CPB FMEA #47 Failure of integrated cardiotomy filter due to unexplained obstruction.

Friends-

This Failure Mode and Effects Analysis (FMEA) is inspired by an article by Dr. Cory Alwardt PhD, CCP and others (Alwardt CM, Wilson DS, Pajaro OE. Unexplained Obstruction of an Integrated Cardiotomy Filter During Cardiopulmonary Bypass. L. Extra-Corpor. Technol. 2017;49, 59-63). They opine that there is no “formal reporting structure for incidents or near miss events” for perfusionists in the USA. Although I am not a legal expert, I (Gary Grist) feel that such a reporting structure may not be protected under current liability law.

In the USA the Patient Safety and Quality Improvement Act of 2005 does confer legal protection via formal Patient Safety Organizations (PSOs) to healthcare providers who wish to discuss adverse events beyond the confines of their own institutions. These PSOs are similar to a hospital’s morbidity and mortality conference that allows the open, non-punitive discussion of incidents and errors with protection from legal discovery except that the discussion is only open to a formal member of the PSO. However this protection is limited only to those Federally-listed PSOs, which at the present time has no specific perfusion organization representation. Unfortunately, the structure of the PSOs may not be useful to the participants in keeping patients safe because 78 of the 163 originally listed PSOs have become delisted primarily due to voluntary relinquishment of their participation <https://pso.ahrq.gov/pso-delisted> . Nonetheless, if you are interested in participating in a PSO here is a simple document which describes all of the designations and rules; https://www.kattenlaw.com/Files/138677\_20160112-PSO-Webinar-Slides.PDF.

What about the “Manufacturer and User Facility Device Experience Database - (MAUDE)” reports by the FDA? Aren’t those as good as FMEAs? https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents.

 I think it is difficult to navigate and search the MAUDE reporting system and I do not think it offers the kind of detail that can be found in an FMEA. Maude reports deal primarily with product failures whereas FMEAs also deal with procedural and human errors as well. So, no, I do not think MAUDE reports are as good as an FMEA.

Dr. Alwardt further states; “ A formal reporting structure would benefit the community in terms of awareness and education to shape a critical response to such an event.” He has suggested to me that a formal reporting structure would really get more incidents reported that the community could learn from and that case reports could be shared without having to go through all the work that comes with publishing. But until such time as a formal reporting structure becomes available to perfusionists in the USA, I think the answer is to compose FMEAs.

FMEAs describe incidents and near misses as “failures”. An FMEA goes on to list the “effects” of the failure; that is what happens to the patient (or in some cases to the perfusionist). The “causes” of the failures are then listed. This is followed by “pre-emptive management” which are actions taken before hand to prevent the failure or “management” actions to mitigate the failure if it actually occurs. Finally, the FMEAs assess the degree of severity (harmfulness) if the failure actually happens, the frequency of the failure occurring, how easily the failure can be detected before it occurs and the types of patients most susceptible to the failure. These numerical values are all combined to form a Risk Priority Number (RPN). The RPN prioritizes the risks for programs that utilize FMEAs so that they can make improvements in equipment and procedures to lower risks. For example, under certain circumstances the Risk Priority Number for this specific FMEA is only 6/375. However without the proper precautionary pre-emptive management, the Risk Priority Number is as high as 75/375 (See below).

Since FMEAs are generic there are no specific incidents, patients or medical personnel who could become involved in a liability issue. FMEAs can be posted for all to see on perfusion list servers by any perfusionist without a lengthy publication process and then archived on the AmSECT Safety Page for access at any time by any perfusionist. A perfusionist can access the AmSECT Safety Page, scroll down the archives of FMEAs and select one of the many dangerous or unusual problems and learn how to recognize them and deal with them, hopefully before they harm the patient. As time goes by and methods change additional CPB FMEAs will be added to these archives.

FMEAs can also be used as “table top scenarios” about which perfusionists can discuss pre-emptive management and management actions needed to prevent or mitigate perfusion problems. Not many perfusion programs have simulation labs where emergency actions can be practiced. The next best things are FMEA table top scenarios where everyone on the perfusion staff can benefit by open discussion and whereby the risks can be assessed and possibly reduced. Furthermore, FMEAs can describe scenarios not necessarily conducive to simulation such as patients with hypertrophic myocardium or sickle cell disease. (See CPB FMEA #9: Hemodynamic instability due to the presence of hypertrophic cardiomyopathy (HCM), idiopathic hypertrophic subaortic stenosis (IHSS) and its variants and CPB FMEA #11: Failure to take proper precautions for the sickle cell disease (SCD), sickle cell trait (SCT) or thalassemia patient undergoing CPB to prevent post-op sickle cell crisis. http://www.amsect.org/page/fmea-archives).

I feel that FMEAs written about real life perfusion failures can provide the “awareness”, “education” and “critical response” called for by Dr. Alwardt and his colleagues without risking the liability of reporting specific true life failures.

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CPB FMEA #46- Failure of integrated cardiotomy filter due to unexplained obstruction.

FAILURE: Failure of integrated cardiotomy filter due to unexplained obstruction.

EFFECT:

1. IV infusion or blood flow on affluent filter side slowed or stopped.

2. Cardiotomy pressurized as evidenced by audible indication when luer lock cap removed.

3. Affluent filter chamber filled with blood causing reduced circulating volume.

4. Cardiotomy suckers and vent use greatly reduced or stopped

5. Inability to clear operative field of blood.

7. Danger of cardiac distention.

8. Cardiotomy reservoir subject to excessive positive pressure on the affluent side can crack or even explode (See CPB FMEA #6: Cardiotomy/venous reservoir over pressurization http://www.amsect.org/page/fmea-archives)

9. Cracked reservoir can cause loss of blood volume and interruption of bypass.

10. Exploding reservoir can expose healthcare personnel to plastic shrapnel and gross blood splatter contamination.

11. Forced premature termination of procedure.

12. Forced cardiotomy reservoir component change out.

13. Danger of emboli, hypotension and organ damage as a result of component change out and interruption of perfusion.

CAUSE:

Cause may be unknown but likely similar to high pressure excursions often seen in oxygenators (See CPB FMEA # 30 High pressure excursion <http://www.amsect.org/page/fmea-archives>):

1. Physiologic:

a. Platelet and fibrin deposition on filter due to patient heparin resistance.

b. Cryofibrinogen can occur in up to 7% of patients and may precipitate on cool cardiotomy filter partially blocking blood flow.

c. Mannitol crystals may precipitate on filter surfaces partially blocking blood flow.

2. Manufacturing defect:

a. Cardiotomy reservoir and filter sub-assembly incorrectly assembled and at least partially obstructed to fluid passage.

PRE-EMPTIVE:

1. Infuse crystalloid prime through the affluent side of the cardiotomy filter while running the suckers and vent pumps at high speed to check for obstruction caused by mechanical defect or abnormal moisture blockage during priming procedure.

2. Add heparin to the circuit and recirculate some through the cardiotomy filter.

3. Prior to use ensure that the caps on top of the reservoir are not stuck on the ports. Ensuring that the caps on a reservoir are able to come off easily in the case of over pressurization should help avoid problems.

4. Add pressure monitoring of affluent cardiotomy filter:

a. Attach a pressure vail with manometer to an affluent filter luer lock OR

b. Attach a 10-20 ml syringe with the plunger loosened to an affluent filter luer lock. Plunger is pushed upwards if pre-filter pressure increases OR

c. Attach an unclamped, empty, crystalloid prime bag to the affluent side of the filter. This would be the least effective monitor and may inflate even when the filter is unobstructed.

5. Have a plan and supplies readily available pump side should cardiotomy reservoir change out become necessary. Change out should be planned without interrupting CPB.

6. Ensure that knowledgeable assistance is immediately available should change out be necessary.

MANAGEMENT:

1. Increase blood temperature if possible. This may reverse filter obstruction caused by cryoprecipitate or mannitol crystals.

2. Change cardiotomy reservoir. Plan for change out should include supplies necessary to connect new cardiotomy reservoir to old venous reservoir, bypassing the old cardiotomy filter, preferably without coming off CPB.

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 Harmfulness failure an RPN of 3 if change out does not interrupt CPB and adequate help is available. If change out requires CPB termination OR adequate help is not available, then the Harmfulness RPN would be 4. If change out requires CPB termination AND no adequate help is available, the Harmfulness RPN should be 5.)

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

1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High. (This failure occurs very infrequently. So the Occurrence is Remote. 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 1 if manometer pressure monitoring of the affluent filter is used. If a syringe plunger pressure monitor is used, the detectability would be 2. If an empty crystalloid solution bag pressure monitor is used, the detectability would be 4. If no pressure monitoring is used at all, the detectability would be a 5.)

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 are 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 for any failure would be 1\*1\*1\*1\* = 1 and 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 very low if Pre-Emptive Management which includes a plan to change out the cardiotomy reservoir without interrupting CPB, if adequate help is immediately available and if manometer pressure monitoring is used: 3\*1\*1\*3 = 9. On the other hand, if the change out plan requires interrupting CPB, there is no help immediately available and no pressure monitoring is used the RPN would be 5\*1\*5\*3 = 75.)