

## EDITOR'S PAGE

# Give Me FREEDOM or . . .

Denial is not just a river in Egypt. There has been long-standing resistance to the idea that diabetes should play a major role in selecting revascularization for patients with coronary artery disease. Despite multiple iterations of guidelines and an NHLBI alert to the contrary, the selection for coronary artery bypass graft surgery (CABG) or percutaneous coronary intervention (PCI) changed little after the long-term results of the BARI (Bypass Angioplasty Revascularization Investigation) trial were published. We kept waiting for the next technical development that would make the presence of diabetes irrelevant in the selection of therapy. A few years ago, the investigators of 10 randomized controlled trials of balloon angioplasty and bare-metal stents combined the patient-specific data of the participants in those studies and found that diabetes was a significant factor in discriminating between surgical and percutaneous survival (1). All of these studies preceded the era of drug-eluting stents and, therefore, findings were treated by some as historic data only. Surely the advent of drug-eluting stents would change this long-term survival advantage for surgery. All we had to do was wait for the outcome of trials using drug-eluting stents. Since drug-eluting stents were well documented to reduce restenosis, they should also improve other outcomes including survival.

Trials in recent years have provided some comfort for the concept that PCI could be selected without much consideration of the diabetic state of the patient. The only randomized trial of diabetic patients has been CARDia, which at 1 year showed similar all-cause mortality for the 2 revascularization methods (2). That follow-up is much too short, as the early percutaneous transluminal coronary angioplasty trials of the EAST (Emory Angioplasty versus Surgery Trial) and BARI showed no survival advantage for surgery in diabetics over the first 2 to 3 years. The SYNTAX trial, which has been extremely influential in changing guidelines and practice, has been largely interpreted as giving license for PCI of left main lesions while making diffuse 3-vessel disease with a SYNTAX score >33 a virtual contraindication for PCI. Much less has been made of the diabetic subset, which at 3 years had all-cause mortality favoring surgery and, although not reaching significance, a cardiac mortality with stenting almost twice that of surgery (3). However, it has been tempting to conclude that the important criteria for selecting surgery or PCI was the extent of disease and not necessarily the presence of diabetes.

Now comes the FREEDOM trial just reported at the American Heart Association's Scientific Sessions in Los Angeles, California (4). The first trial of diabetic patients undergoing revascularization with adequate power and follow-up to test the superiority of CABG surgery in diabetic patients shows the primary endpoint of death, myocardial infarction, and stroke significantly in favor of surgery. Even all cause mortality was better with surgery. Only the early stroke incidence favored PCI. Yes, this NHLBI-sponsored trial with 1,900 patients and an average SYNTAX score of approximately 26 (intermediate range) did use the first-generation drug-eluting stents that were available at the time the study was performed. There will be speculation that the newer stents will do better; however, there is little evidence that survival or freedom from myocardial infarction or stroke will be altered significantly with the use of these devices.

It is time that we stop denying that diabetes is an important factor in deciding which revascularization method should be used in those patients who need revascularization. It is, however, not time to stop thinking. There will be ongoing discussion of the FREEDOM trial



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looking for the exceptions to the overall conclusion that surgery is superior. The SYNTAX score did not provide a predictive interaction although there was the expected trend for greater benefit of surgery in the patients with higher SYNTAX scores. All patients with diabetes and coronary artery disease were not included in the trial. That is the fact with all randomized trials. The surgical risk for patients needs to be an important consideration, as well as the extent of disease and the potential for near-complete revascularization by the 2 methods. The finding of the FREEDOM trial brings into focus the importance of the "Heart Team" approach to selection of therapy. The new guidelines will be that surgery is better for diabetics. The judgment as to whether this rule should be followed or whether there are exceptions should be the consideration for each individual patient. Collaborative informed decision-making with the patient at the center will hopefully be strengthened by the outcome of this trial.

How should interventional cardiologists discuss the news with their patients? One-liners will not help. We should not deny the findings of this trial but embrace them as added information that helps us guide the appropriate decisions. Patients need to know that the trial was broadly inclusive and the results were the average. If the patient has specific conditions that make surgery or PCI problematic, they need to be discussed. Some studies show that patients are unaware that alternative therapies

have been discussed prior to revascularization. This will not do in the future.

Most important for interventional cardiologists, surgeons, endocrinologists, primary physicians, and others caring for these patients is the commitment to optimal medical management which will be critical to the patient's long-term outcome. The patient must also understand that or all else is in vain. As we like to teach our children, with freedom comes responsibility. With the FREEDOM trial results, we have the responsibility to help guide the therapy of our patients for their ultimate benefit.

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