Lessons from major heart trial need implementation

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A NewYork-Presbyterian Hospital/Weill Cornell Medical Center review of almost 500,000 cardiac cases nationally shows that the clinically indicated medical therapy reported in a widely publicized study was lost in translation to real-world heart care after its publication.

The researchers report in the May 11 issue of *JAMA, the Journal of the American Medical Association,* that medical therapy given to patients who received a heart stent improved less than 3 percent as a result of the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial. Overall, fewer than half of all patients received appropriate treatment with the combination of common cardiac drugs used in the COURAGE trial, such as aspirin, before their stenting procedure, and almost one-third didn't receive these drugs afterward.

As we all think about health care for the future, this study provides actionable information for both physicians and policymakers about quality of care and how comparative effectiveness research findings are being implemented, the researchers say.

"We find that an expensive and highly publicized clinical trial had a very limited effect on the clinical practice of providing optimal medical therapy, and this snapshot of what is happening in the real world should be a call for physicians, as well as policymakers, to look at how patient care can be improved," says the study's lead author, Dr. William Borden, assistant professor of medicine and of public health and the Nanette Laitman Clinical Scholar in Public Health at Weill Cornell Medical

College, and a cardiologist at the Ronald O. Perelman Heart Institute of NewYork-Presbyterian Hospital/Weill Cornell Medical Center.

"These findings also should encourage patients to be aware of the need for optimal medical therapy if they are slated to receive a heart stent -- a consideration they should discuss with the physicians who treat them," says co-author Dr. Alvin I. Mushlin, chairman of the Department of Public Health at Weill Cornell Medical College and public health physician-in-chief at NewYork-Presbyterian Hospital/Weill Cornell Medical Center.

In this study, the research team, which includes investigators from the University of California at San Francisco, Duke Clinical Research Institute, and the University of Missouri, sought to see if heart care changed after publication of the $33.5 million COURAGE clinical trial in the New England Journal of Medicine in 2007.

In COURAGE, 2,287 patients with stable coronary artery disease (CAD) were randomized to receive either "optimal medical therapy" alone or the same therapy along with a stent -- a device that presses artery-clogging plaque back against a vessel wall. Optimal medical therapy was sought with all patients, even those having stents placed, assigning them to receive common cardiac agents -- a statin drug, a beta blocker, and aspirin or thienopyridine.

COURAGE investigators found there was no difference in the outcomes of the two groups, except for angina symptoms, which demonstrated that adding stenting to optimal medical therapy is not better than the ability of optimal medical therapy alone to prevent heart attacks and death in patients with stable CAD. Even before COURAGE was published, other studies had shown that medical therapy was beneficial in these patients and its use was encouraged by established cardiac care guidelines.

While previous investigators have shown that translation of clinical trials into patient practice has been "suboptimal," no one had looked at whether this is true in patients who receive a stent through percutaneous coronary intervention (PCI), which is a common and costly procedure, says Dr. Borden.

To find out, the researchers studied 1,013 U.S. hospitals in what they believe to be the largest PCI registry in the United States -- the CathPCI registry, which is part of the American College of Cardiology National Cardiovascular Data Registry. They analyzed clinical data on 467,211 patients who had received a stent between 2005 and 2009 to examine changes in the use of optimal medical therapy before PCI and at the time of discharge, both before and after the March 26, 2007, publication of the COURAGE trial.

They determined that the use of optimal medical therapy in all patients between 2005 and 2009 was 44.2 percent before PCI, and 65 percent upon discharge after patients received their stent. Before results of COURAGE were known, medical therapy was used before PCI in 43.5 percent of patients, and after COURAGE was published, the rate rose to 44.7 percent. After PCI, at discharge, medical therapy was prescribed to 63.5 percent of patients before COURAGE was published, and 66 percent after.

That means that the wide publicity that followed publication of the study resulted in a net benefit of 1.2 percent increase in use of optimal medical therapy before a stent was inserted, and 2.5 percent after the procedure, says Dr. Borden. "While this is a statistically significant result given that thousands of patients were included in the study, it is not clinically significant," he says.

"I was surprised," Dr. Borden adds. "I thought there would be more of an improvement in medical therapy over time, but we have seen this

difficulty in translating clinical trial evidence into practice before."

The authors say the possible reasons for this failure include a "knowledge gap" on the part of physicians and the fact that the health care workers treating PCI patients (referring primary care physicians, general cardiologists, interventional cardiologists and nurses) may not be working together as part of a team.

"Patients who receive a stent are often in the hospital for less than 24 hours. The interventional cardiologist who implants the stent may, or may not, be following the patient over time with an established patient-physician relationship," says Dr. Borden. "Therefore, there must be a shared responsibility among all physicians, including the primary care doctor and general cardiologist, in caring for the patient around the time of PCI."

"We have a real opportunity to improve the care these patients receive," says Dr. Mushlin. "We need to look at the broader health care system -- how hospitals and physicians work together, how the incentive system is structured, how medical care is paid for, and how access to health care can be assured."

One way to do that, the researchers say, is through the Patient-Centered Outcomes Research Institute, established and funded by the Patient Protection and Affordable Care Act.

"We have to make sure the system we have is the best it can be in terms of enhancing optimal practices," Dr. Mushlin says.

"It is always important for patients to play a role in their health care, but this may really be an issue that physicians and policymakers need to address," says Dr. Borden.

More information: JAMA. 2011;305[18]1882-1889.