CPB FMEA #1: Right heart air embolus from an unknown source upon initiation of CPB.

In a effort to make Perflist a more productive and informative tool for perfusionists, the AmSECT Safety Committee will begin to make weekly routine postings that contribute to the general safety and productivity of perfusion. The Safety Committee will focus on cardiopulmonary bypass Failure Modes and Effects Analysis (CPB FMEA). We encourage all perfusionists to visit the AmSECT safety web site. Click on the "Safety" tab, then click on the red box above the drop down menus. That will take you to the page with a downloadable PDF that explains the need for improved perfusion safety: " Perfusion Safety: The Forgotten Priority (PowerPoint converted to PDF)". There is also another PDF containing an entire perfusion safety program that you can download and modify to work with your own perfusion program: "Cardiopulmonary Bypass (CPB) Safety Program and Failure Mode Effect Analysis (FMEA)". You need not be an AmSECT member to have access to this important material.

The FMEA is a tool used by risk managers to anticipate failures in complex systems and prevent their occurrence. There are many instances during CPB where a failure can occur that endangers the patient. These are called Failure Modes. When a failure occurs, it can result damage in varying degrees. This is called the Potential Effects of Failure. The condition causing the failure is called the Potential Cause of Failure. The things that can be done to prevent or mitigate the failure are called Management Interventions to prevent or negate the failure. The potential risk ranking that this failure will occur is called the Risk Priority Number (RPN).

The 2001 Joint Commission Leadership Standard LD 5.2: Support of Patient Safety and Medical/Health Care Error Reduction Goal was written to reduce sentinel events and significant errors. The standard requires hospitals (and by implication perfusionists) to provide a "failure mode analysis" for proactive process review for complex procedures. Below is an example of one CPB FMEA. You can review this as a discussion on Perflist, start your own FMEA or to add this item to your current FMEA. You are also welcome to suggest a Failure Mode of your own on PerfList that you would like other perfusionists to help categorize. We will be having many other Failure Modes on PerfList to aid perfusionists in developing their own FMEAs that can be used to improve patient safety and meet risk management safety requirements.

Thanks-
The AmSECT Safety Committee
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This week's Failure Mode is below:

I. Failure Mode: the sudden appearance of massive air embolism in the right heart during bypass initiation that has no definable source.

II. Potential Effects of Failure:
1. Air embolus crossing to the left heart while it is still beating.
2. Temporary organ dysfunction
3. Permanent neurological and other vital organ damage.
4. Death.
(Can you suggest other problems that can occur?)

III. Potential Cause of Failure:
1. Deviation from standard procedure
2. Air entry originating in the CPB circuit such as unnoticed pressurization of the venous reservoir caused by blocked reservoir vent which pushes air unnoticed up the venous line.
3. Air entry during venous cannulation around purse strings when venous siphon is applied.
4. Air entry originating from central IV or peripheral IV lines with air being sucked in from a loose or broken line connector when venous siphon is applied.
(What other things can cause this particular failure?)

IV. Interventions to Prevent or Negate the Failure:
PRE-EMPTIVE MANAGEMENT:

1. Follow procedural checklist. Double check central line/peripheral line connection integrity.
2. Minimize perioperative distractions.
3. Maintain situational awareness during periods of access to patient vasculature.
4. Cerebral monitor may detect trouble early and guide emergency management. Without a cerebral monitor the detectability RPN should be a 3 which raises the total RPN from 30 to 45.
5. Initiate CPB with arterial flow before removing venous clamp.
6. Monitor reservoir pressure; set positive pressure alarm and other safety devices and avoid priming w/ dry venous line.
7. Use of soft shell venous (bag) reservoir would further reduce the risk of retrograde venous air embolus. With a softshell venous reservoir the RPN should be a 1 which reduces the total RPN from 30 to 15.

MANAGEMENT: An air embolus isolated to the right side in a heart with intact septum may not require all the steps listed below. If an unexpected air embolus develops and air is seen in the heart with possible embolus to the left heart:
1. Go to 100% on sweep and ventilation. Discontinue nitrous oxide and anesthetic agents.
2. Trendelenburg position the patient.
3. Stop bypass if possible, as it may be the source of the air.
4. Transfer aortic cannula to SVC. Debubble cannula if necessary.
5. Retro grade flow to SVC at 40 mmHg max for 1-4 minutes.
6. Apply intermittent carotid compression
7. Ice to head. Start core cooling immediately.
8. Watch aortic cannula site for diminishing air expulsion.
9. When no additional air is expelled, resume antegrade CPB at 20 degrees for at least 45 min. Maintain 80-100 mmHg arterial pressure.
10. Manually strip visible air from coronaries through the coronary circulation.
11. Consider medications: neosynephrine, mannitol, barbiturate, Propafol, steroids.
12. Continue ventilating with 100% oxygen for at least 6 hours for nitrogen removal.
13. Continue treatment with mannitol and steroids for 48 hours post-op.
14. Use hyperbaric chamber post-op if immediately available.
15. Post-traumatic stress disorder (PTSD) therapy should be available if needed for the perfusionist or other surgery team members, particularly if the patient experiences an adverse outcome.

V. Risk Priority Number (RPN): (select the number from each category that you feel best categorizes the risk).

A. Severity (Harmfulness) Rating Scale: how detrimental can the failure be:
1) Slight, 2) Low, 3) Moderate, 4) High, 5) Critical
(Since death is a potential outcome the Harmfulness RPN should be a 5.)

B. Occurrence Rating Scale: how frequently does the failure occur:
1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High
(This is a rare problem. So the Occurrence RPN should be a 1.)

C. Detection Rating Scale: how easily the potential failure can be detected before it occurs:
1) Very High, 2) High, 3) Moderate, 4) Low, 5) Uncertain
(This problem can usually be detected early without harming the patient. So the detection RPN should be 2.)

D. Patient Frequency Scale:
1) Only a small number of patients would be susceptible to this failure, 2) Many patients but not all would be susceptible to this failure, 3) All patients would be susceptible to this failure.
(This could happen to any patient. So the Patient Frequency RPN should be a 3.)

Multiply A x B X C X D = RPN. The higher the RPN the more dangerous the Failure Mode.
The lowest risk would be 1 X 1X 1 X 1 = 1. The highest risk would be 5 X 5 X 5 X 3 = 375. RPNs allow the perfusionist to prioritize the risk. Resources should be used to reduce the RPNs of higher risk failures first, if possible.
(The total RPN for this failure is 30 if a cerebral monitor is used and 45 if no cerebral monitor is used. If a soft shell (bag) venous reservoir is used the RPN would be 15.)

This is a seemingly simple and straight forward failure mode that is deceptively complicated. Some people may focus simply on the risk of an air embolus. But the focus of this failure mode is to PREVENT a right heart air embolus coming from an UNKNOWN source. The management of an arterial air embolus is important, but the pre-emptive management should focus on proper procedure to prevent a right heart embolus. Since right heart air embolus can originate from something besides the pump, this becomes a risk that may be beyond the perfusionist's control but for which s/he will be blamed anyway. If that unfortunate circumstance should occur, the poor perfusionist can show this FMEA to the risk assessors to show that a right heart embolus is not necessarily caused by the perfusionist.

This failure could happen to anyone going on CPB, so the Patient Frequency is a 3. If the failure mode 'specified' a right heart embolus with risk of a left heart embolus coming only from a patient with a PFO which occurs in 10-35% of normal people, that would be a 2. If the failure mode 'specified' a right heart embolus with risk of a left heart embolus coming only from a patient with an ASD which occurs in even fewer people, that would be a 1.

One last point concerns the pre-emptive management of using a cerebral monitor and venous bag in this failure mode. Some monitors and safety devices can for sure improve the detectability score. For example the use of a venous reservoir level sensor reduces the detectability RPN for a drained reservoir from a 4 (without a sensor) to a 1 (with a sensor). In the failure mode under review the detectability RPN was a 2. I don't know if a cerebral monitor will for sure indicate a cerebral embolus problem early, but it certainly doesn't hurt. So I included it in the pre-emptive management. I think that programs who do not use a cerebral monitor should rate their detectability RPN as a 3. That would increase the overall RPN from 30 to 45. Programs that use a soft shell (bag) reservoir would reduce the risk of an air embolus coming up the venous line so that would reduce the detectability score to 1, making the total RPN only 15.