CPB FMEA #3: Heat exchanger leak in the oxygenator or cardioplegia heat exchanger.
The AmSECT Safety Committee
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This week's FEMA is prompted by the recent chatter on the list servers about cleaning heater/coolers (H/C). The discussion centered on two aspects: 1) how to clean the water reservoir to kill microbial contamination without damaging the equipment and 2) addressing the rumored Joint Commission focus on standing water reservoirs in the OR which could be the source of splash contamination. I am assuming this would include mop buckets, wet vacs and warming blankets. But it could also include H/C reservoirs as well.

One thing I did not see discussed on the list servers was the potential of an H/C to injure or kill a patient as a result of a heat exchanger (HE) leak. I fear that this represents a lackadaisical, even cavalier, attitude on the part of some in the perfusion community towards the risk of a HE leak. Over the last decade I have noticed that some students rotating through my program were not well educated on the need to water test the HE, let alone how to deal with a life threatening HE leak.

Quality control for oxygenators and cardioplegia sets has greatly improved over the years. And I have not seen a HE leak in probably 20+ years. But that should not equate to an "out of sight, out of mind" mindset. There are probably many programs with staff perfusionists so young that they are not actively cognizant of HE leak possibility.

This FMEA is an excellent example of providing institutional memory of a rare failure. Of the six perfusionists at my former employer, I think I was the only one who had ever seen a HE leak on CPB or dealt with a patient exposed to a leak. Next to me, the most experienced staff perfusionist had only 15 years in practice, never having seen a leak. After I retired, the program's FMEA was the only thing to remind the staff that an H/E leak was a risk.

I do not know the frequency of HE leaks. It is very rare. But it is not something to dismiss because the consequences for the patient can be devastating. This British perfusion web page has four recent case reports of HE leaks; three while on CPB: http://www.scps.org.uk/index.php?option=com_content&task=view&id=218&Itemid=79

-Gary Grist

This week's Failure Mode is below:

I. Failure Mode: Heat exchanger leak in the oxygenator or cardioplegia heat exchanger.

II. Potential Effects of Failure:
1. Unexplained increase in circuit volume
2. Unexplained increase in K+ (due to hemolysis of RBCs)
3. Unexplained decrease in hematocrit.
4. Unexplained acidosis due to water dilution of HCO_3 in the blood
5. Unexplained hyponatremia due to water dilution blood Na^+.

6. Hematuria
7. Blood visualized in the water lines.
8. Microbial contamination and systemic infection post-operatively, possibly fatal.
9. Hypothermia from discontinued use of the water heating system.
10. Multi-systemic organ failure.
11. Death.
(Can you suggest other problems that can occur?)

III. Potential Cause of Failure:
CAUSE:
1. Manufacturing defect.
2. Damage during transport or storage.
(What other things can cause this particular failure?)

IV. Interventions to Prevent or Negate the Failure:
PRE-EMPTIVE MANAGEMENT:
1. Discard units with any damaged or suspicious packaging prior to use.
1. Maximize water system pressure and flow prior to priming to stress test for heat exchanger failure before CPB. Observe for water entry into dry blood circuit during testing.
2. Document lot#, serial # and stress testing on checklist prior to initiation of CPB. Stress testing my not detect a small leak (Hawkins, 2014).
3. Have backup heat exchanger component system readily available.
4. Have ancillary personnel readily available to assist.
5. Perform regular cleaning/decontamination of H/C water bath to reduce microbial contamination.
MANAGEMENT:
1. Immediately turn off heater/cooler and disconnect water lines.
2. Notify surgeon and anesthesiology of emergency and that emergency cooling cannot be performed.
3. Splice in new oxygenator in parallel using a PRONTO line (Parallel Replacement of the Oxygenator that is Not Transferring Oxygen. Loss of the HE eliminates the ability to cool the patient prior to oxygenator change out. A PRONTO line allows for change out without coming off CPB).
4. Without a PRONTO line, perform series change out of the oxygenator. (Increase Harmfulness score to 5; RPN = 5*1*3*3 = 45)
5. Replace cardioplegia set.
6. Consider entire circuit change out if practicable.
7. Send blood for culture and sensitivity.
8. Obtain stat blood electrolytes and free hemoglobin
9. Consider mannitol, antibiotics
10. Complete incident report.
11. Save oxygenator or CP HE for investigation
12. 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
(The problems that this failure causes are circulating blood contamination and the need to change the oxygenator. The Harmfulness RPN should be a 4, or if there is no PRONTO line, 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 may not become immediately obvious and pre-CPB testing may not work to detect a leak. So the detection RPN should be 3.)

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*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 4*1*3*3 = 36. If no PRONTO line is incorporated into the circuit the RPN would increase to 5*1*3*3 = 45.)