Arterial Filter Bypass Loop: What Occurs in this Area during Cardiopulmonary Bypass and Are There Potential Patient Implications

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Abstract: The arterial filter is an integral part of bypass circuitry. When introduced, manufacturers suggested a bypass loop for retrograde priming and de-airing, and for uninterrupted blood flow in case of malfunction. Practice has shown antegrade priming and de-airing is possible. This questions the necessity of the loop and presents the question—what occurs in the loop during bypass? After obtaining Human Research Ethics Board approval, eight consecutive patients (n = 8) were chosen for this study. Exclusive exclusion criterion was receiving any transfusions during cardiopulmonary bypass, as this could possibly influence results. The choice of patient numbers was based simply on proof of concept. Investigation involved isolation and collection of loop contents after cardiopulmonary bypass was completed. Testing included complete blood count, prothrombin time, international normalized ratio, partial thromboplastin time, activated clotting time, plasma free hemoglobin, slide photography with analysis for platelet clumping, and debris detection. One perfusionist collected samples, providing uniform collection and isolation technique. Regular blood samples were collected from the bypass circuitry, and from patients’ pre-operative blood work. Analysis of data revealed that platelet counts in the bypass loops were statistically lower than control. Evidence of platelet clumping was present in 3 of 8 bypass loop samples, representing 37.5% of the study population. There was no clumping detected in any of the controls. In patients where platelet clumping was present, a positive correlation was noted between mean bypass time and size of platelet clumps. Prothrombin time and international normalized ratio results were immeasurable. Hemoglobin levels were higher in the loop samples. There was no evidence of debris or fibrin monomer present in any of the samples analyzed. The study results indicate that during “normal” cardiopulmonary bypass with an arterial filter bypass loop, platelet aggregates can accumulate in the loop, therefore opening the arterial bypass loop in any case may subject the patient to micro/macropel emboli. Keywords: arterial filter, bypass loop, platelet clumping.

The majority of arterial line filters are made from a hydrophilic polyester material, with an effective surface area ranging from 400–800 cm², enclosed in a polycarbonate housing (1–3). Arterial filters were first reported in the early 1960s and are a standard of care (4). The primary advantage noted with incorporating the filter in the cardiopulmonary bypass circuit is prevention of micro emboli, either being particulate or micro air from reaching the patients circulation (1,5). A landmark study from England in 1994 compared neurological outcome in patients with and without an arterial line filter. Patients without the arterial line filter had more emboli and a poorer outcome (6).

During the time of original introduction, manufacturers suggested a bypass loop be incorporated for retrograde priming and de-airing, and as a means for providing uninterrupted blood flow in the event of filter malfunction over the course of bypass (7).

If the arterial filter becomes unusable during the course of a bypass case, what is the cause? Also, if the main purpose of the filter was to increase patient safety, how prudent is it to open the bypass loop if the filter has been “filtering out” material with embolic potential, and now it is clogged and rendered useless.

More recent filter designs on the market today, such as the Sorin Synthesis® (Mirandola, Italy) integrated oxygenator/arterial filter and the Maquet Quart® (Rastatt, Germany) arterial filter, do not require retrograde filling for priming; neither design incorporates a bypass loop and both are primed in an antegrade fashion (8,9). The Medtronic Affinity® (Minneapolis, MN) arterial filter, which is widely used in conventional cardiopulmonary bypass, is also...
incorporated in their “resting heart system,” and it does not include a bypass loop in this application. This seriously questions the functional need for the bypass loop, and the patient safety aspect. The purpose of this investigation was to determine what is actually taking place in the stagnant pool of blood proximal to the clamp during bypass.

**MATERIALS AND METHODS**

After research ethics board approval was obtained, eight consecutive patients (n = 8) undergoing cardiopulmonary bypass were studied. The only exclusion criterion noted was a patient receiving transfusions during cardiopulmonary bypass. The investigation involved isolation of contents of the bypass loop after bypass had been completed. Samples were drawn from the bypass loop within 5 minutes after termination of cardiopulmonary bypass. Laboratory testing using LH 755 hematology analyzer (Beckman-Coulter, Miami, FL) included complete blood count (CBC), prothrombin time (Pt), international normalized ratio (INR), partial thromboplastin time (Ptt), plasma free hemoglobin, and slide photography for analysis of platelet clumping and debris detection. The same perfusionist performed the cardiopulmonary bypass, and subsequent sample collection for all study cases, providing for uniform collection and isolation technique. All blood collection tubes were from the same lot number for all samples.

**Cardiopulmonary Bypass Circuitry**

The cardiopulmonary bypass (CPB) circuit consisted of Gish Vision Oxygenator (Irvine, CA), Dideco D734 arterial filter (Mirandola, Italy), and Sorin Phosphorylcholine coated tubing incorporating a 5 µm pre-bypass filter in the A-V loop (Mirandola, Italy). The arterial filter used was coated with a biocompatible phosphorylcholine coating called Mimesys™ (Sorin Biomedica, Mirandola, Italy). This coating is phospholipid-based polymer that mimics the bi-lipid surface of cellular membranes. This in turn makes the polyvinylchloride tubing relatively inert to the blood (9). The circuit was first flushed with carbon dioxide for a minimum of 3 minutes. Priming solution consisted of 1800 mL Normosol R® (Hospira, Saint-Laurent, Quebec, Canada) and 10,000 units of porcine heparin (Pharmaceutical partners of Canada Inc., Ontario, Canada). All patients received a dosage of 300–350 units/Kg of heparin prior to bypass. Activated clotting time (ACT) was assessed using the ACT II (Medtronic Inc, Minneapolis, MN). Target value prior to commencing CPB was >480 seconds.

Perfusion technique involved no use of altered priming techniques such as RAP (retrograde priming). Target flow was calculated by formula body surface area (BSA) × 2.4 L/m². During each case patient temperature was allowed to drift to a low temperature of 32°C. Cold cardioplegia was administered by both antegrade and retrograde routes at a 4/1 ratio. Samples for blood gas analysis were drawn every 30 minutes. If ACT dropped to below 480 seconds 10,000 units of heparin was administered and ACT was checked again in 5 minutes. No adverse events, such as failure of any circuit components or mechanical pump problems, occurred during any of the cases, and no cases required reinitiating cardiopulmonary bypass after termination.

**Patient Demographics**

Study patients’ average age was 71 years, with an average weight of 79.3 kg; body surface area (BSA) averaged 1.89. The gender was split 62.5% males and 37.5% females (Table 1).

**Procedure Demographics**

Pump time for cases averaged 117 minutes, with an average clamp time of 87 minutes. The operative procedures were 75% coronary artery bypass grafts and 25% combination coronary bypass grafting and valve replacement (Table 1).

**Bypass Loop Modification and Isolation Technique**

For this study the arterial filter bypass loop was modified to incorporate two uncoated 3/8 connectors with leur ports (Medtronic, Minneapolis, MN). The first Leur port was for sample collection, and the other to alleviate negative pressure, which could cause trauma to blood cells in the collected sample. After termination of cardiopulmonary bypass, and after consultation with attending surgeon, the content of the loop was collected as shown in (Figure 1).

| Age (years) | 71 ± 13 |
| Weight (kg) | 79.3 ± 31.7 |
| BSA (m²) | 1.89 ± .42 |
| Gender (M/F) (%) | 62.5/37.5 |
| Pump time (minutes) | 117 ± 53 |
| Clamp time (minutes) | 87 ± 39 |
| Procedures | 75% CABG, 25% CABG/Valve |

**Table 1. Patient and procedure demographic.**

CABG, coronary artery bypass graft.

**Figure 1. Bypass loop modification.**
Collection tubes for blood samples were from the same lot number for all samples. Blood samples for control hematology (plasma free hemoglobin, Pt, INR, Ptt, CBC, ACT) were drawn prior to termination of CPB. Bypass loop samples were collected after bypass was terminated and after consulting attending surgeon and anesthetist to ensure patient stability was established. The findings were analyzed for statistical relevance.

**STATISTICS**

All statistical analysis was performed using Microsoft Excel 2000 Data Analysis tool pack (Microsoft, Redmond, WA). Values are expressed as plus or minus standard deviation of the mean.

**RESULTS**

Laboratory analysis of data noted that Ptt, Pt, INR tests were deemed immeasurable due impart to the high levels of heparin used during cardiopulmonary bypass. There was no evidence of fibrin monomer present in either the control samples or bypass loop samples.

Composition of the collected samples noted the hemoglobin in the bypass loop was higher as compared to baseline hemoglobin; which would be due to the weight of the red cells settling out in the bypass loop. The difference in plasma free hemoglobin in the control circulation and the loop was not significant (Table 2).

**DISCUSSION**

Platelets contain many molecules which are thromboactive such as adenosine di-phosphate (ADP) thromboxane (TxA²), serotonin and pro-thrombin, adenosine monophosphate (AMP), and platelet factor four (PF4). When platelets are deposited on foreign surfaces these substances are emitted, sending chemical messages to other platelets, which subsequently leads to activation and deposition of more platelets (10–12). Activated platelets adhere and aggregate via GPIIb/IIIa receptors (13). From the results of this investigation it is clear that during cardiopulmonary bypass platelets are precipitating in the arterial filter bypass loop area. This creates an area where conditions are perfect to produce platelet aggregation, as was evident in this study. Li et al. (13) noted, platelets which lack GPIIb/IIIa receptor complexes do not adhere upon activation, which may explain the absence of aggregation in five of the study population.

Bypass loops were incorporated more than 25 years ago as a suggestion by filter manufacturers to facilitate retrograde priming of these devices (14,15). There is no documentation evidence to support retrograde priming of modern day arterial filters and antegrade priming is fully possible and effective (15). Some clinicians argue that the filter bypass loop is a viable means of diverting blood around a filter that becomes obstructed with debris. However, if sufficient thrombus and other debris obstruct the filter media, opening the bypass loop would allow such material to enter the arterial circulation.

Physiology texts note that arterioles range from 5–30 µm, and further branch leading to capillary beds in which the vessel diameter here is in the range of 5–10 µm (16).
Platelet aggregates in this study were found to be in the range of 14–71 µm. Opening of the bypass loop may deliver the accumulated aggregates directly to the brain and other micro-vascular tissue beds. Since these aggregates do not spontaneously dissipate when they enter the general circulation, they might incur a thrombolytic event with associated morbidity to the patient.

As noted earlier, during cardiopulmonary bypass the stagnant pool of precipitated blood elements can contain platelet clumps as large as 71 µm. As well, there is a positive correlation pointing to increased size of clumps as cardiopulmonary bypass time increases. Therefore even during “normal” cases the bypass loop can be accruing embolic material. With this being the case, the bypass loop serves no purpose because it is not necessary for priming and not always a safe option if an emergency situation arises.

CONCLUSIONS

Cardiopulmonary bypass is a dynamic procedure that is intimately connected to the patient’s circulatory system. The statement in the medical oath “first, do no harm” is a powerful reminder to us as clinicians that patient safety is our utmost concern. A critical evaluation of the circuit and techniques must occur particularly as technology changes. If a component is incorporated “just because its always been there” critical questions need to be asked. Sometimes the evidence obtained through questioning and study challenges our current thoughts. The intended purpose noted for the arterial filter bypass loop 25 years ago is not current with today’s modern filters. Newer filter designs are fully capable of being antegrade primed and de-aired efficiently. The sole intended purpose noted for the bypass loop through manufacturer instructions for use (IFU) is retrograde priming; this alone is not a valid reason for keeping this loop in place. Some of the recent filter designs do not require retrograde priming in their IFU (Sorin Synthesis® and Quadrox®, Maquet) (3,8).

To conclude, from the results of this investigation, the arterial filter bypass loop appears to serve no purpose and may compromise patient safety under certain clinical conditions.

REFERENCES