Other novel emboli-capturing systems, such as CardioGard (Cardiogard Medical, Or Yehuda, Israel), that produce both a forward flow and a backward suction for extraction of solid and gaseous matter are also being studied and assessed for safety [11]. TriGuard, another aortic filter used during transcatheter aortic valve implantation, has been shown to be safe and efficacious in reducing cognitive decline at discharge and 30 days postoperatively [12]. A multicentre randomized study for this device failed to show any significant difference in different variables of adverse events including mortality, TIA, renal failure, ICU stays or hospitalizations. More data must be collected to show the efficacy of novel systems.

Limitations to our study include a retrospective observational design with its inherent flaws. It was carried out at a single institution with a limited number of surgeons. Despite thorough preoperative and intraoperative assessment of the aorta, some of the anatomic risk factors, including ascending and arch atheromas and calcifications, are not incorporated into the STS calculator. Specific patient demographics in this study may not be representative of the general population, though the use of the STS calculator to assess mortality risk allows us to standardize our patient population to those of the rest of the country. Propensity score matching is a valid statistical method of analysis, but it cannot circumvent the lack of randomization. To further examine the efficacy of the aortic filter, a multicentre randomized protocol should be created and followed.

In conclusion, the use of the EMBOL-X filter in high-risk cardiac surgical patients may decrease the overall complication rate and respiratory complications. In addition, patients who develop a complication after surgery may also have a shorter stay in the ICU, which could lead to a reduction in the cost for the procedure. Accordingly, we recommend the selective use of the EMBOL-X filter in high-risk cardiac surgical patients.

Conflict of interest: none declared.

REFERENCES


Re: Selective use of the intra-aortic filter in high-risk cardiac surgical patients leads to better postoperative outcomes

Gerhard Wimmer-Greinecker*

Department for Cardiothoracic Surgery, Heart & Vessel Center Bad Bevensen, Bad Bevensen, Germany

* Corresponding author. Department for Cardiothoracic Surgery, Heart & Vessel Center Bad Bevensen, Römstedter Str. 25, 29549 Bad Bevensen, Germany. Tel: +49-5821-821772; fax: +49-5821-821777; e-mail: g.wimmer-greinecker@hgz-bb.de. (G. Wimmer-Greinecker).

Keywords: Intraaortic filtration • Particulate emboli • Neurologic injury • Cardiac surgery

Generation of particulate emboli in cardiac surgery is a severe problem potentially leading to various serious complications [1]. Based on the work of Barbut et al. [2], which mainly showed that most microemboli during cardiac surgery are mobilized at either the time point of cross clamping of the ascending aorta or the removal of the cross clamp, a start-up company by the name of Embol-X was founded in the late 90s to develop an intra-aortic filter initially connected to the aortic perfusion cannula. In the later development period a sole aortic filter to be used in OPCAB surgery was available as well.
To scientifically evaluate the positive effects of this filter on clinical outcomes, the International Council of Emboli Management (ICEM) was initiated, consisting of several well-renowned cardiac surgeons including the author of this editorial comment [3]. Although histological examination of filters showed a capture rate of up to 97% [4], it was extremely difficult to show in a statistically sound way superiority in outcomes after using this intraluminal filter. At that time, in the performed studies, the main focus was on neurologic injury. To show a difference in stroke, which accounts for up to 4.6% in overall cardiac surgery [5], a rather high four-digit number of study patients was calculated in the aspect of a planned randomized study, which at that time was not affordable for a small start-up company. Therefore, several registry trials were carried out resulting in comparisons with historical controls. Two of these analyses showed a positive effect of using intraluminal filtration in cardiac surgery, one in a registry of consecutively enrolled patients of various kinds of cardiac surgery [6], the other one looking at patients undergoing combined intracardiac and CABG procedures [7]. For the analyses in both of these studies rather complex statistical calculations had to be carried out by the guru of statistics in medical science, Eugene Blackstone from the Cleveland Clinic Foundation, who himself was a member of the ICEM group.

This leads me to the discussion of the work presented by Chiba et al. in this issue of the journal [8]. After more than a decade, this is the first publication on this topic, which they have to be congratulated for. Again this is an analysis of non-randomized patient cohorts with an extremely complex statistical analysis, which I may not allow myself to judge since the calculations are far beyond my statistical knowledge.

As far as I can say, there is obviously a bias in which patients an intraluminal filter has been used and in which not. Furthermore, inclusion and exclusion criteria for patients entering into the study are not explained, at least not in the manuscript that I have access to, which makes the data even a bit weaker. My main concern would be the generalization of complications though. It is a fact, that the intraluminal filter captures emboli and obviously we should be looking at complications potentially caused by emboli. These of course exceed neurologic complications and also include renal failure, myocardial infarction, gastrointestinal complications and limb ischaemia. I do not see a causative inter-relation with respiratory failure, sternal infections or reoperations though. And respiratory failure accounted to the only statistically significant parameter after evaluation of the matched groups.

The value of sound statistical work regarding clinical trials has changed over the years. Decades ago, e.g. the transition from using bubble oxygenators to membrane oxygenators in heart-lung-machines has been performed without a randomized trial of any kind. Additionally, in the old days numbers of patients in each cohort had not to be that large, since the margins of improvement after using new strategies or new devices have been more pronounced.

Since the developments in cardiac surgery have led to the excellent results of today, margins became smaller and smaller and proof of superiority of a new procedure or in using a new device or medication in a sound way has almost become impossible. Responsible therefore are not only the high patient numbers which would have to be examined, where enrolment in a study is difficult to be financed. Also the fact that differences in low risk patient cohorts, which are better comparable, are minor and difficult to detect and that differences in high risk patient cohorts are influenced too much by the complex risk profile of every individual are a main factor for this issue. This dilemma leads to the circumstance that many of the new procedures are and will be performed by believers and many of new devices are and will be used by believers as well.

And regarding intraluminal filtration, a particulate emboli capture of up to 97% [4] may give the believers a very strong argument.

REFERENCES