BEST PRACTICES IN PERFUSION, 2007

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Micael Appelblad, SWESECT 2008
OUTLINE

- Introduction: Evidence-based Perfusion !?
- International Consortium for Evidence-based Perfusion (ICEBP)
  - Organisation
  - Mission
- Best Practices in Perfusion 2007, Montreal
- Future?!
PERFUSION
KNOWLEDGE

Experience  Evidence
OBJECTIVE: Evidence-based medicine is emerging as a new paradigm for medical practice. The purpose of this study was to evaluate the amount and quality of scientific evidence supporting principles that are currently applied for cardiopulmonary bypass performance.

METHODS: A survey of all German departments of cardiac surgery regarding cardiopulmonary bypass performance disclosed major differences. Consequently, for 48 major principles of cardiopulmonary bypass performance, relevant Medical Subject Headings were identified, and a literature search of the Medline database was performed. Two sequentially applied sets of inclusion criteria were selected to assess the best available evidence. RESULTS: Thirty-three thousand articles relating to the subject were identified. Among these, 1500 fulfilled the first set of inclusion criteria: meta-analysis of (randomized) controlled clinical trials and in vitro and animal studies. Rigorous methodological criteria were then applied to further select remaining publications. Ultimately, 225 articles referring to major cardiopulmonary bypass principles were identified as providing the best available evidence. These were graded according to their methodological rigor (susceptibility to bias). The scientific evidence on the investigated cardiopulmonary bypass principles did not prove to be of a high enough level to allow general recommendations to be made. CONCLUSIONS: The scientific data concerning the effectiveness and safety of key principles of cardiopulmonary bypass are insufficient in both amount and quality of scientific evidence to serve as a basis for practical, evidence-based guidelines.
EVIDENCE-BASED MEDICINE

- Articles containing CPB

Guidelines:
- American Heart Association (AHA)
- American College of Cardiology (ACC)

Guidelines:
- Cochrane Collaborative
  http://www.cochrane.org

✓ Few guidelines addressing conduct of CPB, per se
## Table 1 – Classification of the procedures

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
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<tbody>
<tr>
<td>Class I</td>
<td>Conditions for which conclusive evidence exists, or in its absence, general consensus that the procedure is useful or effective, or both.</td>
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<tr>
<td>Class II</td>
<td>Conditions for which conflicting evidence or divergence of opinion, or both, exists in regard to usefulness/efficacy of the procedure.</td>
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<tr>
<td>Class IIA</td>
<td>Weight or evidence/opinion favoring usefulness/efficacy.</td>
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<tr>
<td>Class IIB</td>
<td>Usefulness/efficacy less well-established by evidence or opinion.</td>
</tr>
<tr>
<td>Class III</td>
<td>Conditions for which evidence or consensus, or both, exists that the procedure is not useful/efficient, and, in some cases, it may even be noxious.</td>
</tr>
</tbody>
</table>

Adapted from the criteria used in the guidelines of the American College of Cardiology/American Heart Association.
Levels of evidence

**Level I:** At least one properly conducted randomized controlled trial, systematic review, or meta-analysis

**Level II:** Other comparison trials, non-randomized, cohort, case-control, or epidemiologic studies, and preferably more than one study

**Level III:** Expert opinion or consensus statements
INTERNATIONAL CONSORTIUM FOR EVIDENCE-BASED PERFUSION (ICEBP)

Homepage:
http://www.bestpracticeperfusion.org
http://www.icebp.org
The International Consortium for Evidence-Based Perfusion (ICEBP) improve continuously the delivery of care and outcomes for our patients.

**Vision of the ICEBP**
- Evaluate current practice through a dedicated international perfusion registry.
- Develop and publish evidence based guidelines, and support their integration into clinical practice.
- Identify gaps in the medical literature and empower clinical teams to conduct research in areas where evidence is lacking.
- Identify gaps between current and evidence-based clinical practice to promote the improvement in patient care.
MISSION
ICEBP Committees:

Steering committee [Robert Baker, Timothy Dickinson, Donald Likosky, Kenneth Shann]

Adult process improvement subcommittee

Clinically based registry subcommittee

Communication subcommittee

Educational subcommittee

Evidence-based guideline writing subcommittee

Research development subcommittee

Scientific sessions subcommittee
MEMBER ORGANISATIONS

MEMBER ORGANIZATIONS
Home > Member Organizations

ICCEP collaborating and sponsoring organizations:

<table>
<thead>
<tr>
<th>Organization Name</th>
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<tbody>
<tr>
<td>Australian and New Zealand College of Perfusion</td>
</tr>
<tr>
<td>Honda (USA) Perfusion Society</td>
</tr>
<tr>
<td>German Society of Cardiovascular Engineering</td>
</tr>
<tr>
<td>Japan Society of Extracorporeal Technology in Medicine</td>
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<tr>
<td>Minnesota Perfusion Society</td>
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<tr>
<td>Dutch Society for Extracorporeal Circulation</td>
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<tr>
<td>Spanish Association of Perfusionists</td>
</tr>
<tr>
<td>The American Academy of Cardiovascular Perfusion</td>
</tr>
<tr>
<td>The American Society of ExtraCorporeal Technology</td>
</tr>
<tr>
<td>The Canadian Society of Clinical Perfusion</td>
</tr>
<tr>
<td>The European Board of Cardiovascular Perfusion</td>
</tr>
<tr>
<td>The Society of Clinical Perfusion Scientists of Great Britain and Ireland</td>
</tr>
<tr>
<td>The Turkish Society of Perfusionists</td>
</tr>
</tbody>
</table>
BEST PRACTICES MEETING
"TOOL BOX"

REGISTRIES & PUBLIC REPORTING

GUIDELINES
[EBM-Based]

FREE PAPERS

DATA MANAGEMENT
Electronic records
Networks
Databases

QUALITY IMPROVEMENT
Projects
Tools

INTERNATIONAL SYMPOSIUM

PATIENT MONITORING

RISK MANAGEMENT

Micael Appelblad, SWESECT 2008
An evidence-based review of the practice of cardiopulmonary bypass in adults: A focus on neurologic injury, glycemic control, hemodilution, and the inflammatory response

Kenneth W.isher, L.D.R.1, Uteard S. Landab, M.D.1, John W. Martin, M.D.2, Robert A. Jakow, M.D.2, Steven A. Linder, M.D.1, Trevor A. Clements, M.D.1, Anthony J. Daniels, M.D.1, William R. Keenan, M.D.3, Gerald T. O’Halleran, M.D.3, Donald J. Roselli, C.D.B.1, Mark W. Slick, M.D.4, and Trevor W. Wilcox, C.D.B.1

Cardiopulmonary bypass (CPB) can be used during cardiac surgery to oxygenate and dispose of venous blood that has been diverted from the heart and lungs. The practice of CPB has changed—markedly over time and from center to center. However, the rationale for changing—or not changing—surgical practice has been driven by the results of new studies and emerging evidence. Additional surgical techniques, new technologies, and changes in patient population have led to the development of new standards of care. The objective of this review is to identify areas where the practice of CPB has been altered and to determine whether these changes have been associated with improved outcomes.

The guidelines on CPB practice presented here are intended to serve as a general guide to assist surgical teams in improving the conduct of CPB to reduce the risk and complications associated with the procedure.

“STRATEGIC PROJECTS”

- Neurologic Protection
- Euglycemia
- Hemodilution
- Inflammatory Response

ICEBP: Shann KG, et al
J Thorac Cardiovasc Surg. 2006
NEUROLOGIC PROTECTION

- pH-management [a-stat]
- Maintenance of Euglycemia
- Avoidance of Cerebral Hyperthermia
- Aortic Assessment
- Arterial Line Filtration
- Minimizing [Avoidance of Direct] Return of Pericardial Suction Blood

ICEBP: Shann KG, et al
J Thorac Cardiovasc Surg. 2006
Fat contamination of pericardial suction blood and its influence on in vitro capillary-pore flow properties in patients undergoing routine coronary artery bypass grafting

Micael Appelblad, ECP
Bjarne Ingström, MD, PhD

Objectives: Neurologic dysfunction after cardiopulmonary bypass might be due to arterial microembolism. Pericardial suction blood is a possible source of embolic material. Our aim was to determine the capillary-pore flow ability of pericardial suction blood.

Methods: Pericardial suction blood from patients undergoing coronary bypass was collected, and pericardial suction blood and venous blood were sampled at the end of cardiopulmonary bypass and before reinfusion of pericardial suction blood. Pericardial suction blood was (n = 10) or was not (n = 10) perfltered through a 30-μm cartridge screen filter before capillary in vitro analysis. Additionally, in 8 patients the plasma viscosity was measured, and in 3 of these patients, pericardial suction blood capillary deposits were evaluated by using a microscopy-imprint method and fat staining. Capillary flow was tested through 5-μm pore membranes. Tested components were plasma, plasma-eliminated whole-blood reperfusion, and leukocyte-plasma-eliminated erythrocyte reperfusion. Initial filtration rate and plugging slope expressed the blood-to-capillary interaction.

Results: The plasma-flow profile of pericardial suction blood was highly impaired, with a 47% reduction in initial filtration rate (P < .001) and a 142% increase in plugging slope flow deceleration (P < .01). This difference was not due to a change in pericardial suction blood viscosity, such as by free hemoglobin, which corresponded to 3.7% of the erythrocytes. There were no differences in reperfused whole blood or erythrocytes. The cardiotomy filter had no effect. Microscopy suggested the presence of capillary fat deposits in pericardial suction blood that were not seen with venous plasma (P < .05). The pericardial suction blood volume was 458 ± 42 mL and contained 95.6 ± 9.3 g/kg hemoglobin.

Conclusions: The pericardial suction blood plasma capillary flow function was highly impaired by lipid fat. Pericardial suction blood hemoglobin appears worth recovering after fat removal, despite prolonged hemolysis.

The clinical spectrum of neurologic disorders after cardiac operations varies from minor stroke to diffuse symptoms detected in sensitive psychometric tests. This brain damage has several possible causes. General effects of low blood pressure and cardiopulmonary bypass (CPB) with systemic inflammatory response are plausible, but in addition, embolic mechanisms are commonly suspected. These embolic sources might either be air bubbles or particulate matter. They might also be described in terms of microembolism and macroembolism, which can be the result of detached particles from a calcified ascending aorta or plastic or silicone material generated from the CPB circuit. These particles enter the aorta through the arterial line. Recently, the pericardial suction blood (PSB) has been suggested as a source of fat-related deposits in the brain capillaries of animals and human
Continuous Quality Improvement

**DMAIC**

- Define the project purpose
- Measure the process
- Analyze and determine the root cause(s)
- Improve the processes
- Control future process performance

Micael Appelblad, SWEESECT 2008
Understanding Variation in Cardiopulmonary Bypass: Statistical Process Control Theory

Robert Groom, CCP, Donald S. Likosky, PhD, Hans Ruttberg, MD, PhD

Cardiopulmonary bypass (CPB) is a complex clinical process that takes place within an extremely complex care delivery system. During the past 50 years, many technical and device-related improvements have been implemented. However, there remains enormous opportunity to improve. As has been shown in other industries, understanding variation is the key to improvement of any process, and Statistical Process Control Theory (SPCT) is a powerful method for studying variation. SPCT was first described and used by Walter Shewhart in the 1920s to improve telephone component production at Bell Laboratories (1). Shewhart’s hypothesis was that production quality improves when front-line workers are informed and empowered with information necessary for that improvement. He invented control charts as a method for transforming data concerning variation into understandable information. With the application of this theory in the form of control charts, Shewhart provided production workers with a deeper understanding of the variation in their production system. Control charts distinguish random variation that exists in a system from variation that has a specific cause. Shewhart noted, “While every process displays variation, some processes display controlled variation whereas others display uncontrolled variation.” He called the former “common cause” and the latter “assignable cause.” Whereas today these types of variation are referred to as “common-cause” and “special-cause” variation, respectively. Common-cause variation requires no immediate action or intervention whereas special-cause variation should be studied and perhaps acted upon. Acting on common-cause variation is wasted effort and, in many cases, may worsen circumstances because these actions often lead to making a process less stable than it was formerly. Shewhart referred to acting on common cause variation as “tampering” and considered it counterproductive (2). Stable processes are desirable because their outcomes are predictable in their content and quality. Armed with this...
STATISTICAL CONTROLLED
RUN CHARTS

Control Chart

UCL = 7.031

\( \bar{x} = 4.371 \)

LCL = 1.711

Chart by OmniLingua Inc

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CQI: EVALUATION OF RUN CHARTS

Micael Appelblad, SWESECT 2008

Minimum pCO₂

Baker R, Montreal 2007

Micael Appelblad, SWESECT 2008
CQI; SIX SIGMA
PRINCIPLE

1 Million Procedures - 3.4 adverse events

\[ f(x) = \frac{1}{\sigma \sqrt{2\pi}} e^{-\frac{x^2}{2\sigma^2}} \]
CLINICAL MICROSYSTEM

CQI: EVALUATION OF THE MICROCIRCUIT OUTCOME
CLINICAL MICROSYSTEM

Micael Appelblad, SWESECT 2008
STROBEh: Strategies To Reduce the Occurrence of Brain Embolisation and hypoperfusion


Groom RC, Montreal 2007
Northern New England Cardiovascular Disease Study Group
DATA MANAGEMENT

Micael Appelblad, SWEESECT 2008
EXHIBITION

http://www.ctsnet.org/terumo/product/879

PATIENT MONITORING
FORE-SIGHT®

http://www.casmedical.com/FORE-SIGHT.html

Micael Appelblad, SWESECT 2008

FUTURE

✓ SCANSECT Membership ICEBP!
✓ Interactive Membership!
✓ Export data to ICEBP Database.
✓ Guidelines/Recommendations, CPB
✓ Joint research?
✓ Education?
TACK FÖR UPPMÄRKSAMHETEN!

Micael Appelblad, SWESECT 2008