

Academy NEWSLETTER

THE AMERICAN ACADEMY

OF

CARDIOVASCULAR PERFUSION
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WINTER 2009

2010 Annual Seminar

If you haven't already done so, it's time to confirm plans to attend the 31st annual meeting of the American Academy of Cardiovascular Perfusion, scheduled for January 28-31, 2010 at the Loews Vanderbilt Hotel, in Nashville, Tennessee. Meeting preregistration and hotel registration deadline is December 29, 2009.

Registration for the meeting begins Thursday morning from 10 am-3 pm. There is also an option of daily registration. The ever popular Fireside Chats begin at 2:30 pm. The breadth of topics will guarantee something of interest for everyone. A few

Editor

David Palanzo Annville, PA

Contributing Editors

Sherry Faulkner Little Rock, AR

Tom Frazier Nashville, TN

Kelly Hedlund Hays, KS

Michael Hollingsed *El Paso, TX*

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topics have been repeated, such as Aortic Surgery, Blood Management, Evidence Based Medicine, Pediatric Perfusion, Teamwork/Communication and Safety, to lessen the chance of missing one. As seating is limited, be sure to sign up early for these sessions. For those new to Fireside Chats, they are small discussion forums moderated by two Academy Fellows/ Members and are very interactive and informative. Registration will resume from 4:30-5:30 pm. You won't want to miss the Sponsor's Hands-On Workshop and Reception which will be held from 5:30-8 pm. This is our time to thank our Sponsors for their vital support.

The scientific sessions will take place on Friday, Saturday and Sunday morning. There are a number of relevant topics to be presented. On Sunday morning, we also have an invited speaker named John Pietsch, MD. Dr. Pietsch is the Director of Pediatric ECMO at Vanderbilt University Medical Center and will be discussing "What's New in ECMO".

Two special panel sessions are planned for this year. On Friday afternoon, the panel is entitled "Developing a Safety Culture: It's More Than Rules, Policies and Procedures". This dynamic panel will be moderated by Bob Groom, CCP, from Maine Medical Center in Portland. On Saturday afternoon, the panel is entitled "Impact of Healthcare Reform on Cardiac Surgery: Seeing 20:20 in 2010. This panel of experts will be moderated by Dan Fitzgerald, CCP, from Boston's Brigham and Women's Hospital. Based on the changing national headlines, this should prove to be a very timely and relevant session.

The Memorial Session will take place on Saturday morning from 10-11:30 am. We are fortunate to have Dr David Bichell, Chief, Pediatric Cardiothoracic Surgery, from VUMC present on the "Art of Surgery". The Reed Memorial Lecture Presenter is Pia Sprogøe, ECCP. Pia is a Senior Staff Perfusionist at Arhus University Hospital, in Skejby, Denmark and currently the Chairperson of DANSECT and Secretary of SCANSECT.

For me, one of the greatest aspects of the meeting is catching up with friends and acquaintances (and making new ones) in between the sessions and after hours. Thanks to the feedback I received last year regarding what some large volume adult ECMO centers were doing, we were able to confidently recommend a system that my hospital recently adopted to cope with the H1N1 epidemic and other related respiratory indications. We've termed it ECMO lite. See me at the meeting and I'll tell you about it!

I encourage you to join me in Nashville, Music City USA, for the 2010 AACP Meeting. All of the meeting information can be obtained at our website, www.THEAACP.com, or by contacting the National Office at 717-867-1485.

Wishing you and your families a happy and safe holiday season!

lan R Shearer, CCP, LP President, AACP

31st Annual Seminar of The American Academy of Cardiovascular Perfusion

Loews Vanderbilt Hotel Nashville, Tennessee **January 28-31, 2010**

Thursday, January 28, 2010

9:00 AM – 1:00 PM Council Meeting 10:00 AM – 3:00 PM REGISTRATION 2:30 PM – 4:30 PM Fireside Chats

Evidence-Based Medicine

Pediatric ECMO

Pediatrics Grown Up/Adult Congenital Heart Surgery

Perfusion Safety

Teamwork and Communication

5:00 PM – 7:00 PM REGISTRATION

5:00 PM Opening Business Meeting

Fellow, Member, Senior and Honorary Members

5:30 PM – 8:00 PM Sponsor's Hands-On Workshop & Reception

Friday, January 29, 2010

7:00 AM REGISTRATION 8:00 AM – 9:30 AM Scientific Session

9:30 AM - 10:00 AM Break

10:00 AM – 11:30 PM Scientific Session

11:30 PM – 1:00 PM Lunch

1:00 PM – 3:30 PM Special Scientific Session (Panel)

Developing a Safety Culture: It's More Than Rules, Policies and Procedures

Moderator: Robert C. Groom, CCP

Perfusion Safety Report Card

Bruce Searles, CCP

Developing a Team Safety Culture

Jeff Riley, CCT, CCP

Measurement and Safety: Can You Have One Without the Other?

Donny Likosky, PhD

3:30 PM – 5:30 PM Fireside Chats

Aortic Surgery Blood Management

Minimally Invasive Cardiac Surgery

Open Student Forum

Pediatric CPB

6:30 PM Induction Dinner

Fellow, Senior, Honorary Members & Guests



Saturday, January 30, 2010

7:00 AM REGISTRATION 8:00 AM – 9:30 AM Scientific Session

9:30 AM - 10:00 AM Break

10:00 AM – 11:30 PM Memorial Session

11:30 PM – 1:00 PM Lunch

Saturday, January 30, 2010

7:00 AM REGISTRATION 8:00 AM – 9:30 AM Scientific Session

9:30 AM – 10:00 AM Break

10:00 AM – 11:30 PM Memorial Session

The Art of Pediatric Cardiothoracic Surgery

David Bichell, MD

Chief, Pediatric Cardiothoracic Surgery, Vanderbilt University

Charles C. Reed Memorial Lecture
Pia Sprogøe, ECCP, Denmark
Thomas G. Wharton Memorial Lecture
Ian R. Shearer, BS, CCP, LP

11:30 PM – 1:00 PM Lunch

1:00 PM – 3:30 PM Special Scientific Session (Panel)

Impact of Healthcare Reform on Cardiac Surgery: Seeing 20/20 in 2010

Moderator: Daniel FitzGerald, CCP, LP

AdvaMed's Code of Ethics

Terry Chang, MD

Director, Legal and Medical Affairs

Impact of Healthcare Reform on Cardiac Surgery: Surgeon's Perspective

John G. Byrne, M.D.

Chairman, Department of Cardiac Surgery Vanderbilt University Medical Center

Sunday, January 31, 2010

8:00 AM – 10:00 AM Scientific Session (ECMO)

What's New in ECMO John B. Pietsch. MD

Associate Professor of Pediatric Surgery Vanderbilt University Medical Center

plus five scientific paper presentations involving ECMO

10:00 AM – 12:00 PM Fireside Chats

Aortic Surgery Blood Management Evidence Based Medicine

Pediatric CPB

12:30PM Closing Business Meeting

Fellow, Senior and Honorary Members Only

Presentations at the 2010 AACP Seminar

Friday, January 29, 2010 (7:30 – 9:30 AM)

ULTRASOUND DILUTION METHOD TO MEASURE CARDIAC OUTPUT IN PEDIATRICS Ed Darling, Naveen Thuramalla, Bruce Searles

SURGICAL INTERVENTION UTILIZING CARDIOPULMONARY BYPASS FOR CORONARY UN-ROOFING OF ANOMALOUS CORONARY ARTERY

Justin Resley, Reid Tribble, Scott Petit, Jeffrey Martin, Ryan Burke, David Isbell

INTEGRATED ARTERIAL LINE FILTRATION WITH A PEDIATRIC PERFUSION OXYGENATOR, TERUMO FX-05, IN AN IN VITRO COMPARISON WITH TWO OTHER CURRENT PEDIATRIC CARDIOPULMONARY BYPASS CIRCUITS: TERUMO RX-05 / CAPIOX AF02, DIDECO KIDS D100 / D130 Melchior R, Rosenthal T, Glatz A, Gruber P

PULSE CONDUCTANCE AND HEMOLYSIS DURING CARDIOPULMONARY BYPASS Antoine P Simons, P Wortel, RAT van Kan, FH van der Veen, PW Weerwind, JG Maessen

THE EFFECT OF OXYGENATOR HYDRODYNAMIC CHARACTERISTICS ON ENERGY TRANSFER DURING CLINICAL CARDIOPULMONARY BYPASS

Yuri M Ganushchak, KD Reesink, PW Weerwind, JG Maessen

WHAT IS OPTIMAL FLOW USING A MINI-BYPASS SYSTEM? Fernandes P, MacDonald J, Cleland A, Walsh G, Mayer R

Friday, January 29, 2010 (10:00 – 11:30 AM)

OXYGENATOR CHANGE-OUT TIMES: THE VALUE OF A WRITTEN PROTOCOL AND SIMULATION EXERCISES Edward Darling, Bruce Searles

INCORPORATING HIGH FIDELITY SIMULATION INTO PERFUSION EDUCATION Joseph J. Sistino, Nicole M. Michaud

A CONCEPTUAL FRAMEWORK FOR PATIENT SAFETY IN PERFUSION: USING HUMAN FACTORS AND SYSTEMS ENGINEERING TO IMPROVE OUTCOMES

Joseph J. Sistino

HOW DO FILTERS REACT TO AN INCREASED NUMBER OF SMALL AIR BUBBLES? Perthel M, Schulz M, Klauer B, Wimmer-Greinecker G

NEUROCOGNITIVE FUNCTION IN HIGH-RISK PATIENTS UNDERGOING CORONARY REVASCULARIZATION: THE IMPACT OF THE INTENSITY OF INTRAOPERATIVE MICROEMBOLIC SIGNALS Serdar Gunaydin

Saturday, January 30, 2010 (7:30 – 9:30 AM)

THE ROLE OF PENTOXIFYLLINE ON CARDIAC REMODELING GENES Anthony G. Platis, Douglas F. Larson



REVERSAL OF DIASTOLIC DYSFUNCTION WITH VOLATILE ANESTHETICS Elise Slack, Susan Gentry-Smetana, Daniel Redford, Douglas F. Larson

IMPELLA 2.5 PATIENT AIR TRANSPORT; LESSONS LEARNED Kevin Griffith, Eric Jenkins

PLATELET RICH PLASMA APPLICATIONS IN SPORTS MEDICINE - CASE PRESENTATIONS Michael Higgins

CARDIOPULMONARY BYPASS MANAGEMENT OF SEPTIC SHOCK DURING CARDIAC SURGERY: A CASE STUDY

Eric Jenkins, Edward Kahl, Matthew Caldwell, Jacqueline Conliffe, Michael Deeb

COMPLEX REOPERATION OF THE AORTA USING 3F ENABLE SUTURELESS AORTIC VALVE WITH AXILLARY AND FEMORAL CANNULATION AND VACUUM ASSISTED VENOUS RETURN: A CASE REPORT JR Beck, LB Mongero, MR Williams, AS Stewart

Sunday, January 31, 2010 (8:00 – 10:00 AM) ECMO SESSION

WHAT'S NEW IN ECMO

John B. Pietsch, MD Associate Professor of Pediatric Surgery Vanderbilt University Medical Center

EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO) FOR ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS) FROM SILICONE EMBOLISM LB Mongero, D Brodie, MD Bacchetta

HYPERKALEMIC ARREST WITH CARDIOPULMONARY BYASS AND EXTRACORPOREAL MEMBRANE SUPPORT FOR PLACENTA PERCRETA: A CASE STUDY Christine Farrell, Thomas Orr, Linda B.Mongero

LONG-TERM EXTRACORPOREAL OXYGENATION: A CASE REPORT OF A CHILD ON SUPPORT FOR 52 DAYS Marie Fouts, Christopher Mogan, Cristy Smith

AMBULATORY EXTRACORPOREAL MEMBRANE OXYGENATION AWAITING BILATERAL LUNG TRANSPLANTATION FOR CYCTIC FIBROSIS LB Mongero, DM Apsel, JR Beck, MD Bacchetta

THE USE OF PERCUTANEOUS ECMO SUPPORT AS A 'BRIDGE TO BRIDGE' IN HEART FAILURE PATIENTS: A CASE REPORT

David Fitzgerald, Amy Ging, Nelson Burton, Shashank Desai, Tonya Elliot, Lori Edwards

Posters

IMPROVEMENTS IN OUTCOMES USING MICROPLEGIA P Allen, J MacDonald, MA Quantz, S Fox, L Stitt, B Kiaii, R Guo, FN McKenzie, RJ Novick

PRE-REGISTRATION FORM The 2010 Annual Meeting of The American Academy of Cardiovascular Perfusion January 28 - 31, 2010

FIRESIDE CHAT REGISTRATION
Thursday Sessions (make 3 choices each day)

Please read and comply with all instructions and information on opposite page before completing this form.

MEMBER	FEE	Amount	11	
Registration Fee	\$330.00		2)	
2010 Annual Dues	\$145.00		3)	
Adult Guest to Workshop	\$25.00		Friday Sessi	ons (make 3 choices each da
NON-MEMBER (perfusionists, physic	cians nurses tec	chnologists)]	
tort in Embert (portablemote, priyon	FEE	Amount	11	
Registration Fee	\$380.00		11	
Adult Guest to Workshop	\$25.00		11	
·			Saturday Se	ssions (make 3 choices each
STUDENT PERFUSIONIST	FEE	Amount	1)	
Registration Fee	\$30.00*		2)	
Adult Guest to Workshop	\$25.00		11	
MUST include a letter from the school dire			11	sions (make 3 choices each d
o take advantage of the Student rate of \$30 Member of The Academy.	0.00, you must be a	current Student	'	(make 3 choices each c
FELLOW or SENIOR MEMBER	FEE	Amount	2)	
Registration Fee	\$400.00		11	
2010 Annual Dues	\$170.00		I I	assigned in the order they are rec
Guest to Formal Dinner	\$100.00		in the national of	ffice. nat must be limited to 30 attendees
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Adult Guest to Workshop Print or Type NAME	\$25.00		session, each d	AACP
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INSTRUCTIONS and INFORMATION

o Complete each appropriate section of this form by printing or typing.

This form may be copied, but must include both pages.

- o Members must pay their 2010 Annual Dues along with their registration fees by completing that portion of the form.
- o You will receive acknowledgment of your pre-registration by January 15, 2010—bring it with you to the meeting.
- o No pre-registration will be processed after December 29, 2009.
 - After this date you must register at the meeting.
- o Your receipt and meeting credentials will be available for you at the Pre-Registration desk at the meeting.
- o There will be NO ADMISSION to any Fireside Chat without proper admission credentials.
- o If you are joining The Academy with your registration you must:
 - 1) complete appropriate areas of the form;
 - 2) you MUST INCLUDE the membership application form;
 - 3) include the \$25 filing fee:
 - 4) include \$145 for the 2010 Annual Dues;

(Your membership begins with the closing business meeting)

- o ONLY VISA/MasterCard credit cards are accepted with VISA/MasterCard you may FAX your registration to (717) 867-1485
- o The AACP Federal Tax ID Number: 63-0776991 (for hospital use only)
- o Refund policy: Anyone that is pre-registered for this meeting and is unable to attend will receive a full refund minus \$50.00 for handling, mailing, and processing upon written request before January 12, 2010.
- o Make checks payable to AACP (US dollars). Mail completed pre-registration form and check to:

AACP 515A East Main Street Annville, PA 17003

IF YOU HAVE QUESTIONS FILLING OUT THIS FORM, PLEASE CONTACT THE NATIONAL OFFICE (717) 867-1485.

o If paying by VISA/MasterCard you may FAX this form to (717) 867-1485 or mail to above address.

Deadline for Pre-Registration is December 29, 2009. Hotel Registration Deadline is December 29, 2009







The Academy Meeting Registration Fees

PRE-REGISTRATION is available until December 29, 2009. After this date ON-SITE Fees apply.

Registration fee includes entire meeting, including the Fireside Chats, lunch on Friday and Saturday and The Sponsor's Hands-On Workshop.

The following fees will apply:

Pre	e-Registration	On-Site			
ACTIVE MEMBERS	\$400	\$450			
ASSOCIATE MEMBERS	\$330	\$380			
NON-MEMBERS	\$380	\$430			
STUDENTS*	\$ 30	\$75			
GUEST to Workshop	\$ 25	\$ 25			
*requires letter from school director					

Recertification Point Assignment

ABCP

The Program Committee for the Annual Seminar of The American Academy has complied with the rules for CEUs of the ABCP. Signature sheets will be available at various times throughout the weekend. Opening announcements will have further information regarding the sign in sheets. Each attendee will receive a letter of certification after the meeting stating the final CEUs that they signed in for, with a copy to the ABCP. No CEUs may be given without a signature of the attendee for the event. These are Category I CEUs.

NURSING

The American Academy has applied to the California Board of Registered Nursing for contact hours for this program.

Catrina McGrath Class of 2011

Cardiovascular Science Program

Midwestern University

Glendale, Arizona



Increased ECMO Demands Due to the H1N1 Virus

With the flu season rapidly approaching, the number of individuals affected by the H1N1 virus will continue to grow. According to an article published in the online journal JAMA, the United States and the European Union expect to provide extracorporeal membrane oxygenation (ECMO) to approximately 800 to 1300 patients during the 2009-2010 winter season. Of those patients placed on the ECMO support system, a large percentage will be adults. In the past, it was not very common to have adults requiring the need for ECMO. Now, the H1N1 virus is often causing inadequate oxygenation due to the lungs being too congested to allow for proper oxygen exchange in the alveoli. Due to the fact that there are only low-to-mid hundreds of staffed ECMO support beds available in the U.S., this could cause a major problem for patients infected with the H1N1 virus, along with the lack of trained ECMO staff. There might not be enough ECMO machines available for those that need them. In the coming months, there will not be enough extracorporeal circuits and trained staff to supply the demand.

The H1N1 virus, also known as Swine flu, causes upper and lower respiratory tract inflammation and fever. Some individuals are more affected by this than others. If the virus attacks the lungs more severely, ICU admission, intubation and mechanical ventilation are required for the patient's survival. However, the high oxygenation and high inflating pressure ventilator management can cause more damage to the lungs, which can in turn cause more damage to the patient. In cases where the patient would not be able to handle this added stress to their body or fails to respond to the conventional measures, ECMO should be instituted. ECMO may be used when the lungs are failing because it removes the risk of harmful ventilation. The lungs will not have to work as hard for the body, allowing the lungsto recover while the inflammation subsides.

ECMO is considered to be a last re-

sort for patients infected by the H1N1 virus. However, for some patients, ECMO is the only option for a chance to survive. Once the patient can be placed on the ECMO support, it is not a sure thing that the patient will live. The use of ECMO can improve the patient's chance of survival, although currently it is around 50% survival for adult respiratory failure. However, when reviewing early Extracorporeal Life Support Organization (ELSO) H1N1 registry data as currently as October 2009, 72% of patients survived after being placed on ECMO within 6 days of intubation. The goal of ECMO support is to regain lung function within 1-2 weeks of initiation, but depending on the case, the lungs may need a longer period of time to heal. According to a study done in Oslo, Norway, a patient survived on ECMO for 59 days without changing the ECMO circuit. Due to the continuing advancements in the technology with ECMO, the amount of time the patient will be capable of staying on the machine without changing any equipment will continue to grow.

There have been recent changes in the circuit that have reduced some risks to the patient while being on ECMO. The newer pumps, along with coated circuits, reduce the risk of hemolysis that is typically caused by the centrifugal pumps. Also, ECMO can be used for much longer periods of time due to plasma-leakage resistant oxygenators. An example of this type of oxygenator is the QuadroxD. Although this oxygenator is only approved for 14 days of use, as reported earlier, it has been used for 59 days without the need to be replaced.

The oxygenators that can be used for such an extended period of time have various features that other oxygenators do not typically have. The QuadroxD has tight hollow fibers made out of polymethypentene, which aids in elimination of plasma leaks. This also effectively prevents the formation of the microbubbles that would cause harm to the patients. The QuadroxD has a microporous membrane,

as do the other Quadrox oxygenators. However, the QuadroxD oxygenator can also be coated with the safeline coating to ensure optimal blood handling. By adding this coating, it minimizes the transmembrane pressure increase, allowing for greater dependability. A bioline coating is another option and can also be used to reduce thrombocyte adhesion and immune activation. By having these additional features, this allows patients on ECMO to safely stay on ECMO for a longer period of time.

Using the Rotaflow RF 32 centrifugal pump allows ECMO to be used for a longer duration. This particular pump was designed for use in treating patients that need extended support. While using extracorporeal circulation, this pump will handle the blood in a very gentle manner. Some of its beneficial features include a low priming volume, decreased surface area, and minimal mean transit time (MTT). The pump is mechanically designed for maximum biocompatibility. By using mechanical and magnetic bearing along with the flow channel principle, there are no stagnant blood areas of build up while the blood travels through the pump. This will reduce the risk of thrombus and emboli, which is always one of the top priorities for patients on longterm support. This certain pump will keep the flow to the patient constant, regardless of the pressure. The Rotaflow RF 32 will help to ensure the safety of the patients while on an extended period of ECMO support.

By using the QuadroxD oxygenator and the Rotaflow RF 32 pump, patients will be able to stay on ECMO for a longer period of time, allowing the patient's lungs to have proper time to heal. With the increase in demand for adult ECMO due to the H1N1 virus, it is crucial to know which equipment to use to ensure the patient recovers with as little long-term damage as possible. By using equipment that has been proven to last longer in the ECMO circuit with increased longevity, many common problems can be avoided. With the anticipated increase of the H1N1 virus, hospitals need to take certain precautions and prepare themselves with the proper equipment ahead of time in order to be ready for the rise in ECMO demand.

Works Cited

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- 2. "The ECMO option." Avian Flu Diary. 19 Sept. 2009. Web. 14 Nov. 2009. http://afludiary.blogspot.com/2009/09/ecmo-option.html.
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- San Jose, CA: Maquet Cardiopulmonary AG, 2009. Print.
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- Rycus, MPH, Peter. "H1N1 Information." Extracorporeal Life Support Organization. Web. 14 Nov. 2009. http://www.elso.med.umich.edu/H1N1Info.htm.
- Thiara, APS, V. Hoyland, H. Norum, TA Aasmundstad, HM Karlsen, AS Fiane, and O.Geiran. "Extracorporeal membrane oxygenation support for 59 days without changing the ECMO circuit: a case of Legionella pneumonia." *Perfusion* 24 (2009):45-47. Print.



The ACADEMY ANNUAL MEETING DEADLINES

ABSTRACT DEADLINE October 15, 2009

MEMBERSHIPDEADLINE November 28, 2009

PRE-REGISTRATION December 29, 2009

HOTELREGISTRATION December 29, 2009

2010 ANNUALMEETING January 28 - 31, 2010

Others Meetings

Cardiology 2010

Bringing Interdisciplinary Evidence-based Practice to the Patient

Contemporary Resort and Convention Center Walt Disney World, Lake Buena Vista, Florida

February 10-14, 2010

Website: http://www.chop.edu/cardiology2010

Contact Name: Tami Rosenthal Contact Phone: 267-425-6588

Contact Email: rosenthalt@email.chop.edu RECERTIFICATION CEUS AWARDED: Preconference Wednesday-6.7; Plenary

Wednesday-5.2; Thursday-9.8; Friday - 12.3; Saturday-10.8;

Sunday-5.7

Total Category 1 CEUs = **50.5** (**43.8** without preconference)

In Memoriam G. Deitrich Kemna

All About our Corrorate



Innovations in Site-Specific Perfusion Monitoring

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Evidence on the clinical utility of cerebral/somatic oximetry (INVOS System, Somanetics, Troy MI) has now surpassed 750 published papers, abstracts and medical conference presentations. This transcutaneous, near infrared technology reports venous-weighted regional hemoglobin oxygen saturation (rSO₂) in tissue directly beneath the sensor, reflecting the hemoglobin bound oxygen remaining after tissues have taken what they need. Decreases in this venous reserve indicate increased ischemic risk and compromised tissue perfusion.

In the realm of adult cardiac surgery, cerebral oximetry benefits include reductions in major organ morbidity or mortality (MOMM)¹, stroke², post-op cognitive difficulties³⁻⁴, respiratory failure/vent time², adverse surgical events⁵ and coma⁶. The past couple years have also seen increased emphasis on cumulative regional oxygen saturation below threshold, or area under the curve (AUC). Similar to published rSO₂ thresholds, this formula of time and depth of oxygen desaturation below threshold has proven valuable as an indicator of increased risk for neurologic injury^{1, 4, 7}.

Quality and Benchmarking Initiatives

Based on an evaluation of clinical evidence, the STS database committee recommended adding cerebral oximetry metrics – including AUC – to its Adult Cardiac Surgery Database in 2008. To date, it is estimated that more than 30,000 patient records with cerebral oximetry metrics have been collected as an opportunity to validate patient outcome benefits on an even broader scale.

Beginning in January 2010, the STS Congenital Cardiac Surgery Database will also collect cerebral oximetry metrics as well as metrics for somatic (vital organ area) oximetry. Collection will span both perioperative use and post-op ICU use. As with the adult database, AUC will again be one of the metrics collected. Other data

collected will be whether site-specific oximetry provided a "first indication" of a technical problem or physiological change in the patient that could potentially lead to an adverse patient outcome.

Full cerebral/somatic oximetry metrics to be collected in the congenital database may be viewed at the following link.

http://www.sts.org/documents/pdf/ndb/ CongenitalDataCollectionForm3_0_Annotated_ 20090916.pdf

To support this initiative, Somanetics is creating INVOS System software that automatically captures and calculates the cerebral and somatic metrics for convenient entry into the database through STS-certified software programs. Adult database metrics may also be captured via the INVOS System in this same manner.

In a similar quality initiative, Somanetics will be participating in the International Consortium for Evidence-Based Perfusion (ICEBP). To date, this consortium includes the AACP, AmSECT and 15 other perfusion member organizations from across the United States and world. One initiative is to form a CPB patient registry that more fully addresses the needs of the perfusion profession by collecting patient, procedural and outcomeslevel data for the purposes of improving patient care. As an industry sponsor, Somanetics will support the ICEBP's perfusion societies, medical societies and clinicians in their mission to benchmark and evolve perfusion practices to further improve patient outcomes.

Product Labeling Expands

Expanded FDA labeling (Somanetics, FDA 510k #KO82327) now allows a claim of improved patient outcomes after surgery when INVOS technology is used to manage therapies in patients above 2.5 kilograms. There are some misconceptions today about cerebral oximetry values due to confusion of the term "absolute" with the long-accepted concept in analytical chem-



istry of accuracy. The latest FDA expanded labeling includes the INVOS System's ability to provide real-time data accuracy in patients above 2.5 kg, meaning studies have found both its single-point and cumulative ${\rm rSO_2}$ readings to be clinically accurate. In patients weighing less than 2.5 kg, the readings should be used as trend values.

Insights into Cerebral Autoregulation

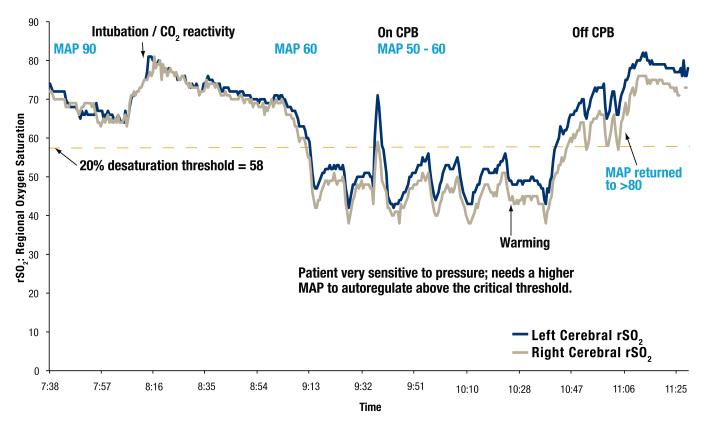
Perfusionists have long recognized the fine balance of maintaining adequate mean arterial blood pressure while also providing surgeons a clear field in which to do their repairs. Traditional teaching is that cerebral autoregulation is intact as long as MAP remains between 50-150 mmHg.⁸ However, research findings demonstrate that many critically ill patients – or even younger, healthier patients undergoing surgery – do not autoregulate to this standard range, putting them at risk of adverse events.⁹⁻¹¹

To help clinicians combat this challenge, Somanetics has acquired an exclusive sublicense to cerebral autoregulation monitoring technology developed at The Johns Hopkins University. Development is underway to utilize this patent-pending method of combining blood pressure measurements and signals from the INVOS System to continuously monitor and display cerebral autoregulatory function information, making the measurement simple enough for routine clinical use. 12 Current methods require monitoring intracranial pressure via invasive access to the brain or via methods that are not designed for continuous monitoring. Cerebral autoregulation readings via the INVOS System would be continuous and noninvasive, enabling clinicians to readily define each patient's requirements and optimize blood pressure to improve outcomes.

Somanetics plans to file a new 510(k) pre-market notification with the FDA to support marketing the new cerebral autoregulation module in the U.S. by late 2010 and initiate product shipments for sale early in 2011.

Abnormally High Lower Limit of Autoregulation

As the graph below shows, clinicians who are adept in cerebral oximetry have long been using rSO₂ values as a reflection of the adequacy of MAP. However, the onus is still on the clinician to simultaneously assess rSO₂, MAP or other disparate metrics in order to arrive at a conclusion. The cerebral autoregulation module currently being developed would instantly generate this information via the INVOS System for enhanced and timely decision making by clinicians.



Continued from Page 11

This senior patient with no known morbidities or complications was undergoing a CABG x 4. It was considered a routine case in which cerebral oximetry was an observation-only technology under evaluation by the surgical team. As such, their standard surgical and intervention protocols were adhered to throughout the case. This included permitting MAP levels for this patient of 60-75 pre-bypass and lower levels of 50-60 during bypass.

An adequate regional oxygen saturation (rSO $_2$) baseline of 74/72 pre-induction was recorded. Baseline MAP was 90. Intubation and induction proceeded without any difficulty and patient reactivity to $\rm CO}_2$ was observed by an immediate rise in rSO $_2$. The patient was maintained at or above rSO $_2$ baseline until 9:08 when MAP was allowed to reach approximately 60. At this point began a dramatic drop of rSO $_2$ to below 80% of baseline values and on to 40-41. No other vital sign indicated any difficulty.

A MAP = 50mmHg is the clinically-accepted lower limit of autoregulation (LLA), and it is standard practice to maintain MAP at this level in order to maintain adequate cerebral perfusion. But in this case, severe drops in rSO $_2$ indicated this patient's autoregulation may be compromised at a MAP <60. Only towards the end of bypass when MAP was allowed to rise did rSO $_2$ return to above threshold levels.

This was a routine case, but one that demonstrates that some patients' lower level of cerebral autoregulation can be significantly higher than the standard 50mmHg. This patient had no known morbidities or complications, showing that it is difficult to predict or detect patients with unique LLAs. In addition, common vital signs can sometimes offer little to no indication of poor cerebral perfusion. In this case, cerebral oximetry via the INVOS System provided the surgical team with new clinical insights about this silent, patient-unique physiology.

Pioneering Better Patient Outcomes

The perfusion community was among the first to recognize the clinical utility of the INVOS System many years ago. Today it is used at more than 750 U.S. hospitals, including 80-90% of the Top 10 Children's and Adult Heart Surgery Hospitals respectively¹³. As the primary medical specialist responsible for monitoring rSO_2 and intervening to avert brewing complications, perfusionists were – and remain today – invaluable in achieving improved patient outcomes.

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