

Database Review: Clinical Outcomes Of Non-Coated And Multi-Coated Cardiopulmonary Bypass Circuits In Infants

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Citation

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Abstract

Purpose: To assess the clinical effects of non-coated and multi-coated circuits used in pediatric cardiac surgery.

Materials: Multi-coated and non-coated cardiopulmonary bypass circuits.

Methods: A retrospective review of a patient database using non-coated and multi-coated cardiopulmonary bypass (CPB) circuits in infants.

Participants: The patient populations were of risk categories two and three as described by Jenkins 2002, kilogram body weights ≤ 6.0 , no aprotinin (Trasyol®, Bayer Pharmaceuticals) administration, and the use of MUF (Modified Ultrafiltration) following bypass.

Results: The use of multi-coated circuits in this population trended toward improved post MUF hematocrits despite less blood administration on bypass, decreased Length of Stay (LOS) during admission, time on ventilator, and mortality. However, the use of multi-coated circuits also trended in an increased anion gap post-surgery, additional chest tube drainage, and higher defibrillation rates post cross-clamp removal.

Conclusion: Multi-coated CPB circuits trended toward benefiting moderate risk group infants.

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INTRODUCTION

Clinical procedures involving extracorporeal blood circulation are potentially complicated due to the interaction of various blood systems with foreign surfaces. In cardiopulmonary bypass (CPB), exposure of blood to synthetic surfaces leads to activation of the fibrinolytic, coagulation, and complement cascades. Activation of these systems is often associated with operative and postoperative complications^(2, 3). Some parameters to be considered for intra-operative complications are the need for post cross clamp defibrillation, the need for additional blood administration during CPB, and increases in pre-CPB to post-operative Anion Gap (AG). Post-operative

complications include volume of chest tube drainage per kilogram, LOS, mortality, and time of ventilator assist.

It is postulated that the application of biocompatible materials in an extracorporeal circuit attenuates clinical complications in operative and postoperative pediatric cardiac surgery. In an effort to validate our current clinical practices, a retrospective review of a patient database was conducted to delineate the difference between the applications of non-coated versus multi-coated CPB circuits.

MATERIALS AND METHODS

Institutional Review Board approval was obtained for this study (IRB # 03 06-067X).

DISPOSABLE SUPPLIES

The multi-coated circuit used for this review consisted of a

Lilliput 1 oxygenator with Ph.ISIO® coating (Dideco, Modena, Italy) with integrated reservoir, a 3/16 inch arterial line and a 1/4 inch venous line with Trillium® coating (Medtronic Cardiovascular, Minneapolis, MN), 1/4 inch raceway and custom 4:1 blood cardioplegia set CSC14 with SMARxT® coating (Cobe, Arvada, CO), a PAN-03 hemoconcentrator (ASAHI, Arvada, Co) and a CX*BT05 pediatric bubble trap (Terumo, Ann Arbor, MI). The static blood volume of this circuit without the cardioplegia set and hemoconcentrator is 380 ml. The non-coated group used the same non-coated components containing medical grade Poly Vinyl Chloride (PVC) (Cobe, Arvada, CO) tubing.

Figure 1

Table 1: Description/Mechanism of action for coated circuit components

| | Trillium® Medtronic * | Dideco Ph.ISIO®* | Cobe SMARxT®** |
|-----------|--|---|--|
| Material | Polyethylene oxide and Heparin | Phosphorylcholine (PC) Inert Surface | Surface Modifying Additive (SMA) |
| Mechanism | PEO polymer is extremely hydrophilic which resists cell adhesion and protein deposition. Heparin is covalently bonded into the surface to provide anticoagulant as does heparan sulfate in the native endothelium. | PC is hydrophilic which maintains a water barrier thus preventing blood contact with a foreign surface as in the vasculature. | A modified surface that alternates hydrophilic and hydrophobic microdomains which binds to sites on fibrinogen, resulting in a mosaic like protein expression. |

Each circuit was primed with Plasmalyte 148® (Baxter Healthcare, Deerfield, IL), followed by 100 mls of 25% human albumin. One unit of packed red blood cells and one unit of fresh frozen plasma were then added and the prime was subsequently hemoconcentrated to a venous reservoir level of 150 ml. The following drugs were then added; 2000 units of heparin, 30 mg/kg of Methylprednisolone, 30 mg/kg of Cefazolin, and 12 mEq of sodium bicarbonate.

Anticoagulation prior to cardiopulmonary bypass consisted of 300 units/kg. The activated clotting time target value using the P215 tube and Hemochron test unit (ITC, Edison NJ) was over 480 seconds.

Flow rates on bypass were estimated using 2.5 liters/min cardiac index and mixed venous saturations were maintained above 65%. Blood gas management consisted of pH stat and hyperoxia during cooling and rewarming phases except with cyanotic patients who were initially exposed to 21% oxygen which was increased to 100% during the cooling phase. Hyperoxia was also used during normothermia unless patients were cyanotic when lower oxygen concentration was used as tolerated. Blood gases, electrolytes, and hematocrit determinations were performed on the Bayer

Rapidpoint 400 (Bayer Diagnostics, Norwood, MA).

Routine hemoconcentration was carried out in all cases during bypass for volume control. This was followed by arterio-venous modified ultrafiltration after cardiopulmonary bypass was concluded.

PARTICIPANTS

The patient population chosen for review was from our database of over 1300 patients between May, 2000 and February, 2005. The review included only those patients meeting the following criteria: 1) operated on by either of two surgeons, 2) risk category two or three as described by Jenkins, 2) weighing 6 kilograms or less, 3) receiving no aprotinin (Trasyol®, Bayer Pharmaceuticals) administration, and 4) undergoing arteriovenous modified ultrafiltration (MUF) following bypass; resulting in a total of 116 patients for review(1). These parameters were chosen to best reflect the impact on a variety of patient outcomes when using multi-coated circuits versus non-coated equivalents.

Figure 2

Table 2: Description of patient population studied

| | Non-Coated (n=87) | | | Multi-Coated (n=29) | | | Significance p = |
|------------------|-------------------|------|--------|---------------------|------|--------|---------------------|
| | Average | SD | Median | Average | SD | Median | |
| Risk Category | 2.5 | 0.5 | 2 | 2.5 | 0.5 | 2 | NS |
| Weight (kg) | 4.6 | 0.9 | 4.8 | 5 | 0.7 | 5 | NS |
| Pump Time (min) | 84.9 | 32 | 80 | 80 | 26.4 | 74 | NS |
| Clamp Time (min) | 41.9 | 19.5 | 41 | 47 | 23.7 | 37 | NS |

RESULTS

Statistical analysis was carried out using an unpaired t-test by GraphPad InStat version 3.01 for Windows XP (GraphPad Software, San Diego, CA). None of the patients were excluded from this review.

The use of multi-coated circuits in this population trended toward improved post MUF hematocrits without the need for additional blood administration on bypass, decreased LOS, decreased time on ventilator, and decreased mortality. However, the use of multi-coated circuits also resulted in a slightly increased anion gap post-surgery, slightly increased chest tube drainage, and slightly increased defibrillation rates post cross-clamp removal. None of the differences were statistically significant although clinical significance seemed apparent particularly in the LOS and the time on the ventilator.

Figure 3

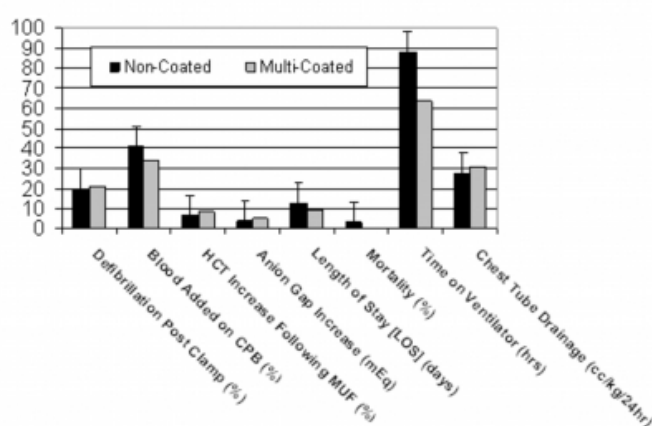
Table 3: Results of non-coated versus multi-coated circuits

| | Non-Coated (n=87) | | | Multi-Coated (n=29) | | | Significance p= |
|----------------------------------|-------------------|-------|--------|---------------------|------|--------|--------------------|
| | Average | SD | Median | Average | SD | Median | |
| Defibrillation post clamp (%) | 20 | | | 21 | | | NS |
| Blood Added on CPB (%) | 41 | | | 34 | | | NS |
| HCT increase following MUF (%) | 6.6 | | 7 | 8.1 | | 8 | NS |
| Anion Gap Increase (mEq) | 4 | 3.2 | 4 | 5 | 3.3 | 5 | NS |
| Length of Stay [LOS] (days) | 12.8 | 21.8 | 8 | 9.4 | 7.7 | 7 | NS |
| Mortality (%) | 3.5 | | | 0 | | | NS |
| Time on Ventilator (hrs) | 87.8 | 246.4 | 33 | 64 | 90.8 | 34 | NS |
| Chest Tube Drainage (cc/kg/24hr) | 27.4 | | 23 | 30.4 | | 23 | NS |

Figure 4

Figure 1: Chart of results for non-coated versus multi-coated circuits

Results of Non-Coated vs. Multi-Coated Circuits



DISCUSSION AND CONCLUSION

The purpose of this review was to determine if the application of multiple biocompatible materials in an extracorporeal circuit results in similar or better outcomes in pediatric cardiac surgery. Currently, there are no published findings on the clinical outcomes associated with multi-coated circuits. However, there is conflicting information on the use of Trillium and Surface Modifying Additives (SMA) coatings during CPB. Dickinson reports that the use of Trillium-coated circuits versus non-coated Trillium circuits resulted in decreased use of blood products, decreased post-operative fibrillation, and fewer reoperations for bleeding⁽⁴⁾. Erath states that Trillium coating did not show any clinical benefit in terms of blood loss or transfusion requirements⁽⁵⁾. Defraigne demonstrated SMA coating to be associated with a decrease blood loss and with patients requiring nearly 50%

less Fresh Frozen Plasma and platelets⁽⁶⁾. Sudkamp on the other hand, saw no difference in decreased blood loss or transfusion requirements⁽⁷⁾. The use of phosphorylcholine as reported by De showed that its use in CPB resulted in 30% reduction in blood loss than in non-coated equivalents⁽⁸⁾. These differences in results demonstrate wide fluctuations in the response to the use of coated circuits for CPB. However, there are no published results demonstrating the positive and/or negative effects of multi-coated circuits during CPB. In conclusion, as shown in Figure 1, our outcomes with multi-coated CPB circuits trended towards benefiting moderate risk group infants over the use of non-coated PVC.

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