The FREEDOM trial

(AUGUST 2013)

TO THE EDITOR: We would like to raise the following points about the paper by Dr. Aggarwal et al[1] interpreting the Future Revascularization Evaluation in Patients With Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM) trial.[2]

The patients enrolled in the FREEDOM trial do not in our opinion completely reflect the real patients that we meet in our daily "real-world" practice.[2] The patients in the FREEDOM trial did not have a high-risk profile. Rather, the mean European System for Cardiac Operative Risk Evaluation score (EuroSCORE) was 2.7 ± 2.4 in the percutaneous coronary intervention (PCI) group and 2.8 ± 2.5 in the coronary artery bypass grafting group—whereas a score of 5 or more on the EuroSCORE is associated with decreased rates of survival.[2]

Furthermore, patients with left main coronary artery stenosis were completely excluded from the FREEDOM trial,[2] but this type of stenosis, with different grades, is found in about 30% of diabetic patients with multivessel coronary artery disease, a fact that may significantly influence the decision regarding the revascularization strategy (bypass grafting or PCI), especially in a clinical setting such as acute coronary syndrome.[3–5]

In addition, the authors did not clearly highlight that diabetes mellitus is an independent risk factor for coronary lesion progression, coronary bypass graft occlusion, and cardiac mortality after bypass grafting surgery.[6–8] Clinical outcomes after bypass grafting in diabetic patients are worse than in nondiabetic patients; diabetic patients have higher rates of morbidity (deep sternal instability, wound infection, stroke, renal dysfunction, and respiratory problems), longer intensive care unit and hospital stays, and poorer postoperative physical functioning and quality of life.[6–8]

The authors correctly explain the reasons for the superiority of coronary artery bypass grafting vs PCI in diabetic patients, either by the ability to achieve complete revascularization or by using more arterial grafts, and especially the left internal thoracic artery.[1] However, clarifying details on the strategy of revascularization in the FREEDOM trial are scarcely provided.[2] All we know from the provided details in this regard is that "for CABG surgery, arterial revascularization was encouraged" and 94.4% of the patients undergoing bypass grafting received left internal thoracic artery grafts.[2]

In addition, whereas off-pump coronary artery bypass grafting surgery is superior to conventional bypass grafting in terms of lower rates of death and major adverse cardiac and cerebrovascular events in diabetic patients with multivessel coronary artery disease,[3] only 165 (18.5%) of the 893 patients who underwent bypass grafting in the FREEDOM trial underwent an off-pump procedure.[2,3]

Therefore, all these considerations should be taken into account as the physician team discusses the therapeutic options (PCI and bypass grafting surgery) with diabetic patients who have multivessel coronary artery disease.

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IN REPLY: We appreciate the comments of Dr. Saeed and colleagues. As stated in our article, given that the patients included in the FREEDOM trial represent a select group with diabetes and multivessel coronary artery disease, they may not represent all patients encountered in a real-world setting. We highlighted that only 10% of the patients screened were included for randomization, which limits the generalizability of the results. Also, the overall patient population may not be at high risk, as evidenced by low mean EuroSCORE and SYNTAX scores and by the low proportion of patients with ejection fractions less than 40%. However, patients with left main coronary artery disease (even without diabetes) have been shown to have better outcomes with coronary artery bypass grafting than with PCI, although a head-to-head trial in a diabetic subgroup is currently not available.[1,2] In addition, it is important to realize that the FREEDOM trial deals with stable angina; therefore, the results may not extend to patients with acute coronary syndrome wherein primary PCI remains the most feasible option in most cases.

Diabetes mellitus is independently associated with complex, accelerated, and multifocal coronary artery disease. Therefore, outcomes after revascularization (with bypass grafting or PCI) are worse in diabetic patients than in those without diabetes. However, this association does not prove the superiority of PCI over bypass grafting.

As we stated in our paper, the FREEDOM trial did not clearly define the strategy for arterial grafts in patients undergoing bypass grafting. The mean number of coronary lesions in the bypass grafting group was high (mean = 5.74), but the average number of grafts used was only 2.9, and data were not provided on the use of sequential grafting and multiple arterial conduits. Lastly, it is true that the FREEDOM trial had relatively fewer patients (18.5%) that underwent off-pump bypass grafting surgery; however, this approach has never been shown to be superior in large randomized trials.[3,4]

In conclusion, no randomized trial should replace clinical judgment to define the targeted revascularization strategy for an individual patient. Rather, results from the FREEDOM trial should help support clinical decision-making in the context of the patient and the institution.

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Electronic health records

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TO THE EDITOR: The July 2013 *Cleveland Clinic Journal of Medicine* includes timely articles addressing the problems of electronic health records (EHRs). At least to this reader, there is little that is surprising in the observations.

A common inside joke among programmers, sometimes displayed at one's cubicle, is: "Fast, good, or cheap (pick two)." In other words, there is always a compromise to be had between a good product and one that is punched out on a given timetable and inexpensive. Economists call this the "second best."

Any truly great software product accomplishes three goals. First, it allows the user to do everything previously doable at least as well or as easily as before. Second, it eliminates drudgery. And third, ideally, it provides new functionality, which previously was difficult or impossible to accomplish or to afford.

The reality is that much software is sold on the basis of the third goal, whereas goal number 1 and sometimes goal number 2 get short shrift. And for EHRs in particular, it is a fallacy for physicians to think that EHRs were brought out primarily for their benefit rather than for the benefit of the front office. This was all the more true a decade ago, when very few physicians were employed by hospitals. Thus, if the physician's workload was increased because of the hospital's choice of EHR, the hospital felt no financial pain. With greater reliance on an employment model, we can hope that hospitals will recognize that physicians should not be turned into very expensive secretaries.

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