"Quality in Cardiovascular Perfusion"

6th European Conference on Perfusion Education and Training

ABSTRACTS

Saturday, 9th September 2006 Stockholm, Sweden
6th European Conference on Perfusion Education and Training
Saturday, 9th September 2006, 09:00 a.m. to 17:00 p.m.
Stockholm International Fairs, Mässvägen 1, SE-125 80 Stockholm, Sweden

Organized by the
European Board of Cardiovascular Perfusion

Chairman:
Prof. Dietrich Birnbaum (Germany)

General Secretary:
Kirk Graves (Switzerland)

Organizing Committee:
Carole Hamilton (Germany),
Frank Merkle (Germany)
Eddy Overdevest (Netherlands)
Heinz Weitkemper (Germany)

Host Delegate to the EBCP:
Ronny Lindholm (Sweden)
Program

9:00 – 9:05 Opening of the Scientific Session / Carole Hamilton
9:05-9:15 Welcome to Sweden / Lena Lindholm:
   “Perfusion, Perfusionists, Perfusion Education and Research in Sweden”
9:15 - 9:45 Keynote Lecture / Alfred Stammers
   „From Evidence Based Medicine to Best Practices in Cardiovascular Perfusion”

Scientific Presentations

9:45 – 10:00 Erich Gygax
   “Adverse Events in Extracorporeal Circulation”

10:00 - 10:15 Longrois D
   “A Retrospective Study on Monitoring and Safety Devices for Cardiopulmonary
   Bypass for Cardiac Surgery in France”

10:15 - 10:45 Colin G Green (Maquet Cardiopulmonary)
   “Perfusion Safety and Risk Reduction Maquet Cardiopulmonary”

10:45 – 11:00 Frank Merkle
   “Qualifying Cardiovascular Perfusionists: Changing Paradigms”

11.00 - 11:30 Coffee Break

11:30 – 11:45 Herman Wiedensohler
   “Recombinant Aprotinin”

11:45 – 12:00 Judita Andrejaitiene
   “Impact of Cardiopulmonary Bypass Perfusion Pressure on Renal Function during
   Early Postoperative Period”

12:00 – 12:15 Paul Murphy
   “Assessing Conductivity Method for Measuring Hematocrit in Patients during
   Cardiopulmonary Bypass”
12:15 – 12:45  Ian Kelly (Spectrum Medical O₂ SAT)  
“Continuous Online Monitoring: Balancing Clinical Benefit with Cost”

12:45 – 13:15  Richard Hayes (Quest Medical Microplegia)  
“Myocardial Protection in the next Milenium”

13:15 – 14:00 Lunch

14:00 – 14:15 Sabine Bleiziffer (M.D.,German Heart-Center Munich)  
“Endovascular Harvesting and Clinical Experience”

14:15 – 14:30 Volker Schmidt, (Chief Perfusionist, Dresden)  
“Endoscopic Vessel Harvesting -Perfusionists Point of View”

14:30 – 14:45 Arthur Melo  
“Expanding the Use of Minimal Prime Circuits Beyond Coronary Bypass Procedures”

14:45 – 15:15 Alfred Stammers (Chief Perfusionist, Geisinger,Health Systems Pennsylvania)  
“Controversies Surrounding Mini-Circuits for Cardiopulmonary Bypass: Panacea or Pandora’s Box?”

15:15 – 15:45 Klaus Görlinger (Anaesthesiology, Essen University Clinic)  
“Detection and Targeted Treatment of Coagulopathy for Cardiac Surgery using the ROTEM® Analyzer”

15:45 – 16:00 Leen Vercaemst  
“The Perfusionist Role during ECMO Procedures“

16:00 – 16:15 Salvatore Agati, (Cardiac Surgeon, Taormina, Italy)  
“Pulsatile ECMO - Myths and Truths “

16:15 – 16:30 Jörg Optenhöfel (Chief Perfusionist, Hannover Medical Center)  
“ECMO/Assist Device-first experience in Hannover “

16:30 – 17:30 Happy Hour Coffee-Break
"Welcome to Sweden": "Perfusion, Perfusionists, Perfusionist Education and Research in Sweden".

Introduction to Sweden and Scandinavia

Summarized presentation of Cardiothoracic Surgery and Extracorporeal Perfusion and Perfusionists in Sweden

Perfusionist education and training in Sweden

Scientific work made by Swedish Perfusionists
From Evidence Based Medicine to Best Practices in Cardiovascular Perfusion

One need only spend a few hours in ‘pump’ or operating rooms anywhere across the globe to observe how perfusionists practice extracorporeal circulation and related functions. In fact almost 30 years ago the debate raged amongst perfusionists on whether or not what we did was more ‘art’ than ‘science’. Today one might think this laughable yet with almost 1,000,000 yearly cardiac surgical procedures performed worldwide, we still have “Centers of Excellence” and ‘go-to surgeons’ or ‘centers’ to whom we would choose for our own care or for the care of those to whom we are most concerned. Science, or at least the scientific method, is predicated on the principle of replication with predictable outcomes based upon some small degree of variability. Each year thousands of research studies in cardiovascular medicine are completed, with numerous more abandoned, that ultimately increase clinical knowledge. The results of these studies, combined with our own clinical judgment, serve as a base to influence our choice of interventions. And when the most relevant of these studies is accumulated it is referred to as an evidenced based approach to medicine, with the results serving as cornerstones by which ‘Best-Practice’ and ‘Standards-of-Care’ of perfusion can be determined (1).

Several perfusion organizations have attempted to determine indicators of quality, which could then be used to direct practitioners to secure a consistency in practice. For instance, for years the American Society of Extra-Corporeal Technology (AmSECT) has convened a group of perfusionists to function as a perfusion quality entity, charged with diverse initiatives. The results of their work can be seen on the AmSECT website (www.amsect.org) under the heading Perfusion Standards. Links such as Scope of Practice, Guidelines, Pump Templates, and Pre-Bypass Checklist take the viewer to downloadable resources. What is unique about these publications is the fact that they have been generated by a large organization of perfusionists and that have been endorsed by the voting membership of AmSECT. Surely highly credible, and oft referenced, resources. However, none of these contain information on the application of techniques of perfusion that would provide clinicians with a basis to direct their clinical actions. Hence, they are unencumbered by a systematic and quantitative review, and are hence, not considered as evidenced based medicine, or if so, represent the weakest of all evidence and can hardly serve as templates for clinical practice.

It is clear, at least to this perfusionist, that what is sadly missing in our profession is the publication of standards based on the review of scientific information, obtained through the mandates of evidenced-based medicine. One publication has stated that such an undertaking would result in insufficient data to imply that best practices are even available in perfusion (2). A recent publication attempted to use an evidenced based approach but was limited by a ‘consensus’ approach and was not validated or endorsed by any perfusion organization (3). Therefore, the necessary publication would go far in establishing mandates for perfusion practice that would enhance safety and improve outcomes. Numerous professional organizations have embraced this concept with the Society of Thoracic Surgeons spearheading this initiative in cardiac surgery.

So what are the mandatory requirements if such an initiative was to be implemented? At a minimum they should include the following:
1. Directed by one or more professional societies of perfusionists
2. Conducted as a systematic review using classification of evidence based upon rating various levels of published research
3. Conducted by perfusionists or individuals intimately involved in the conduct of extracorporeal circulation
4. Published as an ongoing project on all aspects of extracorporeal circulation and perioperative blood management
5. Reviewed and amended on a regular basis
6. International in scope and participation
7. Published in peer-reviewed and indexed journals such as the Journal of ExtraCorporeal Technology and Perfusion.


The benefits of establishing ‘Best-Practices’ and ‘Standards-of-Care’ are immense and everlasting. It is through such activities that perfusionists promulgate the numerous attributes of extracorporeal circulation and begin the transformation from reactive to proactive in the control of our destiny. However, a prerequisite for such a standard must not be limited by geographical borders, and must transcend the entire extracorporeal community. Such a goal, while lofty, is ultimately the challenge that we face to improve the standard of care that we administer to our patients.

References:
Adverse Events in Extracorporeal Circulation

**Introduction:** Current medical literature reports on a 0.3–0.8% perfusion-related incidence of adverse events, with severe consequences for the patient occurring in 0.3–6.0‰ cases and death in 0.1–1.0‰. Even though each perfusion team has its own safety-guard system, a unique scheme is difficult to define as various factors need to be taken into consideration. Indeed, the applied techniques, the quality of training and the availability of post-graduate courses, as well as the local working atmosphere, the influence of Medias, the information from industry et cetera, may all play a significant role.

**Methods and Results:** We analyzed 9820 consecutive patients operated under cardiopulmonary bypass in our clinic over the last 10 years. During this period, 68 (0.7%) adverse events happened, including 8 (0.8‰) patients with severe corporeal consequences and one fatal case (0.1‰). Fifty-five (80.8%) cases were defensible incidents whereas 13 (19.2%) were considered as negligence. We categorized these events in 6 groups: twenty (29.4%) cases were technical failures, 12 (17.6%) were ventricle dilatation, 20 (29.4%) were flow-dynamic problems, 2 (2.9%) were air emboli, 4 (5.8%) were electrical problems and 10 (14.7%) were anecdotic cases. Each group was then carefully analyzed based on the perfusion-physiology, the electro-technical aspects of the equipment and the intra-operative monitoring of air emboli with the aim of improving our safety-guard scheme.

**Conclusion:** Using this strategy, the possibility of false interpreting an event can be reduced and consequently most potential incidents can be earlier recognized and avoided. Finally and importantly, an objective, systematic and regularly updated safety-guard system should permit the improvement of actual technologies and help for the development of new concepts and strategies.
A Retrospective Study on Monitoring and Safety Devices for Cardiopulmonary Bypass for Cardiac Surgery in France

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7 Haute Autorité de santé (Health Technology Assessment Department) ; 2 avenue du stade 93 218 Saint-Denis La Plaine Cedex, France
8 Département d’Anesthésie-Réanimation, CHU de Nancy, 54500 Vandoeuvre-lès-Nancy

The French scientific health authority “Haute Autorité de Santé” (HAS) has recently published recommendations for monitoring and safety devices for cardiopulmonary bypass (CPB) in the context of adult and pediatric cardiac surgery (1). Among the perspectives of these recommendations was a survey of monitoring and safety devices in 2005 in order to estimate the difference between routine practice and the recommendations and this constitutes the principal objective of the present study. The secondary objective was to compare monitoring and safety devices in 2005 to those reported in a previous survey performed in France in 2001 (2).

Material and Methods
In collaboration with HAS and with the support of the “Collège Français de Perfusion” (CFP), all 66 cardiac surgery centres in France were sent a questionnaire with items concerning the routine use of monitoring and safety devices recommended by the HAS (1).

Results
Forty six (70%) cardiac surgery centres that performed a total of 29 822 CPB procedures in 2005 returned the questionnaire. Results are presented in Table 1 and are expressed as percentage of centres that systematically use the monitoring and safety devices during CPB.

Discussion
There is wide differences between the HAS recommendations and routine practice for CPB monitoring and safety devices in France, as shown by the low percentage of use of many monitoring or safety devices. Application into routine practice of some of the recommendations (oxygen gas analyser, arterial and cardioplegia line pressure measurements, etc.) will increase the cost of CPB procedures. For other measures such as pre-CPB check lists prior to initiation or ACT measurements at intervals < 30 minutes, the increase in cost will be absent or minimal.

There are few changes in monitoring and safety devices in the present survey as compared to the 2001 survey. The changes are related to the increased use of venous reservoir level detector (73% versus 52%) and to the systematic use of pump shutdown regulator when the level detector is present (100% versus 85%). All other items concerning monitoring and safety devices did not change between the two surveys.

Conclusion
These results should be an incentive for every centre performing cardiac surgery and CPB in France to improve the use of monitoring and safety devices in order to be consistent with the recommendations published by the HAS.
### Table 1: monitoring used during the procedure

<table>
<thead>
<tr>
<th>General recommendations</th>
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</thead>
<tbody>
<tr>
<td>Use of written protocols</td>
<td>65%</td>
</tr>
<tr>
<td>Use of a check-list before onset of CPB</td>
<td>80%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring and safety devices for cardiovascular function</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ST segment monitoring</td>
<td>65%</td>
</tr>
<tr>
<td>Measure of superior vena cava pressure during CPB</td>
<td>67%</td>
</tr>
<tr>
<td>Arterial line pressure measurements</td>
<td>20%</td>
</tr>
<tr>
<td>Cardioplegia line pressure measurements</td>
<td>74%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring and safety devices for respiratory function</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen gas analyzer</td>
<td>41%</td>
</tr>
<tr>
<td>In-line venous hemoglobin saturation monitor</td>
<td>98%</td>
</tr>
<tr>
<td>In-line PaO$_2$ monitoring for adults/children</td>
<td>33% / 47%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring of temperature</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>One site (or more) during CPB performed in normothermia or</td>
<td>96%</td>
</tr>
<tr>
<td>mild hypothermia</td>
<td></td>
</tr>
<tr>
<td>Two sites (or more) during CPB performed with hypothermia</td>
<td>86%</td>
</tr>
<tr>
<td>Monitoring of the temperature of the heat exchanger</td>
<td>89%</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Biology</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Arterial blood gas</td>
<td>100%</td>
</tr>
<tr>
<td>Kaliemia</td>
<td>100%</td>
</tr>
<tr>
<td>Glycemia</td>
<td>69%</td>
</tr>
<tr>
<td>Calcemia adults/children</td>
<td>64% / 88%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring of anticoagulation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated Clotting Time (ACT)</td>
<td>98%</td>
</tr>
<tr>
<td>One ACT measuring device per operation room</td>
<td>89%</td>
</tr>
<tr>
<td>Interval between two successive ACT measurements &lt; 30 minutes</td>
<td>80%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring and safety devices to prevent gas embolism</th>
<th></th>
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<tbody>
<tr>
<td>Venous reservoir level detector</td>
<td>73%</td>
</tr>
<tr>
<td>Arterial line bubble detector</td>
<td>33%</td>
</tr>
<tr>
<td>Arterial line filter</td>
<td>70%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Electrical safety</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Uninterruptable power supply</td>
<td>84%</td>
</tr>
<tr>
<td>Arterial pump battery backup</td>
<td>96%</td>
</tr>
<tr>
<td>Flashlight or emergency light on pump</td>
<td>67%</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Miscellaneous</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump shutdown regulator (when bubble detector or venous</td>
<td>100%</td>
</tr>
<tr>
<td>reservoir level detector were present)</td>
<td></td>
</tr>
<tr>
<td>Emergency oxygen tank available in the operation room</td>
<td>46%</td>
</tr>
<tr>
<td>Left ventricular vent line one-way pressure relief valve</td>
<td>40%</td>
</tr>
<tr>
<td>Arterial line filter with a one-way valve in a purge line</td>
<td>73%</td>
</tr>
</tbody>
</table>

**Références**

Perfusion Safety and Reducing Risk

Cardiopulmonary bypass (CPB) continues to be a fairly high risk procedure. It is probably the highest risk in connection with cardiac surgery. It should be considered a life sustaining procedure that can be life threatening. Fortunately, it is no longer associated with, or at least very seldom, a direct cause of death. It can contribute to increased post-procedure morbidity. An accident is an unexpected event. An incident is an event that is likely to happen. CPB accidents and incidents continue to occur although they are seldom in the public domain. They can and do result in personal and financial tragedy both to the perfusionist but more importantly to the patient and his or her family. Fortunately most perfusionists in Europe at present are not legally liable for their actions. However, all of us associated with CPB - perfusionists, surgeons, anaesthetists, nurses and those of us in industry - have a professional obligation to the patient, his or her family and our colleagues both inside and outside the operating room. With an increasingly litigious environment the cardiac team including the perfusionist will no doubt be exposed to greater legal risk in future. Taking the necessary steps to reduce this risk will also generally improve the quality and safety of CPB and reduce the risk to the patient. By incorporating some of the procedures and management requirements that are used in the medical device and other industries, for example in connection with ISO and CE-mark compliance, perfusionists and perfusion departments can reduce risk and increase safety.

For example, all perfusionists should have an employment contract with a job description. Likewise an up-to-date training, experience and continuing education record should be maintained for each perfusionist. Perfusion department protocols, policies and procedures should be developed, formally documented and applied consistently. A pre-procedure checklist is mandatory. Record keeping (charts and charting) should be complete and legible. Formal procedures must be in place for reporting and resolving equipment malfunctions. Likewise there should be a documented preventative maintenance programme for all mechanical and electrical equipment. All accidents, incidents and any procedural non-compliances should be reviewed.

With the changing work environment for most perfusionists with a lower CPB case load, an older, younger and sicker patient population and the opportunity to become involved in other perfusion, blood and circulatory management related applications both inside and outside the cardiac operating room, it is increasingly important for all concerned that there is a continuous focus on risk reduction, liability and patient safety.
Qualifying Cardiovascular Perfusionists—Changing of Paradigms and Clinical Needs

Background
The professional education of cardiovascular perfusionists and the expertise required for successful practice have not often been studied. Here the status of professional education of perfusionists in Europe, the necessary skills and relevant developments in the health care professions are described.

Method
The prerequisites for the practice of the profession, expected future developments and the question of the positioning of a future professional perfusionist training within the educational system were discussed with ten experienced German and European perfusionists. These individuals were interviewed in a semi-standardized fashion following an interview manual and the interviews were evaluated within the scope of qualitative research. Additionally, relevant literature on the training of perfusionists was examined.

Results
Current trends in the health professions include persisting differentiation and specialization of existing professions, academic upgrading of the health care professions, the establishment of new professions and the professionalization of new fields of activity. The professional skills currently required of perfusionists correspond to the list of activities published by various national perfusion societies. New areas are knowledge of management and, increasingly, social competence and self-management skills. Future tasks for perfusionists will be more diversified than at present.

Conclusion
Training for perfusionists should be made broader than it is today. The current restructuring taking place in the profession makes interdisciplinary orientation and increased emphasis on practical training necessary. Academic level education is both feasible and desirable.
Verification of effectivity of recombinant aprotinin past extracorporal circulation in dogs.
Wiedensohler H., Miesel-Gröschel Ch., Schulz H., Kosse J., Hagl S., Szabo G.

**Background:** In cardiac surgery, predominantly bovine aprotinin is used to reduce the bleeding risk. Currently only bovine-derived aprotinin is available. The recently developed recombinant aprotinin is of higher purity and prevents potential infections (for example BSE).

Aim of the study was to evaluate the effectiveness of the recombinant Aprotinin in comparison to conventional aprotinin in an experimental (canine) model (normothermic extracorporeal circulation).

**Method:** 24 dogs (Fox) were divided into three groups weighing between 14.0 to 26.4 kg (19.3 ± 3.6 kg). There was a control group “without”, one with “conventional” and one with the “recombinant” (Bayer Health Care Corp.) aprotinin. After left anterolateral thoracotomy in the fourth intercostal space, pericardotomy and preparation of the heart next the great vessels, we injected 300 U/kg sodium heparin (ACT ≥ 400 sec; Hemotec of Medtronic). Extracorporeal circulation (Stöckert) was connected arterially to the left subclavian artery and right atrium. The open perfusion system D 905 of the Sorin Medica Company was used.

Aprotinin was carried out (2 million KIE/30 kg) after the “Hammersmith” treatment scheme. During the test, neither catecholamines nor hormones or pressoractive substances were given. After a perfusion time of 90 min, the ECC was stopped and protamin was given within 10 min. The amount of bleeding was measured during the following 120 min. During the ECC (normothermia), every 15 minutes blood gases and coagulation status were evaluated.

The endpoints of the study were: Bleeding up to 2 hours after protamin, coagulation parameters (ACT, PTT, Quick), and the Myeloperoxidase and Malondialdehyde concentrations as indices for the ECC related inflammatory reaction.

**Result:** All animals were hemodynamically stable throughout the experiments. The blood loss was significantly lower if aprotinin was given (P < 0.05). There was no substantial difference of the effect between the two aprotinin groups. The three coagulation parameters, Quick, PTT and ACT did not show any significant differences. Myeloperoxidase and Malondialdehyde concentrations showed a tendentious increase in all groups during the ECC and returned to baseline after weaning.

**Conclusions:** Similar effects concerning the bleeding risk are to be contained from conventional and recombinant aprotinin. So, the potential advantage concerning the risk of adverse reactions (allergy at repeat intervention, potential transfection of infectious diseases) favors the replacement of conventional by recombinant aprotinin. However, clinical studies are required to approve the beneficial results.
Impact of cardiopulmonary bypass perfusion pressure on renal function DURING EARLY POSTOPERATIVE PERIOD  
J. Andrejaitiene, L. Raliene, L. Nasvytis, E. Sirvinskas

OBJECTIVE: Cardiac surgery on cardiopulmonary bypass (CPB) is associated with postoperative renal dysfunction. The purpose of our study was to investigate if postoperative renal dysfunction is influenced by CPB management.

METHODS: We selected three groups of patients with normal preoperative renal function who had been subjected to cardiac surgical procedures on CPB: there were 68 patients in the group I, whose perfusion pressure CPB was 60-69.9mmHg, there were 49 patients in group II, whose perfusion pressure CPB was 50-59.9mmHg, and 46 patients in group III, whose perfusion pressure CPB was 70-86.3mmHg. Furosemide dosage was adjusted with the target urine output being 0.8-1.5mL/kg/h. Preoperative patient condition, intraoperative and postoperative periods were recorded. Statistical significance was accepted at a level of $P<0.05$.

RESULTS: Currently, the rate of renal impairment (urine output <50mL/h, but serum creatinine level not greater 50% than baseline) was unusual in all of these groups. It was established that volume balance at the end of surgery did not differ among the groups. Furosemide medication on postoperative period was used 13.9% more often in the II group than in I group ($P=0.0164$). Evaluation of the influence of CPB perfusion pressure on renal excretion during the surgery showed that urine output in the II group was 21.5% ($P=0.0331$) lower compared to I group and 36.1% ($P=0.0003$) lower as compared to III group.

CONCLUSIONS: Our data suggest that CPB perfusion pressure as low as 50 mmHg did not impact postoperative renal function. This, future clinical studies are required to optimize CPB management for prevention of renal impairment.
Assessing conductivity method for measuring hematocrit in patients on CPB during cardiac surgery

Abstract:
Hemodilution during cardiopulmonary bypass lowers blood hematocrit levels. Hematocrit is routinely measured during these operations to determine if packed cell transfusion is required. We tested 202 whole blood hematocrit samples of patients on cardiopulmonary bypass during various cardiac procedures over a period of one year. The samples were then measured on two different hematocrit-measuring devices. The first, the Coulter LH 750 (Beckman/Coulter, Fullerton, CA) uses the Coulter method and is used routinely in the laboratory of our medical institution. The same samples were measured on the point of care device, the Gem Premier 3000 blood analyser (Instrumentation Laboratory, Lexington, MA) which uses the conductivity method. The purpose of this study was to examine conductivity as a reliable technique of hematocrit measurement during cardiopulmonary bypass. We found that for the 118 patients with a hematocrit on Cardiopulmonary bypass (CPB)- ≤ .25, there was a lower reading of 2.52 with the conductivity method as compared to the Coulter method. This could lead to unnecessary transfusion and exposure to the many complications associated with donor blood products. Conductivity is unreliable and should be removed from point of care devices and replaced with more accurate methods.
Continuous Online Monitoring: Balancing clinical benefit with cost

Current & Future On-line Monitoring Trends:
Through its introduction to the international perfusion community of the O2SAT saturation monitor in 2004 and extensive post market research Spectrum Medical has formulated a commercial & clinical strategy that, based on the companies recently launched M2 monitor, will offer perfusionists real choice of continuous parameter monitoring combined with a number of financial options that allow clinics access to state of the art monitoring technology in a way to suit all budgetary preferences, from the rental of the M2 for a week right through to a 5 year supported outright purchase option.

The presentation aims to show how the parameter monitoring priorities varies from clinic to clinic and as so device manufactures needs to address this variety and combine this with a flexible approach to how the equipment is financed.
Richard S. Hayes, BSCCP
Quest Medical, Inc
Chief Scientist
Director of Clinical Operations and Research
One Allentown Parkway
Allen, Texas 75002-4211

Quest Medical Sponsored Session:

Myocardial Protection in the next Millennium

Cardiac surgical patients present to us today with advanced cardiac disease, increased myocardial vulnerability, and reduced cardiac function. Cardioprotection represents a unique opportunity for perfusionists and surgeons to protect and preserve myocyte and endothelial function, modify the metabolic and molecular changes associated with ischemia and reperfusion, and promote early recovery of myocardial metabolism and function. The MPS2 and Microplegia enables total control over all parameters that affect myocardial protection and recovery, and does so very simply with the highest level of safety. Adoption of the MPS2 technology is proven clinically to provide better protection and recovery strategies, and has shown to improve outcomes, and will reduce both resource and cost utilization.
Dr. Sabine Bleiziffer
German Heart Center Munich, Germany

Endovascular Harvesting, Experiences of the German Heart Center Munich

In March 2004, we started endoscopic vessel harvesting at the German Heart Center Munich. Up to now, more than 250 patients underwent endoscopic vein or radial artery harvesting for coronary artery bypass grafting. It is presumed, that endoscopic vessel harvesting significantly reduces wound complications while graft quality is equal to the conventional harvesting technique. A scar of only 3cm at the wrist or above the knee provides excellent cosmetic results leading to a higher patients’ acceptance. After a learning curve of about 12 cases, the procedure can be performed within 45-55 minutes. The endoscopic technique is performed with an endoscope inserted into a retractor. Dissection and ligation of the side branches are carried out by bipolar electrocautery with the Clearglide instrument for vein harvesting and by the harmonic scalpel for radial artery harvesting. To avoid emergence of smoke, 8-10 l/min carbon dioxide is flushed into the working channel. The vein or radial artery is proximally transected with a pre-tied endoloop.

Compared to other endoscopic harvesting systems, CardioVation provides safe hemostasis of the side branches in the working channel with the Clearglide instrument and the harmonic scalpel. For endoscopic vein harvesting, the optical retractor facilitates the creation of a working channel. The integration of carbon dioxide insufflation into the device enhances visualization.

At the German Heart Center Munich, the endoscopic harvest is performed as the technique of choice to harvest grafts for coronary artery revascularization.
Endoscopic Vessel Harvesting - the Perfusionist’s Point of View

The conditions within the health system are changing dramatically nowadays. On the one hand, the growing social expenses cannot be financed any more. The financial pressure on hospitals is still growing. Professions like medical doctors and/ or perfusionists are suffering through non-attractive salaries and loss of image. Therefore it is more and more difficult to find well educated young professionals. On the other hand, the change of techniques (for example: OPCAB) causes a change in the perfusionist’s work. Flexible effort by the staff is more and more necessary for hospitals from an economic point of view. Several tasks are no longer attached to a special profession – they are quality- and success orientated.

After the decision of the Dresden Heart Center to put the EVH and ERA business into the hands of the perfusion department, an analysis models used in Germany was done. The objective was to collect information about existing experience and legal aspects.

We could find 3 different training methods in Germany:
- individual, internal and pratically oriented training programmes within the hospitals themselves, which are very successful.
- within several professional associations and schools which created combined training courses, and practice them with great success.
- training done by universities in the context of new studies which are targeting a Bachelor of science degree.

After 6 months of hard work and training sessions, at the Dresden Heart Center, the perfusion department is able to fulfil the new challenge of doing EVH. In spite of a huge number of OPCAB procedures (out of 2300 heart operations we do 480 OPCAPS per year) the perfusionists are running to capacity.

The first patients were included into a study we started to monitor the advantages of EVH compared to open methods.
Expanding the Use of Minimal Prime Circuits Beyond Coronary Bypass Procedures.

Abstract:
The heart lung machine and bypass circuit has been shown to be an insult to the human body since its inception. The Perfusion community, along with manufacturing companies, has tried to minimize this through improved technology. One of the latest improvements has been the development of minimal prime circuits. In North America, institutions have been slow to adopt minimal prime circuits and for the most part limit their use to coronary artery bypass surgery. At Trillium Health Centre, minimal prime circuits have been shown to reduce blood product usage and decrease hospital length of stay in coronary artery bypass surgery. As a direct result of these improved outcomes, the goal of the Perfusion Department has been to extend these benefits to all cardiac surgery patients by replacing conventional cardiopulmonary bypass with minimal prime circuits. Currently over 300 cases have been performed using this technology with no restrictions on type of case. In order to facilitate this transition, perceived technical limitations associated with the minimal prime circuits needed to be resolved. Technical and conceptual adjustments made to optimize the use of minimal prime circuits for all cardiac procedures will be presented. We are able to demonstrate that minimal prime circuits can be used safely and effectively in any situation requiring cardiopulmonary bypass.
Controversies Surrounding Mini-Circuits for Cardiopulmonary Bypass: Panacea or Pandora's Box?

Perfusionists, and those concerned with the techniques of cardiopulmonary bypass (CPB), are constantly searching for ways of minimizing the impact of the interventions. The search for ‘stealth perfusion’ continues to be the holy grail of our practices.

Numerous modalities have evolved with the ultimate testimony to the invasiveness of CPB being the employment of ‘off-pump’ techniques for certain surgical interventions. Such a solution of omission is hardly satisfactory when realizing that the patients who are more likely to require the heart-lung machine are sicker, arriving with more co-morbidities, and represent a challenge far greater than those who present coronary artery revascularization (CAR). As important is the fact that almost the entire cache of data has used the CAR population as the model for its research: hardly applicable for the patients undergoing CPB in 2006.

In addressing these challenges, manufacturers have devoted significant resources in developing a new class of componentry for CPB. Although these systems have been identified as either ‘mini-bypass’ and ‘micro-circuitry’ the real question is do they offer ‘maxi-perfusion’ or ‘macro-benefit’. The systems employ an integrated approach offering combined oxygenators, centrifugal pumps and arterial line filters. The currently available systems are the Medtronic™ Resting Heart System®, the Sorin™ Synergy®, and the Maquet™ MECC® and variations and hybridizations of other commercial devices. The prime benefit is related to reduced surface area exposure and concomitant reduction in prime volumes. When combined with autologous priming, euvoletic perfusion becomes a hittable target.

However, the reduction in size also creates new challenges with the most significant being alterations in safety. Additionally the smaller systems are more dependent upon utilization on the patient’s physiology and anatomy, mandating that perfusionists alter some established dogmas of practice. These will all be discussed when evaluating the potential of these circuits to improve the conduct of perfusion.
Detection and targeted treatment of coagulopathy during and after cardiac surgery using the ROTEM® analyzer

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Introduction: Acute bleeding is a major complication of cardiac surgery and is caused by pre-existing disorders, hemodilution, consumption, hyperfibrinolysis, contact of blood with the bypass circuit and/or the effects of drugs. Various therapeutic approaches are available to treat the bleeding, however the selection of the most effective option is crucial.

Methods: Near-patient whole blood coagulation analysis can be performed using the ROTEM® analyser, which continuously measures the clot formation. Reagents for the detection of the intrinsic and extrinsic coagulation as well as contribution of fibrinogen to the clot firmness are available. Further tests analyze hemostasis with the antagonisation of heparin and fibrinolysis. Within 10-15 minutes most aspects of coagulation can be judged. Electronic pipetting and an interactive software-guided procedure facilitate the application of the analysis. 0.3 ml of blood is required for each test. Limitations include low sensitivity to LMWH, warfarin, Aspirin and Clopidogrel.

Results: The clotting time of the analysis is the time from the start of the test until the initiation of clotting. The clot formation time quantifies the kinetics of clot formation, the maximum clot firmness the mechanical quality of the clot. Both are based on the fibrinogen and platelet content and the clot polymerisation process. After the formation of the clot its stability or lysis are detected.

Conclusion: ROTEM analysis allows for a near-patient analysis of coagulation in order to determine the most efficient therapeutic option in case of bleeding. The system is easy to use, however the training of its application, interpretation and quality control are crucial.
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The perfusionist role during ECMO

Born 30 years after the first successful cardiopulmonary bypass and using the same technology, ECMO can be considered as the 'little' sister of the heart-lung machine. Although similar technology, indications were entirely different and the initial goal was long-term support. Therefore, this technology left the OR, away from the constant supervision of the perfusionist and shifted into the hands of initially inexperienced people. As a result, the perfusionists' role changed; everybody newly involved in ECMO had to be trained, some responsibilities had to be delegated and, automatically, new responsibilities had to be created in order to guarantee similar quality of care as perfusionists provide with their heartlung machine.

Ever since this introduction in 1972, ECMO has known many controversies. Although randomized studies proved superiority over conventional respiratory therapy in neonates - which recently has been confirmed by the follow up after 7 years of the UK neonatal ECMO trial(1)-the numbers of neonatal ECMO cases worldwide have decreased substantially over the last decade. At the other hand, although less indications, ECMO in neonates remains a justified treatment modality.

In adults, ECMO is establishing a position as adjuvant therapy to less aggressive ventilation, which is proven to be the only effective treatment in ARDS (2). In the States, the economical benefit and quality of life in adult ARDS patients after 1 year survival has proven to be superior to that of conventional respiratory therapy (3). Analysis of the first data of the ongoing CESAR trial in the UK(4) indicates similar results. These beneficial results for ECMO promise a potential popularity boost as a treatment modality in this group of patients.

Beside respiratory support, ECMO has always been and remains an effective means to provide cardiac support, ideally in acute right ventricular failure. Intra-operative ECMO is also gaining popularity, and although different indications and a goal of only short-term support, it is also an interesting means to gain technical ECMO experience as expertise always favours outcome. Intra-operative ECMO has been applied in many centres as an effective means of support during OPCAB cases (5) and during lung transplantations (6).

Another option is the use of ECMO in non heart beating donors to reduce warm ischemic injury and to expand the potential organ donor pool.(7)

In summary, ECMO is surely not disappearing from the scene, and with the change in today's workload, it's imperative that the perfusionist seeks all horizons to find new indications for technology adherent to that of his scope of experience.

Regrettably, a recent study in the U.S concerning the team roles in ECMO(8), concluded that perfusionist are hardly 'visible' on the U.S. ECMO scene; publishing is mainly done by physicians and nurses, the technology hardly changed since its introduction 30 years ago and the ECMO responsibilities lay mainly in the hands of the ECMO nurses. Today, perfusionists in the States are trying to renew their involvement, which is illustrated by the joint meetings of ELSO and AMSECT, introduced since 2004.

In Europe, where perfusionist remained actively involved in ECMO and where access to new technology is less restrained by rigid laws, the ECMO set-up has changed much more than in the States. For example; with the introduction of the new PMP fibre, plasma leakage is history. Rotational pumps, which made the circuits smaller and easy
transportable, are being investigated to reduce hemolysis in long-term runs. Invasive inline monitoring is replaced by online and new coating processes are under investigation to make the system even more biocompatible. Lots of these technological improvements are thanks to efforts done by the perfusionists.

Less conventional ECMO technology is also appearing on the market to meet the demands of the respiratory care units; less invasive technology such as the catheter oxygenator, technology demanding minimal skilled personnel such as the pumpless ECMO and technology expanding indications to long-term respiratory support such as the implantable lung. This expanded respiratory support technology is these days more appropriately defined as ‘ECLS’ or “Extra Corporeal Life Support” and should be guarded and kept under the wings of the perfusionists.

With the re-appraisal of ECLS as an effective therapy, with the expanding indications, with the improving technology, no need to state that we, perfusionists, should maintain our important role during ECLS. ECLS as a therapeutic tool remains a medical decision and the success of this therapy is mainly depending on the patient’s condition...but one should always keep in mind that its quality is mainly the responsibility of the perfusionist.

References:
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2. Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. ARDS network, NEJM 2000, 3412; 18: 1301-8)
4. www.cesar-trial.org
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Background:
The failing myocardium leading to low cardiac output syndrome is a common clinical pathophysiologic state in the pediatric cardiac intensive care setting. Support of failing cardiorespiratory function in patients who underwent correction or palliation of congenital heart disease remains a difficult clinical problem. While the mainstay of therapy for the failing heart includes conventional catecholamines and new pharmacological agents such as milrinone and nitric oxide, there are obvious limitations in this form of therapy, especially in neonates due to age differences in sympathetic neurohumoral activity and receptor agonism. In the last decade, the technological improvement in cardiopulmonary bypass and mechanical support even for infants, children, and young adults modified the outcome of this subset of patients. As a consequence, mortality rates have been significantly reduced even if morbidity remains still a major clinical problem.

What’s new in Pediatric CPB:
The clinical impact of the use of pulsatile flow during both CPB and mechanical circulatory support were object of experimental and clinical studies. From an engineering point of view, the major advances come from the study of Undar and colleagues. From it was clarified that a pulsatile flow pattern clinically gives a benefit in terms of energy equivalent pressure and surplus hemodynamic energy both in pediatric and adult population.

In 2005 our group firstly reported the clinical experience with pulsatile ECMO in pediatric population (1). The initial experience was based only on three patients and major findings were considered the reduction in the use of inotropic support, the recovery of lactate levels in the first six hours and hemodynamic stability. Up to now other nine patients underwent pulsatile ECMO for postcardiomyotomy heart failure. Mean age was 9 days (range 2 days-12 years) and mean support time was 63 hours (range 40 – 192 hours). All patients received venoarterial cannulation (right atrium–ascending aorta). Regional tissue oxygenation was continuously measured by frontal cerebral reflectance oximetry probes (rSO2 INVOS; Somanetics, Troy, MI). According to thromboelastograph measurements, intermittent heparin infusion was used during support. In the last six patients no chest revision for bleeding was necessary. Three patients received continuous infusion of fenoldopam in order to optimize splanchnic perfusion during support. In the overall experience three patients died: 1 during support for peritonitis while two patients died after weaning for persistent pulmonary hypertension and low output syndrome. Hemofiltration for acute renal insufficiency was needed in 1 case. One patient experienced isolated convulsion without sequelae. Neither epinephrine or norepinephrine were used during support, lactate levels recovered to normal between the sixth and ninth hour. Five patients received hepatic and renal artery Doppler that demonstrate a clear pulsatile flow curve. Three pumps were replaced during support, one for incorrect anticoagulation management. Our experience confirms how the use of pulsatile ECMO in the pediatric population maintains a physiologic status during support particularly the first 24–48 hours. With our experience we can comment that pulsatile ECMO represents a clear improvement, not only in terms of mortality in such a high risk population, but mainly a reduction in morbidity due to a better end organ perfusion in the acute phase of failure. A meticulous anticoagulation management can reduce even more the periprocedural problems and hospital costs.


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