CPB FMEA #27 Hardshell venous reservoir emptying

Friends-

The FMEA for review this week concerns the most fundamental of perfusion failures; the emptying of a hard shell venous reservoir. One of the first things taught to perfusion students is not to let the system run dry. This is a crucial and fundamental tenet of our profession. I know that we have dealt with air embolus failures earlier, but this one is so important that it needs its own FMEA. I was around before disposable arterial filters were available, as I am sure that many of you were as well. When we started to use disposable bubble oxygenators, the thinking was that the venous reservoir was adequate to catch and remove bubbles. As long as we kept the reservoir at a minimum volume, the patient would be safe. It is hard to believe that we were that naive back then. We did have SS reusable arterial filters back then, but the whole idea behind the disposable oxygenator was that it was “disposable”, and therefor safer from a re-sterilization point of view. Why would be want to mess that rationale up by continuing to use a re-useable arterial filter.

I also want to explore the management of gross air embolus again. There is no “good” management for this. Generally it is about doing what makes sense and hoping for the best. Most patients are not going to have access to a hyperbaric chamber, particularly after just going through heart surgery. I suggest discussing a plan to use a hyperbaric chamber in Pre-emptive management, but I did not include that in the Management list of things to do. Add it into your Management plan if you think it is practical at your hospital. One thing I did mention under Preventative Management is team practice for such an emergency in the form of a simulation exercise. Whether or not that would include simulated transport to a hyperbaric chamber would have to be a team decision. In your opinion, how often should this practice take place? I think a table top discussion of this FMEA by team members should probably occur every 6 months, particularly if there are new team members. But a full blown simulation would test the system’s flaws more thoroughly.

Also, there would be more than one victim of this failure. So I included PTSD treatment under Management. The failure would most likely be caused by human error. So the perfusionist would be dealing with the guilt, possible legal implications and even loss of trust on behalf of other team members. This can make the perfusionist particularly vulnerable to this failure. Perfusionists and patients participating in a foreign medical mission CPB procedure might be at a very high risk if inadequate safety equipment is not available.

Thank you

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FAILURE MODE AND EFFECTS ANALYSIS: CPB FMEA # 27 Hardshell venous reservoir emptying

FAILURE: Hard shell venous reservoir empties.

EFFECT:

1.Air is pumped through circuit with a roller pump and potentially to the patient causing a gross air embolism:

a. brain infarction.

b. organ dysfunction.

c. minor/major disabilities.

d. death.

2. A centrifugal pump is de-primed by air and forward flow stops causing:

a. brain hypoxia

b. organ dysfunction.

c. minor/major disabilities.

d. death.

CAUSE:

1. Human error; lack of attention.
2. Inadequate safety equipment.
3. Inadequate circuit design.
4. Failure of safety systems.

PRE-EMPTIVE MANAGEMENT:

1. Checklist items for level detector and blood line bubble detectors.

2. Activate a level sensor and blood line bubble detectors to automatically turn off the arterial roller pump if the blood level in the reservoir gets too low.

3. The use of a centrifugal (C) pump greatly reduces the possibility of pumping air to the patient from an empty venous reservoir.

4. If using a C-pump with a line clamp, the level sensor can automatically clamp the arterial line to prevent air entry into the patient.

5. If using a C-pump, circuit access should be designed to allow for quick and easy air removal and re-priming of the pump head.

1. Certain hollow fiber oxygenators may filter out some air pumped into them. Certain silicone or silicone coated hollow fiber oxygenators will not filter air

7.Arterial line bubble trap/filter with air purge line removes air that gets past the oxygenator. (\* Not using an arterial bubble trap/filter would increase the Occurrence by one point.)

8. The arterial line has a final bubble monitor to detect any remaining bubbles traveling to the patient.

9. A bubble monitor placed on the venous reservoir effluent line will act as a back-up alarm should the level detector fail. (\* Not using a back-up monitor would increase the Detectability by one point.)

9. The cardioplegia circuit may draw air from the emptied circuit and should contain a bubble trap and air detection alarm with automated shut-off, if available. (\* Not using a cardioplegia air/bubble alarm pump stop link would increase the Detectability by one point.)

10. Consider heart team management practice of gross air embolus by an FMEA table top discussion or by simulation on a regular basis. Include emergency transport to a hyperbaric chamber.

MANAGEMENT: If gross air embolus is suspected:

1. Stop CPB immediately & clamp arterial and venous lines.

2. Place patient in steep Trendelenburg position.

3. Remove aortic cannula.

4. De-air aortic cannula and circuit components.

5. At surgeon's option, perform retrograde SVC perfusion at 100% FiO2 for 1-2 minutes.

6. Utilize intermittent carotid compression during retrograde perfusion, if possible, by anesthesia.

7. Pack head in ice.

8. Institute antegrade deep hypothermic perfusion for 40 minutes at 100% FiO2.

9. Express coronary air if present by massage and cardiac manipulation.

10. Consider administration of barbiturates and steroids by anesthesia.

11. Maintain FiO2 of 100% and sedation for 6 hours after CPB.

12. Maintain negative or siphon pressure on venous line.

If C-pump de-primes and stops forward flow:

1. Stop CPB immediately & clamp arterial and venous lines.

2. De-air and re-prime pump head.

3. Resume CPB employing reperfusion tactics (cooling, head ice, steroids, etc.) as needed depending on temperature and time length of flow stoppage.

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.

RISK PRIORITY NUMBER (RPN):

A. Severity (Harmfulness) Rating Scale: how detrimental can the failure be:

1) Slight, 2) Low, 3) Moderate, 4) High, 5) Critical

(I would give this failure a Critical RPN,5. Either macro or micro gas emboli can severely injure or kill a patient.)

B. Occurrence Rating Scale: how frequently does the failure occur:

1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High

(The Occurrence is remote, so the RPN would be a 1, but could be higher if insufficient monitoring is not used.)

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. (\*The Detectability RPN equals 1 if proper monitoring is available. If not, this number would be higher, depending on the type of monitoring needed.)

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.

(All patients would be at risk. So the Frequency RPN would be 3.)

Multiply A\*B\*C\*D = RPN. The higher the RPN the more dangerous the Failure Mode.

The lowest risk would be 1\*1\*1\*1\* = 1. The highest risk would be 5\*5\*5\*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 5\*1\*1\*3 = 15 with proper monitoring and circuit design. Without these, the total RPN could be as high as 5\*3\*3\*3 = 135. An RPN this high could occur during a foreign medical mission CPB procedure where inadequate safety equipment is available.)