

Friends- Here is the narrative for the fifth ECMO FMEA for your review.

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Narrative #5

ECMO FMEA E1 FAILURE: Pre-pump air in the venous cannula, venous line and compliance chamber.

Go to the AmSECT Safety Page <http://www.amsect.org/page/perfusion-safety>, select ECMO FMEAs, open the PDF and scroll down to section E1 to find the detailed FMEA. (Any opinions expressed in this communication are solely my own and not necessarily those of the Safety Committee or AmSECT.)

E1 Failure: Pre-pump air in the venous cannula, venous line and compliance chamber.

EFFECTS, CAUSES and MANAGEMENT OVERVIEW:

Air usually enters an ECMO circuit on the pre-pump side. Circuit air will cause an air/blood interface that could lead to clotting, air embolus or de-priming of the pump if a centrifugal pump is used. Air entry post pump from hollow fibers is also possible but is dealt with in another ECMO FMEA.

There are many causes for air entry into the venous side. Some are simple and easily corrected. Some are deadly and not easily diagnosed or corrected. For example, simple causes include cracked stopcocks or pigtails in the venous line. A little more difficult to deal with is a pre-pump cracked tubing connector or pump blood port since this may be hard to see (a hair line crack) and requires the cessation of ECMO to repair. Although I have patched hair line cracks with bone wax to reduce air entry, a tubing connector or blood port crack could develop into a serious circuit disruption if the connector fails altogether. Pre-pump medication or volume pushes into the circuit can cause air, especially during an emergency. Another rarer cause of air can be a venous cannula side port coming out of the vessel but still under the skin. Air can come from right atrium from which is getting air from a central line or even peripheral line infusion sites. The worst I have seen is air coming from right atrium as a result of a pulmonary vein to left atrial air embolus. This is potentially caused by interstitial pulmonary emphysema, acute respiratory distress syndrome or idiopathic alveolar rupture with air crossing from the left into the right atrium during positive pressure ventilation. An ECHO would sometimes show an undiagnosed septal defect. At other times the sources of the air entry could not be pin pointed. Of course, if occult air is entering the left atrium as a result of pulmonary over inflation, there is a lot more to worry about than wasting time dealing with venous line air. Seeing small air bubbles at the top of the venous line with subcutaneous emphysema or pulmonary crepitus, think LA air crossing over to the right.

Management depends on the air source. It could be a simple but temporary bone wax fix, changing a stopcock or other circuit attachment component. It is best just not to place any stopcocks directly in the venous line. Although this may not be possible if the silicone bladder with stopcock access is still being used somewhere. In addition, an inaccessible venous line may not be possible if pre-pump negative pressure is monitored by transducer, particularly on a centrifugal pump that is not servo-regulated. Or if a shunt of some sort like from a CDI monitor or the return from a hemoconcentrator is positioned on the pre-pump side. A cracked tubing connector requires at least a temporary patch and eventually cessation of ECMO for inline component change out. If the repair involves anything more than changing a stopcock, always obtain 'pump qualified' assistance. Like airline pilots, one pilot needs to continue flying the plane (or run the pump) while the other pilot focuses on correcting the problem. Anything less is an invitation to disaster. This is true with many other ECMO trouble shooting problems as well.

Volume or medication pushes should be given post-pump between the pump and oxygenator.

Contact surgery to reposition cannula if an exposed side hole is suspected.

Make sure that all peripheral infusion sites are secure. It may be possible to auscultate or Doppler downstream from the peripheral site to detect air entry.

Reduce ventilator pressure and cease pulmonary physiotherapy procedures if LA air is suspected. If LA air is diagnosed, increase the FiO₂ on ventilator and sweep gas to 100% for a minimum of 2 hours to 'off gas' air emboli that have entered the systemic circulation from the left atrium or until the air source can be stopped.

RISK PRIOROTIES:

Only two causes approach certainty after 10 ECMO days. Those are a loose or damaged stopcock on the venous side and surgical adjustment of the right atrial cannula. The other causes do not approach certainty.

REVIEWER COMMENTS:

REVIEWER LP: I really have not much to add to this one, other than that it is probably safer to temporarily (if possible) to reduce flow while identifying the cause of air, to prevent more air from entering the venous line and thus to get pushed into the pump, or beyond. (NOTE GG: This is a simple safety precaution that I did not mention in the FMEA.)

REVIEWER MC: I'm new here, so I don't know exactly how this works...based on my experience with ECMO, should this FMEA include any info about how the air is detected? At one institution I was at, there was no air detector on the ECMO system, at others, there were multiple. Should air detection on the negative side be a FMEA suggestion? What if there is no air detection and they don't see the air until the pump (assuming centrifugal) is deprimed? (NOTE GG: Your message is exactly what you are supposed to do. For example, you mention air detectors. I did not talk about air detectors in the ECMO FMEA or the narrative, making the assumption that the ECMO Specialist or perfusionist had already found the air in the venous line. But maybe I should have put it in a pre-emptive management section. Some programs might want to use an air detector on the venous line and to reduce the Detectability RPN. This, of course, would depend upon where the air leak was coming from and where the air detector was placed. We always incorporated an air detector AND a bubble trap, but they were only used on the arterial line. Arterial line air was never an issue at my old program. It rarely occurred. We used bubble traps, not arterial filters. There were never any clotting issues with the bubble trap. But we had quite a few instances of venous air. Everyone was trained on walking air down to the pump and pushing it through the pump to the oxygenator where we extracted it. ECMO Specialists were also trained people to deal with the air sources depending on where it was coming from. Some types of flow meters incorporate a Doppler for air detection. That might be something to use on a venous line for safety.)

REVIEWER ML: Here is our experience for adults. Peds and Neonate cases are an exception due to limited vascular access. These could be recommendations for reducing the possibility of air entrainment. You have already mentioned a couple in FMEA #5. I'm sure these actions and recommendations could be refined further or expanded.

1. No stopcocks or associated connectors in the circuit tubing for medication or volume infusions
2. Filters for all patient access medication and volume infusion lines
3. Clean (air free) priming technique for patient access medication and volume infusion lines
4. Venous Air Entrainment Algorithm
 - a. call for assistance
 - b. reduce RPM to minimum support level
 - c. increase all FIO₂ delivered to 100%
 - d. investigate source for air entrainment for circuit or patient
 - e. apply bone wax or Tegaderm for circuit source if applicable
 - f. prepare to stop support if needed to replace circuit source
 - g. place patient in Trendelenburg if patient or cannula source
 - h. prepare to address cannula position if applicable
 - i. consider diagnosis with CXR or bedside echocardiography for patient source
 - j. consider reducing airway pressures if applicable to patient source

(NOTE GG: You hit a couple of points that I missed. For instance, I forgot the IV line filters. We used them; I just did not think to put them in. They should go in a pre-emptive management section. Also, your priority is to call for assistance first. I don't think I put that number one, but I should have. I did mention the co-pilot method for

trouble shooting an ECLS circuit, but not as a first initiative. I forgot the Tegaderm as well, there's not much bone wax in the ICU.)

REVIEWER GH: I agree to minimize the stop cocks on the venous side to the minimum, but the stopcocks that I do have we use Luer adapter caps to eliminate air entrainment due to specialist error with the stopcock. I have eliminated venous air with these not including air from the patient or venous cath. Lastly, if it is a circuit issue, I think you will need to do more than increase the fiO_2 to 100% but more appropriate ventilation settings or prepare to bag if you will need to come off for a prolonged period of time. (NOTE GG: Good thoughts. I might also add that if it is a cardiac patient, be prepared for chest compressions. This goes to the heart of always getting knowledgeable assistance when dealing with air in the circuit, venous side or otherwise.

REVIEWER RM: In this scenario, is there ever consideration to switching to a primed backup circuit if the primary circuit cannot be de-aired properly? I have not seen this problem in an ECMO case. You may have more experience in de-airing the circuit. I would think it would be difficult to de-bubble the centrifugal pump. What is the easiest route with RN ECMO Specialists? (NOTE GG: Your comment is very pertinent in a situation where air entrainment is uncontrolled. Thus this ECMO FMEA that attempts to catch air entrainment early. During our program's initial training in the animal lab, there were two instances where ECMO Specialists misdiagnosed a reduction in blood flow and began to hand crank excessively. This resulted in cavitation that foamed the pre-oxygenator part of the circuit. Our circuit had monitor access ports immediately pre and post pump. So we developed a technique to infuse saline into the pre pump site and remove air from the post pump site. We routinely taught this method during simulation exercises for 20+ years. We also had a post oxygenator bubble trap (not filtered) in the circuit where ECMO Specialists could easily view any air post oxygenator and remove it. We never had an instance where air entrainment or circuit foaming required circuit change. But I can certainly see how circuit foaming could occur in a circuit without properly placed access ports or a bubble trap that could not be quickly cleared.

REVIEWER DZ: I know a lot of ECMO circuits don't employ a bubble trap, but I appreciate your comment on its value. I have to admit I was initially concerned that I might see more fibrin/clot formation there when I started using an ECMO circuit with one, but I really didn't. The bubble trap is especially nice when you have to do a fast circuit intervention, like an oxygenator change out. It's another layer of safety that can save your butt. (NOTE GG: Concerning the bubble trap we used, if you think about it, it was about the shape of a centrifugal pump head, except the blood comes in the side and leaves the bottom just opposite of the C-pump blood flow pattern. The trap was smaller than the C-pump and did not have the blood agitation by the churning paddles. So there is less stimulation for coagulation in partially heparinized blood. The bubble trap did have a large mesh screen (250 microns) to help divert bubbles towards the purge line on top. The mesh in the screen was a lot wider than the hollow fiber spaces and added no resistance or platelet catching problems. We used the purge line as the shunt for the CDI and ultrafiltrators. Not only was the bubble trap safer for patients, but it improved the ECMO Specialists ability to spot and remove any air that threatened the patient. You know how difficult it is to spot small bubbles racing thru a blood line. The bubble trap slowed it down just enough for the air to be seen and removed. But, just as important, the bubble trap protected the ECMO Specialist from missing air emboli which can easily happen if no bubble trap is used. A patient being injured or killed from a missed air embolus can damage an ECMO Specialist emotionally, possibly even causing PTSD.