CPB FMEA #46 Failure to reinstitute CPB emergently

Friends-

Recently I was asked by Kevin Fleming if a Failure Modes and Effects Analysis (FMEA) had been done regarding the safe handling and preservation of the heart lung machine circuit after coming off bypass. After our conversation we agreed that a guideline regarding “post pump tear down” could be a beneficial patient risk management assessment. So he and I co-authored this FMEA.

Conduct of maintaining pump integrity during the postoperative phase can vary greatly between surgeons and perfusionists. Regardless of preference, patient safety should always be our number one priority, and we can minimize or eliminate potential life-threatening situations that can quickly arise in the “post-bypass” stage of surgery.

 A main concern involves cases where the pump is torn down prematurely and cannot be reused should the patient experience an unforeseen complication requiring immediate cardiopulmonary support. This can happen easily and more often than you think; the scramble to salvage the discarded circuit or the rush to setup a new circuit can ruin a perfusionist’s day, not to mention the unfortunate patient.

Although relieved to be off bypass, there are many unforeseen things that can happen and we as perfusionists cannot afford to put our guard down. Protamine reactions, bleeding complications, hemodynamic instabilities, lethal arrhythmias, patient specific co-morbities, case complexities, and failed surgical interventions can all result in the need for a rapid return to bypass.

I have actually seen a perfusionist remove all the disposables into a large, wheeled trash barrel while the blood lines were still attached at the field. His purpose was to re-string the new circuit for the next patient on the pump. This was a very busy program doing 1500+ cases per year in only 3 CV surgery OR rooms. So where ever time could be saved, the CV surgery team took those short cuts. Were these short cuts dangerous? I don’t know. (This practice could never be defended if infection control, Joint Commission, or Risk Management were to question it, especially if the patient required urgent re-initiation of bypass.) I never saw an incident related to these practices, but then again I was not at that hospital for very long. But I can easily envision how cross contamination and slips and lapse errors can occur.

 The scenarios and motivation for taking down the pump quickly after CPB are endless, but often are not defendable practices. There seems to be a consensus that the pump circuit should be chased with crystalloid to get the blood back to the patient utilizing the various blood management methods at our disposal. This results in a fluid filled circuit that can be recirculated until the wires are crossed and the sternum is closed. With the presence of hemodynamic stability after closure, the pump circuit can be discarded. However, many institutions choose to keep the circuit intact until the patient leaves the room.

Although we can’t anticipate every emergent situation that can arise, we can develop a procedure based on our experiences, failures, close-calls, and mistakes to come up with optimal patient safety practices in all aspects of care of our cardiac surgery patients.

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FAILURE: Failure to reinstitute CPB emergently due to an unexpected need for extracorporeal resuscitation in the immediate post-CPB or post-operative period.

EFFECT:

Failure to re-initiate CPB in a timely fashion can result in:

1. No oxygenated blood being pumped to the patient

2. Hypotension

3. Acidosis

4. Hypercapnea

5. Hypoxia

6. Organ failure

7. Death

CAUSE:

1. Premature takedown of CPB circuit.

2. No backup circuit ready for immediate use.

3. Absence of the perfusionist from the OR in the immediate post-CPB or post-operative period.

PRE-EMPTIVE:

1. Maintain CPB circuit for possible re-institution of emergent CPB:
2. Add heparin the circuit and recirculate AV loop.
3. Rinse ancillary lines with heparinized saline to prevent blood from drying and causing an embolus.
4. Cover AV loop and ancillary lines with sterile sheets if they are removed from the operative field.
5. Ensure perfusion personnel are immediately available in the critical post-CPB and post-operative periods.
6. Do not tear down circuit until patient is delivered to the ICU and evaluated for vital stability.

MANAGEMENT:

1. If early CPB circuit tear down is performed, a back-up, assembled circuit on a pump should be immediately available.
2. If the perfusionist leaves the OR, a method of instant communication should be maintained and the perfusionist should be able to return within 3 minutes.

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 of 2. If the CPB circuit is not maintained for immediate use, the Harmfulness RPN should be increased to 4. If no backup pump and circuit is immediately 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 because the need for emergent reinstitution is readily apparent to a perfusionist in attendance in the post pump period. If the perfusionist is absent from the OR or cannot be immediately contacted or cannot return within 3 minutes, the Detectability RPN should be 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 and perfusionists 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 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 very low if Pre-Emptive Management is used: 2\*1\*1\*3 = 6. The maximum RPN could be 75 if the recommended precautions are not taken.)