of the known increased risk for mortality for this group of patients. An algorithm was developed to direct physician response to changing lactate levels (Fig. 1). Medical management of patients was escalated if the arterial blood lactate was rising or was failing to decrease at a rate of 0.5 mmole/l per hour. Arterial blood lactate was measured serially during the acute post operative period in all patients. Routine measurement of blood lactate was discon-

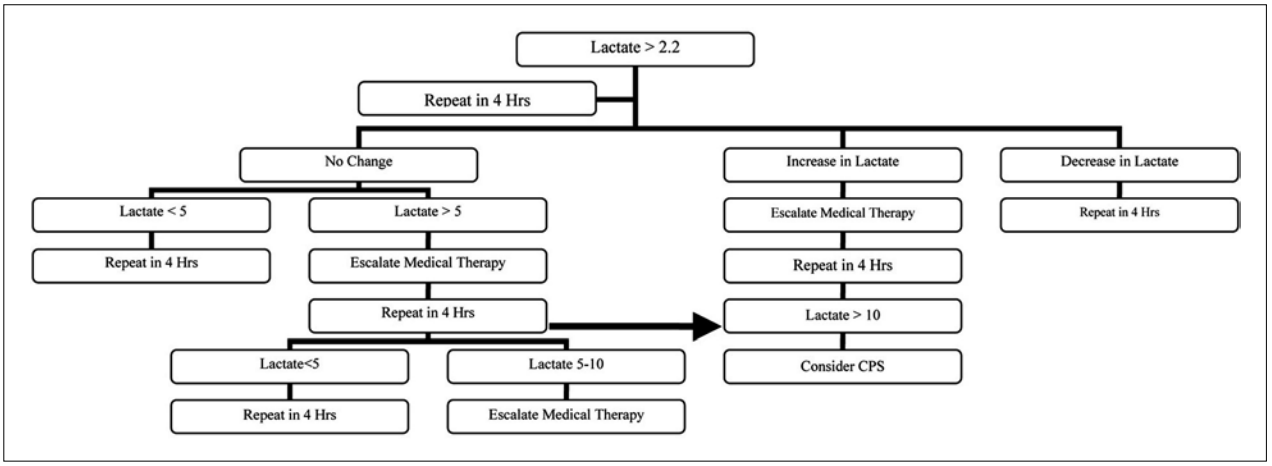


Fig. 1 Clinical algorithm for postoperative management of patients based on serial lactate determinations.

tinued when the blood lactate level was in the normal range. In neonates (patients less than one month of age at the time of surgery), blood lactate was measured hourly for the first 4 to 6 hours after admission to the CICU. For all other patients, lactate was measured serially every 4–6 hours. If the lactate level was less than 5 mmole/l or if the lactate trend was acceptable (decrease of more than 0.5 mmole/l per hour), lactate was then measured every 4 to 6 hours until normal (<2.2 mmole/l for the purpose of our study). The reference value for arterial blood lactate is 0.36–1.25 mmol/l for the i-STAT™ analyzer. The frequency of serial lactate monitoring could be increased at the physician discretion if they believed the clinical situation warranted it.

Outcome data for patients included in this study was collected prospectively for later review. Outcome data was collected and stored utilizing the CardioAccess™ database (CardioAccess Fort Lauderdale, FL, USA).

The study patients were divided into two groups: those patients who had undergone congenital heart surgery from June 1995 to June 2001, before the implementation of the GDT protocol utilizing lactate, were included in Group A (pre i-STAT™), while Group B, the GDT group, was comprised of infants and neonates undergoing cardiac surgery from July 2001 to September 2008 (post i-STAT™).

The operative risk for all patients undergoing heart surgery was determined according to the Risk Adjustment for Congenital Heart Surgery-1 (RACHS) scoring system.[5] RACHS-1 scoring was devised to categorize the risk for death associated with various congenital heart operations. RACHS-1 divides the surgeries into 6 categories, with category 1 being the simplest surgeries with the lowest mortality and category 6 being the surgeries with the highest mortality.

A nursing survey relating to the use of the i-STAT™ blood gas analyzer in the Miami Children's Hospital CICU was performed over a one week period in October 2007. The respondents were blinded to the reviewers. The results of this survey are included.

Statistical analysis was performed using Sigma Stat for Windows Version 2.03, SPSS Inc (Chicago, IL, USA). Chi square analysis was used to detected differences in mortality between groups. Mann Whitney rank sum analysis was used to determine differences in demographic data between groups.

Results

1. Clinical Outcomes

There were a total of 1,656 patients in Group A (June 1995 – June 2001) and 1,919 in Group B (July 2001 – September 2008). Patient demographics are demonstrated in Table 1. Patients in Group B were significantly younger and smaller. RACHS-1 scores were similar between groups. Patients in Group B had significantly longer cardiopulmonary bypass times and aortic cross clamp times (Fig. 2).

Fig. 3 demonstrates mortality for patients undergoing surgery in Groups A and B and also in the 24 month period immediately preceding the introduction of the i-STAT™ technology. Mortality for all patients in Group B was lower than that for patients in Group A (2.2 vs. 6.2%, $p<0.001$). Infant mortality was reduced by 2/3. Neonatal mortality was significantly decreased for patients in Group B (4.3 vs. 12%, $p=0.001$). When comparing mortality of Group B patients

Table 1

	Group A	Group B	p value
Total number of patients	1,656	1,919	
Neonates	321 (19%)	503 (26%)	
Infants	533 (32%)	700 (36%)	
Median age in days (range)	327 (0–14,854)	161 (0–19,746)	p<0.001
Median weight in kg (range)	8 (1–103)	6.2 (1–114)	p<0.001
RACHS score (mean)	2.3	2.2	NS
Mean cardiopulmonary bypass time (mins)	118 (+/–3.5)	147 (+/–1.7)	p<0.001
Mean aortic cross clamp time (mins)	57 (+/–2.2)	83 (+/–4.6)	p<0.001

mins: minutes, NS: no significance

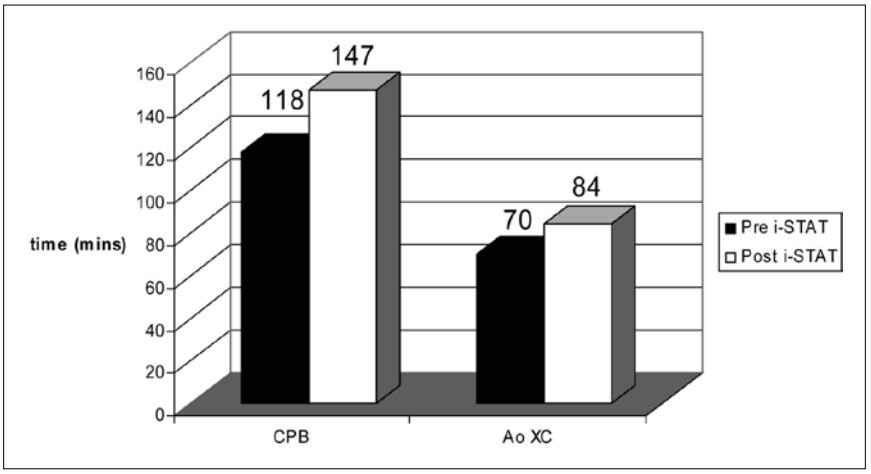


Fig. 2 Bar graph representing differences in CPB (cardiopulmonary bypass) times and Ao XC (aortic cross clamp) times between Group A (Pre i-STAT) and Group B (Post i-STAT).

with patients operated on in the 24 months preceding i-STAT™, significant reductions in mortality were noted for infants and for neonates (p<0.01 for both).

The patients were also grouped according to the complexity of the surgery performed (RACHS-1 scores). This is demonstrated in (Fig. 4). Since the number of patients is small, for statistical analysis, the patients in RACHS-1 categories 1 & 2, 3 & 4, and 5 & 6 were grouped together. For patients in the lower risk RACHS-1 groups 1 & 2, there is no difference in mortality between Groups A and B. However, in RACHS-1 groups 3 & 4 and in groups 5 & 6, Group B has significantly lower mortality than Group A (p=0.01 for RACHS 3 & 4, p<0.001 for RACHS 5 & 6).

2. Nursing Survey

There were 23 nurses and 2 physician assistants who responded to our survey, 5 nurses had advanced degrees. The respondents had an average of over 11 years of post graduate experience. All of the respondents believed that POCT improved outcomes. The majority thought that POCT created a safer environment and reduced medical errors without increasing the work of the bedside nurse. None of the respondents would go back to a traditional laboratory model for "STAT" lab tests and the i-STAT™ device was graded 9.8/10 points by the group.

DISCUSSION

In July of 2001, the i-STAT™ blood gas analyzer was introduced to the CICU at Miami Children's Hospital. The i-STAT™ was intended to replace most of the functions provided by our "STAT lab", and allow us to rapidly measure blood lactate levels. The decision to incorporate the

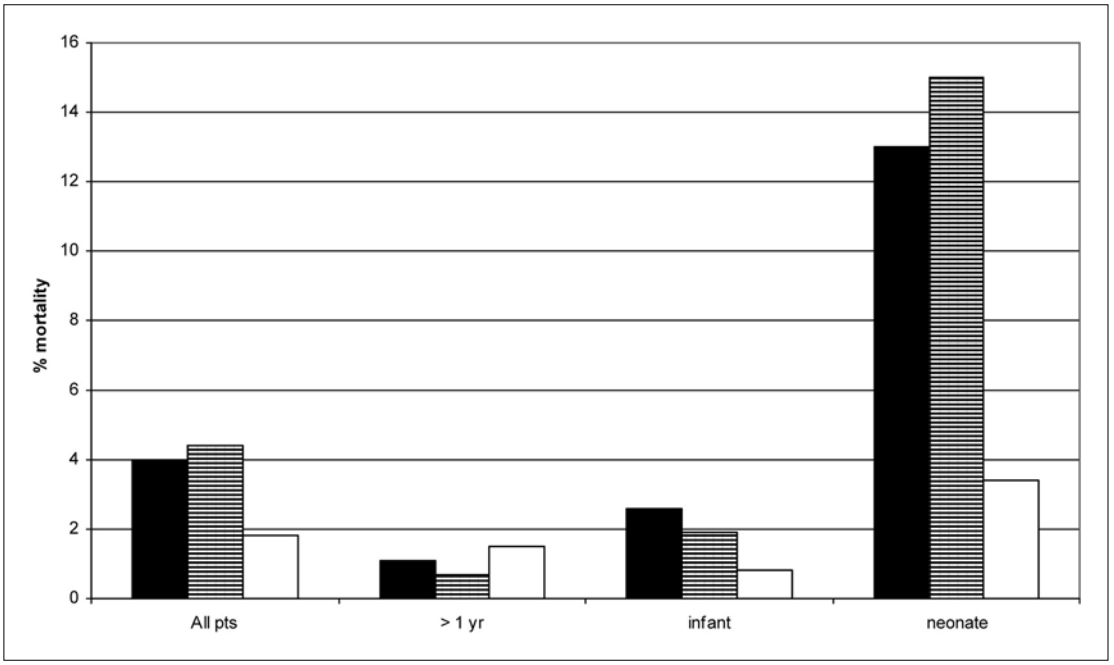


Fig. 3 Mortality as related to age at surgery. Pre-GDT era (Group A) is shown in solid black bars, era in the 24 months preceding GDT is shown with stripped bars, GDT era (Group B) is denoted in white bars.

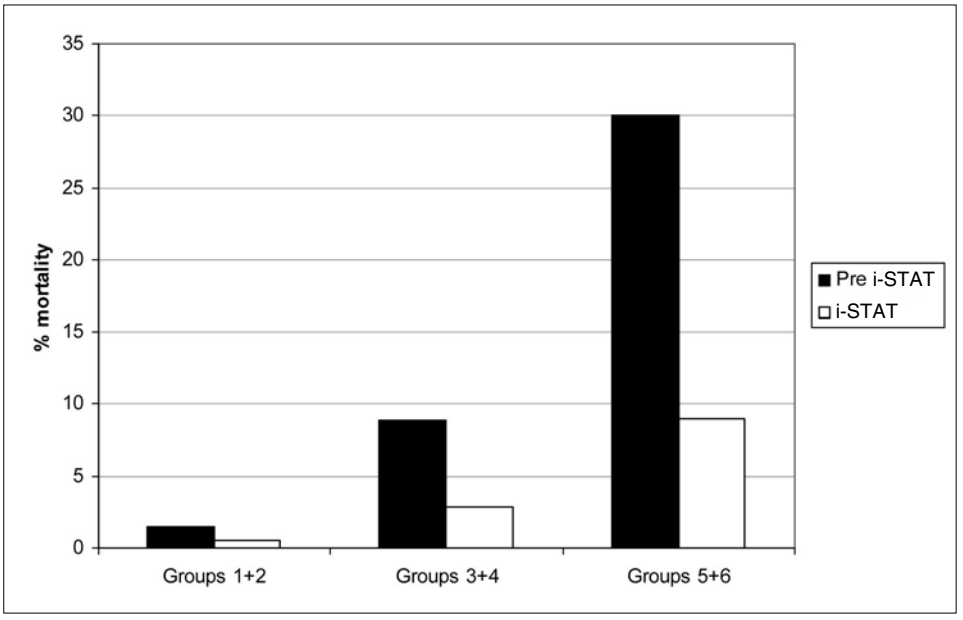
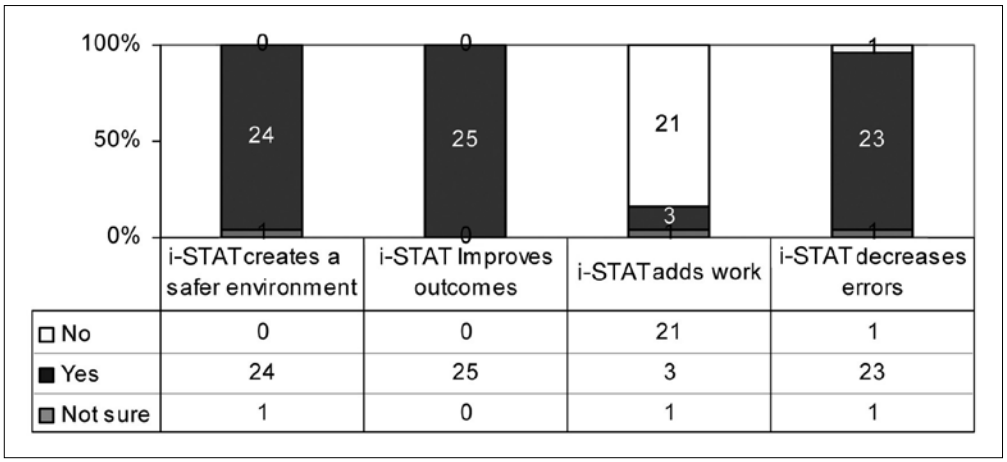


Fig. 4 Graph depicting difference in mortality between Group A (black bars) and Group B (white bars) for patients classified by their respective RACHS categories.



	i-STAT creates a safer environment	i-STAT Improves outcomes	i-STAT adds work	i-STAT decreases errors
No	0	0	21	1
Yes	24	25	3	23
Not sure	1	0	1	1

Fig. 5 Results of nursing survey.

i-STAT™ into our routine practice was based on the following premise. We wanted to establish a practice that incorporated near patient testing associated with the shortest possible TAT of essential laboratory data for managing patients after heart surgery. Our belief was that this would allow the clinician to react quickly to changing physiologic conditions. We also elected to establish lactate as an end point for a GDT paradigm. We then sought to establish clinical guidelines directed at normalizing blood lactate levels, thereby minimizing oxygen debt. We believed that utilizing this combination in clinical practice would improve survival for patients undergoing congenital heart surgery.

Prior to the availability of POCT testing, it would not have been possible to implement a GDT module at our institution, since the TAT for lactate laboratory results was prohibitively long at times (ranging 15 minutes to 2 hours), and would have made it impractical to base minute-to-minute decisions on changes in blood lactate levels.

Some obstacles needed to be overcome to bring POCT to our CICU program. Laboratory control issues and quality control needed to be addressed. We developed a solution that allowed our hospital laboratory to maintain complete responsibility for management and quality control of our POCT program. Nursing concerns needed to be addressed. There was a general feeling that incorporating a POCT device to the practice of bedside nursing would add work and take nurses away from other tasks, most importantly critical care nursing practice. In fact, once our POCT program became established, it was rapidly embraced by the nursing staff, who were no longer asked to draw blood samples, package them, fill out excessive paperwork and leave the bedside to deliver the blood work to the appropriate unit secretary. The i-STAT™ device had an unexpected positive impact on patient care. The rapid turn around time of laboratory tests resulted in clinicians being much more likely to stay at the bedside to await the results. This led to impromptu discussions relating to patient care while awaiting the results. Team communication was greatly enhanced as was team esprit de corps.

POCT has expanded rapidly in the last few years, much faster than the growth of the central laboratory.[6] As technology improved, smaller portable instruments have been developed to perform multiple tests accurately and in a short amount of time, while requiring minimal or no calibration.[7–9] While POCT has shown to indirectly affect outcome in disease states such as diabetes,[8] improvement in outcomes has not been shown in critical care areas. This despite the intuitive notion that rapid TATs associated with near patient testing devices, such as the i-STAT™ analyzer, should allow clinicians to make critical decisions in patients with rapidly developing clinical problems more promptly.

This use of lactate as an end point of resuscitation in this study is not novel.[9] With the availability of POCT in July of 2001, we decided lactate might be the ideal treatment end point of resuscitation in our patient population. Lactate has repeatedly shown to predict morbidity and mortality in critical illness, including patients undergoing congenital heart surgery.[10–16]

Moderate to severe elevation in lactate in patients following congenital heart surgery is most likely related to inade-

quate tissue oxygen delivery, complicated by liver and renal dysfunction (the organs primarily responsible for the metabolism of lactate). Improving tissue oxygen delivery in this population may therefore diminish the production of lactate and increase the metabolism of lactate (by improving both renal and hepatic function). Patients recovering from congenital heart surgery are noted to have evidence of inadequate oxygen delivery that usually resolves within 24 hours of surgery in survivors.[16–19] Estimating the adequacy of oxygen delivery in this patient population remains difficult. Blood lactate sampling is an excellent, noninvasive indicator of adequate tissue oxygen delivery.

The efficacy of GDT has been the subject of numerous clinical and experimental studies along with meta-analysis.[20–24] In 1988, Shoemaker showed that therapy aimed at increasing indices of oxygen delivery in high risk surgical patients to values noted in survivors could result in reduced morbidity and mortality.[20] Later, in a study of adult patients recovering from heart surgery, a protocol aimed at maintaining a mixed venous oxygen saturation of 70 and a lactate level of 2 mmole/l or less resulted in shorter hospital stays and fewer postoperative complications.[21]

The introduction of the i-STAT™ blood gas analyzer along with the clinical algorithm for GDT to normalize blood lactate resulted in a marked reduction in mortality for patients undergoing heart surgery in our institution. This reduction was also apparent when comparing the patients in Group B to those patients operated on in the 24 months prior to the beginning of the POCT program. This suggests that the decrease in mortality seen after starting POCT was not part of some overall trend that began earlier. There was a 2/3 reduction in mortality after surgery for all patients under one year of age and 70% for those less than one month. The reduction in mortality is even more impressive when one considers that patients undergoing congenital heart surgery utilizing the GDT approach were at much higher risk of dying than patients in the previous era, as indicated by their smaller size, younger age, and longer cardiopulmonary bypass and aortic cross-clamp times. It was clear that the greatest reductions in mortality had occurred in the youngest and highest risk patients undergoing surgery (those with RACHS-1 scores greater than 3).

At our institution, a patient management algorithm based on serial lactate measurements was only made possible with the introduction of the i-STAT™ blood gas analyzer. Prior to this, TAT for testing blood lactate was considered prolonged (often greater than one hour). Since blood lactate can change rapidly (within minutes) under adverse conditions or period of recovery,[25] a TAT of longer than a few minutes for the evaluation of blood lactate in the critically ill is less than optimal.

The results of our nursing survey were most interesting. As a group, the nursing staff was perhaps the strongest objectors to the institution of a POCT program. POCT was believed to increase the workload of the bedside nurse, perhaps interfering with her ability to focus on direct patient care. Based on the results of our survey, just the opposite has occurred. As a whole POCT has not apparently increased the nursing workload, was embraced by all and felt to increase efficiency and outcomes.

Conclusions

The introduction of a POCT device, which provides rapid TAT of blood lactate, into a pediatric CICU coupled with the development of a management protocol based on serial analysis of arterial blood lactate resulted in a marked improvement in outcomes for infant and neonates undergoing heart surgery. The remarkable reduction in mortality noted here suggests this treatment strategy warrants further study in this population and other populations of critically ill patients. Also, a POCT program was introduced into our CICU and was rapidly embraced by the nursing staff, who believe POCT reduced medical errors and improved outcomes.

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