The Academy NEWSLETTER

THE AMERICAN ACADEMY
OF
CARDIOVASCULAR PERFUSION
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SPRING 2009

30th Annual Seminar of The American Academy of Cardiovascular Perfusion

The Adolphus Hotel
Dallas, Texas
February 5-8, 2009

Inside This Issue

This year's *Annual Seminar* was a hugh success. The meeting started off on Thursday afternoon with the always popular *Fireside Chats*. There were a total of 19 sessions conducted throughout the meeting, a new record.

Thursday night's *Sponsors' Hands-On Workshop and Reception* allowed all attendees to meet and greet with old friends and acquaintances while examining our Sponsoring Partners' newest products.

The General Sessions started on Friday morning with scientific paper presentations. There were a total of 23 papers and three posters presented at the meeting which covered all aspects of perfusion.

Two panels were held at this year's conference. Friday's panel was a dynamic session that covered the importance of teamwork within cardiac surgery. Members of the panel were Ross Ungerleider, MD, MBA, Jamie Dickey, PhD, Thoralf Sundt, III, MD and moderator Daniel FitzGerald, CCP, LP. Saturday's panel gave the attendees a thorough update on mechanical circulatory support. The panel consisted of Emma Birks, MD, Mark Slaughter, MD, Kathleen Princer, BSBME, MBA, Karen Jones, MSHA, CCP and moderator Michael Sobieski II, RN, CCP.

The Memorial Session was filled with three very special presentations. Invited speaker, Tim Willcox, Dip. Perf. CCP (Aust) delivered the Charles C. Reed Memorial Lecture. Tim addressed the audience on 50 years of perfusion in New Zealand. President Thomas Frazier, CCP presented the Thomas G. Wharton Memorial Lecture. The title of Tom's talk was "Vision for Opportunity." Another special presentation entitled, "30 Years of Perfusion Education, Excellence and One Gold Medal" gave us a snapshot of the first thirty years of The Academy. The presentation was delivered by Charter Member Bill Keen, CCP.

This year's meeting was filled with excellent educational presentations, group discussions and social events all within a great venue.

The Student Section

Renal Dysfunction in Cardiac Surgery

Jennifer Barnum, BS and **Joseph Sistino**, MS, MPA, CCP

Medical University of South Carolina

Charleston, South Carolina

Introduction

Multiple studies have identified the potential risk factors for renal failure during cardiac surgery. These risk factors include: increased age, increased preoperative serum creatinine, low bypass hematocrit, blood product administration, and type of antifibrinolytic agent. Recently some antifibrinolytics have come under fire. Aprotinin has been associated with increased renal failure and mortality when used in cardiac surgery. Aprotinin is a non specific serine protease inhibitor. In addition to its antifibrinolytic activity, aprotinin blocks kallikrein production and reduces platelet activation.

An observational study by Mangano of 4374 patients found an increased risk of renal failure and death associated with aprotinin(1). The perioperative risk factors were evaluated for association with the outcomes and then entered into multivariable logistic models for all three antifibrinolytic agents. Renal failure was defined as requiring dialysis or in-hospital death with evidence at autopsy of acute renal failure. The Blood Conservation Using Antifibrinolytics in a Randomized Trial (BART) was terminated early because of the higher death rate in patients receiving aprotinin(2). The 30 day mortality rate in the aprotinin group was 6%, which was significantly higher than the other antifibrinloytics. The purpose of our retrospective study was to compare the incidence of renal failure and mortality in our patient population to the published rates accounting for risk factors associated with renal failure.

Methods

After IRB approval; using the STS Database and cardiopulmonary bypass pump records, a total of 2292 cardiac patients were identified from January 2004 through June 2008. Forty nine patients were excluded because they were on renal dialysis preoperatively. There were 1226 coronary artery bypass patients. Patients were separated into groups according to which antifibrinolytic agent was used. This study included a total of 716 CABG patients who were given aprotinin (N=436), tranexamic acid (N= 61), or no antifibrinolytic (N=219) was used as the control group (OPCAB). Epsilon aminocaproic acid (AMICAR) was given by anesthesia to the majority of the remaining 510 patients and was not recorded on the bypass record. Therefore, patients given AMICAR were not included in this study. Outcomes included renal dialysis after surgery and mortality. Risk factors were identified and compared to patients in a study published in the *New England Journal of Medicine*.

Results

The results of our study showed Aprotinin vs. control group had no significant difference in risk factors for diabetes mellitus, hypertension, creatinine level above 1.3 mg/dl, or low ejection fraction. The percentage of patients requiring renal dialysis and mortality was less in MUSC patients than the other published study. (See Figure 1) Overall the patients in the MUSC study had greater risk factors for renal failure except for a lower percentage of patients with preoperative creatinine of >1.3 mg/dl (8.3 vs. 15.1%). This study does not show the same risk for renal failure associated with aprotinin that has been published elsewhere. (See Figure 2)

Why bother?

Since aprotinin is no longer available for clinical use it would seem like an academic exercise to review the outcomes. After having used aprotinin for more than 10 years, and the large expense involved with this drug, we were curious to see if our outcomes had been negatively impacted. As far as we can evaluate, based on the outcomes that we looked at, there

was no increase in renal failure or mortality related to aprotinin in our clinical experience.

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Pre-operative Risk Factors	Aprotinin		Tranexamic Acid		OPCAB/ Control	
	MUSC	Mangano	MUSC	Mangano	MUSC	Mangano
Diabetes Mellitus	42.20%	27.30%	52.46%	26.80%	38.26%	28.00%
Hypertension	84.17%	70.0%	77.05%	64.80%	79.00%	60.50%
Creatinine >1.3mg/dl	8.03%	15.10%	6.56%	14.8%	5.48%	13.8%
Ejection Fraction <44%	20.18%	15.40%	21.31%	17.00%	18.26%	18.00%

Figure 1. Comparison preoperative risk factors between Mangano and MUSC study groups.

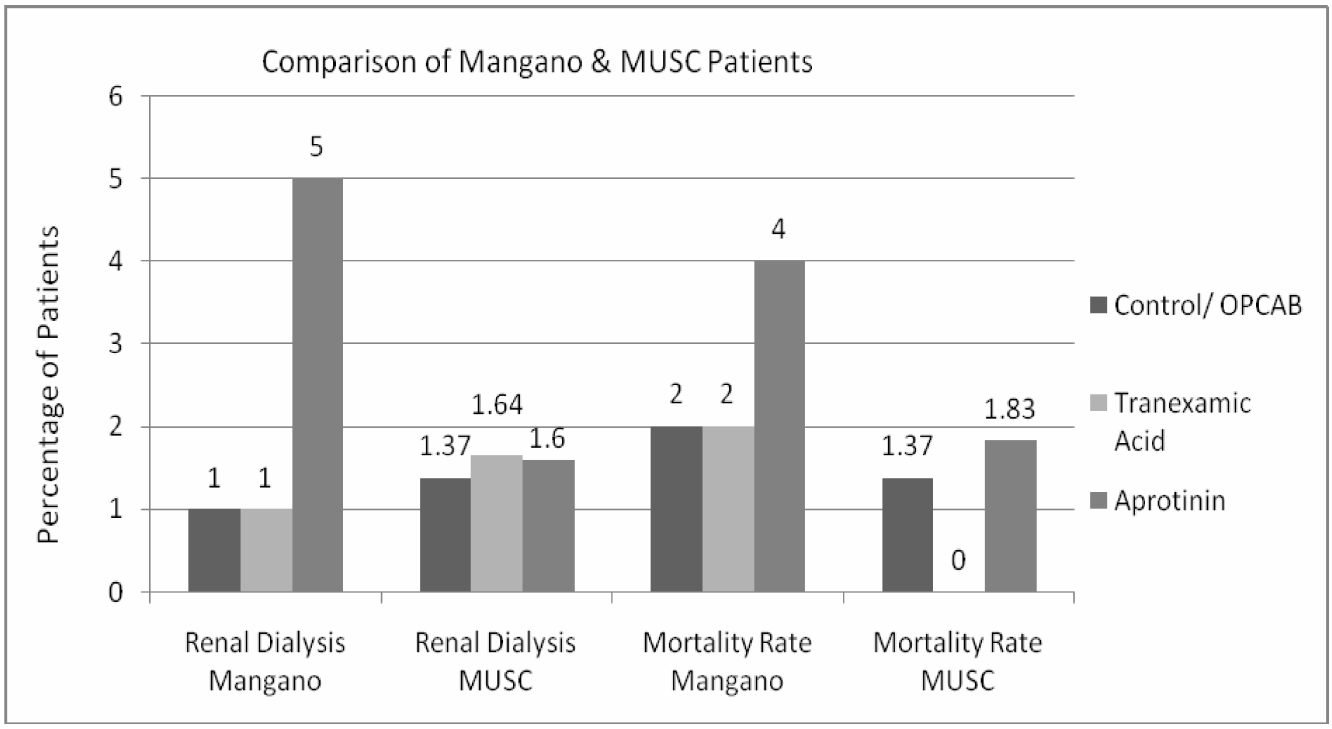

Figure 2. Percentage of patients with renal failure requiring dialysis and mortality rate.

ON Bypass

VAD Transport Team

Karen L. Jones, MSHA, CCP

University of Rochester Medical Center

Rochester, New York

The need for ventricular assist devices (VADs) is apparent when looking at heart failure statistics. According to the American Heart Association (2009) 5.7 million people in the United States had the diagnosis of heart failure in 2006, and 292,000 people die of heart failure each year. There are over 400,000 new cases of heart failure diagnosed annually. The six year survival rate for heart failure is less than twenty percent, making it a worse prognosis than most cancers. While the gold standard for treating heart failure is cardiac transplantation, the reality is that there are not enough donated hearts for all of the people in need of transplantation. In 2007 there were 2,200 heart transplants, yet several thousand more patients would have benefited from a transplant. The aging population, post cardiotomy shock patients, acute myocardial infarction patients, as well as patients undergoing high risk percutaneous interventions (PCIs) will all increase the need for VADs in the future.

Abiomed (2008) reports that there are about 900 hospitals in the United States performing open heart surgery. Of these centers about 120 are heart transplant centers with advanced treatments for heart failure, including long tern VADs. It is speculated that there are about 15,000 patients annually that could benefit from a short term VAD, yet only 25 percent of open heart surgery centers have a short term VAD to be used as a temporary treatment for heart failure. The remaining 75 percent of open heart surgery hospitals could use extracorporeal membrane oxygenation (ECMO) to support their acute heart failure patients. These patients on short term support would have to be relocated to an advanced center with heart failure therapies for further treatment.

In addition to hospitals with heart surgery using VADs, several cardiologists in catheterization labs are using devices to support patients through high risk PCIs. Abiomed (2008) predicts that there are about 160,000 patients that could benefit from a percutaneously inserted device providing partial circulatory support during high risk cath-lab procedures. Most of these patients will be able to come off support after the procedure, but some may not and will need advanced care that can be provided at a heart failure and transplant center.

At the University of Rochester Medical Center we have set up a “Hub and Spoke” system to safely transfer patients with heart failure to our hospital for further treatment. The University of Rochester is the hub with several spoke hospitals and cath labs in the surrounding area. It is a network set up between the physicians at neighboring medical centers to support them in treating patients with heart failure. The hub supports the spoke centers in using short term devices as well as providing a place for their patients to go to if they need additional and advanced care.

There are special needs that must be considered when building a team to transport a heart failure patient on VADs from the spoke centers to the hub. An integrated team, specially equipped ambulance or aircraft, and small devices with portable consoles are needed. The transport team includes a paramedic and EMT who ensure that the ambulance is safe for the staff as well as the patient. They can be utilized to prepare drips and help the nursing staff as needed. They are also in charge of making sure that the patient and equipment are secured once in the ambulance. A critical care nurse has several responsibilities as well. They oversee all patient care, hemodynamics, communicate with family and physicians, are in charge of medications, and documentation. Respiratory care is another important team member. They oversee ventilation of the patient and ensure that the vent settings are appropriate for a safe trip. The perfusionist oversees the VAD. They are in charge of checking for clots, coagulation or anticoagulation, positioning of the VAD, preventing heat loss, securing all connections, and having a plan on how to fit into the ambulance or aircraft. A physician is in charge of patient assessment and consent.

The ambulance and aircraft have special requirements to transport a VAD patient safely. The goal of the transport is to continue care as if the patient was still in the ICU. The patient may have additional oxygen requirements than a traditional ambulance or medical aircraft. A back-up oxygen supply and several oxygen and air ports are necessary for the ventilator and possible ECMO hook-ups. The extra equipment and consoles involved in a VAD transport require additional power sources. A back-up generator and extra outlet plugs are necessary to be sure to have enough power to supply electricity to all of the equipment. A hydraulic lift in the ambulance allows for the patient and equipment to be loaded onto the ambulance dependent of each other. As much space as possible in the ambulance or aircraft is necessary to fit extra equipment, supplies, and team members. It also allows the team members to move around if needed to care for the patient. Additional supplies are needed for VAD transport. Extra fluids including banked blood should be brought along for transport. Supplies need to be ready and pre-checked for a moments notice to transport.

The decision to transport VAD patients by land or by air is centered on the safety of the patients as well as the staff. Transporting a patient by air decreases the out of hospital time. Forty minutes by land is equal to ten minutes in the air. This is limited by the weather, the size of the aircraft available, the weight of the equipment and team members needed for a safe transport. If any of these conditions is questionable it is safest to go by ambulance. Several team members will make the decision on which mode of transportation is most appropriate.

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The Student Section

INTERPRETATION OF THROMBOELASTOGRAPHY: CAN THE USE OF THROMBOELASTOGRAPHY EFFECTIVELY MONITOR COAGULATION ABNORMALITIES IN PATIENTS UNDERGOING CARDIAC SURGERY?

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NSUH/CW Post School of Perfusion

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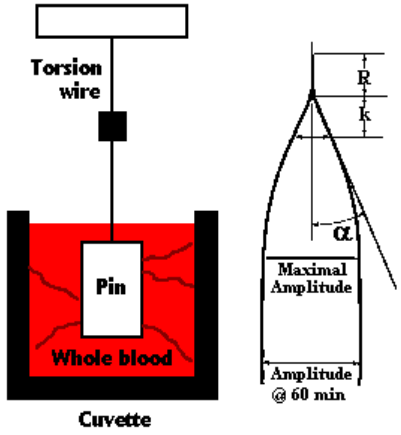
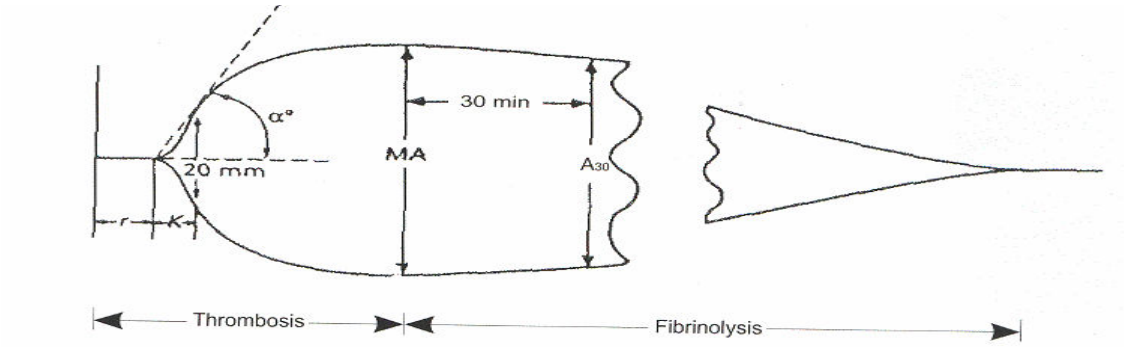
Rapid assessment of coagulation parameters remains a great benefit of point of care testing in the perioperative period. Hemostasis requires the interaction of platelets, coagulation factors, and the vascular endothelium. The thomboelastogram (TEG) incorporates the first two of these three factors. TEG was originally described by Harter in 1948. It monitors hemostasis as a whole dynamic process instead of revealing information of isolated conventional coagulation screens.

TEG measures the viscoelastic properties of blood as it is induced to clot under a low shear environment resembling sluggish venous flow. The patterns of changes in shear-elasticity enable the determination of the kinetics of clot formation and growth as well as the strength and stability of the formed clot. The strength and stability of the clot provides information about the ability of the clot to perform the work of hemostasis, while the kinetics determines the adequacy of quantitative factors available to clot formation.

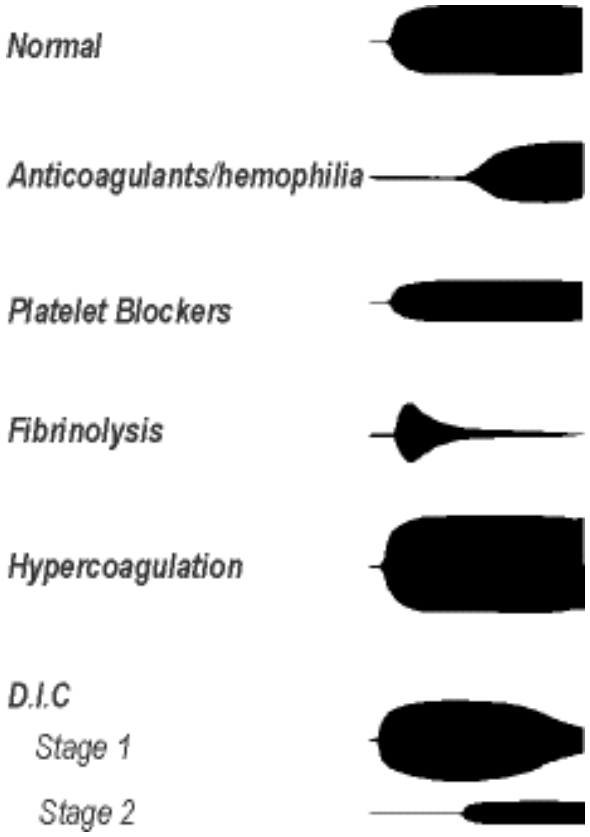
A sample of celite activated whole blood (0.36 ml) is placed into a prewarmed cuvette. A suspended piston is then lowered into the cuvette which moves in rotation of a 4.5 degree arc backwards and forwards. The normal clot goes quite fast through an acceleration and strengthening phase. The fiber strands which interact with activated platelets attach to the surface of the cuvette and the suspended piston. The clot forming in the cuvette transmits its movement onto the suspended piston. A "weak" clot stretches and therefore delays the arc movement of the piston, which is graphically expressed as a narrow thromboelastogram. A strong clot in contrary will move the piston simultaneously and proportionally to the cuvettes movements, creating a thick thromboelastogram.



There are five parameters of the TEG(r) tracing: R, k, alpha angle, MA and MA60, which measure different stages of clot development. **r**: is a period of time from initiation of the test to the initial fibrin formation. Factor deficiency, severe hypofibrinogenemia/thrombocytopenia will prolong r time, while hypercoagulability syndromes will decrease it. **k**: is a measure of time from beginning of clot formation until the amplitude of thromboelastogram reaches 20 mm, and represents the dynamics of clot formation.



A prolonged k time will caused by factor deficiency,thrombocytopenia, hypofibrinogenemia, while hypercoagulability states will decrease k time. **alpha angle**: is an angle between the line in the middle of the TEG(r) tracing and the line tangential to the developing "body" of the TEG(r) tracing. The "á" angle represents the acceleration (kinetics) of fibrin build up and cross-linking. "á" angle will be elevated in hypercoagulable conditions and decreased in hypofibrinogenemia and thrombocytopenia. **MA** - Maximum amplitude reflects strength of a clot which is dependent on number and function of platelets and its interaction with fibrin. Hypercoagulable states will increase MA, while a decreased MA will be caused by thrombocytopenia, thrombocytopathy, hypofibrinogenemia. **MA60**: measures the rate of amplitude reduction 60 min. after MA and represents the stability of the clot.



Another test designed to examine the entire clotting process is the Sonoclot, which provides information regarding coagulation, fibrin gel formation, clot retraction and hyperfibrinolysis.

Modifications of the TEG include the *heparinase thromboelastograph* (allows the indentification of abnormal coagulation in heparinized patients, prior to heparin reversal with protamine), and the *TEG/$_c$7E3*, a monoclonal Ab which binds to platelets GPIIb/IIIa receptors to the TEG sample and eliminate platelet function, thus allowing MA to become a function of fibrinogen activity.

The advantages of TEG in comparison with other conventional tests include: a) TEG is a dynamic test, giving information on entire coagulation process, rather than just on the formation of the first fibrin strands (ACT), b) it gives information on areas that is normally difficult to study easily (fibrinolysis & platelet function), c) rapid results, rapid monitoring of intervention, d) uses actual cellular surfaces to monitor coagulation, rather than plasma tests, e) it is cost effective, compared to all other conventional tests.

Thrombelastography was a significantly better predictor (87% accuracy) of postoperative hemorrhage and need for reoperation than the activated clotting time ACT (30% accuracy) or coagulation profile (51% accuracy)[1].

According to Shore-Lesserson te al study[2], 52 patients from a routine transfusion group, and 53 patients from a TEG-guided group were compared. The proportion of patients receiving blood was 22/53 (42%) in the TEG group vs 31/52 (60%) in the control group. 4/53 (8%) of the TEG group received FFP, while from the control group received FFP 16/52 patients (31%). Also, patients receiving platelets were 7/53 (13%) in the TEG group, compared with 15/52 (29%) in the control group.

After their research (14/170 articles which represent the best evidence on TEG) , Ronald and Dunning [3] concluded that thromboelastography may be useful in predicting patients who are likely to bleed postoperatively but more importantly, it can guide transfusion therapy algorithms in the bleeding cardiac surgical patient, resulting in significant decreases in blood and blood component transfusion requirements.

Also, I. Kouerinis et al[4,5] used TEG to monitor hemostatic status in diagnosed HIT patients. They conclude that TEG may prove to be useful supplementary methods to detect those HIT patients who may suffer complications of HIT type II, as well as to classify who will suffer the thrombotic and who the hemorrhagic complications. In their case report, TEG results revealed platelet and enzymatic hypercoagulability with abnormal values in all coagulation parameters (R=1.6min, K=0.8min, a=81.2^0, MA=74.5mm), confirming the strong thrombotic diathesis of their patient. In this way they were able to adjust and individualize the dosage of their therapy, and thus minimizing the risk of hemorrhagic complications by administrating blindly full doses of direct thrombin inhibitors. Also, Dr. I. Kouerinis et al[5] designed a multicenter study which will include 800 HIT patients diagnosed with ELISA or platelet aggregation tests. In this study they will use a two stage TEG, in order to confirm the expressed clinical thrombotic or hemorrhagic coagulation profile.

Many transfusion medicine specialists feel that near-site hemostasis monitoring could significantly improve clinical decision-making in patients undergoing surgery. Until recently, the vast majorities of studies using the TEG® have been descriptive in design and, therefore, have had a limited impact on clinical decision-making. The next major advance will require a multicenter, interdisciplinary approach to design the studies needed to establish evidence-based transfusion al-

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gorithms. If multidisciplinary teams do not address these remaining issues, use of the TEG® in the perioperative period will remain limited.

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5. Ilias A. Kouerinis *et al*. Heparin Induced thrombocytopenia diagnosis in cardiac surgery: Is there a role for thromboelastography? Department of Cardiac Surgery, Evangelismos Hospital, Athens, Greece.

The 2010

Annual Academy Meeting

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Continued from Page 5

In addition to transporting patients on short term devices, the VAD transport team may be needed to transport a long term VAD patient, who is living out in the spoke center's community, back to the hub hospital. Several patients are now going home on long term devices and may live several driving hours from the implanting hospital. Problems may arise, rarely with the VAD itself that may require the team to fly or drive out to get the patient.

Having a dedicated VAD transport team ensures a safe transport of a patient on a device to a center with advanced heart failure treatment options. It is an additional responsibility for a perfusionist and a great opportunity to be a vital member of an important integrated team outside of the OR. Also, more and more VADs will be placed into patients both in the OR and the Cath Lab due to more difficult interventions, the aging population, and the availability of the devices. These patients on devices in non-transplant centers will need to be transported to a center with advanced treatments and a VAD transport team ensures that the trip is safe and successful.

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Welcome to New Members

The American Academy of Cardiovascular Perfusion would like to welcome the following individuals whom were voted into membership at the Closing Business Meeting of our annual meeting in Dallas.

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All About our Corporate Partners

VIPER: Electronic Charting Are You Ready?

Stephen B. Turner
CEO
Spectrum Medical Inc.

Within the perfusion community there is an ever-increasing awareness of the need to capture factual real–time data to improve patient outcomes and to protect clinicians from discrepancies in charting when events occur.

There is little doubt that electronic data collection is a current and hotly debated topic at meetings and within the community at large. However, focusing on the electronic generation of the current paper record is to exclude the potential benefits of new technology and the wider implications of improving patient outcomes.

Increased Efficiency

The ideal electronic charting system needs to do more than just chart in order to contribute to the goals of better patient care and outcomes. In order to do this, the first objective of a system should naturally be to make it easier for the clinicians to do their job. Electronic Charting needs to be intuitive and contribute to time efficiency, allowing the clinician to focus on clinical decisions and actions which then benefit the patient.

New products wherever possible should minimize user intervention and provide information only when it is needed. Manufacturers, particularly designers of software, can often get carried away with complex software interfaces and as a consequence ignore one of the principle needs of the patient, “focus”.

At Spectrum Medical, we are grateful to the perfusion community for their contribution to what have become the core concepts and goals of our Variable Input Patient Electronic Record (VIPER). We believe that our VIPER Data Acquisition System is in fact a patient first perfusion tool that will, as just one of its functions, generate your electronic record.

Utilizing only four icons allows for complete system wide navigation of the VIPER system. Also, making use of only a two-level structure and an events-driven focus, the perfusionist is able to chart faster and more accurately.

Flexibility

Flexibility and data independence are critical issues in the selection of any system.

Another major objective of an ideal electronic charting system should be the ability to customize the system in order to meet the needs of the various configurations and specifications of each patient, OR and clinician.

Our first and most important observation was that no one system would work for all. Individual users have individual needs and in this regard VIPER has been set up to be totally configurable. Personnel, pre-Op stats, priming configuration, consumables, equipment, checklists, etc., are all configurable by the user. User flexibility to document events quickly and comment at any time during the case allows the user to further document pertinent information. In addition, flexibility is extended by having the ability and freedom to connect to any device of your choosing.

The VIPER system has also been designed with a number of unique concepts that will complement and develop existing clinical protocols. An example of this philosophy is called “The Surgeon Profile Function”. This function allows the C.V. team to construct a surgeon, patient or procedure protocol that includes a specific chart configuration. The specific chart configuration will allow the selection of critical physiological parameters and their quality control limits. Data whether its blood gases, continuous measurements or car-

dioplegia is monitored against these pre-programmed quality control limits in real-time. In the event of a control limit breach, VIPER will notify the perfusionist with a dialog box and plot the data to correspond with the timing of the exception.

Another factor to consider when looking at the flexibility of a system is the fact that technologies change, supplier service levels change, and capital equipment budgets are phased. Therefore it is imperative that data collection systems have the flexibility to connect to whatever pump you want, when you want. To support this, the VIPER system has the unique capability to allow the standardization of parameters entering your database. To simplify future data base search instructions Spectrum Medical has designed each of its device drivers with the capability to re-name incoming data parameters within a standardized hospital naming convention.

Accuracy of Data

A third objective when using electronic charting should be the quality of the data being collected. Although electronic charting has many implications, users often forget that it's not how you chart that really matters, it's what you chart.

With the ability to automatically collect data from monitoring devices, it becomes more important than ever that this information is real-time and accurate at the time it is collected. Your charting system will record data whether your parameters are good or bad, whether the surgeon is manipulating the heart or not. In other words, devices that trend these fast changing physiological parameters are no longer acceptable. It will be difficult to argue that your trending device was of a known accuracy when it was last calibrated twenty or thirty minutes ago.

Electronic data collection has also made the measurement of the arterial and venous flow differentials much more important. We believe it to be imperative that restricted venous flows are recorded in your perfusion record. The VIPER data acquisition unit is the only product of its kind that combines electronic data collection with the real-time non-invasive measurement of Arterial and Venous Saturation, Venous and Arterial Flow, Flow Differential and Venous and Arterial Emboli Detection.

Measurement of Quality Improvements

A fourth and fundamental objective and an ultimate goal for implementing electronic charting is the measurement of quality improvements. The electronic collection of data can be easily downloaded to a database in which queries can be made on specific data points important to your practice and hospital. Various measures can then be instituted based upon this data to improve quality of care.

We believe that the goal of continually looking for ways to improve patient outcomes is the goal of everyone in healthcare. Electronic charting should help achieve that goal. The ideal system should be flexible, intuitive, improve efficiency, function as a tool for the clinician and allow for easy downloads to a data base. We believe the VIPER system meets all of these expectations and is not just a charting system, but a workable perfusion tool.

The Academy welcomes Spectrum Medical, Inc. as its newest Sponsoring Partner.

Important Academy Dates

The ACADEMY ANNUAL MEETING DEADLINES

ABSTRACT DEADLINE	October 15, 2009
MEMBERSHIP DEADLINE	November 28, 2009
PRE-REGISTRATION	December 29, 2009
HOTEL REGISTRATION	December 29, 2009
2010 ANNUAL MEETING	January 28 - 31, 2010

Others Meetings

13th European Congress on Extracorporeal Circulation Technology
Scandinavian Congress Center
June 17-20, 2009
Aarhus, Denmark
Contact Name: Mrs. M.J. Wijers-Hille
Contact Phone: + 31 10 7035208
Contact E-mail: m.wijers@erasmusmc.nl
Website: www.fecect.org

12th Annual Duke Cardiothoracic Update and TEE Review Course
Crowne Plaza Beach Resort, Hilton Head Island, SC
June 18-21, 2009
ABCP accredited CEU hours: 32.4 CEU credits
Meeting Website: http://anesthesiology.duke.edu
Online registration: www.events.duke.edu/cardiothor09
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SOMANETICS CORPORATION
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Fax: 248-689-4272
Website: somanetics.com

SORIN GROUP USA, INC.
Phone: 800-221-7943 or 303-467-6517
Fax: 303-467-6375
Website: www.sorin.com

SPECTRUM MEDICAL, INC.
Phone: 800-265-2331
Website: www.spectrummedical.com

TERUMO CARDIOVASCULAR SYSTEMS
Phone: 734-663-4145 or 800-521-2818
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Website: terumo-cvs.com