Perfusion Safety Review in Japan

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and

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Thoracic and cardiovascular surgery in Japan

Population: 127 million
Number of open heart center: 544 (97.1%)
Total number of OH Surgery: 53,741 cases

Annual report by the Japanese Association for Thoracic Surgery
Number of CPB in Japan (2006)

- **IHD**: 7,835 (18%)
- **Others**: 4,343 (10%)
- **910**: 910 (2%)
- **OPCAB**: 61%
- **11,021**: Conv.- CABG 7,124 (16%)
- **39%**: C–CABG
- **17,941**: CABG
- **61%**: OPCAB
- **15,092**: Valve
- **34%**: Conv.- CABG
- **7,386**: Congenital 7,386 (17%)
- **21%**: Vascular 9,376
- **7,835**: IHD 7,835 (18%)
- **MAZE, tumor, VAD, DCM, constrictive pericarditis, Htx, others**
Case load distribution of CPB

Average: 71 cases / hospital / year

<table>
<thead>
<tr>
<th># of Operations</th>
<th>Number of Centers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-24</td>
<td>68</td>
<td>12.5%</td>
</tr>
<tr>
<td>25-49</td>
<td>104</td>
<td>19.1%</td>
</tr>
<tr>
<td>50-99</td>
<td>164</td>
<td>30.1%</td>
</tr>
<tr>
<td>100-149</td>
<td>90</td>
<td>16.5%</td>
</tr>
<tr>
<td>150-199</td>
<td>39</td>
<td>7.2%</td>
</tr>
<tr>
<td>&gt;200</td>
<td>79</td>
<td>14.5%</td>
</tr>
</tbody>
</table>

in 2006: 544
Who is allowed to run CPB?

- Pacemaker technician*
- Bio-medical engineer
- VAD technician*
- Respiratory therapist
- Hemodialysis technician
- Clinical Perfusionist
- Clinical Engineer (Legal ground for allowing clinical related practice)

Certificates by respective Societies

Nat’l License grant by the government

*Certificate system in preparation
Who is allowed to run CPB?

A CLINICAL ENGINEER: Governmental Licensee

- A “Clinical Engineer” is the one who officially allowed to perform CPB as well as Hemodialysis, Respiratory therapy and Bio-medical engineering services.

- 21,500 persons licensed.
  - More than 85% dedicated for HD
  - Approx. 7% dedicated for CPB

- Requirements
  - 3 to 4 years education after High school education.
  - Pass national examination for permanent license.

- Limited education and training provided for CPB related subjects
Who is allowed to run CPB?
A “Certified Clinical Perfusionist”

- Certification grant from the joint board of three physicians’ societies: JSAO*, JATS*, JSCVS*.

- Requirement:
  - Licensee of “Clinical Engineer”
  - Membership of JaSECT and JSAO*
  - More than 3 years clinical experience with >30 CPB cases
  - Complete the 3 year education program (total 6 days) as a continued education seminar provided by JaSECT and JSAO*
  - Pass an examination including individual interview

- Currently 602 persons certified (1987-2007)
- Re-certification required every 5 year
  - Minimum 30 CPB cases experience within the period

JSAO: The Japanese Society for Artificial Organs
JATS; The Japanese Association for Thoracic Surgery
JSCVS; The Japanese Society for Cardiovascular Surgery
“Perfusion Safety Standard Measures”
Established by JaSECT
April 2007

Level 1: Minimum requirements <6 items>
(Crucial for safety and less barrier for implementation)

Level 2: Strong recommendations <9 items>
(Crucial, but some investment required. Expect to be in level 1 in near future)

Level 3: Moderate recommendations <9 items>
(Preferred, alternative methods can be acceptable)

Based upon consensus at the Council of Professional Perfusionists board of JaSECT
## Compliance of the standard measures

Survey data as of March 2008
Date collected from 305/454 hosp. (67.3%)

<table>
<thead>
<tr>
<th>Overall Implementation rate</th>
<th></th>
<th>(waited average)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1 (6 items)</td>
<td></td>
<td>76.5%</td>
</tr>
<tr>
<td>Level 2 (9 items)</td>
<td></td>
<td>55.5%</td>
</tr>
<tr>
<td>Level 3 (9 items)</td>
<td></td>
<td>58.0%</td>
</tr>
</tbody>
</table>
Level 1 (minimum requirements) % : Implementation rate

Cardioplegia

Vent

Suction

Venous return

Arterial

Cardioplegia / vent pump

Suction pump

Arterial pump

Reservoir

(1) Reservoir level sensor 82%

(2) Continuous pressure monitor prior to Ox. 23%

(3) Pressure monitor line prior to arterial filter 67%

(4) Flow monitor for centrifugal pump 99%

(5) Arterial line filter or bubble trap 99%

(6) Pressure monitor at cardioplegia delivery line 99%
Level 2 (strong recommendation)  
% : Implementation rate

1. SvO₂ monitor - 85%
2. Pump auto-regulation system link to reservoir low level detector - 35%
3. Bubble detector - 31%
4. Pump shutdown system link to bubble detector - 17%
5. High pressure alarm at arterial line - 80%
6. Pump shutdown system link to the high pressure alarm for roller pump - 55%
7. Arterial filter (Not bubble trap) - 79%
8. Bubble detector - 38%
9. High pressure alarm at cardioplegia delivery line - 80%

Cardioplegia / vent pump - 138%
Suction pump - 17%
Arterial pump - 80%
Reservoir - 55%
Oxy - 80%
(1) Arterial blood gas monitor 56%
(4) Pressure monitor line prior to arterial cannula 56%
(8) One way valve at filter purge line 56%
(3) Pressure monitor prior to arterial filter 47%
(9) Pump shutdown system link to high pressure alarm at CP delivery line 90%
(2) Pump flow regulation system link to high pressure alarm for centrifugal pump 15%
(6) Reverse flow prevention system for centrifugal pump 71%
(5) Low flow alarm for centrifugal pump 60%
Conclusion

- JaSECT has introduced “Perfusion Safety Standard Measures” in 2007 for “Better Practice”.
- The survey conducted one year after the introduction showed better implementation result than the past, however, it looks more time required to establish firmly among the all society members.
- Faster implementation is crucial especially for “pre-Oxy arterial line pressure monitor”, “alarm-linked pump shutdown system” and “bubble detector at the arterial line”.
- We will continue to educate our members for more higher implementation rate.