

# Particulate emboli capture by an intra-aortic filter device during aortic valve replacement

*Avaliação da captura de fragmentos por meio da filtração intra-aórtica em pacientes submetidos à troca valvar aórtica*

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RBCCV 44205-1014

## Abstract

**Objective:** This study aims to analyze the embolic activity in patients with calcified aortic stenosis who underwent aortic valve replacement using intra-aortic filtration with an EMBOL-X® System device (Edwards Lifesciences Inc., Mountain View, CA, USA).

**Methods:** From January 2007 to July 2007, 13 consecutive patients with calcified aortic stenosis, who underwent isolated aortic valve replacement using intra-aortic filtration by an EMBOL-X® System for 5 minutes after aortic clamp release, were evaluated. Mean patient age was 63.7 years (range 34 to 79 years) and 61.5% were female. The mean bypass time was  $60.2 \pm 7.5$  minutes (range 45 to 72 minutes) and the mean cross-clamp time was  $50 \pm 7.5$  minutes (range 35 to 63 minutes). Following removal, each filter was fixed in formalin and analyzed macroscopically with the captured fragments being counted. Histological examinations of the captured material were performed.

**Results:** There were no strokes or gross neurological events. There were no cases of postoperative renal failure. No deaths were reported during hospitalization. Particulate emboli were found in five (38.5%) of the filters. On histological analysis of the particulate emboli captured, two (40%) contained fibrin, two (40%) presented conjunctive tissue, one (20%) contained red blood cells and in two it was not possible to determine the nature of the particulates captured.

**Conclusion:** The EMBOL-X® System device was effective in particulate emboli capture in aortic valve replacement surgery of patients with calcified aortic stenosis.

**Descriptors:** Aortic valve stenosis/surgery. Embolism/prevention & control. Stroke/prevention & control. Filtration/instrumentation. Heart valve prosthesis implantation.

## Resumo

**Objetivo:** O objetivo deste estudo foi avaliar a atividade embólica de pacientes portadores de estenose aórtica calcificada submetidos a troca valvar aórtica por meio da filtração intra-aórtica com dispositivo EMBOL-X® System (Edwards Lifesciences Inc., Mountain View, CA, USA).

**Métodos:** De janeiro de 2007 a julho de 2007, foi utilizado o filtro intra-aórtico EMBOL-X após o despinçamento aórtico em 13 portadores de estenose aórtica calcificada submetidos a troca valvar aórtica consecutivamente. A média de idade dos pacientes foi 63,7 anos (34-79) e 61,5% eram do sexo feminino. A média do tempo de CEC foi  $60,2 \pm 7,5$  (45-72) minutos e a média do tempo despinçamento aórtico foi  $50 \pm 7,5$  (35-63) minutos. Após a retirada dos filtros, eles foram fixados em formalina, analisados macroscopicamente e quantificados os fragmentos capturados. Foi realizado exame histológico do material capturado.

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Article received on March 19<sup>th</sup>, 2008

Article accepted on July 7<sup>th</sup>, 2008

**Resultados:** Não foi observado nenhum caso de complicação neurológica. Nenhum paciente apresentou insuficiência renal pós-operatória. Não houve óbitos hospitalares. Partículas embólicas foram encontradas em cinco (38,5%) dos filtros. Das partículas embólicas capturadas, em dois (40%) filtros havia fibrina, dois (40%) apresentavam tecido conjuntivo, um (20%) continha hemácias e em um não foi possível determinar a natureza.

**Conclusão:** O dispositivo EMBOL-X® System foi efetivo na captação de fragmentos intra-aórticos na substituição da valva aórtica em pacientes com estenose aórtica calcificada.

**Descritores:** Estenose da valva aórtica/cirurgia. Embolia/prevenção & controle. Acidente vascular cerebral/prevenção & controle. Filtração/instrumentação. Implante de prótese de valva.

## INTRODUCTION

Strokes are the third leading cause of death in developed countries and the main cause of physical disability [1]. Over the last few years, neurological lesions during heart surgery have received special attention from surgeons. About 3.8% of patients submitted to coronary artery bypass grafting and up to 10% of those who undergo aortic valve replacement suffer strokes [3,4].

Neurological events are associated to substantial increases in mortality, hospitalization and costs over the medium and long terms. Much effort has been spent to minimize the risks of these complications. Although the causes of neurological complications are multifactorial, age and atherosclerosis have been identified as the main risk factors [5,6].

Studies have evaluated the capacity and safety of intra-aortic filters to capture fragments released in the intra-operative period of patients undergoing CABG. The results not only demonstrated the safety of the device but also its capacity to capture fragments in the intra-operative period and the histological composition of the fragments (predominantly of atheromatous origin), as well as identifying that aortic de-clamping was the moment of greatest risk [5].

However specific studies to evaluate the use of this device in patients with calcified aortic stenosis have not been performed. This research aimed at analyzing the embolic activity of patients with calcified aortic stenosis submitted to aortic valve replacement by means of morphological and histological analyses of fragments captured by intra-aortic filtration using the EMBOL-X® device (Edwards Lifesciences Inc., Mountain View, CA, USA).

## METHODS

Consecutive patients with calcified aortic stenosis of degenerative (12 cases) or rheumatic (one case) etiologies with indication for elective surgery were included in this study. All were informed about the procedures to be

performed and signed the written consent form approved by the Ethics Commission of Hospital das Clínicas Medical School of the University of São Paulo. Patients submitted to emergency surgery, reoperations and other associated procedures such as CABG, other valve surgeries or repair of congenital heart diseases were excluded from the study.

The preoperative clinical data (Table 1) were obtained by completing a standard questionnaire, which followed the model of that of surgical risk evaluation denominated EuroSCORE [7].

Table 1. Demographical characteristics

Parameter	Mean ± SD	Variation
Age	63.7 ± 13.9	34-79
Gender M/F (%)	38.5/61.5	
BMI (kg/m <sup>2</sup> )	26.9 ± 4.8	19.5-33.5
SAH (%)	61.5	
DM (%)	23	
Area of AoV (cm <sup>2</sup> )	0.72 ± 0.06	0.64-0.78
Mass index of LV (g/m <sup>2</sup> )	142.5 ± 49	80-234
Gradient LV-Ao (mmHg)	82.7 ± 30.3	46-137
Ejection Fraction (%)	55.5 ± 19.1	17-74

M/F = male/female; BMI = body mass index; SAH = systemic arterial hypertension; DM = diabetes mellitus; AoV = aortic valve; LV = left ventricle; LV-Ao = left ventricle-aorta; SD = Standard Deviation

All patients were operated on by the same surgical team. Access was by median sternotomy. After routine exposure of the pericardial cavity, the aorta was measured using a standard gauge to choose the correct size of the EMBOL® intra-aortic filtration device. Cardiopulmonary bypass was installed using arterial cannulation of the ascending aorta and simple two-stage venous cannulation through the right atrial appendix. The arterial cannula has a side port for the EMBOL-X® System device (Figure 1).



Fig. 1 – Aortic cannula with EMBOL-X® System device

The patient was cooled to 28°C, the aortic was clamped and myocardial protection initiated with blood cardioplegic solution (Saint Thomas) being infused at 4°C in the coronary artery ostia, a procedure repeated at 20-minute intervals. Then the aortic valve was resected with thorough decalcification of the aortic ring. After this, the biological prosthesis was positioned using 2-0 mersilene ‘U-shaped’ sutures anchored utilizing Teflon. After the removal of air from the left cavities and re-warming to 36.5°C, the EMBOL-X® filter system was attached to the arterial cannula and the intra-aortic filter was inserted into position. Following this, the aortic clamp was removed. Five minutes after the contractile activity of the heart had been re-established, the intra-aortic filter was removed and retained for analysis. The mean cardiopulmonary bypass time was  $60.2 \pm 7.5$  (range: 45-72) minutes and the mean aortic clamping time was  $50 \pm 7.5$  (range: 35-63) minutes.

The filters were fixed in formalin and sent to the Pathological Anatomy Laboratory (Heart Institute of Hospital das Clínicas Medical School of the University of São Paulo) where they were macroscopically analysed using

the Quantimet® measurement system with magnification of at least 10x. The particles contained in each filter were counted and digitally photographed. Morphometrical analysis was achieved using Scion Image Software® (NIH image). Histological examinations of the material were performed to detect the nature of fragments, by fixing them and subsequent hematoxylin-eosin, Masson’s trichrome and Verhoeff staining.

All the patients were evaluated every day during hospitalization by the team responsible for postoperative care in respect to the presence of type-I and II neurological events. Renal insufficiency was diagnosed when the creatinine serum level of higher than 2.0 mg/dL or more than 1.5 times the level in the preoperative period [8].

The numerical variables of demographical data are presented as means with standard deviation. The comparison between means of independent groups was performed using the Student’s t-test with the WINKS SDA 6.0.4 computer program. Statistical significance was set at 5%.

## RESULTS

No injuries to the aorta or adverse events related to the use of the intra-aortic filter were identified. There were no neurological events and no patient presented with renal insufficiency in the postoperative period. No deaths occurred during hospitalization.

Embolized particles were captured in five (38.5%) of the filters, as illustrated in Figure 2.

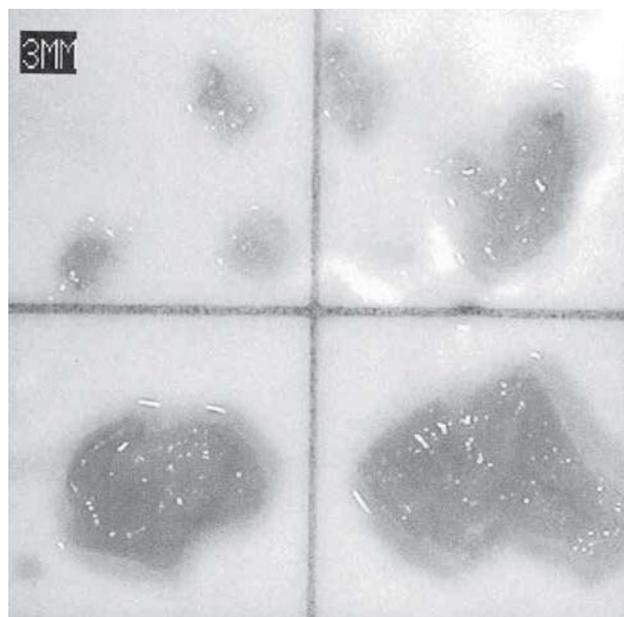


Fig. 2 – Embolic matter captured in the intra-aortic filter of patient 1 (magnification 10x - each square represents 3 mm)

Histological analysis (Figure 3) showed that the captured particulates composed of: fibrin (two cases), conjunctive tissue (two cases) and red blood cells (one case): in one filter, more than one type of material was found (fibrin and red blood cells) however, the identification of the nature of the embolus from one filter was impossible.

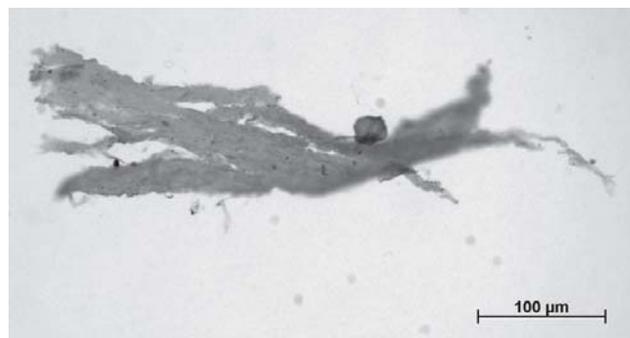


Fig. 3 – Histological examination of a captured particulate revealing the presence of conjunctive tissue (Patient 5)

The patients in whom intra-aortic filters captured embolized particles presented with statistically smaller mass indexes of the left ventricle than the patients in which no particulates were captured. The ejection fraction and the gradient between the left ventricle and the aorta were lower for patients of filters that did not capture particulates, but without showing any statistical significance (Table 2).

Table 2. Echocardiographic data of patients with filters that captured emboli and of those with filters that did not capture emboli.

Parameter	With Capture	Without Capture	p-value
Mass Index of			
LV (g/m <sup>2</sup> )	98.5±18.5	171.8±39.4	0.009
LV-Ao Gradient (mmHg)	100.4±38.1	71.6±19.5	0.097
Ejection Fraction (%)	65.6±5.4	49.2±19.1	0.08
BMI (kg/m <sup>2</sup> )	26.3±5	28.7±4.2	0.45

LE = left ventricle; LV-Ao = left ventricle-aorta; BMI = body mass index

## DISCUSSION

Knowledge concerning atheromatous disease of the aorta has increased over the last few years. Barbut et al. [9,10] demonstrated a strong correlation between the severity of aortic atheromatosis and the number of dislodged particulates. Moreover, they showed that most of the particulate emboli are liberated during the removal of aortic clamps and that the emboli are associated to

neurological injury. Thus, they suggested that the use of a filter might reduce adverse neurological events.

The EMBOL-X® System proved to be safe, as no intraoperative complications occurred related to its use, corroborating published data [8,11].

In this study, no neurological injury or renal dysfunction occurred in the postoperative period of the 13 patients who were submitted to aortic valve replacement. Two large randomized studies demonstrated that the use of a filter reduced postoperative morbidity, in particular neurological and renal complications, as well as decreasing the hospitalization stay and mortality [12,13].

It has been shown that intra-aortic filters capture embolic matter in 99% of cases, with histological analysis showing that fibrous cap and fibrin deposits are the main components of embolic matter captured by filters. However, other diverse materials including cartilage, lung and myocardial fragments, sutures and fragments of Teflon have already been found, showing that the origin of these particles is mainly surgical manipulation [5,8,14]. In this research, the intra-aortic filters captured embolic matter in 38.5% of cases, a smaller proportion than that mentioned above, probably, because the filter was implanted for only 5 minutes while, in the aforementioned studies, it was employed until weaning from cardiopulmonary bypass, a procedure that may have taken longer.

Recently, researchers have tried to determine the group of patients that would benefit with the use of the EMBOL-X® filter. In this study, we discovered that the patients whose filters captured particulates had left ventricle mass indexes significantly smaller than patients whose filters did not capture emboli (p=0.009). On the other hand, the gradient between the left ventricle and the aorta and the ejection fraction were lower in the group of patients where the capture of particulates occurred, although without statistical significance. The present study is limited by the small sample size, and, hence, studies with larger samples are necessary in order to identify patients who would most benefit by the use of intra-aortic filters. Bonatti et al. [15], analyzing 113 patients submitted to CABG utilizing EMBOL-X® filters, did not find any correlation between the thickness of the aorta measured by epiaortic ultrasound and the number of particles captured by intra-aortic filters or the surface area of captured particulates. In another study, the degree of aortic disease was correlated with the number of particles captured by the intra-aortic filter. Additionally, obesity, hypertension and number of proximal anastomoses had a significant influence on the number of particles captured [16].

Christenson et al. [17] used the intra-aortic Edwards EMBOL-X® Slim Protection Device in 15 patients, who underwent heart surgery, before aortic clamping and after aortic declamping and showed that in two thirds of the

filters used before clamping there was a similar or greater number of particles captured. They suggested that to improve protection against embolism in heart surgery, the intra-aortic filter should be used not only during aortic declamping, but also during aortic clamping.

#### CONCLUSION

The EMBOL-X® System was effective to capture intra-aortic particulates in aortic valve replacement surgery for calcified aortic stenosis.

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