CPB FMEA # 23 Failure: rupture of the coronary sinus (CS) with retrograde cardioplegia (RCP).

Friends-

# This has been a difficult FMEA for me to write because I do not have very much experience with retrograde cardioplegia (RCP). My original FMEA on this subject was written by a former staff perfusionist that I worked with. To flesh it out, I relied on the experienced volunteer FMEA reviewers to provide the additional information that I needed.

# As I wrote this FMEA I realized that RCP is a procedure that requires great finesse on the part of the perfusionist and surgeon working together. A ruptured coronary sinus (CS) is a rare complication, but it can be catastrophic when it does occur. I believe there is a great danger for a CS rupture as the result of experienced teams losing momentary focus on the intricacies of the procedure because it has become a such rote process (almost an unthinking reflex) for them.

I also came to realize that there are many variations to performing RCP. This FMEA only hits the high spots. If you use RCP and want an FMEA for it, you should re-write this FMEA to fit your specific needs. If you have any comments to add please post them on Perflist or contact me.

As I was planning to send out this new FMEA, I had a nightmare about a CS rupture. I dreamt that I completely ripped open the back of the heart while doing RCP. Since I retired, I don't have as many work related nightmares. When I had them I was always greatly relieved when I awoke to find that it was only a dream! I guess that nightmares are just one of the stresses of being a perfusionist, at least for me. I pray that a CS rupture remains only a nightmare for you and never a reality.

On that happy note, let me wish you all a Happy New year!

AmSECT Safety Committee

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FAILURE MODE AND EFFECTS ANALYSIS

FAILURE:

Rupture of the coronary sinus (CS) with retrograde cardioplegia (RCP).

EFFECTS:

1. Inadequate myocardial protection.

2. Increased morbidity with additional surgical procedure to repair coronary sinus.

3. Death.

CAUSE:

1. Damage to CS during insertion of RCP cannula.

2. Damage to CS during infusion of RCP because of high CS pressure.

3. Migration and misplacement of the RCP cannula during manipulation of heart.

4. Overinflating of balloon.

5. Loss of focus by the surgeon or perfusionist to quickly recognize inappropriate pressures.

6. When utilizing a multi-perfusion device, ports left open inadvertently giving false pressure and flow readings to the intended RCP target area.

7. Women low body mass index\*.

8. Overly forceful insertion due to coronary sinus web\*.

9. Fragility of vessels in thin patients\*.

10. Small CS\*.

11. Elderly patients have friable tissues and are more liable to rupture.

12. Frequency of CS rupture is about 1%\* with an experienced team.

\*Sabzi 2012

PRE-EMPTIVE MANAGEMENT:

1. Care during insertion of RCP cannula to avoid trauma to CS.
2. If the patient is not on CPB during insertion of the RCP cannula, the perfusionist should monitor EKG closely for ectopy; risk of patient going into V-Tach.
3. Monitor of MAP during insertion of RCP cannula for loss of cardiac output (if patient is not on CPB) secondary to positioning and manipulation of the heart.
4. Perfusionist should be prepared to go on CPB emergently to provide cardiac support.
5. If the patient is on CPB when the surgeon is inserting the RCP cannula, the perfusionist should assist the surgeon by providing adequate filling of the right heart to assist in palpating the CS and placing the RCP cannula.
6. Once the RCP cannula is placed, the CVP line should be re-zeroed.

7. If CS pressure >20 mmHg after zeroing and before RCP infusion, the cannula may be wedged in either the greater cardiac vein or posterior descending vein.

8. If CS pressure < 20 mmHg during RCP infusion, the balloon may not be occluding the CS, the RCP cannula may have slipped back into the right atrium, or there may be an anomalous left superior vena cava or unroofed CS.

9. Initiate RCP flow slowly starting at 2.5%-5% of total calculated cardiac output while monitoring RCP line pressure and CS pressure.

1. Monitor CS pressure during RCP infusion with a target pressure of 25-30 mmHg and a safe pressure range of 20-40 mmHg.
2. Pressure >40-50 mmHg suggests that the CS is becoming distended or that the RCP cannula has entered a coronary vein, both of which increase the chance of the sinus rupturing.
3. Should the pressure spike the perfusionist should immediately STOP the delivery.

13. The perfusionist should confirm that the surgeon sees the cardioplegia coming out of the aorta if the aorta is open.

14. If the aorta is closed the aortic root vent should always be on. Without proper venting the coronary arteries could dissect.

15. Maintain meticulous communication among the team with each delivery.

16. If the frequency of use is common (3\*) then the occurrence will be low (1\*) and the total RPN will be 60. However it the frequency of use is low (1\*) then the occurrence will be high (4\*) and the total RPN will be 80.

MANAGEMENT:

1. Since retrograde flow is so dependent upon adequate pressure and flow, any disparity in either pressure or flow should cause concern. Some examples would be:

a) high flow with small pressure increase

b) barely able to flow with very high pressures.

1. Discontinue RCP cardioplegia and repair CS.

REFERENCES:

1. Drinkwater DC Jr, Cushen CK, Laks H, Buckberg GD. The use of combined antegrade-retrograde infusion of blood cardioplegic solution in pediatric patients undergoing heart operations. J Thorac Cardiovasc Surg. 1992; 104(5): 1349-55.

2. Hensley FA Jr, Martin DE. A Practical Approach to Cardiac Anesthesia, 2nd Ed. Boston: Little, Brown and Company; 1995.

3. Gravlee GP, Davis RF, Utley JR. Cardiopulmonary Bypass, Principles and Practice. Baltimore: Williams & Wilkins; 1993.

4. Lich BV, Brown DM. The Manual of Clinical Perfusion, 2nd Ed. Fort Myers, FL: Perfusion.com; 2004.

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, 5.)

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 when used with great frequency. If only used infrequently the Occurrence of this failure would be more common, 4.)

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 4. Detecting the proper placement of the RCP cannula is difficult even with pressure monitoring.)

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.

(Only patients with RCP procedures would be at risk. If RCP is only used on a small number of patients the Frequency would be 1. If RCP is commonly used the Frequency 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 5\*1\*4\*3 = 60 if the procedure is commonly used. If RCP is only used on a select few patients the total RPN would be 5\*4\*4\*1 = 80. )