EMBOLUS PROTECTION WITH THE EDWARDS EMBOL-X SYSTEM

Adverse cerebral outcomes after coronary artery bypass grafting (CABG) surgery are not uncommon and they are serious. They are associated with substantial increases in mortality, length of index hospital stay, and greater social and economic burden. Recently, there has been an emphasis on the life-changing effects of CABG, with particular attention to the reduction of strokes and neuropsychological changes. Consequently, stroke prevention is the most formidable challenge facing heart surgery today.

Strokes and adverse neurological outcomes are a major financial burden, among other things, to hospitals as well as to the individual. Although rare, the cost of a perioperative stroke has been estimated to be between $60,000 and $200,000. Roach has estimated that perioperative neurological injury occurs in as many as 6.1% of patients undergoing CABG (Table 1). Predictors of a frank stroke (Type I injury) or cognitive changes (Type II injury) include, but are not limited to, hypertension, proximal aortic atherosclerotic burden, and pulmonary disease. Unfortunately, the stroke rates associated with CABG have not changed appreciably in the past fifteen years despite major advances in the revascularization itself.

Table 1: Adverse Cerebral Outcomes After Coronary Bypass Surgery

- Design: 2108 CABG patients at 24 U.S. centers evaluated for adverse neurological outcomes
- 6.1% of patients had neurological injury (3.1% Type I, 3.0% Type II)
  - Type I patients: 8 deaths, 55 non-fatal strokes, 2 TIs, 1 stupor
  - Type II patients: 55 deterioration of intellectual function, 8 seizures
- Predictors of Type I and Type II injury (odds ratio)
  - Type I: proximal aortic atherosclerosis (4.52), prior neurological disease (3.19), age (1.75/decade), history of pulmonary disease (2.09)
  - Type II: history of excessive alcohol consumption (2.64), CHF on surgery day (2.46), age (2.20/decade), prior CABG (2.18), postoperative arrhythmia (1.97)
- Average additional length of hospital stay and additional costs compared to patients without neurological injury (assuming $890 per day in an ICU and $370 per day on a ward)
  - Type I patients: ICU 8 days, Ward 7 days; $10,266 in additional costs
  - Type II patients: ICU 4 days, Ward 7 days; $6,150 in additional costs

Considering the multitude of variables required to accomplish heart surgery, it is too simplistic to conclude that the heart-lung machine, a common scapegoat, is the only source of emboli during cardiopulmonary bypass (CPB). Some studies have failed to show a discernable difference in neurocognitive function in patients after undergoing off-pump CABG (OPCAB) when compared to a similar cohort of on-pump CABG patients. While other reasons may explain these findings including low cardiac output during OPCAB, this highlights the importance of understanding the source of emboli and their direct causal role in neurocognitive changes and strokes.
Transcranial Doppler (TCD) data has provided insight into this issue. Over 20 years ago, Pugsley et al examined the relationship between TCD signals and actual emboli in the laboratory setting. Microspheres were injected into the blood stream and confirmed by TCD, suggesting that the TCD signals were indeed from small emboli in the arterial blood. Moreover, the distribution of the microspheres correlated with distribution of the experimentally induced strokes confirming a positive correlation of TCD signals with stroke. In human patients, Pugsley and his associates also observed that the number of emboli correlated with the severity and the duration of Type I and II defects measured 8 weeks after completion of the CABG operation. High intraoperative counts of emboli (>1000) resulted in 45% of patients exhibiting either Type I or II deficits. Conversely, when the number of emboli detected was less than 200, the incidence of either Type I or II defects was less than 9%. This relationship confirmed the correlation of TCD signals with the ensuing stroke and neuropsychological impairment. Similarly, TCD became useful as a marker for estimating injurious peripheral emboli.

While emboli can be released throughout the entire CABG operation, they are more prevalent during use of the cardiopulmonary bypass machine. Stump and Newman measured all emboli released during a CABG operation and noted that nearly 60% were released near the time (<1min) of aortic clamping or surgical manipulation. Barbut also noted that nearly 60% were detected upon removal of the aortic cross-clamp or aortic partial occlusion clamp. Investigators have shown that a correlation exists between the estimated quantity of emboli released and the length of hospital stay (Figure 1).

When emboli were first studied, it was determined that the use of a filter in the arterial blood return could greatly decrease the number of emboli pumped back into the patient’s arterial circulation, and thus prevent strokes. This principle became the foundation for the development of the EMBOL-X system (Figure 2).

The system consists of a net attached to a cannula (not unlike the catheters used by cardiologists for vein graft interventions) that deploys just proximal to the aortic perfusion cannula. When emboli are showered, which mainly occurs when the clamps are released, they are potentially trapped in the net. Because of the net’s proximal location, it does not interfere with arterial perfusion from the bypass cannula (Figure 3). In clinical trials, nearly 97% of deployed filters were shown to have captured emboli. Furthermore, deployed filters have been shown to catch not only atheromatous plaque, but also platelet and fibrin aggregates, calcific debris, and mechanical debris (i.e. sutures).

Figure 1: LOS is Directly Related to Emboli Detection

![Figure 1: LOS is Directly Related to Emboli Detection](image1.png)

Figure 2: EMBOL-X System

![Figure 2: EMBOL-X System](image2.png)

Figure 3: EMBOL-X System Deployed

![Figure 3: EMBOL-X System Deployed](image3.png)
Schmitz et al showed that fewer adverse neurological events occur with use of the EMBOL-X system than without it on initial study.\textsuperscript{10} In this prospective, controlled study of over 500 CABG and/or valve operations, patients were alternately assigned to an embolic collection (filter) arm or a traditional (control) arm. The endpoints included stroke, transient ischemic attack, coma, delirium, and memory deficit. Patients in the filter group had a lower incidence of adverse neurological outcomes (the sum of Type I and II injuries) than patients in the control arm (4.3\% v. 11.9\%; \(p <0.001\)). Furthermore, there were significantly less transient ischemic attacks (0\% vs 1.4\%), delirium (3.0\% v. 6.5\%), and memory deficits (1.5\% v. 6.2\%) in the filter group (Figure 4). There was a trend toward fewer strokes (0.7\% v. 2.2\%) in the filter group, although the sample size was too small to achieve statistical significance. The authors concluded that the extraction of particulate emboli using intra-aortic filtration decreases adverse neurological outcomes.

**Figure 4: Adverse Neurologic Events\textsuperscript{10}**

In the operating room, cardiopulmonary bypass was established by cannulating the ascending aorta with the EMBOL-X protection system. A clamp was applied to the aorta, and a tri-leaflet aortic valve was removed. The calcific annulus was debrided. A 23mm Carpentier-Edwards PERIMOUNT Magna valve with Carpentier-Edwards TheraFix process was sutured into position with simple sutures. There was no leak by transesophageal echocardiography. The Atricure device was then used to encircle the paired pulmonary veins on both sides. The EMBOL-X filter was deployed before the cross-clamp was released, and then it was retracted just as the cardiopulmonary bypass was being weaned. There was a calcific embolus grossly visible in the net measuring approximately 6 x 5 x 3 mm (Figure 6). The patient was in second-degree heart block at the completion of the operation. She returned to the surgical intensive care unit, where she had an uneventful stay with the exception of intermittent post-operative atrial fibrillation that was managed with amiodarone. She was discharged home 4 days later in normal sinus rhythm without any evidence of a stroke or a neuropsychological deficit.

**CASE REPORT**

An anxious 70-year-old woman was admitted for elective aortic valve replacement (AVR) for symptomatic aortic stenosis. The patient had visited with two other cardiac surgeons prior to coming to us and conveyed to her the risk of stroke with AVR (about 5\%) (Figure 5). Despite her symptoms, the patient was reluctant to embark on AVR because of her fear of having a stroke. After a long discussion about the surgery, our techniques, and results, the patient willfully consented to valve replacement surgery.

Her comorbidities included paroxysmal atrial fibrillation, diabetes mellitus, hypertension, and hypercholesterolemia. Physical examination was remarkable for an irregular heart rhythm and a 3/6 systolic ejection murmur best heard at the right upper sternal border. Cardiac catheterization revealed no flow-limiting lesions in the coronary arteries and a calculated ejection fraction of 75\%. The aortic valve was calcified with a peak systolic gradient of 48 mm Hg, mean gradient of 33 mm Hg, a valve area of 0.93 cm\(^2\), and a cardiac index of 3.32 L/min/m\(^2\). Echocardiogram demonstrated moderate aortic stenosis and the electrocardiogram showed normal sinus rhythm with left ventricular hypertrophy. Laboratory data was normal.

**Figure 5: Procedures at Risk for Stroke\textsuperscript{11}**
Complications of open heart surgery are related to the complexity of the case, physically opening the heart, manipulating the valves, the time spent on the pump and comorbidities. Although the EMBOL-X system is slightly larger than a standard aortic cannula and requires a secondary step to deploy the filter, its ability to remove emboli and thereby potentially prevent strokes justifies the use of the device. Some cardiac surgeons routinely use the EMBOL-X system in all valve cases as well as cases with an opened aorta where significant proximal aortic atherosclerotic burden can be demonstrated by echocardiogram, x-ray, or computerized tomography scan.

References:

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