PROGRAMME & ABSTRACTS

11th European Conference on Perfusion Education and Training

Saturday, 1st October 2011
9:00 to 17:00
Lisbon, Portugal

Lisbon Congress Centre
Centro De Congressos De Lisboa (CCL)

"Developments in Perfusion" & 20th Anniversary EBCP
This year’s motto “Developments in Perfusion” reflects our challenges and directions taken to achieve a significant event. *The European Board of Cardiovascular Perfusion was founded in 1991 in order to unite European perfusionists in their desire for equality of standards in both training and professional status. For this purpose, a democratic Organization with representatives from the perfusion societies of all European countries which, at that time were members of the European Community (EC) or the European Free Trade Association (EFTA) was initiated. Supporting organizations of the European Board of Cardiovascular Perfusion include the European Association for Cardio-Thoracic Surgery (EACTS), the European Society for Cardiovascular Surgery (ESCS) and the European Association for Cardio-Thoracic Anesthesiologists (EACTA). * excerpt from www.ebcp.org

The European Board of Cardiovascular Perfusion (EBCP) now celebrates its 20 year Anniversary.
Over the years, Perfusionists, Cardiac Surgeons and Cardiac Anesthesiologists representing Perfusion Societies have met and progressed together to help develop and maintain ideas that represent professional awareness.

With this theme we welcome you to the 11th European Conference on Perfusion Education and Training.

Carole Hamilton CCP, ECCP, DC
Director Organizing Committee ECoPEaT
Member EBCP Academic Committee
Chief Perfusionist
Vogtareuth Schoen Clinic, Germany

The European Board of Cardiovascular Perfusion

Chairman: Prof. Alexander Wahba (Norway)
General Secretary: Mr. Frank Merkle (Germany)
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ECoPEaT Scientific Reviewer, Secretary Accreditation Sub Committee: Conny Nielson (Denmark)
Perfusion Safety: New Initiatives and Enduring Principles

Perfusion safety has been studied and discussed extensively for decades. Many initiatives occurred through efforts of professional organizations to achieve recognition, establish accreditation and certification, promote consensus practice guidelines, and develop peer-reviewed journals as sources for dissemination of clinical information. Newer initiatives have their basis in other disciplines and include systems approach, Quality Assurance/Quality Improvement processes, error recognition, evidence-based methodologies, registries, equipment automation, simulation, and the Internet. Use of previously established resources such as written protocols, checklists, safety devices, and enhanced communication skills has persisted to the present in promoting perfusion safety and has reduced current complication rates to negligible levels.

A Practical Affair

On the Road to Stealth Perfusion

20 Year Anniversary Review
The national registry for perfusion is a tool that allows easy and simple data collection that may be processed showing the perfusion activity and displays all results. This reveals what other units are using for techniques along with their progress and confirms competent actions.

**Objective:** To describe the annual care activities in perfusion units, to document changes in the parameters of the patients, including type of procedure, to document emergency situations and materials used.

**Material and methods:** Presentation and interpretation of results collected since 2002 to 2011. Database national consensus, identifying the necessary parameters, simplifies information retrieval and provides an analysis that reflects our business. This will make the collection and processing of all information reflected in the different units that voluntarily agreed to participate in the registry.

**Results:** Evolution of the average age of patients’ changes in the practice of perfusion (centrifugal pump, acceptance of the arterial filter, disappearance of the crystalloid cardioplegia) changes in the type of surgery, increase in combined surgery, deviations of the incidence of urgent activity and gradual increase in the number of units recorded.

**Conclusion:** The database is another tool for the justification and demonstration that perfusionists perform an activity that is recorded and can be used to claim our recognition. We believe that there is a need to update, revise and agree on new standards for registration, enabling the development on a European registry for cardio-vascular perfusion.
The European Perfusion Registry: A Work in Progress
Luc Puis, ECCP (Belgium), Ian Johnson, AACP (UK), Else Nygreen, ECCP (Norway), Pia Sprogøe, ECCP (Denmark), Timothy Jones, MB BS, MD, FRCS (CTh)

Introduction:
The importance of a registry for clinical practice observation has been well described and is also well established as a tool for clinical practice evaluation and improvement\(^1\), and even decision making on a governmental level\(^2\). The establishment of such a database, however, is a long, cumbersome and labor-intensive work. Many problems need to be overcome: after funding has been found, a dataset has been chosen, and a medium for data collection has been found that is suitable for everyone, individuals and centers need to be motivated to collect data. When data finally starts rolling in, the real work begins. The quality of the scored data needs to be controlled and error reporting with feedback to the participants is a requisite that cannot be overlooked. Finally, the data needs to be statistically processed and the results of that process need to be interpreted and reported to the centers for benchmarking of practice.

Materials and Methods:
Different European countries are at different stages of establishing some kind of national registry. Countries like Spain, the Scandinavian countries, Belgium and probably others, already have an extended form of a registry, but so far, no reports or publications have been produced from these databases. Moreover, the data that is currently being collected is heterogeneous between the different countries and consists mostly of procedural, descriptive data, which only allows for enumeration of procedures, materials and techniques. No risk-stratification or outcome can be measured. Other European countries are on the verge of setting up a registry, or have no data collection at all, or it should be on a centre-based level. To avoid that all European national organizations should need to go through the time-consuming process as described above, and to enable uniform data collection with the possibility of preoperative risk-stratification and postoperative outcome measurement, the idea of a European Perfusion Registry (EPR) was born.

Results:
While still in an evolutionary phase of development, the ultimate goal of the EPR is to move towards strong collaboration with the surgical discipline, which has a proven record with the EACTS Adult Cardiac Surgery Database\(^3\). A parallel perfusion database embedded in the existing adult database of EACTS would be a win-win situation for both groups of clinical practitioners. Regarding the point of view of the surgeons, the additional collection of perfusion data to the existing surgical data will certainly add value. Broadening the scope of parameters will increase the quality of the database. From a perfusionists’ perspective, advantage could be taken from the fact that much data is already being collected, thereby avoiding unnecessary double data collection. This is a unique chance to bring together two disciplines of care practitioners that work so closely together.
At this moment, the European Perfusion Registry is working on establishing such collaboration with the surgical community, through contacts with the safe keepers of the data of the European Cardiac Surgery Database, a partner with a large experience in setting up medical databases.

Conclusion:
The aim of the European Perfusion Registry is to collect data from cardiopulmonary bypass procedures of patients undergoing cardiac surgery. The collection and analysis of this data will allow comparison of techniques, conduct of perfusion and outcomes from different extracorporeal circulation procedures. The analyzed data will enable risk-stratification and support the perfusion community in finding the optimal strategies to perform cardiopulmonary bypass in general, and also in specific subsets of patients who are increasingly exposed to higher morbidity and mortality.

The purpose of the EPR is improving the quality of care we provide to our patients, by benchmarking existing practice against evidence-based guidelines and recommendations, and thus defining the optimal treatment that is needed for patients on cardiopulmonary bypass.

Once the necessary administrative work is done, the project will be presented to all the European national societies and they will be invited to participate in this project, be it on a national level, or on a centre-based level.

References:
10:30-11:00  
1st Coffee Break

11:00-12:30  
Scientific Abstract Presentations

Session Moderators

Adrian Bauer ECCP; MCVT  
Perfusionist, Coswig Cardiac Center, Germany  
EBCP Delegate to Germany

Prof. Alexander Wahba, MD  
Cardiac Surgeon Tronstein, Norway  
EBCP Chairman
LVAD Implantation Employing ECMO
Maik Foltan, Perfusionist, University of Regensburg, Germany
Department of Cardiothoracic Surgery, University Hospital Regensburg

Introduction: Use of a VA-ECMO for patients suffering from refractory cardiogenic shock is an established treatment option. ECMO-support is usually limited to the acute phase. In case of persistent ventricular restriction the implantation of a left ventricular assist device (LVAD) is the treatment of choice. The implantation of a LVAD usually takes place with the assistance of a conventional heart-lung machine. We describe a new procedure of LVAD-Implantation using the VA-ECMO instead of a conventional heart-lung machine.

Methods: Five Patients (54 ± 4 years) suffering from a refractory cardiogenic shock were stabilized with an ECMO-system. According to availability of the ECMO-systems: Cardiohelp or PLS-system (Maquet Cardiopulmonary AG, Hechingen, Germany) respectively the Deltastream DP3-system (Medos AG, Stollberg, Germany) were used. All patients were percutaneously cannulated via the femoral vessels using the Seldinger-technique.
One patient was cannulated with local anesthesia without ventilation support. Another was cannulated during mechanical resuscitation. For the third patient the approach of the IABP was used to introduce the arterial cannula after the removal of the IABP-catheter.
The implantation of the 3 LVAD-systems EXCOR and 2 INCOR (Berlin Heart GmbH, Berlin, Germany) took place using the common surgical technique but without the switch from ECMO to a conventional heart-lung machine.

Results: During period 3/2010-4/2011 five patients were provided with an LVAD using the ECMO-system without need for conventional heart-lung machine support. All patients were successfully bridged from ECMO to LVAD. ECMO-support time amounted to 11.0 ± 1.5 days. Immediately after LVAD-Implantation three patients required a temporary right ventricular assist device (RVAD) using the centrifugal pump.
One patient was successfully transplanted after 298 days. Two others are currently waiting at home for transplantation. A further is waiting in an external hospital. One patient died after 43 days on the LVAD due to mesenterial infarction.

Conclusion: Implantation of a LVAD under ECMO, without using a conventional heart-lung machine is safe and feasible. The advantages of this strategy are more stable hemodynamics during the implantation procedure and a lower requirement of blood products. Blood loss sets limits to the benefits of this procedure.
Initial results of this method suggest a good outcome for the patients. Further investigations and more patient numbers are necessary for additional evaluation.
Influence of Intra-Aortic Counterpulsation on Renal Function

Department of Cardiovascular Surgery, Heart Center Coswig, Coswig, Germany

BACKGROUND: Intra-aortic balloon pump (IABP) is the most commonly used mechanical circulatory support worldwide. The effect of the IABP on the blood flow to the superior mesenteric, celiac and renal arteries is being increasingly discussed. A recent study [1] showed an increased risk of compromise to the renal and visceral arteries due to misplacement or "oversizing" of the IABP catheter, despite compliance with the size specifications of the manufacturer.

OBJECTIVE: Contrary to the manufacturer's specifications, patients between 162 and 170 cm body height routinely received 34 ccm IABP at the Heart Center Coswig. To further assess this strategy, a retrospective study was performed to show the relationship between the size of the implanted IABP catheters and the occurrence of renal dysfunction. The aim of the investigation was to determine whether the use of 34 ccm balloons in patients within this range of body height are less harmful to renal function. Furthermore, both balloon sizes were compared to each other in terms of the quality of cardiac support.

MATERIAL & METHODS: From January 2007 to December 2007, 127 IABP patients (75 cardiac surgery and 52 cardiology patients) were evaluated. All patients were treated with the Fidelity IABP Catheter (MAQUET GmbH & Co. KG, Rastatt / Germany)

Mean study endpoints:
1. GFR; glomerular filtration rate as a marker for renal function (GFR in ml / min / BSA)
2. CI & CPI; Cardiac Index (CI: L/min/m2) and Cardiac Power Index (CPI: CI * MAP * 0.0022).

Exclusion criteria:
1. The GFR is assigned to gender-specific normal values, for this reason the study group decided to exclude all female patients (n = 50).
2. Patients with previously implanted IABP (n=3)
3. patients with an IABP duration <12 hrs. (n=5).

Study path I (control group):
All patients were divided according to the size of the implanted balloon catheter Group 1: 34 ccm (n=14), Group 2: 40 ccm (n=63); N=77

Study path II (study group):
Only patients with a body height from 1.62 m to 1.70 m were divided according to the size of the implanted balloon catheter,
Group 1a: 34 ccm (n=10),
Group 2a: 40 ccm (n=14); N=24.

The data collection for the parameters was carried out from the day of implantation (Day 0) to day 3. Mean values and standard deviations (SD) were calculated and compared with each other and a student's t-test was performed. A p-value of <0.05 was regarded as statistically significant.
RESULTS:
Study path I: No statistically significant differences for GFR, CI and CPI were recorded.
Study path II: The values for GFR, (34 ccm vs. 40ccm 73.8 ± 18.1 vs. 67.7 ± 24.1 p=0.540) and for the CI and CPI showed no significant differences.
Additional findings: Regardless of the size of IABP catheters, all patients on CVVH (continuous venous hemofiltration) had a lower cardiac output (CI 2.53 ± 0.49 L/min/m²) compared to patients without CVVH (3.04 ± 0.56 L/min/m²), p<0.001.

CONCLUSIONS:
The results of this study show no advantageous effects to renal function during usage of 34 ccm IABP catheters in patients taller than 162 cm. Furthermore, this retrospective investigation proved no deleterious effects to the renal function by usage of 40 ccm balloons in patients with a body height from 162 to 170 cm. Additionally, no differences in cardiac support between patients treated with 40 ccm and 34 ccm balloons were detected. Translating these results into clinical practice, we currently can not recommend to abandon the manufacturer’s guideline to use 40 ccm balloons in patients with a height greater than 162cm.

References:
Use of Bivalirudin for a Combined Surgical Coronary revascularization and Carotid Artery Endarterectomy in a Patient with Heparin Induced Thrombocytopenia
R. Carrier, C. Armstrong, F. Brisebois, A. Garg, T. Jessup, S. Mathur, L. Prevost, D. White

Objective: To describe the successful use of Bivalirudin as the sole anticoagulant in a patient with confirmed heparin induced thrombocytopenia (HIT) undergoing combined surgical coronary revascularization and carotid artery endarterectomy.

Method: An initial bolus of 0.75mg/kg of Bivalirudin followed by an infusion of 1.75mg/kg/hr was used for the carotid endarterectomy. The kaolin activated clotting time (ACT) was maintained above 250 seconds. Upon completion of this segment of the operation the infusion was stopped. Ten minutes prior to cannulation for cardiopulmonary bypass a 1mg/kg bolus of Bivalirudin was administered followed by an infusion of 2.5mg/kg/hr in order to maintain the ACT greater than 400 seconds. The infusion was discontinued upon termination of cardiopulmonary bypass. Perfusion technique modifications were undertaken in order to minimize the risk of circuit thrombosis.

Results: The surgical procedures proceeded without complications. There was no evidence of thrombus formation in the extracorporeal circuit and the patient’s post-operative course was uneventful. No excessive bleeding, increase in blood product transfusion or neurological deficits were observed.

Conclusion: Bivalirudin can be used safely as an alternative to heparin in patients with heparin induced thrombocytopenia undergoing combined surgical coronary revascularization and carotid endarterectomy. The use of the dosing regimen recommended in the REPLACE-2 trial for the carotid component of the operation, and the manufacturer’s recommended dosage for cardiopulmonary bypass provided an effective anticoagulation strategy. Bivalirudin combined with modifications in cardiopulmonary bypass management techniques, and careful surgical haemostasis, is a safe anticoagulation alternative.
Speaker: Bill O'Reilly, Manager Cardiac Perfusion Department
Affiliation: New Brunswick Heart Centre, Canada
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The Effect of Organon (Hepalean), PPC and Sandoz Brand Heparin on Blood Product Utilization following Cardiac Surgery
Bill O'Reilly RN, CCP, CPC; Ansar Hassan MD PhD FRCSC(C), New Brunswick Heart Centre, Canada

Background: For years, the New Brunswick Heart Centre in Saint John, Canada has used Hepalean brand heparin to achieve therapeutic anticoagulation during cardiopulmonary bypass. In response to the Hepalean brand heparin no longer being manufactured, the hospital instituted a change to PPC brand heparin in February 2010. In June 2010, as the result of the United States Pharmacopeia (USP) having adopted new manufacturing controls for heparin, a revised PPC brand heparin that was 10% less potent than the former PPC brand heparin was put into practice. Following this, anecdotal reports of greater heparin requirements and increased peri-operative bleeding in patients undergoing cardiac surgery began to surface prompting a switch in November 2010 to Sandoz brand heparin.

Objective: The purpose of this study will be to examine the effect of heparin brand (Hepalean, PPC pre-USP change, PPC post-USP change and Sandoz) on dose of heparin, blood product utilization and rates of re-operation for bleeding.

Methods: All patients having undergone first-time, non-emergent, on-pump coronary artery bypass grafting (CABG), isolated valve, or combined CABG-valve procedures from July 1, 2009 until April 30, 2011 will be considered. Patients who had known bleeding disorders, allergy to heparin, history of heparin induced thrombocytopenia or who were Jehovah’s Witnesses will be excluded. Eligible patients will then be separated into one of four time periods based on which heparin brand was being used (Table 1). Comparisons between the four groups will be made on the basis of pre-, intra- and post-operative variables. The risk-adjusted impact of heparin type on amount of heparin used and blood product utilization will be determined through the creation of multivariate logistic regression models which will adjust for differences between time periods in terms of baseline characteristics.

Conclusion: The results of this study will provide valuable insight into the impact of heparin brand on intra-operative heparin dosages as well as peri-operative blood loss and blood product transfusion requirements.

Table 1: Time periods and corresponding heparin brand

<table>
<thead>
<tr>
<th>Time frame</th>
<th>Heparin product in use</th>
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<tbody>
<tr>
<td>July 1, 2009 – Dec 31, 2009</td>
<td>Hepalean brand</td>
</tr>
<tr>
<td>Feb 1, 2010 – June 8, 2010</td>
<td>PPC brand pre USP standard change</td>
</tr>
<tr>
<td>June 9, 2010 – Nov 5, 2010</td>
<td>PPC brand post USP standard change</td>
</tr>
<tr>
<td>Nov 6, 2010 – April 30, 2011</td>
<td>SANDOZ brand</td>
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</tbody>
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Objective:
Based on our current knowledge of pulsatile flow and microcirculatory alterations under certain pathological conditions, the primary objective of this research is to investigate the benefits of pulsatile versus non-pulsatile perfusion on the sublingual mucosal microcirculation in high-risk cardiac surgical patients.

Methods:
Twenty patients undergoing cardiopulmonary bypass were randomly assigned to pulsatile or non-pulsatile flow group. The sublingual mucosal microcirculation was assessed for the proportion of perfused vessels and leukocyte activation within post-capillary venules using orthogonal polarization spectral imaging. Baseline images were recorded pre-operatively followed by various time intervals during and after cardiopulmonary bypass. A semi-quantitative analysis was performed on all discernable microvessels and expressed as mean ± standard deviation.

Results:
Microcirculatory blood flow patterns were similar between groups at baseline and during cardiopulmonary bypass. Peaking twenty-four hours post-operatively, a significantly higher proportion of normally perfused microvessels occurred in pulsatile versus non-pulsatile (56.0 ± 3.9% vs. 33.3 ± 4.1%; p < .05). Concurrently, pulsatility resulted in a reduction in the prevalence of pathological hyper-dynamically perfused vessels (6.0 ± 3.4% vs. 19.6 ± 8.8%; p < .05). Leukocyte adherence was also significantly decreased relative to non-pulsatile during and after cardiopulmonary bypass. Furthermore, a post-operative decrease in peripheral white blood cell count, plasma lactate, and serum creatinine levels were also present under pulsatile conditions.

Conclusion:
The implementation of pulsatile flow in high-risk patients may be more effective than non-pulsatile systems in the prevention of post-operative vital organ injury and dysfunction through preservation of a normal microvascular perfusion profile and subsequent decrease in systemic inflammatory response.
**Temperature Management for Valvular Surgery Patients**

R. Mrkonjic, N. Marusic, M. Solaric, N. Lukacevic, M. Sentic, D. Baric

*Clinical Hospital Dubrava, Zagreb, Croatia*

**Introduction:**

There have been a variety of changes in temperature management trends in cardiac surgery. In the early days of Cardiopulmonary Bypass (CPB) the practice was conducted at normothermia. The addition of hypothermia to CPB has been standard practice since Bigelow, in 1950 demonstrated improved tolerance of the entire organism to ischemia accompanied by hypothermia. Hypothermia served as a means of reducing tissue metabolism hence decreasing tissue oxygen consumption which protects the organs against hypoperfusion and hypoxia. Many cardiac centers today use moderate hypothermia and normothermia in adult surgery.

The aim of this study is to evaluate the efficiency and safety of normothermic versus moderate hypothermic CPB in valvular surgery patients.

**Methods:**

We retrospectively reviewed the records of 50 consecutive patients undergoing valvular surgery from May 2010-May 2011. Normothermic CPB (36°–37°C) n=23 and hypothermic CPB (29°–31°C) n=27. Outcome measures included mortality, major morbidity (cardiac, renal, neurologic, or major infection), need for perioperative inotropic support, extra volume on CPB, total units of red cell transfused and post-operative chest tube bleeding.

**Results:**

There were no significant demographic and surgical characteristic differences between the group of patients. There was no perioperative mortality. No patients required dialysis in the early postoperative period.

**Normothermic group:**

- CPB vasopressor requirement (MAP > 60 mmHg): 82%
- Early postoperative period, systemic vascular resistance 1162 ± 302
- 24 hour post-op blood loss 599±309 ml
- Administration of extra volume during CPB: 666±494ml of infusions p=0.484
- Transfusion requirement (keep HCT > 20%): n=7 (30.4%)
- Mean total RBC transfusion during perioperative period: 1030±417ml
- Delirium: n=1
**Hypothermic group:** 30 day mortality n=2 (sepsis)
CPB vasopressor requirement (MAP > 60 mmHg): 66%
Early postoperative period, systemic vascular resistance 1249 ± 402 dyne·s·cm⁻⁵, p=0.461
24 hour post-op blood loss 642±329 ml p= 0.653
Administration of extra volume during CPB: 796±653 ml of infusions
Transfusion requirement (keep HCT > 20%): n=8 (29.6%)
Mean total RBC transfusion during perioperative period: 1036±524ml
Delirium: n=1
Moderate increase in serum creatinine level (30-50%) n=2.
Prolonged ventilation ( ≥ 24h): n=1
Perioperative myocardial infarction: n=1
Superficial surgical site infections: n=3 (13%)

**Conclusion:** Current evidence does not support one temperature management strategy for all patients. These data suggest that normothermic systemic perfusion during CPB in valvular surgery patients is as safe as moderate hypothermic CPB.
12:30-13:30  LUNCH

****Viewing of Posters*****

Poster Presentations:

*20th Anniversary EBCP updated Posters from each individual member state: Full, Associate and Affiliate*

Name of Country, number of inhabitants
Country map with hospitals indicated
Logo of National Society
Organigram of National Society, number of members, when was the society founded
Brief description on development of cardiac surgery in the country
Data on cardiac surgery programs, such as number of hospitals, number of patients in heart surgery (with CPB)
Data on perfusionists tasks/scope of practice
Data on Perfusion Education Training programme, such as legislation, length, academic level/degree, prerequisites, location of training programmes
Scientific Posters:

Influence of Arterial Blood Pressure during Cardiopulmonary Bypass on Postoperative renal Function in Diabetic Patients
E. Sirvinskas, L. Raliene, J. Andrejaitiene
Institute of Cardiology, Clinic of Cardiothoracic and Vascular Surgery of Lithuanian University of Health Sciences, Kaunas, Lithuania

Objective: The aim of study was to evaluate effects of mean arterial blood pressure (MAP) during cardiopulmonary bypass (CPB) on renal function in diabetic patients during the early postoperative period.

Methods: We have analyzed the data of 58 pts with diabetes mellitus with normal preoperative renal function who had been subjected to coronary artery bypass grafting (CABG) procedures on CPB. Patients were divided into 3 groups according to MAP during CPB: group I (n=21) included patients who MABP was maintained 60-70, group II (n=17) MAP was 46-59 and group III (n=20) – it was 71-80 mmHg. Patient clinical data were evaluated during three postoperative days in ICU.

Results: The rate of oliguria defined asurine output <50mL/ was not differ among the groups. It was 11.8%, 15.4% and 18.8% in the I, II and III groups respectively. Urine output during the first postoperative day was 1723±176mL, 1632±143mL and 2550±382mL in the I, II and III groups respectively (p=0.0383). There were no differences in the level of creatinine in blood serum. It was established that volume balance at the end of surgery and during the early postoperative period did not differ among the groups. Length of postoperative hospital stay was not significantly different among the groups.

Conclusion: MAP during CPB within the range of 46-80 mmHg is safe and did not contribute to postoperative renal dysfunction in diabetic patients after CABG surgery.
**Evaluation of Effectiveness of a new Oxygenator Device “REMOWELL” in Leukocyte and Lipid Removal**
MC Costa, R Caruso, S Capalbi, C Gambarini, S Mariani, S D’Alessandro
Cardiac surgery Ospedale S. Gerardo Monza (Milano)

**Objective:**
Retransfusion of shed mediastinal blood represents a source of microembolization not only affecting the brain, but also kidneys, liver and spleen. The aim of this study was to evaluate the effectiveness of a new oxygenator device in removing lipid particles and leucocytes from pericardial suction blood and to assess the cerebral embolic load after the lipids filtration.

**Methods:**
31 consecutive patients undergoing elective cardiac surgery were randomly assigned to the study group (group A: n=16) or control (group B: n=15).

Blood samples for leukocytes concentration and lipid particles have been collected before and after the filtration camera. The lipid particles counting has been performed by use of a Thoma-Zeiss count-chamber. Cerebral microembolization during surgery was recorded by transcranial Doppler monitor over the right middle cerebral artery.

**Results:**
A significant post-filtration reduction of lipids and leucocytes was detected.
- Lipids: 3200 (n°/dl) ± 1500 (n°/dl) (- 54% ± 5%; p<0.01).
- Leucocytes: 4.54 x 10³µl ± 2.8 x10³µl (- 48% ±3%; p<0.01).

Mean sedimentation time was 43 ± 12 min and mean collected shed blood volume was 350 ± 70 ml. The median microemboli counted throughout ECC was 31 (13-183). A significant reduction in microemboli in the study group (median= 29) compared to the standard cardiotomy (median= 79) p< 0.01 was observed.

**Conclusions:**
This oxygenator device has been useful in the lipids removal of shed mediastinal blood and this may represent a useful tool in order to limit the embolic load during ECC. However no correlation between the significant reduction of cerebral microembolization on CPB and neurological events was noticed. Further studies as CT or MR brain scan and early indicators of brain injury serum protein levels could be better to assess the real importance of this device.
Optimized perfusion circuit: a new idea for CPB

1Sabrina Meloni CP; 1Laura Radomile CP; 1Simona Bartoccini CP; 2Andrea Farinaccio MD; 3Pasquale De Vico MD PhD; 4Luigi Chiariello MD PhD

1Perfusionist, division of cardiac surgery, Policlinico Tor Vergata, Rome, Italy; 2Department of anesthesiology, Policlinico Tor Vergata, Rome, Italy; 3Department of anesthesiology, Tor Vergata University hospital, Rome, Italy; 4Division of cardiac surgery, Tor Vergata University hospital, Rome, Italy

Objective: We reviewed the performance of an optimized perfusion circuit with CAPIOX RX 15 oxygenator (Terumo, Ann Arbor, USA) in terms of clinical safety and efficiency in priming and oxygenation.

Methods: Since January 2011, 80 patients were submitted to Coronary Aortic Bypass Graft (CABG) associated with aortic and/or mitral valve surgery. Cardiopulmonary bypass (CPB) was instituted with an Optimized Perfusion Circuit, and patient’s management was conducted by a single team, according to criteria-driven protocols. Inclusion criteria were the following: (1) Coronary artery disease associated with valve disease (aortic and/or mitral) necessitating surgical treatment; (2) age range between 18 and 85 years of age. Exclusion criteria were considered: (1) immunologic disease or malignancies; (2) acute inflammatory disease; (3) alteration in coagulation cascade; (4) steroid treatment; The Optimized Perfusion Circuit –OPC– system with Capiox RX15 oxygenator is a system designed specifically for miniaturized extracorporeal circulation. It is based on a very small CPB circuit with a 3/8 venous and arterial line. CAPIOX RX 15 is a PMEA-coated, polypropylene hollow-fiber oxygenator recommended for a maximum blood flow of 5000 ml/min with a membrane surface area of 1.5 m², static priming of 135 ml and validated to be used up to 6 hours. Carbon dioxide elimination was obtained with a 1:0.6 blood flow/air flow ratio and 65% of oxygen.

Results: All 80 pts (BSA 166 ± 9) were supported by an OPC system with CAPIOX RX15 oxygenator (CPB time 82±34 minutes and Xclamp 57±24 minutes). The blood flow was 4000±376 ml for minutes and pressure drop during CPB was 89±33 mmHg. The effective priming volume was 900 ± 145 ml and the hemodilution at the end of CPB was only 15% of the total patient volume.

These results also reflects the hematocrit (HT) trend during procedures (HT in % before CPB was 30.7 ± 7; HT during CPB was 24.5 ± 4; HT after CPB was 27 ± 4). Figure 1.

The numbers of transfusion of RBC bag (Red Blood Cells) during the first 24 hours were drastically reduced and only 26 patients received RBC bag (2.3 ± 1.4 n° of unit). Regarding platelets depletion, the value that we observed at end of CPB was 34% lower than the initial value (148.000 ± 49.000 vs 226.000 ± 64.000). This trend was translated to a much lower chest output measured at 24 hours: (176ml ± 142 ml). About the value of WBC (White Blood Cell) we observed a peak 6 hours after CPB but the value decrease after 24 hours (initial value 7.300 ± 2.900; after 6 hours 15.500 ± 5.900; after 24 hours 13.600 ± 5.600). The intubation time was been 13,2± 7,4 hours and patients were discharged from the intensive care unit after 33,7± 23 hours.

Discussion: We extended the use of the OPC on all patients including even those of BSA up to 2 meters of body surface area. The hemodilution is greatly reduced and the management of the CPB was improved and we have reduced the use of Red Blood Cell bag during CPB while maintaining a high level of hematocrit. At the end the organs perfusion was optimal and we also see a clear reduction of inflammatory response due to CPB.

Conclusion: In our initial experience the use of the new OPC with Capiox RX15 oxygenator clearly demonstrates clinical safety and efficacy when compared to traditional system for CPB in terms of end organ perfusion and in-hospital outcome. A perfusionist training program must be imposed before routine use.
Simple Antegrade Cerebral Perfusion Technique for Aortic Arch reconstruction
A Babaev¹, G Maharajh², K Murto³, D Rosen³, GS Gill¹, D Hubble¹, K Marrin¹
Ottawa/CANADA ¹ – Department of Cardiovascular Perfusion, University of Ottawa Heart Institute
2 – Department of Cardiac Surgery, Children’s Hospital of Eastern Ontario, ³ – Department of Anesthesia, Children’s Hospital of Eastern Ontario

Objective:
To describe a method of selective antegrade cerebral perfusion (ACP) combined with antegrade coronary perfusion for aortic arch reconstruction in pediatric cardiac surgery.

Methods:
The ascending aorta is cannulated high, and laterally. After circulatory arrest and cross-clamping of the aorta, the tip of the aortic cannula is advanced into the brachiocephalic artery (BCA). The BCA is snared and ACP is initiated. The flow is adjusted to maintain a mean pressure of 35-45 mm Hg in the right arm. Cerebral Near-Infrared Spectroscopy saturations are maintained at, or above baseline established before cardiopulmonary bypass (CPB). Myocardial perfusion is sustained with continuous flow of cold blood through a standard cardioplegia delivery system at 6-8°C. The systemic temperature is 24-25°C. The resulting arterial pump flow is between 20-50 ml/kg/min. After the completion of correction, the snare is lifted and aortic cannula is retracted into the aorta. The cross-clamp is released and systemic body perfusion is restarted. The patient is re-warmed and weaned off CPB. Modified ultrafiltration is performed prior to cannulae removal.

Results:
26 patients, ranging in age from 1 to 122 days, successfully underwent aortic reconstruction with the use of this technique between May 2005 and February 2011. No new gross postoperative neurological morbidity was identified. The only death was attributed to undiagnosed pre-existing lung disease.

Conclusions:
We have been successfully using this method of ACP since 2005. In our institution, this technique has proven to be simple, effective and with minimal risk of complications for correction of interrupted and/or hypoplastic aortic arch.
13:30-15:10  

**Sponsored Sessions**

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**Session Moderators**

Christoph Benk, Chief Perfusionist  
University Clinic of Freiburg, Germany

Bill O’Reilly Chief Perfusionist  
New Brunswick Heart Center, Canada
Prescriptive Oxygenation with Capiox FX Oxygenator: A Concept for Improved Blood Conservation

Hemodilution during Cardiopulmonary Bypass (CPB) is associated with several deleterious effects such as decreased oxygen carrying capacity, vasodilation, generalized edema, and organ dysfunction. Despite the recent introduction of a number of technical and pharmacologic blood conservation measures, bleeding and allogenic transfusion remain persistent problems in open heart surgical procedures. Consequently, the Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists have updated their Clinical Practice Guidelines on Blood Conservation and now recommend the use of minimized and reduced prime circuits with the highest level of clinical evidence (class 1, level A).

We have performed a series of clinical evaluation studies on low prime circuits during CPB. In our first study, we compared the inflammatory response and fibrinolytic activation of fully coated/uncoated and open/closed extracorporeal circuits in high risk patients. Use of closed and coated circuits reduced neutrophil degradation, cytokine release and thus improved clinical outcome in high risk patients.

We later studied minimized CPB. Over a ten-month period, 60 patients were prospectively randomized to one of the two perfusion protocols. Group 1: Minimized extracorporeal circuits (MiniCPB)(RocsafeRx, Terumo); Group 2: Conventional open circuits (Control). MiniCPB provided a comfort and safety level similar to conventional control via satisfactory air handling, attenuated inflammatory response and hemodilution with a better clinical outcome in patients undergoing high risk CABG.

We then focused on hemodilution and blood transfusion. Relative clinical and biomaterial effects of blood transfusion and surface coated circuitry on perioperative outcome were studied in Euroscore 6+ patients undergoing coronary revascularization with CPB. Allogenic red blood cell transfusion attenuated inflammatory response and increased the surface protein adsorption. The use of polymethoxyethylacrylate-coated circuit systems had a limiting effect on these processes. The combination of transfusion and not using a coated system had the highest risk for increased inflammatory response and protein adsorption.

Finally we started evaluations of novel circuits with integrated arterial filter. We explored the relative clinical and biomaterial effects of blood transfusion and novel low prime surface coated circuitry on perioperative outcome in pediatric population undergoing cardiac surgery with CPB. Over a 12-month period, 80 patients weighing >10 kg, underwent VSD repair with CPB were prospectively randomized into two groups according to the type of CPB circuit used, then each randomized group was enrolled into two groups again according to the need for transfusion. Group 1- Tx-free procedures on low prime surface coated extracorporeal circuitry (FX05, Terumo); Group 2- Procedures requiring Tx on coated circuitry; Group 3- Tx-free procedures with standard uncoated circuitry (D902, Sorin), Group 4 (Control): Procedures requiring transfusion on uncoated circuitry. Allogenic transfusion amplified CPB related inflammatory response. It was feasible to do congenital
procedures safely without transfusion for patients weighing >10 kg by using combined blood management strategies.

As a conclusion, a comprehensive multimodality blood conservation protocol with reduced circuit length and prime volume by using the smallest totally surface coated oxygenator with an integrated arterial line filter; reduced circuit size by pole-mounting roller head pumps on its heart-lung machine in combination with a RAP bag as a hybrid system would be one of the best solution.
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Italian Clinical Evidences during Surgical Corrections of Congenital Heart Defects in Extracorporeal Circulation

Speaker: Giuseppe Ciccarello, Perfusionist, Rome, Italy  
Affiliation: Cormed Cardiovascolare S.r.l – Heart Surgery Division  
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1Fabio Zanella CP; 2Rita Carbonari CP; 3Marianna Palmeri CP; 4Mauro Bosi CP; 5Anna Colapietra CP; 6Marco Pesce CP; 7Michele Guarino CP; 8Francesca Manfrini CP; 9Davide Ghitti CP; 10Erica De Toni CP; 11Paola Guariglia PhD; 12Giuseppe Ciccarello CSM; Pediatric Cardiac Surgery Units of: 1University of Padova; 2Hospital Bambino Gesù, Roma; 3Hospital Monaldi, Napoli; 4Hospital Niguarda Ca’ Granda, Milano; 5Hospital OIRM-S.Anna, Torino; 6Hospital Gaslini, Genova; 7Hospital G.Pasquinucci, Massa; 8Hospital G.M.Lancisi, Ancona; 9Hospital Riuniti, Bergamo; 10Hospital S.Orsola-Malpighi, Bologna. 11PhD of statistic, Department of psychology, University of Enna; 12Clinical Support Manager, Cormed Cardiovascolare, Rome.

Objective:
We reviewed with an observational, nonrandomized, multicentre study, the conduction method of the cardiopulmonary bypass (CPB) during surgical corrections of congenital heart defects in terms of:
1) verify whole organ perfusion adequacy, during the CPB, and particularly the renal perfusion (following the R.I.F.L.E. classification) and related to: Blood flow from HLM (Heart Lung Machine), Hemoglobin level present in the blood and temperature of the patient (normothermia and hypothermia).
2) Investigation on the “prime” quality in terms of hemoglobin concentration, analyzing the possibility of a crystalloid prime volume in relation to the weight and blood volume of patient.

Materials and Methods:
Between July 2010 and December 2010 in 10 Italian pediatric cardiac hospitals we observed the CPB conduction in 70 pediatric patients. Enrolled patients in this study must satisfy the following criteria: Group A1: weight ≤ 5Kg; Group A2: weight from 5 to 10 Kg; Group B: weight from 10 to 20 Kg. All blood parameters are monitored 5 times: T0- Base value; T1- 5 minutes after the start of CPB; T2- 5 minutes after the end of CPB; T3- arrive ICU unit; T4- 24 hours after surgery. During CPB the parameters are monitored by the emogas-analyzer “on line” CDI500 Terumo (Terumo, Ann Arbour, USA). The parameters evaluation is updated and shown on the monitor every 6 seconds. This high performance allows a complete and continuous vision on the perfusion quality and also a fast “reaction time” for the correction of the blood parameters when they aren’t within the best values. The CDI500 monitoring system reports the following parameters: pH, PCO₂, PO₂, HCO₃⁻, BE, SVO₂, SAO₂, K⁺, Hct, Hgb, Qb, VO₂, temp. The study data are collected by DATA TRIAL Form and SOFTWARE PROGRAMME of DATA TRIAL; (Parca/Ghitti system, Italy). The statistical significances are been evaluated by the ANOVA.

Results:
Data analysis show significant differences for three groups A1(3.75±0.56 Kg), A2(7.2±0.53 Kg), B(14.6±3.1Kg) and their interaction (p <0.005). Major differences were observed in effective priming volume (A1: 230±22ml; A2: 369±88ml; B: 527±55ml), diuresis (A1: 60±10ml; A2: 77±43ml; B: 226±44ml), use of RBC units (A1: 300±30 ml; A2: 264±50ml; B: 363±125ml) and hemoglobin level in different T and especially: A1 group T0-T1(p<0.000001) and T2-T3(p<0.000001); A2 group T1-T2(p<0.000001) and T2-T3(p<0.00005); B group T0-T1(p<0.005) and T2-T3 (p<0.0005). Regarding platelets depletion, significant statistical differences were observed at 5 minutes after end of CPB:
group A1 (p<0.000005) group A2 (p<0.000005) group B (p<0.000001) and at 24 hours after surgery: group A1 (p<0.0005) group A2 (p<0.0001) group B (p<0.000001).

**Conclusion:**
Besides the scientific community confirms that the mortality and morbidity risk is associated to several factors (Aristotle score) and the reduction of the post-operative renal insufficiency (R.I.F.L.E. score) is directly proportional to the mortality index, during the CPB is possible the preservation of the renal function maintaining an appropriated organ perfusion in terms of blood flow and hemoglobin level relating them to the patient temperature. An exiguous perfusion blood flow and low hemoglobin level may expose small patients to post-operative renal insufficiency. In the initial Italian experience, we have seen that the high quality of CPB associated with innovative techniques and tools as constantly monitor the blood parameters are very important to help perfusionists to maintain high quality standards during CPB.
A New Diagonal Blood Pump for Infant and Pediatric ECMO
Jörg Optenhöfel, Sebastian Tiedge, Hannover Medical School, Clinic for Cardiac Surgery, Hannover, Germany

Introduction:
Because of the improved development of infant and pediatric ECMO equipment, the average runtime nearly doubled from 131 hours (1985) to 253 hours (2007). The oxygenator and the pump are the most important components of the ECMO circuit. Crucial progresses for the oxygenator were the launch of the polymethylpentene fiber and several heparin and heparin free coatings. The durability and hemolysis of the pumps has been improved as well.
One of the latest developments is the DELTASTREAM® DP3 blood pump.

Results:
Between October 2009 and August 2011 we used the DELTASTREAM® DP3 for 17 clinical cases (16 times: ECMO and 1 time: pulsatile LVAD) for over 58 days runtime. The pump proved to have a high durability and less hemolysis.

Conclusion:
Particularly the optional pulsatile operating mode expands the range of application. Meanwhile we established the DP3 as standard blood pump for extracorporeal support systems for neonates and infants in our center.

Keywords
Diagonal flow pump, DP3, ECMO, hemolysis, neonate and infant perfusion
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Microemboli during cardiac surgery encompasses three areas of concern for the clinician; solid emboli, fat emboli and gaseous emboli. Knowledge about the presence of gaseous microemboli and the harmful effects it creates in the microvasculature has been around since the development of the first bubble oxygenator. But we now have the latest generation of ultrasonic detection devices which allow us to more accurately find and prevent GME in the extracorporeal circuit (both in vivo and ex vivo).

Since the introduction of membrane oxygenators in the early 80’s, postoperative stroke and neurocognitive insults have made dramatic improvements … however, problems with post operative neurocognition continues to be a daunting and persistent part of the morbidity associated with cardiac surgery and cardiopulmonary bypass.

In the late ‘90’s, clinicians were somewhat reassured with the micro air handling abilities of membrane oxygenators and the many arterial filters that were available for use. But a turning point in both the clinical and manufacturing awareness around GME and perfusionist involvement seemed to appear around the time of the publication of two papers;


Since then, there has been a tremendous amount of awareness on the potential sources of gaseous microemboli from an industrial, medical and perfusion perspective. Clinicians now expect all new devices entering the extracorporeal arena to be vigorously tested for their ability to handle micro air in the presence of both sanguineous and asanguineous primes. In the operating room, Perfusionists are also expected to make critical choices for patient safety that is not only based on ease of use or lower priming volumes … but the oxygenator and arterial filter’s ability to reduce or prevent GME from going to their patients. But in the past ten years, what exactly have we learned about GME in the devices we use and the techniques we practice on a daily basis during cardiac surgery?
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Blood Conservation Using the Xtra system as Part of a Comprehensive Blood Management Programme

Ann Clements, Department of Clinical Perfusion Science, Essex Cardiothoracic Centre, UK, Department of Clinical Perfusion Research, Imperial College Health Science Centre, London, UK

The aim of a good Blood Management Programme (BMP) should be to maintain the patient’s own haemoglobin, plasma and platelets at a level that facilitates healing and recovery without the need for Homologous Transfusions. Transfusion related mortality is well published throughout the literature\(^1,2\) and there is growing evidence to suggest that this increased mortality is due to the clinical condition of the patient that merits transfusion, rather than the actual transfusion.

Based on the increased risk described, we should strive to:

a. address the source of the problem;

b. focus on avoiding the clinical conditions that require patient transfusion;

c. only use transfusion rates to audit the success of achieving ‘a’ and ‘b’.

Whilst there is no isolated blood saving technique that will address the problem at source, some components like peri-operative mechanical cell salvage play a more significant role in a BMP than others, specifically because it is widely available, easy to use and cost effective.

Our team recently evaluated a new generation of cell saver, The ‘Xtra’. This process highlighted that cell salvage technology is changing and has to change\(^3\). These changing expectations were demonstrated by the fact that our evaluation criteria have evolved since we last evaluated cell salvage hardware. Quality indicators, quality of monitoring, data collection and data management have all come to the fore. The presentation discusses our teams’ findings. We essentially revisited what we felt was ESTABLISHED technology, gained a better understanding and found that improvements and could be made in our teams practise.

This presentation concludes that:

- A good BMP focuses on avoiding clinical conditions that require patient transfusion.
- Peri-operative cell salvage plays a significant role in a BMP.
- There are many ways to optimise peri-operative cell salvage – it is worth revisiting established technology.
- Think carefully about quality indicators for peri-operative cell salvage.
- The Xtra offers good ‘Plug and Play’ technology.
- The future will demand good data management from our speciality – this will include peri-operative cell salvage.

15:10-15:40

2\textsuperscript{nd} Coffee Break

15:40-17:00

Sponsored Sessions

Session Moderators

Jouko Jalonen M.D.
Department of Anesthesiology, Turku University Hospital, Turku, Finland

Nuno Raposo
Chief Perfusionist, Lisbon, Portugal
Initial Clinical Experience with the Spectrum Medical M4

The Spectrum Medical M4 is a non-invasive patient monitoring system designed to allow blood gas, Hematocrit and saturation real-time while not requiring regular calibration. Since late August 2011 we at the Rigshospitalet have been clinically evaluating the new M4 patient monitoring system in routine extracorporeal circulation. The Spectrum Medical M4 extends the range of non-invasive diagnostic measurements, already available with the current M2 and M3 products, to include the key parameters of pO2, pCO2, and associated measurements. The presentation includes an overview of the product and how it has performed in routine clinical use at our institution as a patient monitoring system in routine CPB, as well as evaluation and confirmation of its ability to accurately measure flow and blood parameters as compared to the output of the institutional gas analyzers. Data to validate claims on need for minimal calibration will also be shared and discussed, as will the overall utility of the data representation and recording capability of the monitor.
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Great Ormond Street Hospital for Children NHS Trust ranks amongst the most prestigious paediatric medical institutions in the world, and was the first hospital in the world to clinically use the new Medtronic pediatric oxygenation system. At least 8 out of every 1000 babies born each year have a heart defect. Approximately half of these babies have a minor defect and will not need any treatment but the rest need medical treatment or surgery. The majority of congenital heart defects are detected at birth. Symptoms of congenital heart defects can include rapid or difficult breathing; fatigue (tiredness); cyanosis (a bluish tint to the skin, lips, and fingernails); poor feeding and poor blood circulation.

This presentation is an overview of one year’s clinical experience in routine use of the Affinity Pixie™ Oxygenation System as a part of the standard treatment protocol at Great Ormond Street. Topics will include a discussion concerning the ranges of perfusion and patient management from neonate to large children. Clinical parameters typically measured including pressure drop, gas transfer, temperatures, flow rate and patient demographics will be presented and discussed. The discussion of different protocols for fluid management as well as the use of the Gampt Bubble Detection system in routine cases will also be presented. Case examples of gaseous microembolic load are presented and discussed, as will the positioning of the heart lung machine, set up, prime, and use in ECC per the standard institutional protocol for ECC, as well as any institutional advantages regarding the implementation of the system into routine clinical use.
ECLS with CARDIOHELP: First Experience

Objectives:
In the last decade we saw a lot of improvements in the ECMO components, but often a patient have to be transported. So there is still a need for smaller, lighter, safer and reliable systems.

Methods:
Maquet launched the smallest Heart-lung machine in 2010, suitable for use in ICU, Cardiology cath. lab, Transport and OR. It’s a complete pump with all the features which you need to do an Extracorporeal circulation. It has continuously integrated pressure- and temperature measurements, safety features (bubble, level sensor and backflow prevention) and it is small and light. With a plasma resistant oxygenator with integrated pump makes the device tremendously compact. The oxygenator is build in a reinforced housing, which make them suitable for long-term use up to 30 day’s legally.

Results:
Our first two patients who suffered both from lung failure showed that the system was reliable, easy in use and comfortable to work with. The benefit which we saw on these cases where the continuously measurement of saturation of the venous blood. One of the patients we had to transport to the CT scan, the bottle of oxygen wasn’t totally open. This was creating a lack of oxygen. The Cardiohelp was alarming us that something was wrong. The saturation falls down under the 65%. We resolve this problem in an early phase.

Conclusion:
The Cardiohelp is a new device for already proven therapy ECLS, but with new challenges in and outside the OR/ICU to save more lives.
What if there was a smart VAD System to support the heart for up to 30 days, offering clinicians precise information about pre and afterload and all essential blood parameters to eliminate guesswork and to improve patient safety?

Thanks to MAQUET’s commitment to providing innovative technologies for operating rooms and intensive care units worldwide, this is no longer a concept of the future. For more information about the new ROTASSIST VAD, please visit the MAQUET Booth.

16:40-17:00 Eurosets Medical Devices Sponsored Session

Speaker: Seanne Azzolina, MS ECCP, Perfusionist
Affiliation: Department of CV Surgery Maria Beatrice Hospital, Firenze Italy
E-mail: sazzolina@gvm-vmb.it

Multicenter Study on a new Extracorporeal Vacuum-Assisted Device to Optimize Cardiopulmonary Bypass
Seanne Azzolina, MS ECCP*, Antonio Petralia, MS ECCP**, Andrea Cavallucci, CCP**, Claudio Costantini, MD***, Giuseppe Speziale, MD***, Mauro Lamarra, MD** *The Department of Cardiovascular Surgery Maria Beatrice Hospital, Firenze Italy** The Department of Cardiovascular Surgery Maria Cecilia Hospital, Cotignola (RA) Italy*** The Department of Cardiovascular Surgery Anthea Hospital, Bari ItalyGVM Care & Research

Background: Cardiopulmonary bypass (CPB) is still necessary for many surgical procedures, although we know it has serious physiological effects on most organ systems of the body. Deleterious effects of CPB such as cell activation on contact with foreign surfaces, mechanical injury to red blood cells and hemodilution can be reduced by optimizing conventional CPB. We evaluated a versatile system known as Extracorporeal Vacuum-Assisted Device (EVADO) based also on the elimination of roller pumps used for blood suction during CPB.

Methods: We randomized 261 patients undergoing a variety of cardiac operations to either EVADO or conventional CPB. Intraoperative hemolysis levels were assessed (free hemoglobin (FHb), and Haptoglobin (HPT)). Postoperative blood loss, hemoglobin levels and need for blood transfusions were also assessed.

Results: In all patients randomized to EVADO, surgery could be easily completed without conversion to conventional CPB. The use of EVADO significantly reduced the intraoperative hemolysis (lesser increase in FHb levels, p<0.0001 vs. control, and lesser decrease in HPT levels, p=0.01 vs. control). Among patients undergoing surgery with EVADO, we observed a reduced postoperative total bleeding (p=0.011 vs. control), and reduced need for transfusions of blood products (p=0.009 vs. control). Hemoglobin levels were higher in the EVADO group at all timepoints during both CPB and the ICU stay, although not statistically significant.

Conclusions: All cardiac procedures (coronary, valvular, thoracic aortic or combined) could be completed using EVADO. Compared with a conventional system, the application of EVADO was associated with a reduction in hemolysis, less hemodilution and blood loss, and fewer transfusion requirements. However, we could not demonstrate a clinical advantage in terms of perioperative mortality/morbidity rates. Further studies with larger sample size are required to this issue.
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