CPB FMEA # 24 Defoamer Failure

Friends-

Many years ago when my program started taking students on rotation, I was impressed that they had been well schooled in running the CPB system. They could even verbalize how they would handle emergency situations like a failing oxygenator or a heat exchanger leak. But when I asked them what they would do if their cardiotomy/venous reservoir suddenly filled with foam, they did not have a clue. In fact they did not even know that a foam filled reservoir was a possibility. Perfusionists trained only in the use of membrane oxygenators have little appreciation for the challenge of removing foam from blood in a CPB system. Those who have been around long enough know what I am talking about. I am not talking about a little bit of foam floating on the blood pool surface in the reservoir. I am talking about foam completely filling the entire reservoir above the blood pool surface. And if you should say “foaming is an old man’s problem, it doesn’t happen anymore”, I beg to differ with you. In fact, before I retired we trialed a new membrane oxygenator whose reservoir, unbeknownst to me, had a propensity to foam up. One of my most experienced staffers was using it when the venous reservoir began overflowing with foam. She had never used anything but a membrane oxygenator before and, in my complacency, I had never discussed with her the possibility of over foaming a reservoir on a membrane oxygenator. Although I knew that was always a possibility. She urgently called me wanting to know what to do. As a result I wrote the original FMEA for this failure which has been revised since then.

In olden days when I was using the disk system, we used a glass and steel cardiotomy/venous reservoir. The only defoamer we had was a SS sponge mesh soaked in silicone spray. The mesh was jammed in the top of the reservoir where suckers and vent lines entered. The mesh was supposed to remove the foam as the air/blood mixture came spurting into the system. And there was no ‘sock’ on the venous reservoir entrance. If air was siphoned into the venous line it would foam the blood as the air/blood mixture entered the reservoir.

When disposable bubbler oxygenators came along they had a very good defoaming filter built into them. It had to be good to remove all of the foam generated during the bubble oxygenation process. Even though the visible foam was removed, bubblers still generated a lot of gaseous microemboli. These weren’t too dangerous because they were composed of 5%CO2/95%O2; no nitrogen to speak of. Many of these bubbler oxygenators had fittings at the top to allow for the suckers and vent to be connected directly into the defoamer filter above the reservoir. However I never used these connectors in this way because the foam entering from the suckers and vent contained a lot of nitrogen bubbles from room air. So I always used a separate cardiotomy reservoir to filter out the nitrogen containing foam before I dropped the defoamed blood into the oxygenator reservoir.

As membranes came into common use, the foam problem was less critical. The cardiotomy/venous reservoirs still required a defoaming filter (usually about 40 microns) and the venous entry port contained a defoaming ‘sock’ to remove entrained air bubbles coming down the venous line. The problems of a foam-filled reservoir were less and less common. Today, with normal use, most systems will remove the visible foam, but not necessarily the gaseous microemboli. However it is still possible to pump enough foam into a filter to overload its function. And with vacuum return being used commonly, it can generate a lot of nitrogen filled foam from air sucked into the venous line around the purse strings and vena cava ligatures. One of the surgeons I worked with did not like to dissect around the vena cava to place ligatures on redo cases. He did this to reduce the bleeding. Air often got sucked in around the purse strings and pulled down into the reservoir by the vacuum.

This FMEA is what I call an “institutional memory” that preserves the knowledge of a once common (but now very rare) problem and how to deal with it. This FMEA could be a lot better. So I am relying on you guys to improve it. Please send me your comments. Thanks a lot.

AmSECT Safety Committee

Gary Grist RN CCP, contributor.

<garygrist@comcast.net>

FAILURE MODE AND EFFECTS ANALYSIS: CPB FMEA # 24 Defoamer Failure

FAILURE:

Cardiotomy/venous reservoir defoamer filter fails to remove air from the entering the blood in the venous reservoir resulting excessive foaming.

EFFECT:

1. Air embolus causing organ damage, hypoperfusion, discontinuation of bypass, and increased transfusion donor exposure.

CAUSE:

1. The defoaming capacity of the cardiotomy filter can be exceeded by excessive field sucker or ventricular vent flow.
2. The blood/air interface results in blood foaming.
3. Dangerous foam build-up can occur within seconds in extreme situations.
4. Excessive foaming may be associated with low heparin dose response (HDR), despite ACT > 400sec pre-CPB, by partially clotting the defoaming filter and decreasing its effectiveness.
5. Albumin added to the cardiotomy reservoir may initiate foaming.
6. Patients with volume over load conditions such as valve repair or transplants may have 30%-50% increased blood volume needing better heparin management to prevent defoamer filter clotting.

PRE-EMPTIVE MANAGEMENT:

1. Special circumstances may indicate the need for increased field sucker or ventricular vent use, such as redo procedures in patients with excessive collateral circulation
2. In these instances, larger oxygenator/cardiotomy units that exceed the patient's calculated cardiac output may be utilized.
3. These larger units have the capability to handle increased defoaming needs.
4. Using coated circuits may maintain defoamer function longer.
5. Add piggy-back cardiotomy reservoir as needed to catch and remove foam.
6. \*Heparin dose response testing may detect the potential for cardiotomy filter clotting which can lead to foaming. With such testing the Detectability RPN would be 1.
7. Notify surgeon if the risk of excessive foaming is developing.
8. Surgical intervention such as ablation of collateral vessels may help to reduce the excessive cardiotomy blood flow.

MANAGEMENT: If excessive foaming develops in the cardiotomy reservoir:

1. Slow the field sucker or vent pump speed, if possible.

2. Remove vacuum assist.

3. Allow excess foam in the cardiotomy to overflow from the ventilation port.

4. Add piggy-back cardiotomy reservoir as needed to catch and remove excess foam.

5. If a closed system is in use, and the bag receives foam, it can be evacuated into the cell saver with very light vacuum.

4. Add fluid volume to the cardiotomy reservoir to increase bubble buoyancy and reduce the egress of bubbles from the venous reservoir.

5. Use 100% oxygen in the sweep gas to minimize nitrogen entrainment and convert bubbles from nitrogen to oxygen.

6. Consider cooling the patient to allow for a reduction in arterial blood flow to prevent air embolus.

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 high RPN, 4.)

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.)

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 2. Detecting the early development of foam should give adequate time to mitigate it unless the foam develops quickly during an emergent situation. Using heparin dose response testing may provide additional detectability for foaming potential and reduce the Detectability RPN to 1.)

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 4\*1\*2\*3 = 24. If HDR testing is utilized the total RPN would be 4\*1\*1\*3 = 12.)