Intraaortic Filtration Captures Particulate Debris in OPCAB Cases Using Anastomotic Devices

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ABSTRACT

Background: Studies associate atheroemboli with neurologic complications following cardiac surgery. The International Council of Emboli Management (ICEM) has demonstrated debris is captured when intraaortic filtration is employed during cardiac surgery. Particulate debris has been extracted from over 98% of ICEM patients and fibrous atheroma from 73%. Anastomotic device use may reduce aortic manipulation, minimizing debris. This study compares particulate capture among three patient groups: Cohort 1 (n = 745) patients receiving on-pump CABG-only procedures; Cohort 2 (n = 24) patients receiving off-pump CABG-only procedures with conventional anastomoses; Cohort 3 (n = 10) patients receiving off-pump CABG-only procedures with automatic proximal anastomoses.

Methods: The intraaortic filter was placed distal to anastomoses, and proximal to the innominate artery. Upon removal, filters were fixed in formalin and shipped to a core lab (Stanford, CA). Demographic, procedural, and outcomes data were collected in the ICEM Registry.

Results*:* Of the 745 patients receiving stopped-heart CABG, complete data on preoperative risk factors was reported for 673 patients. At least 19 patients reported complete data in Cohort 2, and 10 reported in Cohort 3. One adverse outcome, a death, occurred in the 24 off-pump patients reporting (4.2%). Histologic analyses showing the number of filters successfully extracting particles, the number of particles and total particulate surface area per filter, and the ranges are shown in below.

Histologic Finding	Cohort 1	Cohort 2	Cohort 3
Filters with particles	98%	100%	100%
Mean # of particles	8.5	9.6	5.6
Range # of particles	0-76	1-29	2-13
Mean surface area (mm2)	11.8	18.4	6.1
Range surface area (mm2)	0-171	0.5-61	0.2-14

Conclusions: These data clearly suggest that there is no difference between the amount of particulate debris generated in OPCAB cases versus CPB cases. In OPCAB cases where an anastomosis device was used without a partial clamp, particulate debris may be reduced but not eliminated. These findings may demonstrate the importance of aortic manipulation, particularly clamping, as a source of particulate material in cardiac surgery. However, more study needs to be done to confirm these findings with a larger number of patients.

INTRODUCTION

Neurologic injury following cardiac surgery remains a perplexing and elusive phenomenon. Much effort has been expended to understand the etiology of neurologic complications, and to develop procedural techniques and technological advancements to reduce the occurrence of these devastating events. [Barbut 1996, stump 1996] The development of pharmacological strategies such as aprotinin, the elimination of cardiopulmonary bypass, and avoiding the aorta with "no touch" surgical techniques have all been posited as methods to reduce the incidence of neurologic injury. [Bonatti 1999, Murkin 1999, Taylor 1998] Yet while the sources of neurologic complications are multifactorial, the single most important risk factor predictive of neurologic events has been shown to be the presence of atheromatous disease in the ascending aorta. [Roach 1996, vaage 2000] The International Council of Emboli Management (ICEM) study group, formed to investigate the impact of particulate capture and removal during surgery, has reported that particulate material, most often fibrous atheroma, is generated in most cardiopulmonary bypass procedures. The ICEM study group reported that particulate material is captured in 98% of all cardiac surgery cases using cardiopulmonary bypass, and that 73% of filters contain fibrous atheromatous material. In a subset of CABG patients, the ICEM study group has reported that the incidence of Type I or severe neurologic complications has been reduced by as much as 50%.

It can be theorized that there is a connection between this risk factor that has been shown to be predictive of adverse neurologic events and the reduction of those events in patients in whom atheromatous material is removed. Studies of embolic activity during cardiac surgery have shown that most emboli are generated during the application and removal of aortic and partial cross clamps, with other embolic activity coming from suturing grafts, onset of CPB, and cannulation. The development of beating heart surgery may eliminate the need for aortic cross clamping, but the majority of off-pump surgery is done through a median sternotomy in which partial cross clamps are used to perform proximal anastomoses. More recent developments to eliminate the use of the partial clamp include the new proximal anastomosis devices that can be used during off-pump surgery to perform the central anastomoses automatically.

The purpose of this study was to investigate whether embolic activity is decreased in OPCAB cases, including those in which a proximal anastomotic device is used.

MATERIALS AND METHODS

Patients

The ICEM study is an ongoing, prospective, non-voluntary, consecutive enrollment registry of patients receiving intraaortic filtration. At the time of this analysis a total of 1292 patients had been enrolled in the database between February 1999 and June 2001. Since this study examined a subset of patients receiving automatic anastomoses, and such patients all received off-pump CABG procedures, a comparison of three groups was performed. These three, mutually exclusive groups we defined as follows: Cohort 1 (n = 745) patients receiving on-pump CABG-only procedures; Cohort 2 (n = 24) patients receiving off-pump CABG-only procedures with conventional anastomoses; Cohort 3 (n = 10) patients receiving off-pump CABG-only procedures with automatic proximal anastomoses.

Intraaortic Filtration

In stopped heart cases, the intraaortic filter (Embol-X, Mountain View, California) was placed in the aorta by means of an access port attached to the arterial return cannula. The filter was placed just prior to cross-clamp removal, and was removed when the heart was ejecting fully. The location of the filter was immediately distal to the cross clamp, but proximal to the arterial return cannula and the innominate artery.

An Introducer device that allows the filter to be placed independently of the cannula was used in beating heart cases. In OPCAB cases with conventional anastomoses, the filter was placed in the aorta just prior to the first application of the partial cross clamp and removed after the final release of the partial cross clamp. The filter was placed distal to the clamping site, but proximal to the innominate artery.

In beating heart cases with automatic anastomoses, the filter was placed in the aorta before the incision was made for the first anastomosis. After the final proximal anastomosis was completed, the filter was removed. Filter location was distal to the anastomoses sites, and proximal to the innominate artery. No partial or aortic cross clamp was used on cases receiving automatic anastomoses.

Automatic Anastomotic Device

All automatic anastomoses were performed with the Aortic Connector (St. Jude, St. Paul, Minnesota). Use of this device is in three stages. First, the saphenous vein is harvested and loaded with an anastomotic clip onto a deployment device. The aorta is then prepared by using a coring device to cut a circular incision in the aorta that will receive the clip and the vein graft. Finally, the deployment device is inserted into the incision and activated with the push of a button. A nitinol clip secures the vein to the aorta by applying pressure to the graft from inside and outside the aorta.

Filter Analysis

Upon removal, filters were fixed in formalin and sent to a core lab (Stanford University, USA) for gross observation and analysis. Particles contained in each filter were hand counted and digitally photographed. Morphometric analysis using Scion Image Software (NIH Image) was performed to measure surface area. For each cohort, the mean number of particles found in each filter and the mean total surface area of particles per filter were computed.

RESULTS

Of the 745 patients receiving stopped-heart CABG, complete data on preoperative risk factors was reported for 673 patients. At least 19 patients reported complete data in Cohort 2, and 10 reported in Cohort 3. Preoperative clinical risk factors are summarized in Table 1.

One adverse outcome, a death, occurred in the 24 off-pump patients reporting (4.2%). Complete clinical outcomes by cohort are summarized in Table 2.

Histologic analyses showing the number of filters successfully extracting particles, the number of particles and total particulate surface area per filter, and the ranges are shown in Table 3.

DISCUSSION

The ICEM study group has used technology that enables the capture and removal of particulate debris from stopped-heart cases for over two years. The advent of two new technologies, one enabling the application of the filter independently from the arterial return cannula, the other enabling proximal anastomoses without the use of cross clamps, has made research on emboli filtration of OPCAB and automatic anastomosis cases possible for the first time. These preliminary data are our first glimpse of what these technologies may mean for the future.

We chose to isolate the effects of different types of surgery by creating the three cohorts. While this approach allows easy comparison of preoperative variables, outcomes, and histologic results, it also makes each study group small, and may make conclusions riskier. Nevertheless, several trends in the data are provocative and highly suggestive of areas for further research.

Preoperative risk factors showed that the three cohorts did not diverge grossly. Cohorts 1 and 2 were very similar in terms of preoperative hypertension (72% vs. 74%), TIA (6% vs. 5%), and calcification in the ascending aorta (33% vs. 45%). Due to the small size of Cohort 3 (n = 10), it is hard to draw conclusions, other than to note that Cohort 3 is grossly similar to the other two cohorts.

Clinical outcomes for Cohort 1 reflect the results in CABG patients receiving CPB and conventional anastomoses. Previous studies (Schmitz) have shown that neurologic outcomes in CABG patients receiving intraaortic filtration are roughly half of the risk-adjusted expected outcomes. In this Cohort, occurrence of aortic dissection was 0%, TIA 0.7%, stroke 1.4%, delirium 2.4%, and mortality 2.3%. Cohorts 2 and 3 experienced one adverse outcome in all patients, a death. More study is needed of intraaortic filtration in OPCAB to determine if this excellent result is a trend or a real effect.

Histologic analysis of the contents of the filters showed interesting trends in the amount of material captured during these three types of cases. When CPB cases are compared to OPCAB cases with conventional anastomoses, the trend is for slightly more material to be captured in the OPCAB cases. This may be due to the fact that partial clamping occurs under full aortic pressure and pulsatile flow conditions, thus creating an environment more conducive to embolization. However, it may simply be an artifact of small cohort size. There is clearly no trend for reduced particulate capture in OPCAB cases with conventional anastomoses when compared to CPB cases.

When compared to CPB cases, automatic anastomotic cases are trending towards reduced number of particulates and reduced particulate surface area.. In comparing these two cohorts (Cohorts 1 and 3), mean surface area is reduced almost by half in the automatic anastomotic cases (6.1 mm2 vs. 11.8 mm2 per filter).

The most suggestive comparison is between the OPCAB groups both with and without conventional anastomoses (Cohorts 2 and 3). In this comparison, cases using an automatic anastomotic device demonstrate roughly 50% reduction in mean number of particles per filter (9.6 vs. 5.6), and roughly 66% reduction in mean surface area (18.4 mm2 vs. 6.1 mm2).

One technology that may help decrease the chances for embolization is epiaortic ultrasonographic scanning. Studies show that epiaortic scanning provides enough data to alter surgeries about 25% of the time (Murkin). Epiaortic scanning was used in some of the patients in this series, and helped determine optimal placement of the automatic anastomoses. This may partly account for the observed reduction in captured material in Cohort 3. Since epiaortic scanning was not applied consistently to all patients we can not draw conclusions at this point. Nevertheless, it remains an exciting technology that may be even more powerful when used in conjunction with intraaortic filtration and automatic anastomotic devices.

CONCLUSION

These data clearly suggest that there is no difference between the amounts of particulate debris generated in OPCAB cases versus CPB cases. In OPCAB cases where an anastomosis device was used without a partial clamp, particulate debris may be reduced but not eliminated. These findings may demonstrate the importance of aortic manipulation, particularly clamping, as a source of particulate material in cardiac surgery. However, more study needs to be done to confirm these findings with a larger number of patients.

Appendix

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Table 1. Preoperative Risk Factors

Risk Factor	Cohort 1 N	%	Cohort 2 N	%	Cohort 3 N	%
Prior MI	125/732	17%	1/19	5%	0/10	0%
Hypertension	526/735	72%	14/19	74%	3/10	30%
TIA	45/711	6%	1/19	5%	1/10	10%
Calcified asc. aorta	225/673	33%	9/20	45%	3/10	30%
Prior stroke	39/734	5%	0/19	0%	0/10	0%

Table 2. Clinical Outcomes

Outcome	Cohort 1 N	%	Cohort 2 N	%	Cohort 3 N	%
Aortic dissection	0/698	0%	0/15	0%	0/9	0%
TIA	5/713	0.70%	0/15	0%	0/9	0%
Stroke	10/714	1.4%	0/15	0%	0/9	0%
Delirium	17/701	2.4%	0/15	0%	0/9	0%
Mortality	16/705	2.30%	1/15	7%	0/9	0%

Table 3. Histologic Analysis

Histologic Finding	Cohort 1	Cohort 2	Cohort 3
Filters with particles	98%	100%	100%
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