Strategic-Directed Perfusion: Current status

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Disclosures
• No Relevant Financial Disclosures for this presentation

Objectives
• Review and share an understanding of patient and goal directed perfusion
• Share current literature and practice
• Synthesize a draft “evidence based recommendation” for clinical practice

Flipped Classroom 2019
• Key elements “Goal Directed Therapy Symposium”
  • Rivers
    • Genesis of goal directed therapy and benefits of a systematic approach to the detection and resolution of tissue hypoxia
  • Groom
    • Shared Ranucci’s 2005 work: low DO₂ associated with AKI
    • Desomer’s 2011 work: supported low DO₂ associated with AKI reported DO₂/VCO₂ ratio associated with AKI
  • Justison
    • GDP is about enhancing our current knowledge of adequate perfusion and using respiratory-based parameters to give us a whole new level of detail of what’s happening to the patient on a tissue level.”
The terminology of perfusion adequacy

### Conventional CPI Terms
- $\text{SvO}_2 > 60-70\%$
- $\text{PvO}_2 > 40 \text{ mm Hg}$
- pH: 7.35–7.45
- pCO$_2$: 32–42 mm Hg
- Cardiac index: 2.2–2.6 l/min/m$^2$
- Lactate < 2.0 mmol/l

### GDP Terms
- Oxygen delivery index (DO$_2i$)
- Oxygen consumption index (VO$_2$)
- Carbon dioxide production index (VCO$_2$)
- DO$_2i$/VO$_2$
- VCO$_2$/VO$_2$

### GIFT Trial
- Prospective RCT, 10 centres
- Adult CPB, >90 minutes
- 1° Endpoint: development of any postoperative AKI
- Measured parameters of DO$_2$ and VCO$_2$

### Flipped Classroom 2019
- **Justison**
  - Amount of time “cumulative effect” of low DO$_2$ and a low DO$_2$/VCO$_2$ ratio
- **Baker**
  - Focused on how we measure and report these and other parameters of perfusion
  - $\text{DO}_2i = \text{Flow} \times \left( \frac{\text{Hct}}{2.94} \times 1.36 \times \text{SaO}_2 \right) + \text{PaO}_2 \times 0.003 \times \frac{10}{\text{BSA}}$

### Primary outcome significantly less AKI and any AKI in GDP

<table>
<thead>
<tr>
<th>Outcome</th>
<th>GDP arm (n = 156)</th>
<th>Control arm (n = 156)</th>
<th>RR or difference (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td>10 (6.4)</td>
<td>10 (6.4)</td>
<td>1.00 (0.48–2.10)</td>
<td>0.99</td>
</tr>
<tr>
<td>AKI stage 1</td>
<td>4 (2.5)</td>
<td>5 (3.2)</td>
<td>0.80 (0.24–2.93)</td>
<td>0.65</td>
</tr>
<tr>
<td>Any AKI</td>
<td>4 (2.5)</td>
<td>5 (3.2)</td>
<td>0.80 (0.24–2.93)</td>
<td>0.65</td>
</tr>
<tr>
<td>Mortality</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1.00 (0.00–6.82)</td>
<td>1.00</td>
</tr>
<tr>
<td>Major morbidity</td>
<td>13 (8.3)</td>
<td>16 (10.3)</td>
<td>0.77 (0.29–2.03)</td>
<td>0.62</td>
</tr>
</tbody>
</table>

GDP: N=156, AUD: N=156. AKI: Defined as stage 1 or higher. CI: Confidence Interval. Open: indicates no significant difference between the intervention and control arms.
Central Message
A goal-directed perfusion strategy aimed at preserving oxygen delivery during cardiopulmonary bypass is effective in reducing AKIN class 1 postoperative acute kidney injury.

Where are we now?
Do we provide adequate perfusion?
Results in wide variation in practice
Part way there

- Goal directed therapy is designed as a strategy to manage patients by individualising perfusion management to the patient
  - Rigorous monitoring
  - Responsiveness to monitoring
  - "The strategy is based on continuous monitoring of cardiac index, $SvO_{2}$, $DO_{2i}$, $DO_{2i}/VCO_{2i}$, $rSO_{2}$" Kyrakos Anastasiadis Perfusion 2017
  - More "physiologic bypass", patient focussed, rather than optimal
    - Measurement: lactate, pressure, flow, oxygen delivery
    - Blood management
    - Circuit build

Are we ready for an evidence based statement?

- Are we ready for an evidence based statement?  
  GIFT Trial 2018
  Newland and Baker 2011
  DeSomer et al 2011
  Ranucci et al 2005
  ANZCPR 2019
  Magruder et al 2017
  Magruder et al 2016
  Magruder et al 2015

...
Increased time with a DO\textsubscript{2i} below 270 ml/min/m\textsuperscript{2} was an independent predictor of AKI with OR 2.74 (1.01-7.41).

Results support the relationship between oxygen delivery and AKI, if the amount of time below threshold is greater than above (i.e., AUC is negative), then more likely to get AKI.

Evidence
Conclusion: Our results confirm previous findings that oxygen delivery during CPB is independently associated with AKI and that a minimum threshold for DO$_2$ during CPB of 270 ml/min/m$^2$ can be reasonably considered.

What about VCO$_2$?

- De Somer 2011
What about VCO₂?

- DeSomer 2011, supported up by Justison (2017, non peer reviewed data)
- Not enough evidence at this time for DO₂/VCO₂ ratio
- Challenge:
  - Measuring exhaust CO₂ reliably
  - Prospective studies

Conclude: Draft statement?

- For low - moderate risk patients undergoing cardiac surgery with CPB, avoidance of NADIR DO₂ below 280 ml/min/m² is recommended. (Class 1 Level of Evidence: B)
Thankyou
Challenges to Adopting a Goal Directed Perfusion Paradigm

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Disclosures

No financial disclosures to report.

Challenges to Adoption

- The perception of GDP
- How we monitor GDP
- Changes to clinical practice
- Data Collection and Review
Adequacy of Perfusion Parameters

- Venous saturation
- pH
- pO₂
- Serum Lactate
- pVO₂
- Cardiac Index
- NIRS

“The ultimate aim of perfusionists is to provide satisfactory tissue gas exchange”

Oxygen Delivery and Acute Kidney Injury

How We Monitor GDP

- Technology Used
- Formulas - How we calculate GDP
- Variations in measurements

Technology - Electronic Medical Records / Inline Monitoring

- LivaNova CONNECT
- Spectrum Medical Quantum
- Terumo CDI 550
- EpicCare EMR
What target $DO_2$ value?

- $> 262 \text{ mL/min/m}^2$
  - de Somer et al.
  - Critical Care 2011,15:R192
- $> 270 \text{ mL/min/m}^2$
  - Ranucci et al.
- $> 280 \text{ mL/min/m}^2$
  - GIFT Trial.
  - J Thorac Cardiovasc Surg 2018

Potential Changes in Practice - Flow

- Flow rates
  - Based on $DO_2$ and not just protocolized index
  - Higher cardiac indices $> 2.6 \text{ L/min/m}^2$
- Cannula size and placement
  - Minimally invasive surgery
- Position of heart
- Increased use of VAVD

How Do We Calculate GDP?

- Formula variation
  - LivaNova CONNECT
    - $DO_2_{\text{Flow}} = (12.34 \times 0.136 \times \text{SaO}_2 - \text{PaO}_2 \times 0.000) / 10$
  - Spectrum M4 formula
    - $DO_2_{\text{M4}} = 10 \times \text{Hb} \times 1.34 \times (\text{SaO}_2 / 100)$
- Pump Flow
  - Number of shunts in use
  - Flow probe distal to all shunts
  - Guideline 7.6
    - Attempt should be made to maintain continuity of flow probes in the CPB circuit where possible to reflect the flow delivered to the patient during CPB, any changes in flow should be noted
- Point of Care Devices / trending devices
  - Hg/HCT accuracy (Conductivity, co-oximetry)
  - Trending devices calculating $DO_2$

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Potential Changes in Practice - Hgb/HCT

The Big Picture - Cellular Respiration and GDP

Oxygen delivery during cardiopulmonary bypass (and renal outcome) using two systems of extracorporeal circulation: a retrospective review

Potential Changes in Practice - Hgb/HCT

Potential Changes in Practice - Hgb/HCT
**GDP - Determinants of Cellular Respiration**

**Anaerobic Metabolism During Cardiopulmonary Bypass: Predictive Value of Carbon Dioxide Derived Parameters**

Data Collection and Reporting

- Data collection tools
  - Spreadsheets
  - EMR reporting
  - Registry reporting
- Returning data back to key stakeholders
  - Dashboards
  - Quality Assurance
  - PDSA Cycles
  - Quality Improvement

**Summary**

- Incorporating ‘Strategic-Directed’ Perfusion parameters is not an insurmountable goal.
- Leveraging the published literature and professional guidelines can assist teams in designing these goals.
- Multidisciplinary QA/QI projects can assess overall effectiveness.
How to run a PDSA QI change project?

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Associate Professor of Cardiac Surgery
University of Michigan

Disclosures
• Director of the PERForm Registry
• Serve as consultant to AmSECT

Goals
• Discuss distinctions between quality assurance vs. quality improvement
• Discuss quality improvement approaches for addressing goal-directed perfusion

Goal is to make quality improvement practical; not an academic exercise
Quality Assurance vs. Quality Improvement

Quality Assurance Measures
• Ventilator associated pneumonia rates per 1,000 ventilator days
• Percent of AMI patients receiving prescriptions for beta-blockers at discharge
• Percent of diabetics with annual foot exam
• Percent of patients developing stroke after CABG

Tools for Quality Assurance
CABG Surgery Measures
• IMA use
• Beta blocker use
• Prolonged intubation
• Postop renal failure
• Etc.
Tools for Quality Assurance

Perfusion Measures?

How do you measure the health of your perfusion program?

Quality Improvement

“Systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care”

PMID: 16898359

Quality Improvement

Goal-Directed Perfusion

All of you already have experience with QI
Questions we need to answer

1) What problem are we trying to solve?

Problem 1: My patients seem to develop higher creatinine bumps than my colleagues.
• Does increasing my flow to manage DO2 > 272 mL/min/m² contribute to lower AKI rates?

Problem 2: Our team seems to manage patients very differently on bypass. Perhaps that’s why we have a lot of acute kidney injury.
• Does adherence to a goal-directed perfusion protocol contribute to lower AKI rates?

Just like a research project, we need to be clear about what we are trying to solve.

2) What approach do we take?

• For Question 1: Does increasing my flow to manage DO2 > 272 mL/min/m² contribute to lower AKI rates?
  • Single perfusionist study
  • Use of a q5 or q10 min written record will likely be inadequate

• For Question 2: Does adherence to a goal-directed perfusion protocol contribute to lower AKI rates?
  • Could be a single perfusionist or program study
  • Need to specify what is in your protocol (AmSECT’s Standard 1)

The method “Do” is not uniform, but dictated by the question you are asking.
3) Who is on your team to help make necessary practice changes?

For both study questions:
• Who would be impacted by changes in this practice?
• Someone to convene your team.
• Someone to take time to develop new protocols, address unanticipated issues (e.g., personnel, structure).
• Database manager to provide you with updated datasets for your team meetings.
• Someone to support displaying your data for your team meetings.

The activities “Study” may not be uniform, but are invariably multi-disciplinary (like the OR).

4) What might be our future needs?

• Much like your own practice, QI cycles are never ending
• More “real-time” measurement will be needed to evaluate Do2
• Goal is to hardwire the simple things into your practice
  • Allows you to focus on “bigger ticket” problems

We should always anticipate needing next steps, the “Act”. Often times; however, findings from our PDSA cycle(s) take us in a different direction than we anticipated.

AmSECT Resources
Objectives

- Strategic Directed Perfusion
- Adopting change in a large center
  - Maintenance of Hematocrit
  - Target MAP
  - Prescriptive Oxygenation
  - Volume Maintenance
  - Circuit Management
  - DO2 measurement
  - Data Mining

Montefiore System
Montefiore Doing More

- Large Academic Center
- Three Campus system: 1565 beds
- Two CT surgery programs
- Multiple outpatient surgery centers
- Multiple Hospital Acute Care Facilities
- Competitive NYC Market

Cardiovascular Perfusion Department

- 15 Staff members
- Multidisciplinary Team
- ECMO 21,283.5 hours in 2018
- 96 ECMO patients
PROGRAM CONSIDERATIONS

- 1300 procedures annually
- 4 day work week
- 5 staff members on call each day
- The need for contact hours with staff in the OR to have a goal directed program

Electronic Charting

- Sorin Data Management System (DMS) 2010 through 2015
- Sorin Connect Upgrade
- Montefiore moved to epic 2015
- Anesthesia Hybrid Perfusion module 2019

Data Collection

- NYS
- STS
- PERForm
- Perfusion Staff/PA service enter all data

Protocol driven CPB

- Standard Circuit setup
- Standard operating procedure
- Volume expander use
Hemodilution

- Six different Circuits
- Post dilution calculations: initial room air blood gas
- Volume status awareness: limiting volume given during induction prior to CPB initiation
- Transfusion trigger 23%
- RAP/ VAP as tolerated
- ANH when appropriate
- Hemoconcentration is employed for each case
CPB Protocol

- Maintain a BP of 70 - 80
- @800ug of neo its required that we have a conversation with anesthesia to determine best methods for BP maintenance
- Flows are calculated using 2.4 index
- DO2 is not measured/guideline to determine best DO2 delivery

MAP Maintenance

Improvement of outcome after coronary artery bypass. A randomized trial comparing intraoperative high versus low mean arterial pressure.  

Adult DO2 Worksheet
Quality Control

- Chart audits to ensure proper documentation
- Rounding while on CPB
- 2.0 perfusionist per case 1.5 if all ORs are being used
- PERForm/STS/NYS
- Individual Perfusion reports

PERForm

PERForm Fall Report 2018

Volume Management

Hemodilution

Last 200 Isolated CAB Operative Hematocrits
Summary Report

Process Indicators

Summary

- Challenging being in two different places with a large team it means identifying leaders in the department that can help manage systems and maintain protocol adherence
- Leverage of our IT support group
- 3 year, 5 year, 10 year plan for improvements
- Delegation is key to stay on top of ongoing issues
- Critical conversations to stay on course
- Annual reviews, Chart reviews, Data requests

Panel discussion to Follow

- Thank you
Disclosures

- No financial disclosures

Objectives

- Our story
- Decision process of using GDP
- Implementation
- Early results
Gainesville, Florida 83 & Sunny

HCA / NFRMC
- 489 Bed “Community Hospital”
- 2016 – 223 cases
- 2017 – 547 cases
- 2018 – 732 cases (5 ECMO)
- 2019 – YTD 137 cases (5 ECMO)
- 3 Cardiothoracic Surgeons
- 4 Perfusionist
- Case Mix Index – 2.5 fold

“HYBRID CENTER”
- Complexity changed
  - From CABG and CABG/Single VALVE
  - Multi-valve
  - Complex aortic repair
  - Minimally invasive procedures
  - Percutaneous – TAVR / TMVR / Mitral Clip
  - VADs (3Q 2019)

STS – ACSD : Adult Cardiac Surgery Database
- Case Mix Index - Risk Adjustment for:
  - Operative mortality
  - Stroke
  - Renal failure
  - Prolonged ventilation
  - Sternal wound infection
  - Reoperation
  - Major morbidity or mortality composite
  - Prolonged postoperative length of stay
Opportunities

Change in practice
- Desires of hospital administrators
- Desires of “new-old” surgeon
- Competitive opportunities
- Goal: Best in class/area

Prescription
- Organizations that have achieved
  - Higher-quality care
  - More patient-focused
  - Lower-cost care
- Leadership = alignment between Physicians and Administrators
- Driving force – financial incentives
- Data driven transformations

Needs
- Why do we care?
- “Continuous” Quality Program
  - Standardize perfusion practice
  - Reduction in blood usage
- What else?
  - PERForm
  - STS
  - RLP

Patient specific strategies
- Patient specific anticoagulation
  - Medtronic HMS Plus
- Patient specific hemostasis
  - Haemonetics TEG 6s
- Patient specific OXYGENATION
Our Challenges

- Clinician “buy in”
- Adaptability of clinical staff
- Cost
- Concomitant use of EMR
  - Liva Nova CONNECT™
- Legal concerns

Are we doing enough?

2.4 CI flow = 4.8 LPM

<table>
<thead>
<tr>
<th>Height</th>
<th>Weight</th>
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<tbody>
<tr>
<td>163 cm</td>
<td>90.1 kg</td>
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<tr>
<td>185 cm</td>
<td>77.8 kg</td>
</tr>
<tr>
<td>155 cm</td>
<td>94.9 kg</td>
</tr>
</tbody>
</table>

2.02 m²

Early Results

Changes in practice

- AKI – no change; Already low incidence
- Other:
  - Practice standardization
  - Data mining opportunities
  - Quality initiatives
  - Team enthusiasm
Data mining

Strategic Goal Maintenance

KEYS TO SUCCESS

- Data collection
  - Perfusion staff
  - EMR – accurate data feed

- Data management
  - Perfusion director – scrub data / intra-op data validation
  - CV abstractors – non bypass data validation

- Quality Improvement
  - Creation of dashboards & individualized performance review
  - Physician lead / multidisciplinary M&Ms

NFRMC Time line
Summary

- Physician Buy In
- Change in Practices
- Data Collection
- Quality & Outcomes Review Forum
- Return on Investment

Thank you

Grateful for the opportunity to learn more and do more.