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USE OF CLAMPLESS FACILITATING DEVICES IN PATIENTS WITH LOW-GRADE AORTIC DISEASE: IS THE COST JUSTIFIED BY THE THEORETIC RISK REDUCTION?

Reply to the Editor:

I appreciate the commentary of Formica and colleagues regarding the use of clampless facilitating devices (CFDs) in patients undergoing coronary artery bypass grafting (CABG). The quest to reduce stroke after CABG has led to numerous observational and prospective trials with a variety of approaches, including off-pump CABG, anaortic approaches, hybrid revascularization, and CFDs. With regard to my group's recent prospective, randomized trial,¹ we agree with Formica and colleagues that there were limitations with our study, specifically that the primary end point was a surrogate for stroke, transcranial Doppler high-intensity transient signals (HITS) rather than a hard clinical end point. Nonetheless, we anticipated a reduction in HITS in the CFD group, supporting the use of these devices, but the results did not support our hypothesis. Selection bias, which is a major limitation of many observational studies, including those from our own institution,² was minimized in this study with randomization.

Nonetheless, what our randomized, controlled trial did show was that HITS increased proportionally to the number of devices used and that the total numbers of gaseous and solid HITS detected were higher in the CFD group than in the partial-clamp group. I agree with Formica and colleagues that many of these HITS may have represented gaseous rather than solid microemboli, but the transcranial Doppler technology used in this trial was insufficiently sensitive to differentiate reliably the two. Furthermore, I agree that transcranial Doppler technology is associated with its own limitations.

The current issue is whether patients with low-grade aortic disease in whom CABG is performed off pump truly benefit from the use of CFDs. This is not the same as an anaortic approach, which I also agree is probably associated with the lowest stroke risk. It is important to acknowledge

that this trial excluded patients with more advanced aortic disease (grade III-V), because our current practice is to avoid any clamping of these aortas. The use of epiaortic ultrasonography in this study allowed us to evaluate a homogeneous group of patients undergoing CABG. In addition, because of the current climate of cost containment, it is important to consider that the cost of each Heartstring device (MAQUET Holding B.V. & Co. KG, Rastatt, Germany) to the hospital is approximately \$500 to \$700, without a clearly defined benefit in the patient population that was studied.

Our recommendations on the basis of our results was that for patients undergoing off-pump CABG with low-grade aortic (grade I-II) disease, as determined by epiaortic ultrasonography, there was no observed benefit in HITS between patients randomized to receive CFDs versus partial clamping of the aorta. Clearly, surgical decision making in the operating room is needed to determine the best proximal anastomosis strategy for patients undergoing CABG, and we agree that CFDs are an important tool when clinically indicated.

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A TUG ON THE HEARTSTRINGS Reply to the Editor:

After the publication of "Operative Strategies to Reduce Cerebral Embolic Events During On- and Off-Pump Coronary Bypass Surgery: A Stratified, Prospective Randomized Trial" by Halkos and colleagues¹ from Emory University School of Medicine, a letter to the editor was submitted by Drs Formica, D'Alessandro, and Amerigo Messina² from

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the Cardiac Surgery Unit at San Gerardo Hospital, Department of Medicine and Surgery, University of Milano-Bicocca, Monza Italy. They contended that although the clampless off-pump technique championed by the Emory group facilitated graft-aortic anastomoses with the Heartstring device (MAQUET Holding B.V. & Co. KG, Rastatt, Germany) to reduce cerebral damage during off-pump coronary artery bypass grafting (CABG) would be an easier solution to continue to perform graft-aortic anastomoses without aortic clamping.²

I was asked to write an Editorial Comment, which was published in the same issue of the *Journal*,³ and I complemented Halkos and colleagues for their careful examination of several techniques to facilitate the graft-aortic anastomosis with the intent to avoid embolic damage to the brain. Unfortunately, this study was performed on patients with no or minimal ascending aortic atherosclerosis, which would make the chances for embolism low. This would almost guarantee low numbers of patients with brain injury, an end point difficult to analyze. This point was discussed by Formica and coauthors,² who took issue with the results of the study of Halkos and colleagues¹ because of the low number of patients with ascending aortic disease. The study Formica reads like an advertisement for Heartstring, citing as proof a meta-analysis of 37,720 patients published in *Journal of the American College of Cardiology*.⁴ A large series of patients undergoing anaortic off-pump CABG showed a 76% reduction in stroke (no graft-aortic anastomoses) relative to patients undergoing conventional CABG (aorta clamped, graft aortic anastomoses below the crossclamp). Off-pump CABG with Heartstring demonstrated a 52% reduction in stroke, 26% less protection than anaortic surgery. Although these results are impressive, they cannot be compared with the patient volume and aortic disease numbers in the article of Halkos and colleagues.¹ It is my

opinion that recommending off-pump surgery and Heartstring use to all patients undergoing CABG denies many patients the salutary effects of cardiopulmonary bypass.

I agree that Heartstring and other graft-aortic facilitating devices should not be forgotten, because they allow safe aortic graft anastomoses without aortic clamping. On the other hand, this technique is not free of problems. In my medical center, use of the aortic punch when carotid Doppler imaging is used almost always demonstrates particulate material passing the transducer, leading our surgeons to refrain from using multiple graft-aortic Heartstring-facilitated graft-aortic anastomoses. Although stroke is rare we have often seen postoperative cognitive deficits in patients with Heartstring use. We have not forgotten the Heartstring, but I would suggest that the ease of application on the aorta may not be so easy on the patient. The fact that the stroke rate is so low in the article of Halkos and colleagues¹ is not surprising but reassuring, in that most patients with minimal or no aortic disease will do well with aortic clamping and graft-aortic anastomoses.

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