Effient® (prasugrel) is indicated to reduce the rate of thrombotic cardiovascular (CV) events (including stent thrombosis) in patients with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI) as follows: [1] patients with unstable angina (UA) or non-ST-elevation myocardial infarction (NSTEMI); [2] patients with ST-elevation myocardial infarction (STEMI) when managed with primary or delayed PCI.

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HEART FAILURE

Telemonitoring Flops in Heart Failure Trials

BY BRUCE JANCIN
FROM THE ANNUAL SCIENTIFIC SESSIONS OF THE AMERICAN HEART ASSOCIATION

CHICAGO – Two major new clinical trials have failed to show improved outcomes for home telemonitoring of patients with heart failure – and I think the weight of evidence demonstrates that it is noncontributory,” Dr. Clyde W. Yancy said following presentation of the two randomized trials at the meeting.

“Evidence-based, guideline-driven therapy is the standard of care and should always be our first priority in the treatment of heart failure. The benefit of telemonitoring that has been demonstrated to be present has always been less in the few randomized controlled trials than the cohort studies, and we’ve allowed hyperbole and excitement to guide our judgment, rather than evidence,” added Dr. Yancy, medical director of the Baylor Heart and Vascular Institute and chief of cardiothoracic transplantation at Baylor University Medical Center in Dallas.

One of the studies presented at the AHA meeting was the Telemonitoring to Improve Heart Failure Outcomes (Tele-HF) trial, a National Heart, Lung, and Blood Institute–funded study involving 1,653 U.S. patients enrolled less than a month after discharge for acute decompensated heart failure.

After 6 months of daily remote telemonitoring using the commercially popular Tel-Assurance system marketed by Pharos Innovations, death and rehospitalization rates in patients using the automated telephone monitoring system were similar to those in controls receiving usual care, reported Dr. Sarwat I. Chaudhry of Yale University, New Haven, Conn.

“In this regard, Dr. Yancy noted that his recent Google search of the terms “telemonitoring and heart failure” brought up 87,000 entries. The entire first page consisted of commercial advertisements for available systems.

“There was no benefit seen in either [trial] on outcomes that are important to patients with heart failure.”

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Electronic telemonitoring for heart failure isn’t dead, but for it to be effective, the right physiologic variables related to fluid balance need to be monitored.

...unbridled rush to a technology which, even though seemingly benign, is one that comes at a cost and is not proven to benefit our patients with heart failure;” he concluded.

Another discussant of the trials, Dr. Lynne Warner Stevenson, stressed that telemonitoring for heart failure isn’t dead, but for it to be effective, the right physiologic variables related to fluid balance need to be monitored. What’s being monitored now – changes in body weight and symptoms – are inadequate as harbingers of decompensation. They often occur too late for out-of-hospital correction. Ambulatory hemodynamic monitoring via implanted devices, now under study, holds more promise.

With more responsive physiologic measures and improved electronic technology, it should be possible for heart failure patients to monitor their disease status and adjust their own diuretic therapy without the labor-intense daily remote involvement of physicians and nurses required by today’s telemonitoring systems, predicted Dr. Stevenson, professor of medicine at Harvard Medical School and director of the cardiology and heart failure program at Brigham and Women’s Hospital, both in Boston.

“It has certainly been achieved for diabetic management. We never thought this would be possible, but most of our diabetic patients actually adjust their own medications several times a day according to their glucose readings,” she noted.

Dr. Chaudhry, Dr. Yancy, and Dr. Stevenson declared having no relevant financial interests. The TIM-HF trial was funded by the German Federal Ministry of Economics and Technology in partnership with several technology companies. Dr. Anker disclosed that he serves as a consultant to one of those companies, Robert Bosch Healthcare.