

Embol-X Intra-Aortic Filtration System: Capturing Particulate Emboli in the Cardiac Surgery Patient

Michael A. Sobieski II, CCP; Patroklos S. Pappas, MD; Antone J. Tatoes, MD;
Mark S. Slaughter, MD

Division of Cardiac Surgery Advocate Christ Medical Center Oak Lawn, Illinois

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Abstract: We sought to evaluate the effectiveness of using an intra-aortic filtration system for the prevention of particulate emboli transport and the minimization of significant postoperative complications associated with particulate emboli. Between October of 2000 and October 2001, a total of 146 patients were enrolled at Advocate Christ Medical Center as part of the multi-institutional randomized trial (1289 patients at 22 centers). A total of 74 patients (51%) received the Embol-X intra-aortic filter and 72 patients (49%) were enrolled in the control group. Patients were evaluated for neurological deficit, myocardial infarction, renal insufficiency/failure, limb ischemia, and death at 12-hour, 24-hour, 72-hour, 7-day, and 30-day postoperative intervals. All filters received histological examination for particulate matter. Particulate matter was isolated in 70 (94.5%) of the

filters successfully deployed. There was no statistically significant difference in the device related events between the filter and conventional cannulation groups (9/74 = 12.1% vs. 7/72 = 9.7%). Although not clinically evident, the primary event for both groups was ascending aortic intimal tears. There was one death in each of the groups not related to the filter or cannula used. The use of the Embol-X intra-aortic filter system has proven to be a safe and effective means to reduce the introduction of particulate emboli into the systemic circulation. Clearly, the reduction of particulate matter by as much as 95% justifies its use in cardiac surgery patients identified with an increased pre-operative embolic risk. **Keywords:** Embol-x, filtration, embolic. *JECT. 2005;37:222–226*

The most recent data from the Society of Thoracic Surgeons (STS) database for the decade of 1990 thru 1999 has demonstrated a statistically significant increasing trend in most of the risk stratification of patients presenting for cardiac surgery (Figure 1; 1). Despite the increased pre-operative risk stratification, overall morbidity and mortality rates for patients undergoing cardiac surgery have declined steadily since the introduction of cardiopulmonary bypass (CPB) by Dr. J. Gibbon in the early 1950s (2). The dramatically lower rate of adverse outcomes is clearly linked to improvements in surgical technique and the development of new technology (3). Unfortunately, there still exist a small percentage of cardiac surgical patients who have less-than-desirable outcomes. The incidence of postoperative neurocognitive dysfunction, pulmonary

compromise, and renal complications continue to affect cardiac patients' quality of life (1). Impaired cognitive function has specifically been linked to poor quality of life issues and a higher incidence of mortality (4–6). In the early to mid-1970s, a focus on removing particulate microemboli from the CPB circuit developed. Early studies suggested that although the arterial line filter was effective in removing debris and microemboli from circulation, the overall conclusion was lacking validation of use based on clinical outcomes (7–9). The International Committee on Emboli Management (ICEM) 2000 study was designed to evaluate an intra-aortic filtration system to capture particulate emboli during CPB, the hypothesis being that the capture of particulate emboli in the ascending aorta would mitigate the morbidity associated with cardiac surgery that instituted the use of CPB.

Address correspondence to: Michael A. Sobieski II, RN, CCP Cardiac Surgery Clinical Research Center, Inc 4400 West 95th Street, Suite 205 Oak Lawn, IL 60453. E-mail: cardiacresearch1@aol.com

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METHODS AND MATERIALS

With Institutional Review Board approval, written informed consent was obtained from each patient before

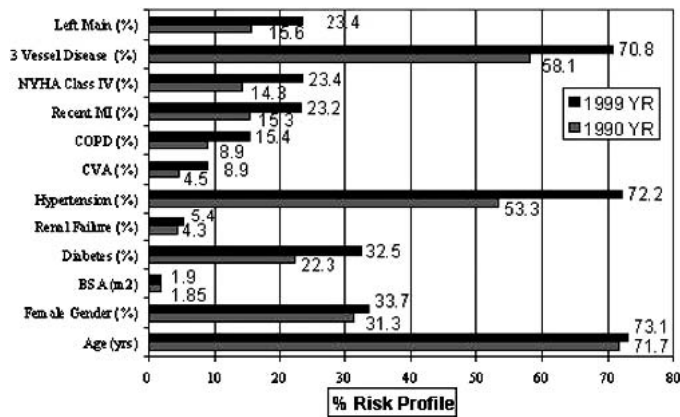


Figure 1. STS database risk variables (1).

randomization. From February 2000 and October 2001, a total of 146 patients were assigned randomly and enrolled at Advocate Christ Medical Center (ACMC) as part of the multi-institutional randomized trial (1289 patients at 22 centers in the United States and Canada). Inclusion criteria for enrollment were patients greater than or equal to 60 years of age who were suitable candidates for isolated, first-time, nonemergent, conventional (arrested heart), coronary artery bypass grafting (CABG), or aortic valve replacement or mitral valve repair/replacement, performed through a median sternotomy using CPB. Patients were evaluated for neurological deficit, myocardial infarction, renal insufficiency/failure, limb ischemia, and death at 12-hour, 24-hour, 72-hour, 7-day, and 30-day postoperative intervals. Research nurses collected all clinical data prospectively, and follow-up was 100%.

Intra-Aortic Filter System

The Embol-X intra-aortic filter system (Edward Life-Sciences, Irvine, CA) consists of a modified 24-Fr metal tip aortic cannula, designed to accommodate the filter insertion via a side port proximal to the outflow tip. The filter component of the system consists of a 120- μ heparin-coated polyester mesh, which is designed to capture particulate emboli, with diameters of greater than 120 μ , without obstructing flow (Figure 2). The filter is held in place by a flexible wire frame designed to conform to the inner diameter of the aorta. The filter comes in five sizes to accommodate internal diameters between 2.2 and 4.0 cm (Table 1).

Operative Technique

The surgical technique was tailored to the individual procedures performed. A radial arterial line and Swan-Ganz catheter were inserted for hemodynamic monitoring and obtaining blood samples. An endotracheal tube was inserted and the patient placed in a supine position. All procedures were performed through a 16- to 18-cm median sternotomy incision. After the ascending aorta was

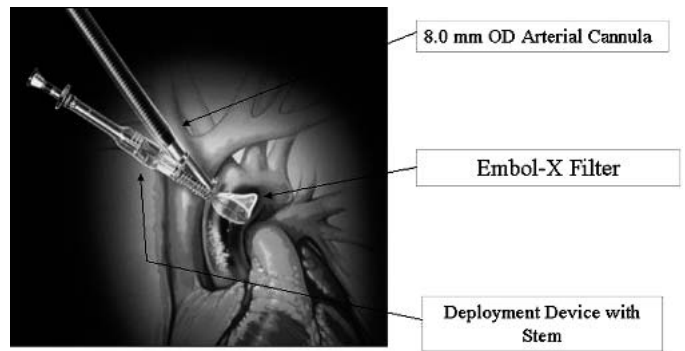


Figure 2. EMBOL- X Intra-Aortic Filter.

Table 1. Embol-X arterial filter size and aortic internal diameters.

Arterial Filter Size	Minimum Aortic Inner Diameter (cm)	Maximum Aortic Inner Diameter (cm)	Maximum Filter Deployment Time
Extra small	2.2	2.6	60 minutes
Small	2.6	2.9	60 minutes
Medium	2.9	3.2	60 minutes
Large	3.2	3.5	60 minutes
Extra Large	3.5	4.0	60 minutes

evaluated with Epi-aortic Doppler (Hewlett Packard, Palo Alto, CA), the patients were assigned randomly to receive either the Embol-X cannula or a DLP 24-Fr metal tip cannula (Medtronic, Minneapolis, MN). The outer diameter of the aorta is measured at this time to correlate sizing of the filter. The ascending aorta was cross-clamped and cold blood cardioplegia was delivered at 4°C. The filter is prepped by submerging it in an electrolyte-balanced fluid (Plasmalyte, Baxter, Deerfield, IL) while holding the deployment stem in a vertical position to facilitate de-airing. Keeping the tip of the deployment stem submerged, the filter is retracted into the deployment stem. The filter and stem must remain in a vertical position so as not to alter the function of the hydrophobic de-airing mechanism. The filter is deployed by inserting it through the side port of the aortic cannula just before the removal of the aortic cross-clamp. The filter remains in place until near the time for separation from CPB or 60-minute dwell time. Multiple filters may be used on the same case if dwell times would exceed 60 minutes. All patients were rewarmed to 37°C before their separation from CPB.

All filters were visually inspected for captured debris after completion of the procedure. Filters were separated from the stem and fixed in formalin for submission to a central pathology laboratory (Stanford University, Stanford, CA) for analysis and histological examination. Intra-operative assessment of the ascending aorta by Epi-aortic Doppler imaging was performed in all cases to detect endothelial disruptions or injuries. Images were obtained be-

fore and after CPB and were evaluated by a single echo cardiographer at the core facility (Medstar Research Institute, Washington, DC). The echo cardiographer was blinded to the randomization protocol and examined the images focusing on detecting endothelial disruptions or injuries to the aorta produced by the cannula, clamping of the aorta, or the intra-aortic filter.

Perfusion Techniques

A Sarns 7000 CPB machine (3M/Sarns, Ann Arbor, MI) and a closed circuit with preassembled Duraflo®-coated components (Jostra/Bentley, Irvine, CA); 1/2-inch venous tubing, 3/8-inch arterial tubing, a BMR 1900G venous reservoir bag (Jostra/Bentley, Irvine, CA), a Spiral Gold oxygenator (Jostra/Bentley, Irvine, CA), a BCR 3500 cardiectomy reservoir (Jostra/Bentley, Irvine, CA), and an AF-1040 arterial blood filter (Jostra/Bentley) were used on all cases. No alteration in perfusion technique was required to accommodate the use of the Embol-X cannula or filter.

RESULTS

Between February 2000 and October 2001, 146 patients were enrolled and randomly assigned either to the Embol-X intra-aortic filter arm or the DLP cannula control arm (Table 2). Demographic characteristics between the two groups, ie, sex, age, left ventricular ejection fractions <25%, hypertension, diabetes, previous stroke, renal insufficiency, cerebrovascular disease, peripheral vascular disease, atrial fibrillation, and aortic disease, showed no significant difference. There were no statistically significant differences between the two groups in any of the targeted study areas. There was one death in each arm of the study. The control arm patient had profound right ventricular dysfunction that progressed to biventricular dysfunction after a re-op CABG ×4 and died during postoperative day 1. The filter arm patient died on postoperative day 6 from a massive pulmonary embolism. Neither of these adverse events was related to the study device.

Of the 74 intra-aortic filters deployed in the treatment group, 70 (94.5%) successfully captured at least one particulate. Fibrous atheroma composed most of the captured embolic particles (Table 3; Figure 3). Platelet/Fibrin for-

Table 2. Subject accountability.

	Embol-X Filter, n (%)	Control, n (%)
Randomized	74 (51)	72 (49)
Not randomized	4	0
Treated off pump	N/A	N/A
Treated according to protocol	74 (100)	72 (100)

Table 3. Histological categories and characteristics of particulates captured in the Embol-X filters.

Histological Description	Randomized Filter, Percentage
Fibrous atheroma	54.1%
Platelet/Fibrin	31.1%
Tissue dissolved (during processing)	14.7%
Particulate capture rate (70/74)	94.5%

mations composed the second largest captured component.

Intraoperative assessment of the ascending aorta by epi-aortic Doppler imaging resulted in 15 identified intimal disruptions by the core lab (Table 4). None of the intimal disruptions required any surgical repair or intervention. Although the filter group had a larger percentage ($n = 10/74$, 13.5%) versus the control group ($n = 5/72$, 6.9%), there was no clinical difference as demonstrated by the length of stays, 5.3 days versus 5.8 respectively.

DISCUSSION

The ability to minimize the production and transport of microemboli directly relates to the level of major postoperative morbidity associated with cardiac surgical procedures (10–12). Blauth et al. (13) demonstrated the distribution of particulate microemboli from the ascending aorta and their resulting location in the end organs in 1992 (Figure 4). Most of particulate microemboli released (58%) has been correlated to the removal of the aortic cross-clamp and partial occlusion clamp (Figure 5; 14). Although arterial line filtration is effective in minimizing the introduction of microemboli from the CPB circuit (15–17), particulate emboli from the heart and manipulation of the ascending aorta remain a concern.

Our experience and that reported by Banbury et al. (18) demonstrated that the Embol-X intra-aortic filter can be used safely and is effective in removing particulate emboli

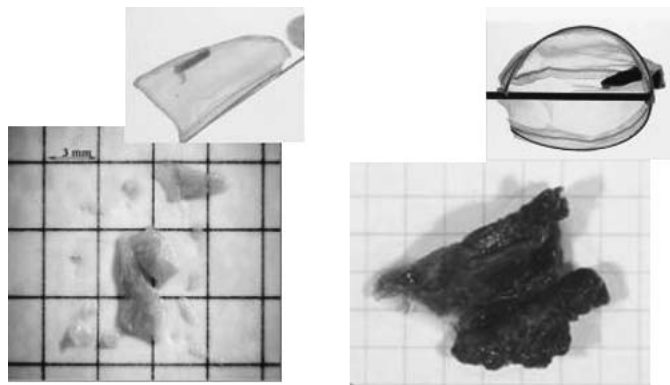


Figure 3. Histological slides fibrous atheroma and thrombus. (a) Fibrous atheroma in filter. (b) Fibrous atheroma. (c) Thrombus in filter. (d) Organized Thrombus.

Table 4. Intimal disruptions identified by core lab.

No.	Date	Filter?	DC Date	LOS (days)	Observed in OR?	Required Surgical Repair?	12-month Follow-Up?
1	11/28/00	Y	12/5/00	8	N	N	Y
2	12/8/00	Y	12/15/00	8	N	N	Y
3	1/4/01	Y	1/8/01	4	N	N	Y
4	2/8/01	Y	2/13/01	5	N	N	Y
5	2/13/01	Y	2/18/01	5	N	N	Y
6	2/20/01	Y	2/24/01	4	N	N	Y
7	3/14/01	N	3/19/01	5	N	N	Y
8	4/27/01	N	5/3/01	8	N	N	Y
9	5/1/01	Y	5/5/01	5	N	N	Y
10	5/14/01	Y	5/18/01	4	N	N	Y
11	2/27/01	N	3/4/01	5	N	N	Y
12	5/4/01	Y	5/9/01	5	N	N	Y
13	5/15/01	N	5/20/01	6	N	N	Y
14	5/17/01	N	5/21/01	5	N	N	Y
15	8/28/2001	Y	9/2/2001	5	N	N	Y

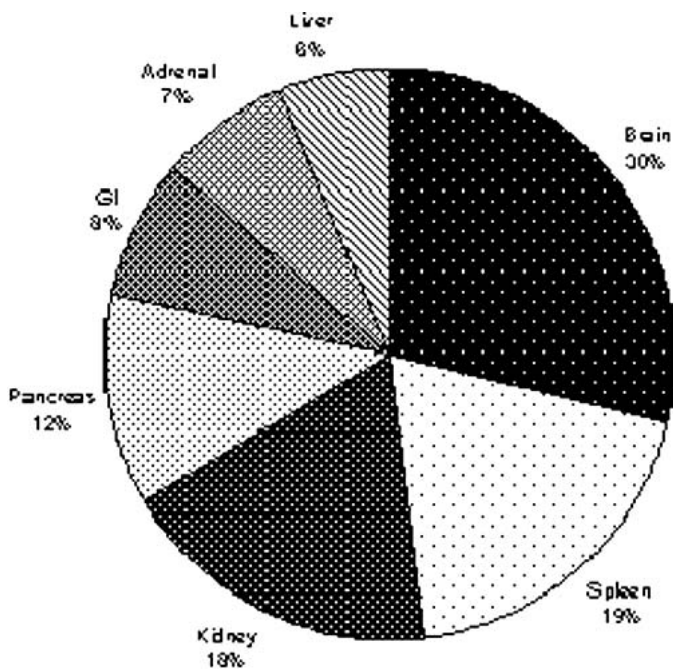


Figure 4. Distribution by organ of atheroembolism from ascending aorta. Determination performed by autopsy (13).

from systemic circulation. The fact that 94.5% of the filters used at our center (96.8% multicenter stats) captured particulate matter indicates a productive utilization of this technology. More recent data from Schmitz et al. (19) demonstrated a 2.7 times greater risk of experiencing an adverse outcome in patients not receiving intra-aortic filtration.

The literature clearly shows a link between manipulation of the ascending aorta and the amount of particulate emboli dislodged or produced. Great strides have been made to eliminate particulate emboli from the CPB circuit. The development of hollow fiber oxygenators, filtered cardiotomy reservoirs, coated circuits, and arterial line filters are all accepted standards of care. The techno-

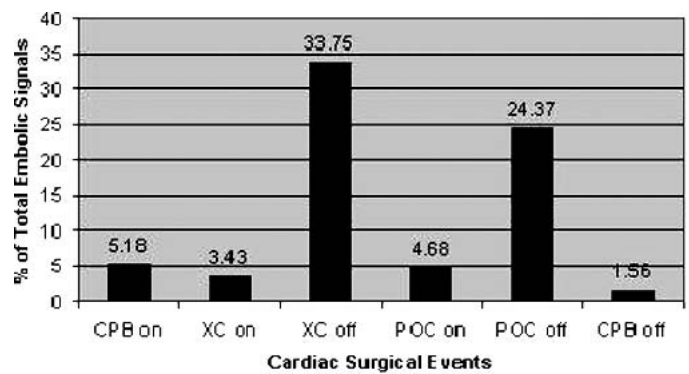


Figure 5. Emboli rate in relation to cardiac surgical events. Emboli signals detected using transcranial Doppler (14).

logical advancements in the products used during cardiac surgery are all positively affecting the quality of life our cardiac patients' lives by lowering morbidity and mortality. Despite all the technological advances, the impact that embolic events have on postoperative morbidity has lead some cardiac surgery programs to aggressively pursue performing coronary artery revascularization without the use of CPB (20–22).

Clearly, using the Embol-X intra-aortic filtration system can be performed safely, allowing effective removal of a significant portion of particulate microemboli from entering the systemic circulation. The filtration system is easily adapted to current surgical techniques. A comprehensive national database to track long-term results would be the next step in affirming significant benefit in reducing morbidity and mortality.

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