Patient Safety and the Anesthesia Gas Machine

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Acknowledgement:
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Outline

- APSF
- AGM-related problems
  - Closed Claims
  - Errors
    - Human factors and/or equipment failures
  - Absorbents
- Workstation Standards
- Machine Checkout
- New machine technology

APSF History and Mission

- No patient should be hurt by anesthesia
- Formal organization since 1984
  - Ellison ‘Jeep’ Pierce at ASA meeting
- CRNAs added to the board in the late 80’s
  - Letter on APSF letterhead re: supervision late 90’s
  - CRNAs withdrew- returned to board in 2001
- All CRNAs started receiving newsletters again in 2005

Patient Safety

- Institute of Medicine (IOM) report
  - Recognizes APSF’s leadership in the cause of patient safety
  - The Agency for Health Care Research and Quality (ARHQ) has enlisted APSF’s assistance in developing a National Center for Patient Safety
  - Current 2006 strategies
    - Adverse events requiring communication and disclosure

Is there a safety problem related to the AGM?

- Incidence of equipment-related critical events is relatively low:
  - However morbidity associated with events can be quite high
  - Human factors or errors are the leading contributors to equipment related problems
- Implication
  - Perhaps greater training with our equipment is needed

Near catastrophes and other reported/potential problems

- Failure to discover total obstruction of disposable breathing circuit (Quality Review in Anesthesia AANA Journal March April 2002)
- O₂ flowmeter ‘misconnection’ made possible by altering the oxygen-specific quick connect - N₂O (Surgery mixup causes 2 deaths. New Haven Register, January 20, 2002)
- Heliox use during laser surgery
  - O₂ flush can deliver 100%
ASA Closed Claims (1997)

- Caplan (10/1997):
  - Analysis from 1961-1994
  - 72 of 3,791 claims – 2% related to machine/delivery
  - Most Common Adverse Outcome
    - Patient Death – 47%
    - Brain Damage – 29%
  - Injury
    - Hypoxia, excessive airway pressure and agent overdose
    - In 78% of cases – it was thought that better monitoring would have prevented adverse outcomes

- Most Common Injuries
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- Key Findings
  - Payment – 76% of cases
  - Median award - $306,000
  - Range - $542 - $6.33 million

Equipment Misuse verses Failure

<table>
<thead>
<tr>
<th>Equipment Group</th>
<th>Claims Characterized by</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Misuse</td>
</tr>
<tr>
<td>Breathing circuit (n = 28)</td>
<td>26</td>
</tr>
<tr>
<td>Vaporizer (n = 15)</td>
<td>7</td>
</tr>
<tr>
<td>Ventilator (n = 12)</td>
<td>8</td>
</tr>
<tr>
<td>Supply tanks or lines (n = 8)</td>
<td>7</td>
</tr>
<tr>
<td>Anesthesia machine (n = 5)</td>
<td>2</td>
</tr>
<tr>
<td>Supplemental O₂ tubing (n = 4)</td>
<td>4</td>
</tr>
<tr>
<td>Total (n = 72)</td>
<td>54 (75%)</td>
</tr>
</tbody>
</table>

**Misuse:**
- 70% direct action primary anesthesia provider
- 30% contributory actions of ancillary personnel

ASA Closed Claims (2004)

- James Eisenkraft (2005)
  - March 2004 personal communication
  - Events are still being processed
  - Total: 6,448 claims - 95 anesthesia gas delivery equipment
  - 1990 to 2000
    - 5 deaths
    - 2 brain damage
    - 4 pneumothorax
    - 4 awareness
    - 1 cardiac arrest with full recovery
    - 3 cancellations of surgery (no actual injury)
    - 1 claim with no apparent injury
  - Payments - 79% of cases (15/19)
    - Median award - $63,250
    - All were less than $500,000

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ASA Closed Claims

- 1990-2000 Events
  - 4 breathing circuit problems
  - 4 supplemental O2 line
  - 7 machine problems
  - 3 vaporizer problems
  - 1 ventilator problem

- Good news:
  - Gas delivery problems over the decades are decreasing as a proportion of claims (3% in '70s, 2% in '80s and 1% from 1990-2000)

Report: Gas delivery problem prior to reaching the AGM

- FDA Public Health Advisory in March 2001 (Compliance)
- One example of an adverse event:
  - In October 1997, a hospital in Nebraska received a shipment of medical grade oxygen in large cryogenic vessels. The shipment included one cryogenic vessel of industrial grade argon properly labeled.
  - The hospital was running low on oxygen and sent a maintenance employee to connect an oxygen vessel to the oxygen supply system.
    - Without examining the label, the employee selected the argon vessel, and was unable to connect the vessel to the oxygen supply system. The solution?
      - This employee removed a fitting from an empty oxygen vessel, installed it on the argon vessel, and connected it to the oxygen system.
  - Argon was administered to a patient undergoing minor surgery. The patient died.

Human Factors and Errors

- When possible, design of equipment should be such that human error cannot occur:
  - e.g. keyed connections for tanks, gas lines and vaporizers

- If human error cannot be prevented:
  - Design should be prevent errors from causing injury e.g. proportioning devices that prevent >75% N2O or high pressure limit device on ventilators

- Monitors, alarms and vigilance
  - Gas Machine Check-out

Distribution of Reports by Event Type in PA (2005)

During 2005, the Patient Safety Authority collected almost 170,000 reports of adverse events and near-misses which were submitted by healthcare facilities through the Pennsylvania Patient Safety Reporting System (PA-PSRS).

Good news:
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CO₂ Absorbents

Two main problems:
- Presence of strong monovalent bases
- Desiccation or drying

These can lead to the following problems:
- Compound A
- Carbon Monoxide
- Exothermic reactions

Desiccated absorbents

How does it happen?
- The retrograde flow of fresh gas through the absorber affected by:
  - Design of the anesthesia breathing system, the presence or absence of the reservoir bag, whether the APL valve is open or closed, the relative resistance through the components of the breathing circuit, the fresh gas flow rate, I:E ratio, use of heat and moisture exchangers, and scavenger suction.

Desiccated absorbents

Degradation:
- Desiccated absorbents can remove large amounts of potent inhaled anesthetics
  - Delay in induction

Absorbent becomes unusually warm:
- Temperature increases with all potent agents, greatest with sevoflurane

Compound A

Sevoflurane
- Degradation product is fluoromethyl-2, 2-difluor-1-(trifluoromethyl) vinyl ether (AKA Compound A)
  - By-products of sevoflurane include carbon monoxide, formaldehyde, methanol, methyl formate, dimethoxymethane, and perhaps hydrogen gas at high temperatures

Is nephrotoxicity a real problem in humans?
- Its effect is small and, in all but rare patients, of minimal or no clinical significance.


Composition of CO₂ Absorbents (wt %)

<table>
<thead>
<tr>
<th>Absorbent</th>
<th>Ca(OH)₂</th>
<th>KOH</th>
<th>NaOH</th>
<th>H₂O</th>
<th>Ba(OH)₂</th>
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</thead>
<tbody>
<tr>
<td>Baralyme*</td>
<td>73</td>
<td>&lt;5</td>
<td>0</td>
<td>11-16</td>
<td>+</td>
</tr>
<tr>
<td>Sodalime</td>
<td>&gt;80</td>
<td>2.6</td>
<td>1.3</td>
<td>15</td>
<td>-</td>
</tr>
<tr>
<td>Baralyme</td>
<td>&gt;80</td>
<td>0</td>
<td>2.6</td>
<td>16</td>
<td>-</td>
</tr>
<tr>
<td>Sodasorb</td>
<td>89</td>
<td>3</td>
<td>2.7</td>
<td>16</td>
<td>-</td>
</tr>
<tr>
<td>Sodasorb</td>
<td>92</td>
<td>0.0005</td>
<td>3.75</td>
<td>15.5</td>
<td>-</td>
</tr>
<tr>
<td>Amsorb Plus</td>
<td>&gt;80</td>
<td>0</td>
<td>0</td>
<td>13-18</td>
<td>-</td>
</tr>
</tbody>
</table>

APSF Conference on CO₂ Absorbent Desiccation: Safety Considerations
Dr. Michael Olympio / Dr. Evan Kharasch April, 2005
**Carbon Monoxide**

- All agents produced some CO
  - Use of des > iso = enf > sevo
    - Only desflurane in clinically meaningful amounts
- Elevated COHb levels have been reported, no patient injury has been* Above the symptoms of mild poisoning are confusion, headache, nausea & failure to emerge rapidly


**Desflurane**


**Isoflurane**


**Sevoflurane**


**Carbon Monoxide**

- Increased risk:
  - Desiccated absorbent
  - 1st case / inactive OR for 24+ hours
  - 1st case, flows left on or high flow, reservoir bag left off circuit
  - Depends on the circuit
  - Remote locations


**Carbon Monoxide**

- Prevention:
  - Flush system with O₂ prior to use on patient
  - May not work
  - Hydration- new absorbent q Monday
  - Add a cup of water to your canister?
  - Consistent use of low flow to sustain moisture
  - Keep reservoir bag on
  - Eliminate CO₂ absorbers with strong bases

Fires & Explosions

- Exothermic reaction

- Desiccated Baralyme & sevoflurane
  - Fires have been reported in the USA with sevoflurane only and desiccated Baralyme
  - Color indicator does not necessarily change as a result of desiccation
    - Exception - Amsorb® Armstrong Medical

- Desiccated absorbents without KOH or Ba(OH)₂, and with lesser amounts of NaOH, produce less heat and no fires

APSF Consensus statement on prevention of desiccation

1. Turn off all gas flow when the machine is not in use.
2. Change the absorbent regularly, on Monday morning for instance.
3. Change absorbent whenever the color change indicates exhaustion.
4. Change all absorbent, not just 1 canister in a 2-canister system.
5. Change absorbent when uncertain of the state of hydration, such as if the fresh gas flow has been left on for an extensive or indeterminate time period.
6. If compact canisters are used, consider changing them more frequently.

Fires & Explosions

- Audience: Anesthesia healthcare professionals
  - Abbott Laboratories issued a "Dear Healthcare Professional" letter concerning reports of fire or extreme heat in the respiratory circuit of anesthesia machines when (sevoflurane) is used in conjunction with a desiccated CO₂ absorbent
  - Sevo compromise from FDA-package label:
    - FG rates \(\geq\) 1 L/min at 1 MAC for no more than two hours
    - For lengthier cases FG \(\geq\) 2 L/min
  - The letter went on to provide suggestions to reduce the risk of occurrence of these adverse events

Speaking of fires

- FDA has received 12 reports in which regulators used with oxygen cylinders have burned or exploded, in some cases injuring personnel.
Oxygen cylinder fire

- FDA and NIOSH Recommendations
  - Plastic crush gaskets never be reused
    - They may require additional torque to obtain the necessary seal with each subsequent use.
    - This can deform the gasket, increasing the likelihood that oxygen will leak around the seal and ignite.
  - Always “crack” cylinder valves (open the valve just enough to allow gas to escape for a very short time) before attaching regulators
    - Expel foreign matter from the outlet port of the valve

ASTM F1850-00: The 2000 AGM standard

- To comply these, work stations must have monitors that measure:
  - Continuous breathing system pressure
  - Exhaled tidal volume
  - Ventilatory CO₂ concentration
  - Anesthetic vapor concentration
  - Inspired O₂ concentration
  - O₂ supply pressure
  - Arterial hemoglobin O₂ saturation
  - Arterial blood pressure
  - Continuous electrocardiogram

- Prioritized alarm system:
  - Alarms – high, medium & low priority

ASTM F1850-00

- Flowmeters:
  - Single control for each gas
  - Each flow control next to a flow indicator
  - Uniquely shaped oxygen flow control knob
  - Valve stops (or some other mechanism) are required such that excessive rotation will not damage the flowmeter.
  - Oxygen flow indicator is to the right side of a flowmeter bank
  - Oxygen enters the common manifold downstream of other gases

ASTM F1850-00

- An oxygen flush is present
  - Capable of 35-75 L/min flow which does not proceed through any vaporizers

- Vaporizers
  - Concentration-calibrated
  - An interlock must be present
  - Liquid level indicated, designed to prevent overfilling
  - "Should" use keyed-filler devices
  - No discharge of liquid anesthetic occurs from the vaporizer even at maximum fresh gas flow

New

- Efforts underway to revise the preuse checkout (FDA 1993) recommendations
  - ASA Newsletter Fall 2005
  - Request for anonymous survey through University of Florida’s Virtual Anesthesia Machine Web
  - Final recommendations from task force are expected by ASA 2006 meeting
  - Automated checkout

- How are practitioners expected to keep up?
Near catastrophes and other reported problems
- FDA Center for Devices and Radiological Health MAUDE (manufacturer and user device experience)
- Deliberate omission of machine checkout is inexcusable and has had serious consequences

Avoiding $V_T$ augmentation to ensure set $V_T = \text{delivered } V_T$
1. Fresh Gas Decoupling
   - Dräger
     - Narkomed 6000 & Fabius GS
   - Anestar
     - Hanging bellows
2. Fresh Gas Compensation
   - Datex-Ohmeda
     - Aestiva & S/S ADU

Summary of Safety Features of Modern Gas Machines
- More accurate and/or corrected tidal volume through compliance and fresh gas compensation (avoiding $V_T$ augmentation)
- Potential return of sampled gas to facilitate low-flow
- Fresh gas decoupling may prevent hyperinflation of the lung
- Some forms of decoupling will even reroute the high flow of oxygen flush if it is depressed during mechanical inspiration


References
- Eisenkraft JB. A Commentary on Anesthesia Gas Delivery Equipment and Adverse Outcomes. Anesthesiology 1997;87:731-3
- Cooper JB. An Analysis of Major Errors and Equipment Failures in Anesthesia Management: Considerations for Prevention and Detection. Anesthesiology 1984;60:34-42
- FDA checkout: http://www.fda.gov/cdrh/humfac/anesckot.html
- Standard Specification for: Conical Fittings (F1054-01), Minimum Performance and Safety Requirements… (F1208-89(200)e1), and Particular Requirements for Anesthesia Workstations… (F1385-00), American Society for Testing and Materials. F-29 Subcommittee.