

PARTICULATE EMBOLI CAPTURE BY AN INTRA-AORTIC FILTER DEVICE DURING CARDIAC SURGERY

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Objective: Particulate embolization is associated with neurologic morbidity after cardiac surgery. Crossclamp manipulation has been identified as the single most significant cause of particulate emboli release during cardiac surgery. A new intra-aortic filtration method has been assessed with regard to its safety and its ability to capture particulate emboli before they enter the central circulation. **Methods:** Patients undergoing cardiac surgery with cardiopulmonary bypass through standard median sternotomy were selected for emboli management by means of intra-aortic filtration. A novel intra-aortic filter device was inserted through a modified 24F arterial cannula immediately before releasing the cross-clamp in 77 patients. Filters remained in the aorta until cardiopulmonary bypass was discontinued and the heart was fully ejecting. The procedure was assessed for facility, safety, and effect on routine cardiopulmonary bypass operation and function. **Results:** The insertion and removal of the intra-aortic filter were safe, easy, and uneventful in most patients. Patient hemodynamics and bypass flow rates remained normal throughout the filter dwell period. No strokes or gross neurologic defects were noted. Electron microscopic analysis of 12 filters revealed an insignificant degree of platelet adhesion on filter surfaces. Histology samples (n = 44) were examined, and 66% (n = 29) showed evidence of atheromatous material, 36% (n = 16) with platelet-fibrin, 25% (n = 11) with true thrombus and/or blood clot, 7% (n = 3) with normal vessel wall, and 2% (n = 1) with aggregates of cholesterol or grumous portion of atheromatous plaque. **Conclusion:** The intra-aortic filter can be safely deployed and captures particulate emboli, the predominant origin of which is atheromatous. The beneficial effects of this device on neurologic outcomes have yet to be determined. (J Thorac Cardiovasc Surg 2000;119:233-41)

Despite advances in technology (anesthesia, cardiopulmonary bypass circuits, techniques, and instrumentation), neurologic sequelae continue to

plague patients undergoing cardiac operations at a significant rate. Age risk factors notwithstanding, it is a widely held belief that the incidence of neurologic injury after surgery is underestimated. In 1996, Roach and colleagues¹ published that the prevalence of stroke, coma, seizure, and cognitive impairment is high and ranges between 6.1% and 33%.² The subtle and gross manifestations of neurologic dysfunction potentially result in significant cost to the patients, families, and the health care system overall.

The pathogenesis of these neurologic and neurobehavioral sequelae is multifactorial, with studies indicating hypoperfusion, anesthesia, cardiopulmonary bypass, and patient comorbidity among the potential predisposing factors.²⁻⁸ Although the prevalence of each of these contributors is not well understood, recent studies have indicated that particulate embolization (atheromatous or other nature) during surgical manipu-

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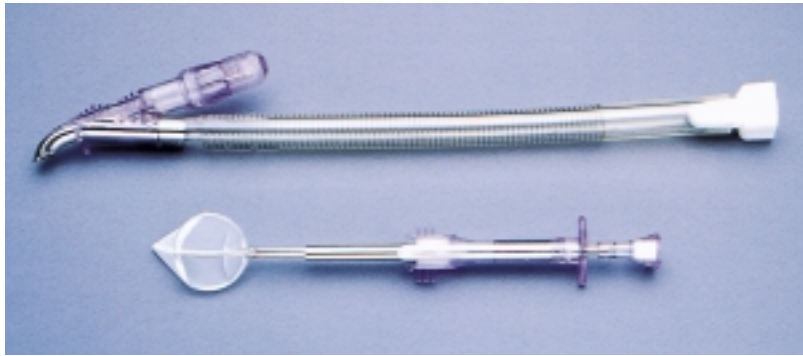


Fig 1. Intra-aortic filtration system composed of a modified 24F arterial perfusion cannula and 120- μ m filter (EMBOL-X).

lation of the aorta is significantly linked with neurologic complications.⁹⁻¹² Gold and colleagues¹³ and Barbut and colleagues¹⁴ assessed the timing and quantity of microemboli release during cardiac surgical procedures by means of transcranial Doppler scanning. They demonstrated that up to 60% of perioperative emboli are attributed to clamp manipulation, primarily clamp removal, during cardiopulmonary bypass. These emboli have the potential to cause widespread, devastating, cerebral and peripheral ischemic damage when released into the circulation.

These findings led to the assumption that providing a means of filtration during unclamping of the aorta may significantly reduce the incidence and severity of neurologic injury related to particulate embolization. The device and method of filtration were designed to eliminate a need for additional incisions into the aorta, as well as to be ideally situated in the aorta for optimal efficiency. Experimental studies of the device were performed *in vitro* and *in vivo* to evaluate safety and efficiency.¹⁵ Results demonstrated that the device was atraumatic, had excellent thromboresistance, and was effective at capturing particulate matter.

The purpose of this study was to evaluate, in human subjects, the feasibility of a novel method of particulate emboli filtration during routine cardiopulmonary bypass, specifically during the period when the aorta is unclamped. Furthermore, the study was aimed at evaluating the nature of captured particulate emboli by means of histologic and scanning electron microscopy analysis in a core laboratory.

Patients and methods

Patients undergoing cardiopulmonary bypass for cardiac operations were considered for this study. Patient selection was at the discretion of the investigator; however, only

patients with aortic aneurysm or congenital anomalies of the aortic arch were excluded from the study. Additionally, candidates were limited to those undergoing median sternotomy to avoid potential technical challenges related to lesser invasive incisions. Seventy-nine patients who were selected and gave consent for intra-aortic filtration were included in the analysis from December 1997 to December 1998; 40 patients were operated on in Munich, and 39 were operated on in Buenos Aires. Protocol approval was obtained from institutional review boards at the University Hospital Munich-Grosshadern and the Italian Hospital of Buenos Aires, and all patients signed an informed consent form.

After routine anesthesia induction, the aorta was evaluated by palpation and transesophageal echocardiography (TEE) for assessment of size, integrity, and presence of calcification. An intra-aortic arterial filter (EMBOL-X, Inc, Mountain View, Calif) size (extra small, small, medium, large, or extra large) was selected on the basis of the TEE findings or external measurement estimating the internal diameter of the aorta.

Patients were then cannulated for cardiopulmonary bypass per usual routines. A modified 24F arterial return cannula (EMBOL-X, Inc) with a side port designed to house the filtration device was inserted into the ascending aorta with double purse-string sutures in accordance with standard surgical technique (Fig 1). Choice of venous return cannula was at the discretion of the surgeon.

After completion of the surgical procedure and before removal of the aortic crossclamp, the intra-aortic filter was then inserted through the side port of the arterial return cannula and remained in the ascending aorta until cardiopulmonary bypass was discontinued (Fig 2). The filter device is a butterfly net-type filter, which is provided in a cartridge that locks into the filter lumen of the side port. The filter is inserted into the aorta by depressing a syringe-like plunger (Fig 1). The filter mesh had a pore diameter of 120 μ m, and the mesh was coated with heparin. The aortic clamp was then removed, and the filter was left in place in the ascending aorta during placement and removal of the partial occlusion clamp

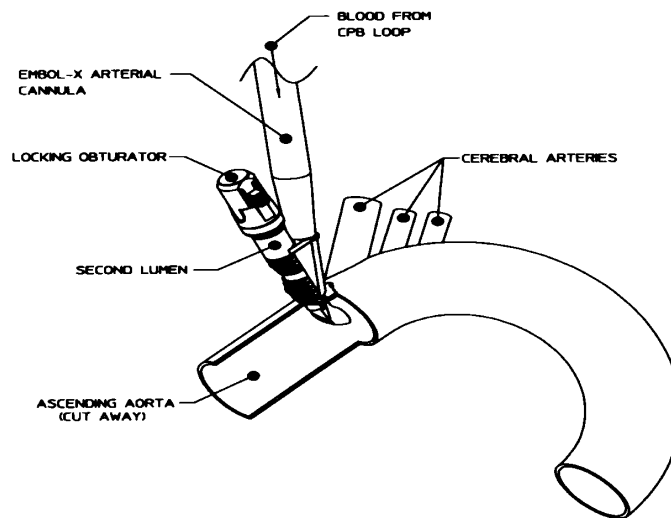


Fig 2. Schematic of Embol-X Arterial Cannula and Filter System within the cardiopulmonary bypass circuit.

Table I. Patient characteristics

Patient demographics	Mean	Range
Age (y)	64 ± 10.6	41–85
Weight (kg)	75.6 ± 12.0	47–107
Sex, M/F (%)	73/27	
Aortic characteristics		
Diameter (cm)	3.3 ± 0.36	2.5–4.0
Wall thickness (mm)	1.1 ± 0.69	0.5–3.2

and was withdrawn after the heart began to fully eject. Patient hemodynamics, clotting times, and cardiopulmonary bypass flow rates were monitored during filter deployment.

The filter was then removed from the aorta through the side port. After the patient was fully weaned from cardiopulmonary bypass, the purse-string sutures were loosened, the arterial cannula was removed, and the sutures were pulled tight to establish hemostasis.

All filters were visually inspected on removal for captured material. Filters were collected in specimen tubes and fixed with formalin for analysis. Particulate emboli were analyzed, and filter analysis included gross visual examination at 10× magnification to identify the particulate matter (with 74/77 [96%] having particulate matter). Particulate matter was collected from 44 (59%) of 74 filters and sent to a central pathology laboratory (Stanford University) for histologic examination of the captured material. The histologic sections were stained with hematoxylin and eosin, trichrome, and elastica van Gieson's stain. Histologic analysis included examination for presence of platelets and fibrin deposition, true thrombus, and/or blood clotting, grumous portion of plaque-cholesterol, fibrous atheroma, or fibrous cap, and the normal vessel wall.

Scanning electron microscopy was performed on a subset

Table II. Procedural details and bypass data

	Mean	Range
Bypass time (min)		
Bypass time	103 ± 29	50–197
Crossclamp time	67 ± 23	24–145
Bypass flow during filter dwell		
Maximum flow (L/min)	4.5 ± 0.91	3.0–6.34
Minimum flow (L/min)	3.8 ± 0.75	1.82–5.46
Hemodynamic values during filter dwell		
Mean arterial pressure (mm Hg)	58 ± 9.3	
Mean ACT (s)	557 ± 162.1	

(n = 12 [16%]) of filters with the longest dwell times to assess thrombogenicity of the filter in the clinical application.

Clinical assessments included basic neurologic examinations preoperatively, first day postoperatively, and before discharge.

Results

A total of 79 patients were enrolled in the study. Patient demographics represented the usual distribution of age, sex, and aortic diameters (Table I). Procedures consisted of regular coronary artery bypass grafting (CABG) in 66%, isolated valve operations in 26%, and combined procedures in 8% of the patients.

Average filter deployment duration was 26 minutes (range, 5–58 minutes). Cardiopulmonary bypass times, flow rates, and pressures were not compromised because of the presence of the device and are listed in Table II. The arterial cannula performance was found to

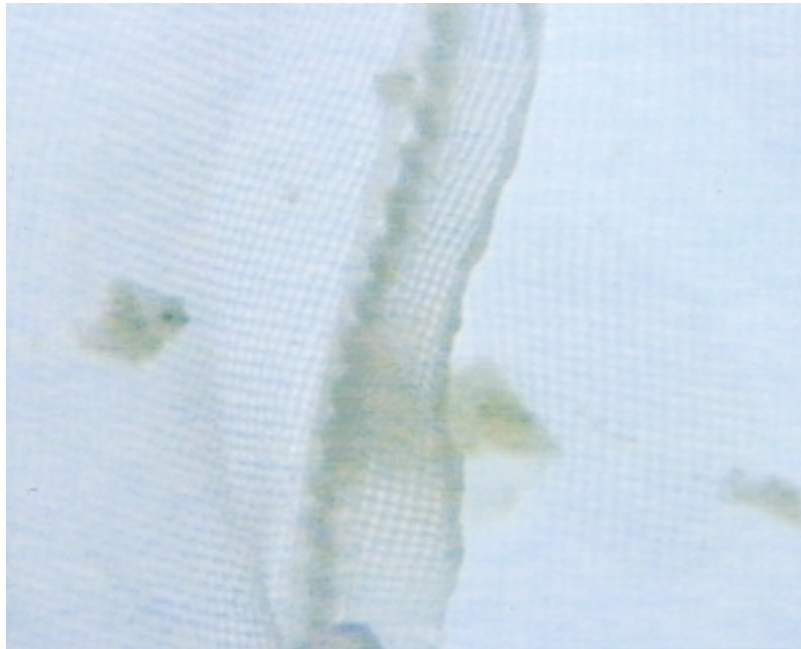


Fig 3. Particulate emboli found in filter mesh (gross visual examination at 10 \times magnification). Patient was a 75-year-old man who underwent aortic and mitral valve replacement and thrombus excision from the left atrium. The filter was deployed for 32 minutes.

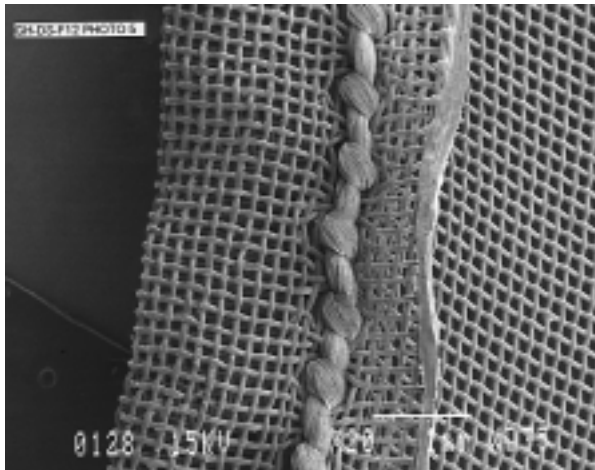


Fig 4. Scanning electron micrograph of filter mesh, showing a relatively clean surface with scattered focal sites of platelet and fibrin (magnification 20 \times). Patient was a 61-year-old man with 3-vessel disease. The filter was deployed for 26 minutes.

be equivalent to a standard 20F arterial cannula in effective flow. Patient hemodynamics remained normal throughout the filter dwell period in the aorta. Activated clotting times (ACTs) during the procedure were main-

Table III. Histology ($n = 44$)

Material	No.	%
Fibrous atheroma or fibrous cap	29/44	66
Platelet-fibrin	16/44	36
Thrombus and/or blood clot	11/44	25
Normal vessel wall	3/44	7
Grumous portion of plaque-cholesterol	1/44	2
Hyaline cartilage	1/44	2

tained within normal limits, and during filter dwell time, the mean ACT was 557 seconds.

Cardiopulmonary bypass peak flows and line pressures were recorded on 7 patients in the initial series. Mean flow rates (4.42 ± 0.47 L/min) and line pressures (217 ± 27.8 mm Hg compared with 62.0 ± 6.9 mm Hg mean arterial pressure) were found to be very similar between patients and within normal limits expected for a 20F arterial cannula. These clinical results also confirmed data previously obtained during in vitro and in vivo animal testing before the human clinical study. Further data were not collected because the values were within the expected range; only minor variances existed between patients, and the information was not found to be of clinical significance.

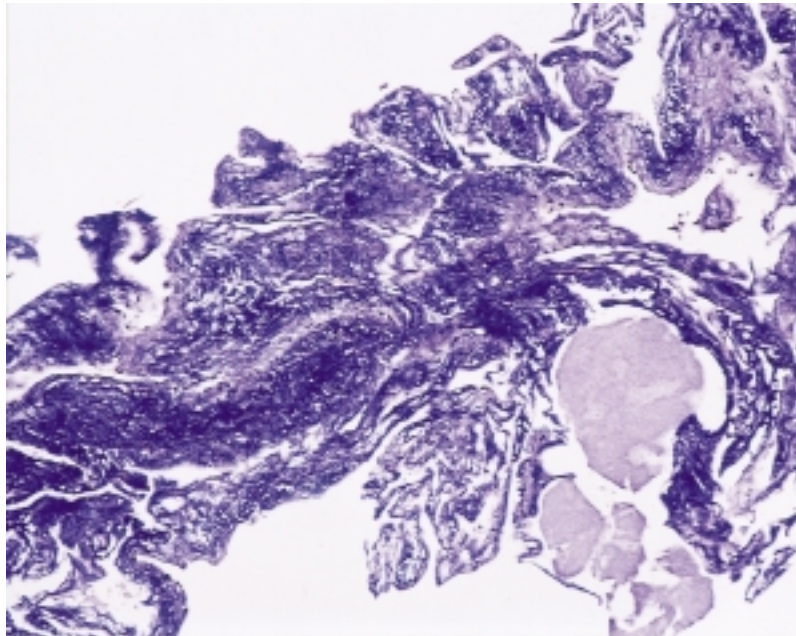


Fig 5. Elastica van Gieson stain demonstrating fibrous atheroma. Stain highlights irregularly arranged collagen and elastic fibrils, suggesting fibrous cap or fibrous atheroma containing aggregates of fibrin and fragments of abnormal vessel wall. The patient was a 77-year-old man with 3-vessel disease, and the filter was deployed for 28 minutes.

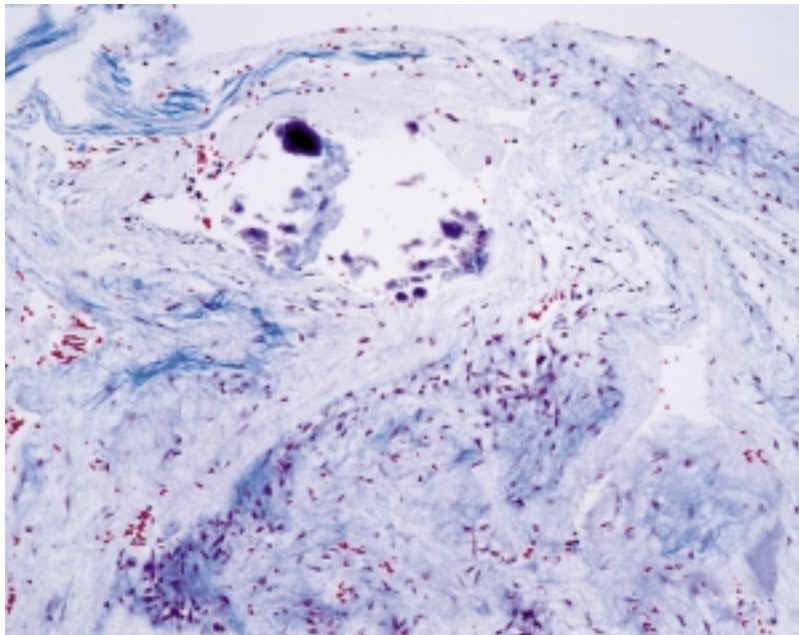


Fig 6. Trichrome stain demonstrating fibrocalcific atheroma. Stain highlights fibrocalcific atherosclerotic wall admixed with fibrous and elastic tissue and microscopic collections of clot and calcium deposits. The patient was a 75-year-old man who underwent aortic and mitral valve replacement, and filter dwell was 32 minutes.

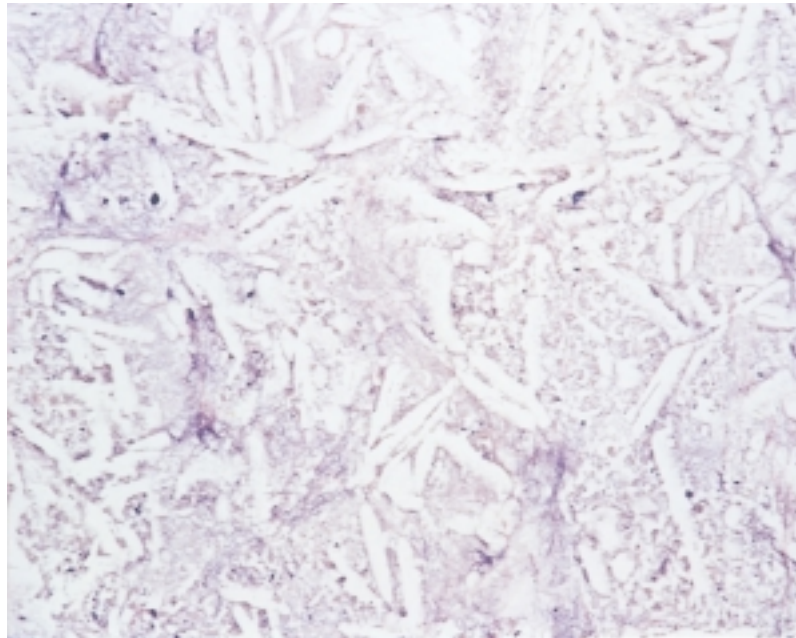


Fig 7. Elastica van Gieson stain demonstrating the presence of needle-shaped cholesterol fragments characteristic of the grumous portion of atheromatous plaque. The patient was a 67-year-old man with 3-vessel disease, and the filter was deployed for 30 minutes.

Deployment of the filter was facile, and no filter-related adverse events occurred. Two patients did not receive the filter device. One patient had a “porcelain” aorta detected intraoperatively, and the procedure was performed off-pump. In the other patient it was difficult to insert the filter. The latter case occurred very early in the study, and there were no further technical difficulties in filter deployment.

Clinical follow-up yielded no strokes that were observed in the perioperative or postoperative follow-up. Immediately after the operation, 4 (5%) patients had a short transient delirium ranging from 24 to 48 hours after surgery. At time of discharge, gross neurologic examination did not reveal any pathologic abnormalities, such as deficits in memory or any focal symptoms. There was one death unrelated to the filter in a high-risk patient unable to be weaned from bypass; this patient already had a preoperatively severely decreased left ventricular ejection fraction. One patient had a myocardial infarction after CABG.

Visual inspection after filter removal revealed hard granular particles, soft material, or both in 74 (96%) of the 77 filters (Fig 3). The average number of particulate emboli was 5 to 10 per filter, ranging from 1 to 20 per filter. The average particle size was 0.6 mm, ranging from 0.1 to 6 mm. The majority of filters (66 [85.7%]) were analyzed by either scanning electron microscopy

(12 [18%]) to evaluate thrombogenicity of the device or by histology (44 [66%]) to evaluate the actual composition of the particles. A total of 12 (15.5%) filters did not undergo pathologic analysis for varied reasons, including risk related to blood-borne pathogens and loss of particles in processing.

Scanning electron microscopy examination of 12 filters show filter mesh surfaces that are mostly clear with scattered evidence of red blood cells, fibrin cells, and activated platelets, usually numbering less than 10 particles in total. One filter did show evidence of what appeared to be a spot of thrombus; this filter was one of the initial units used early in the study. None of the scanning electron microscopy photographs demonstrate the presence of atheromatous material or vessel wall. One filter contained a small but fresh thrombus along the central seam near the luminal center of the filter mesh. This single particle was characterized by fibrinous material adherent to the meshwork admixed with leukocytes, erythrocytes, and platelets, as verified in a subsequent histologic analysis. No other abnormalities were found within the remaining portions of this filter. All other filters analyzed did contain patchy focal sites of fibrin with platelet deposition. Although every filter examined showed evidence of platelet and fibrin deposition, when all the focal sites are combined together, the total area of obstruction was less than 5%

of the total filter mesh pore surface and was not considered to be of any clinical significance (Fig 4).

Histologic results of the 44 filters revealed significant evidence of fibroatheromatous material, including needle-shaped cholesterol fragments and loose myxoid tissue containing collagen and spindle cells. The cell types, organized into categories of interest, were as follows: presence or absence of platelet-fibrin deposition, true thrombus (blood clot), grumous portion of plaque-cholesterol, fibrous atheroma or fibrous cap (with or without calcification), and normal vessel wall (Table III). By far, the most common finding was the presence of fibroatheroma or fibrous cap in 66% ($n = 29$) of the samples, two of which contained discrete punctate foci of calcified material (Figs 5 and 6). Fibrin, with and without the obvious presence of platelets, was associated with 36% ($n = 16$) of the filters. True thrombus, including clot rich with erythrocytes, was found in 25% ($n = 11$) of the filters. One of these filters was used during a procedure in which the thrombus was excised directly from the left atrium. Because the particles were removed from the filter mesh to enable histopathologic analysis, the origin of the thrombus could not be determined. Grumous portion of the atheromatous plaque (needle-shaped cholesterol fragments highlighted by trichrome and elastica van Gieson stains) was found in 1 (2%) filter (Fig 7). Normal vessel wall was identified in 3 filters; however, in at least 4 other filters, the core laboratory reported the tissue fragments as small, making definitive classification between fibrous atheroma and tangentially sectioned (normal) vessel wall difficult. An interesting finding in one filter was the presence of a small aggregate of mature hyaline cartilage, likely to be from the costochondral junction of a rib. The case was a regular coronary bypass operation, and the filter dwell was 32 minutes.

Discussion

The issue of neurologic deficits occurring in cardiac operations is gaining increased attention because of its severity. In recent years, there has been an increasing awareness of atheromatous disease within the aorta and its role as a source of emboli during cardiac surgery. Recent studies have demonstrated a link between the degree of embolic material and neurologic damage.^{9,10} The evidence in these studies over the past 14 years shows that as the age of the patients undergoing cardiac operation procedures with cardiopulmonary bypass has increased, the central nervous system complications associated with the surgery have increased. Catastrophic neurologic sequelae of bypass surgery, such as stroke and diminished mentation, occur in part

because cerebral arteries are blocked by emboli released during specific surgical events. Emboli are released in significant amounts, primarily at the inception of bypass and at the release of aortic clamps.^{9,14,16} The emboli released at the inception of bypass are thought to be small gaseous emboli generated in the bypass system and can be removed by extracorporeal filter membrane within the cardiopulmonary bypass system. The emboli released during removal of aortic clamps are in both particle and gaseous form because of debris from atheromatous plaques in the ascending aorta and air released during manipulation of the heart.

The described filter and cannula system is a first-generation device demonstrating the concept of intra-aortic filtration and is designed to address a potential source of complications, specifically particulate emboli generated during aortic manipulation. This clinical study demonstrates that this system is safe and easy to use and that the filter clearly captures particulate emboli, ranging from 0.1 to 6.0 mm, that are readily visible to the naked eye.

The pore size of the filtration system of 120 μm enables this device to capture particles greater than 120 μm . In the 1997 study by Barbut and associates,¹⁰ which characterized emboli size by using TEE and transcranial Doppler studies, 72% of the particles were seen to be greater than 0.6 mm in size, with 28% of the particles greater than 1.0 mm, 44% between 0.6 and 1.0 mm in size, and 27% being 0.6 mm or less in diameter. This is well above the 0.12-mm diameter filter pore size of the device. On the basis of these data, the filter device is well designed to capture a majority of particulate emboli that may be generated during the course of the cardiac operation.

The scanning electron microscopy findings confirmed device safety relating to thromboresistance of the filter mesh, as demonstrated by the insignificant degree of platelet adhesion on the surface of the filter. In one patient in whom thrombus was detected, the procedure involved excising thrombus directly from the left atrium. Thus although the origin of the thrombus could not be determined from the specimen, it is plausible that the thrombus originated from the left atrium. There did not appear to be a correlation in filter dwell time and the microscopy findings of thrombus. Because 5% or less of the total filter mesh area was obstructed in all cases, these findings were not considered to be of clinical significance.

The histologic findings raise questions with regard to the incidence, quantity, and type of surgical debris released into the central circulation that have been heretofore undocumented in the surgical literature. The

remarkable predominance of particles of fibroatheromatous origin (66%) must give us pause as to the amount of debris typically released into the circulation because of routine surgical procedures. Moreover, these preliminary findings beg a mandate for management of such surgical debris, which intuitively must be minimized or eliminated if possible. Theoretically, prevention of the embolization of these particles to the brain would reduce the risk of neurologic deficit. Furthermore, although cerebral injury relating to emboli generation is considered to be one of the most devastating results, other complications relating to systemic injury (eg, renal, pulmonary, and peripheral vasculature) that may be due to emboli generation during cardiac operations remain problematic as well.

The postoperative gross neurologic follow-up in the examined patients was completely uneventful, except for a brief period of fully reversible postoperative delirium in 5% of the patients. This low incidence of neurologic events was present despite the fact that complex cardiac surgical procedures were included.

Clearly, further research and clinical studies are needed to fully evaluate and quantify these preliminary findings. Specific efforts must be undertaken to understand the origin and the clinical significance of the capture of particulate debris during routine and complex cardiac operations. Clinical studies are underway (International Council on Emboli Management) to more fully explore the efficacy of emboli management with intra-aortic filtration. International Council on Emboli Management is planned as a prospective, consecutive observational study to evaluate the potential benefits of intra-aortic filtration by means of collection of clinical data related to preoperative disposition, surgical and procedural details, evaluation of the aorta with the degree of aortic manipulation, and postoperative clinical outcomes.

Conclusion

Intra-aortic filtration is a feasible method of capturing particulate emboli in patients undergoing cardiopulmonary bypass during cardiac surgery. The filter design is simple, and implementation is easily incorporated into standard cardiac procedures. Histologic analysis confirmed the presence of atheromatous material recovered from the filters. More prospective studies are needed to fully demonstrate the efficacy and clinical benefit of intra-aortic filtration in both high-risk and low-risk patients undergoing cardiac operations.

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Discussion

Dr G. Hossein Almassi (Milwaukee, Wis). I have a couple of questions. It appears that you did your proximal anastomosis on a side-biting clamp after the crossclamp has been released. Do you have any data in which you use only a single crossclamp, do all your anastomoses, and compare those data with data from this set of patients to see what the differ-

ence is in terms of the contribution of the side-biting clamp to the release of this material?

Second, for the material that you recovered, did you correlate that with your echocardiographic findings in terms of the nature of the aortic wall in relation to the amount and the nature of the material you recovered?

Dr Reichenspurner. To address your first question, in most of the patients I used a side-biting clamp to do the proximal anastomosis. However, 20% of the procedures were done with the proximal procedures done on the clamped aorta. As you saw before, over 90% of the filters did have material in them independent of whether we used the partial crossclamping.

We are so far not able to correlate the amount of material captured according to the degree of the condition of the aorta as verified by TEE.

Dr Mohamed Emara (*Cairo, Egypt*). I have a question and a comment. Do you think that you have to put this filter in earlier than bypass, especially for valve cases, where you can embolize things during manipulation of the heart?

Your results are perfect. What about the air embolism especially in valve cases?

Dr Reichenspurner. At the beginning, we were concerned whether if you leave the filter in too long, there may be evidence of thrombosis that might obstruct quite a bit of the area of the filter, leading to a higher resistance and an increased afterload for the heart. That is why we started off with relatively short dwell times, which were gradually increased. However, even in filters that stayed in for about an hour, we did not see an obstruction of more than 5% of the mesh area. Therefore it is probably safe to leave it in longer. When you clamp the aorta, there is already the possibility of generation

of particulate emboli, and therefore it would be justified to put it in earlier.

Air embolism is certainly a concern with transcranial Doppler studies. It is always hard to differentiate on transcranial Doppler scanning between particulate and gaseous emboli. I think that you might be able to catch gaseous emboli, but I do not think you will actually get them out because once you pull the filter back, you squeeze the filter through the side port, and that will probably squeeze the air out again. Therefore I do not think you will get rid of all the air, but you will definitely get rid of the particulate material, which is probably the more dangerous material.

Dr Hazim J. Safi (*Houston, Tex*). Have you mapped the ascending aorta by using TEE? Without the hand-held probe, we have had little luck in detecting atheromatous debris or plaque in the ascending aorta.

Dr Reichenspurner. You are fully right. It is a challenge to assess the atheromatous, diseased ascending aorta because it is not easily accessible, but we did use TEE before, and in about half of the patients we used epi-aortic scanning during the surgical procedures, which is probably the best way to verify aortic disease. But as mentioned before, we did not find a correlation of the degree of the aortic disease and the amount of captured material.

Dr Paul Kurlansky (*Miami Beach, Fla*). I congratulate you on a potentially extremely useful addition to the cardiac surgical armamentarium. I would like to recommend that in your future studies you assess not only neurologic function but renal function as well because I suspect that you will cause a significant decrease in postoperative renal complications.

Dr Reichenspurner. Thank you very much.