Implications of Contemporary Clinical Trials

New Section in Circulation: Implications of Contemporary Clinical Trials

We are pleased to announce to our readers the launch of a new section in Circulation. The purpose is to provide a perspective on contemporary clinical trials in cardiovascular medicine. These trials need not be published in Circulation but must fulfill a minimum set of criteria so as to allow a multidisciplinary discussion of the trial across at least three of the following domains: clinical practice (medical/interventional), trial design and interpretation, regulatory implications, cardiovascular physiology, epidemiology, and health services research. Authors representing the three domains are invited to write a brief and independent commentary from a focused point of view.

Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D)1 is a suitable trial to inaugurate this effort. Its purpose was to evaluate two management strategies for ischemic heart disease and 2 treatment approaches for glycemia in patients with type 2 diabetes mellitus and coronary artery disease (≥50% stenosis and positive stress test or ≥70% and classical angina). All patients had to be considered eligible for elective percutaneous coronary intervention or coronary-artery bypass grafting prior to randomization. However, it is important to note that BARI 2D was not a comparison of percutaneous coronary intervention versus coronary-artery bypass grafting; the prespecified intended form of revascularization was used to stratify the randomization. Using a factorial design, the investigators compared an initial medical management strategy versus immediate revascularization and either an insulin-sensitizing or insulin-providing therapy. At 5 years, all cause mortality did not differ between the groups assigned to an initial medical therapy approach or immediate revascularization or between those receiving an insulin-sensitizing or insulin-providing glycemic treatment. Freedom from major cardiovascular events was significantly lower in the coronary-artery bypass grafting stratum among those allocated to immediate revascularization compared with initial medical therapy; a significant interaction with glycemic strategy was observed favoring the use of an insulin-sensitizing approach in those patients undergoing coronary-artery bypass grafting.

Drs. Allison Goldfine and Vivian Fonseca discuss the impact of BARI 2D on management of diabetes mellitus; Dr. Valentin Fuster discusses the general cardiologist’s decision making regarding revascularization in patients with type 2 diabetes mellitus; and Dr. Scott Solomon discusses the lessons learned from BARI 2D with respect to design and interpretation of cardiovascular trials in patients with diabetes mellitus.

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