Monitoring Microemboli during Cardiopulmonary Bypass with the EDAC® QUANTIFIER

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Study Objectives

1) Monitor gaseous microemboli (GME) during CPB and determine which of the following influence GME activity post arterial filter:
   - Circuit design
   - Surgeon
   - Perfusionist
   - Type of procedure (CABG vs. valve repair)

2) Review case data to assess which events are most associated with increase GME activity
Study Methods

1) 20 cases monitored, with three EDAC channels placed on the venous input line, post venous reservoir, and post arterial filter:
   • 2 circuits (10 Circuit “A” and 10 Circuit “B”)
   • 3 perfusionists (11 “A”, 7 “B” and 2 “C”)
   • 5 surgeons (9 “A”, 8 “B”, 1 “C”, 1 “D” and 1 “K”)
   • 10 CABG, 4 CABG/AVR, 4 AVR, 1 MVR, 1 REDO
   • Perfusionists, surgeons, circuits and cases were assigned to evenly divide values between groups

2) General linear statistical models used to assess each relationship of each effect on GME counts

3) Surgical events recorded on EDAC using event annotation feature and case data reviewed to determine which surgical events were responsible for increased counts

1 Circuit A: Oxygenator - Sorin Primox with hardshell reservoir, Arterial Filter - Sentry 21 micron purged to cardiotomy reservoir (intermittently), Cardioplegia - Terumo MP4, Entire circuit except cardioplegia - Smart Coating, Prebypass filtration - 5.0 microns

Circuit B: Oxygenator - Capiox SX25 with hardshell reservoir, Arterial Filter - Capiox 37 micron purged to the venous line (intermittently), Cardioplegia - Terumo MP4, Entire circuit X coating, Prebypass filtration - 0.5 microns
Results: Case Overview

Max Counts Post Filter = 13348

Min Counts Post Filter = 138

Mean = 4191

Std Deviation = 3872
Valve replacements produced a statistically significant increase in emboli counts at 2 of 3 monitoring sites over CABG cases.

<table>
<thead>
<tr>
<th>Site</th>
<th>Valve</th>
<th>CABG</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venous</td>
<td>279,398</td>
<td>54,974</td>
<td>0.03</td>
</tr>
<tr>
<td>Post VR</td>
<td>312,284</td>
<td>84,128</td>
<td>0.05</td>
</tr>
<tr>
<td>Post ALF</td>
<td>5,510</td>
<td>2,212</td>
<td>0.06</td>
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</tbody>
</table>
There was no significant difference in counts between the two circuit types, the two primary perfusionists or the two primary surgeons.¹

<table>
<thead>
<tr>
<th>Variable</th>
<th>A</th>
<th>B</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circuit post filter mean</td>
<td>4050</td>
<td>4332</td>
<td>0.72</td>
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<tr>
<td>Perfusionist post filter mean</td>
<td>5626</td>
<td>2681</td>
<td>0.85</td>
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<tr>
<td>Surgeon venous input mean</td>
<td>213467</td>
<td>170953</td>
<td>0.74</td>
</tr>
</tbody>
</table>

¹ For circuit type and perfusionist analysis, statistical analysis employed a general linear model that controlled for venous line inputs.
• 55% of counts occurred between start of CPB until after cross-clamping
• 34% from start of cross clamping to removal of clamps
• 11% from removal of clamp to stop of bypass
A Comparison of Two Cases

Case 5: CABG/AVR (13348 total counts post arterial filter)

Case 17: CABG/AVR (1514 total counts post arterial filter)
Two More Cases

Case 16: AVR (10400 total counts post arterial filter)

Case 12: CABG (138 total counts post arterial filter)
Start of Bypass

Quality Assurance for Perfusion
Procedure: Venous Air

Quality Assurance for Perfusion
Procedure: Drug Sampling

Quality Assurance for Perfusion
Cross Clamp Removal
Conclusions

1) For the perfusionist, circuit and surgeons evaluated there was no significant differences in counts

2) Significant differences were seen between CABG cases and valve repairs, suggesting that more complex cases are more likely to entrain venous air into the circuit

3) Changes in the following show potential for reducing GME delivered to the patient:
   - Retrograde air flow into arterial line pre-bypass
   - Large volumes of venous air during bypass
   - Clamp removal technique