HEART OF THE MATTER

Late-Breaking Clinical Trial: A Habit Hard to Break

BY SIDNEY GOLDSTEIN, M.D.

Readers of this column know that we cardiologists have become addicted to the late-breaking clinical trial. Played out in an auditorium large enough to hold at least a quarter of the attendees of the annual scientific sessions of the American Heart Association, the LBCTs are selected as the most important clinical trials of the season. They are presented with huge fanfare to an attentive and anticipating audience of cardiologists, nurses, and Wall Street "gurus" waiting for the latest trend and the next "blockbuster." When none are revealed, which is often the case, the disappointed audience retires to the nearest coffee shop waiting for the next session.

This fall, 23 LBCTs were presented at the AHA meeting, compared with 13 regular LBCTs and 18 mini-LBCTs at the spring meeting of the American College of Cardiology. Much of the anticipation hinges on the possibility that the presentation of a trial will open new avenues of therapy. Disappointment ensues if none occur. Yet important clinical information is always revealed. Some are explorations up the blind alleys of science; others are either confirmatory or expansive of previous observations. This season, although there was no blockbuster revealed, there was a lot of important clinical science.

Some studies achieved their primary objectives; some failed and others added information about previous studies. A substudy of reperfusion imaging conducted in 314 of the more than 2,000 patients with stable coronary artery disease in the Clinical Outcomes Using Revascularization and Aggressive Drug Evaluation (COURAGE) trial provided new data about a previously negative trial. It compared nuclear reperfusion imaging in patients receiving percutaneous coronary intervention plus standard medical therapy with that in patients receiving standard medical therapy alone. Not surprisingly, PCI was significantly better at restoring flow to ischemic areas than was standard medical therapy alone. However, the observation that a full 20% of patients with standard medical therapy improved flow without a PCI, compared with 33% of those who received PCI, was particularly encouraging.

The Controlled Rosuvastatin Multinational Trial in Heart Failure (CORONA) study, however, surprised many when it failed to reach a positive outcome in patients receiving rosuvastatin with heart failure secondary to ischemic heart disease. Patients with proven ischemic heart disease with an average ejection fraction of 31% and increased serum LDL cholesterol levels were randomized to receive either rosuvastatin or placebo. Although a significant decrease in LDL cholesterol was achieved with rosuvastatin, the combined end point of cardiovascular death, nonfatal MI, and nonfatal stroke was unaffected by the therapy. (See article on p. 8.) This is one of the first studies that failed to show any benefit of statin therapy in patients with ischemic heart disease.

The application of 64-slice CT angiography was examined in the CORE 64 study, which compared that technology to standard angiography and showed a close relationship of the two methodologies. However, the discussant of the report chastised the presenter for showing benefit in a study that put patients at risk of radiation-induced cancer without providing any morbidity of mortality benefit to patients. (See article on p. 1 and editorial on p. 11.)

Another trial, Resynchronization Therapy in Normal QRS (RethinQ), examined the importance of atrial fibrillation in heart failure (AF-HF) and observed no adverse effects associated with the arrhythmia in patients with heart failure. Resynchronization of patients with normal QRS time, considered to be the next horizon in biventricular synchronized pacing, also failed to show any benefit in patients with QRS times of less than 130 msec in patients with left ventricular systolic dysfunction.

The Master I trial unfortunately failed to provide any significant predictors for life-threatening ventricular events in patients with implantable cardioverter defibrillators, but the MASS Stent study (see p. 12) dispelled much of the concern about drug-eluting stents in a nonrandomized population study. It compared outcomes of mortality and revascularization in more than 17,000 patients who received bare-metal or drug-eluting stents over a 2-year period in Massachusetts. They observed that, despite recent reports, drug-eluting stents appeared to show safety and benefit.

LBCTs have become fixtures of national scientific meetings. In them, unfortunately, large studies are overemphasized while very important, but less glamorous, research reports are eclipsed.

I vow to overcome my addiction and skip the LBCTs at the next meeting and listen in on some of the science being presented in the back rooms of the meeting. Stay tuned. ■

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POSTMASTER Send changes of address (with old mailing label) to Circulation, CARDIOLOGY NEWS, 5635 Fishers Lane, Suite 6000, Rockville, MD 20852.

CARDIOLOGY NEWS (ISSN 1544-8800) *is published monthly by Elsevier Inc., 60 Columbia Rd., Bldg. B, Morristown, NJ 07960, 973-290-8200, fax 973-290-8250. Subscription price is $90.00 per year.*

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